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LEGISLATION, REGULATIONS & STANDARDS

GAO: FDA Should Finalize Plans to Implement New Traceability Rule

The Government Accountability Office (GAO) has recommended that the U.S. Food and Drug Administration (FDA) finalize its plans for implementing a rule that would aim to help trace the sources of outbreaks of foodborne illness. In developing the 2022 rule, FDA established a list of certain foods requiring enhanced recordkeeping, setting a compliance date of January 20, 2026. Entities handling items on the list will be required to maintain certain records, including a traceability plan, at certain points in the item's supply chain.

As of October 2023, FDA had not yet finalized or documented an implementation plan, according to FDA officials. GAO found that components of such a plan could help address challenges stakeholders identified in preparing for the rule's compliance deadline, include more information on nonfederal regulators' roles in the inspection process and FDA's enforcement strategy and needed resources. "By finalizing and documenting an implementation plan, FDA will have better assurance it is well positioned to make progress toward its regulatory goals and address the various challenges that stakeholders identified to achieving compliance by the deadline," GAO said. The U.S. Department of Health & Human Services agreed with the recommendation.

Advocacy Group Petitions FDA to Limit Use of Solvents

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The U.S. Food and Drug Administration (FDA) has received petitions from several advocacy groups, including the Environmental Defense Fund, to limit the use of ethylene dichloride, methylene chloride and trichloroethylene both as color and food additives. The petitioning organizations also request that benzene be removed for use as a food additive. The organizations argue that the substances "have been found to induce cancer in humans or animals and, therefore, are not safe," and thus should not be permitted for use in food.

EFSA Issues Update on Inorganic Arsenic Assessment

The European Food Safety Authority (EFSA) has updated its risk assessment on inorganic arsenic in food. Exposures to inorganic arsenic occur primarily through consumption of rice, rice-based products, grains, grain-based products and, to a lesser extent, drinking water. The updated assessment asserts that inorganic arsenic exposure is associated with an increased incidence of skin cancer, while other findings were consistent with previous assessments finding an associated increased risk of other cancers, including bladder and lung cancer.

NAD Finds Some Jerky Claims Puffery, Recommends Others Be Modified

BBB National Programs' National Advertising Division (NAD) has determined that some claims made by Old Trapper Smoked Products Inc. for its Old Trapper Beef Jerky are puffery, while recommending the company modify or discontinue other claims surrounding its products' ingredients. The company's competitor, Link Snacks, Inc., challenged its use of "The Best" and "Clearly the Best." NAD determined that the statements are puffery and not objective assertions of fact.

NAD recommended that Old Trapper modify or discontinue the challenged ingredient claims. NAD said Old Trapper made a claim on its social media account stating, "We use only the highest quality ingredients in every Old Trapper flavor. That's just one of the reasons why Old Trapper is #ClearlyTheBest." NAD said it determined the language "We use only the highest quality ingredients" is an objective claim that requires support.

"In the absence of any support that Old Trapper uses the highest quality ingredients, NAD recommended that Old Trapper discontinue or modify these claims to avoid conveying the message that they are using superior ingredients," NAD said in a

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ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

release. The organization indicated that Old Trapper has agreed to comply with the recommendations.

FSA Warns of Fake Prime, Wonka Chocolate Bars

The U.K. Food Standards Agency (FSA) has warned consumers not to buy or eat fake Wonka Bars or Prime chocolate bars after receiving reports of falsely branded chocolate for sale. In 2023, fake Wonka Bars were removed from sale after they were found to contain allergens not listed on the label. Prime reportedly told the agency that it exclusively manufactures beverages and does not manufacture or sell food products.

"We know there is a problem with potentially unsafe fake chocolate bars such as Wonka and Prime bars and we're working with Trading Standards to protect consumers," an FSA representative said in a statement. "Please do not buy or eat these bars and if you think you've bought a fake chocolate bar, or if you see something that does not seem right when you are shopping, report it to your Local Authority."

LITIGATION

WanaBana Faces First Suits Over Lead-Contaminated Fruit Puree Pouches

Consumers have filed proposed class actions against WanaBana stemming from lead-contaminated apple cinnamon fruit puree pouches the company sold. *Marsh v. WanaBana LLC*, No. 23-11090 (S.D.N.Y., filed December 21, 2023); *Bell v. WanaBana LLC*, No. 23-24861 (S.D. Fla., filed December 22, 2023). In October, the U.S. Food and Drug Administration (FDA) advised consumers against buying or feeding WanaBana Apple Cinnamon Fruit Puree Pouches to children because of elevated lead levels in the products, and WanaBana voluntarily recalled all lots of the affected products. FDA announced that as of January 8, it had received 87 confirmed reports of adverse events potentially linked to the recalled products. In an interview with *Politico* in December, FDA Deputy Commissioner for Human Foods Jim Jones said the agency was still investigating "but so far all of the signals we're getting lead to an intentional act on the part of someone in the supply chain."

The plaintiffs allege WanaBana misled consumers into believing their products were free of dangerous materials like lead and failed to disclose them. "The Products included undisclosed levels

of lead due to WanaBana's failure to sufficiently monitor for its presence in the ingredients and finished products. WanaBana was or should have been aware of this risk," the plaintiffs in *Bell* alleged. Their claims include negligent misrepresentation, unjust enrichment, breach of express warranty, breach of implied warranty, and violations of the plaintiffs' state consumer-protection laws. The plaintiffs in *Marsh* also seek medical monitoring as part of their requested relief.

Oatly Wins UK Trademark Dispute Over Use of "Milk"

Oatly has reportedly won a ruling from the United Kingdom's High Court allowing it to use "milk" on its packaging, specifically the slogan "Post Milk Generation." *Food Ingredients First* reported that Dairy UK, which represents the UK's dairy industry, contested Oatly's 2019 trademark for "Post Milk Generation." According to the opinion, Oatly filed the application for the mark for use on a variety of goods, including oat-based drinks as milk substitutes, oat-based ice cream and oat-based food spreads. Dairy UK argued that the phrase violated pre-Brexit regulations restricting the use of "milk" in non-dairy product marketing, but the High Court rejected Dairy UK's claim, finding that the trademark did not imply dairy-based products.

Quaker Oats Hit With Proposed Class Action After Recall

A South Carolina consumer has filed a proposed class action against the Quaker Oats Co. alleging the company's negligence led to a recall of more than 90 formulations of its granola products. *Herendeen v. Quaker Oats Co.*, No. 23-17103 (N.D. Ill., filed December 27, 2023). According to the complaint, the company recalled its granola products because of concerns of potential bacterial contamination, including *Salmonella*.

"Plaintiffs and consumers did not know, and did not have a reason to know, that the Quaker granola and oat products purchased were contaminated with Salmonella. Consumers expect the food they purchase to be safe for consumption and not contaminated by Salmonella or other harmful bacteria," the plaintiff asserts. "Defendant's omissions are material, false, misleading, and reasonably likely to deceive the public. This is especially true, considering the long-standing campaign that markets the Recalled Products as healthy and high quality, as to induce customers to purchase the products."

The plaintiff's claims include negligence, breach of express warranty, breach of implied warranty of merchantability, fraudulent misrepresentation, fraud by omission and unjust enrichment. She seeks class certification, declaratory judgment, injunctive relief, damages, prejudgment interest, restitution and reasonable attorney's fees.

Court Revives Baby Food Heavy Metals Suit

The Second Circuit has revived a putative class action brought by consumers against Beech-Nut Nutrition Co. alleging the company sold baby food products containing elevated levels of heavy metals. *Thomas v. Beech-Nut Nutrition Co.*, No. 23-0220 (2d Cir., issued January 18, 2024). The lower court granted the company's motion to dismiss arguing that the U.S. Food and Drug Administration (FDA) had primary jurisdiction over the plaintiffs' claims.

On appeal, the Second Circuit concluded that any advantages to deferring to FDA are outweighed by the potential costs resulting from the delay in administrative proceedings. The court said in a summary opinion that in making its decision to defer to FDA, the district court reasoned that the agency is presently working on its initiative "Closer to Zero: Action Plan for Baby Foods," stating that by April 2024, FDA planned to finalize action levels for lead and propose action levels for arsenic, and later address cadmium and mercury. FDA no longer expects to finalize lead action levels in April 2024 and has revised its expected timeline for issuing draft guidance on proposed action levels for arsenic and cadmium, the Second Circuit said. "While this type of agency decisionmaking is typically time-consuming, deferring to the FDA would 'unnecessarily prolong [this] case,' likely for upwards of several years," the Second Circuit said. "On balance, we conclude that the potential costs resulting from these indefinite delays outweigh any possible benefits that could be obtained from deferring to the agency." The court vacated the district court judgment, remanding the case for further proceedings.

MEDIA COVERAGE

Consumer Reports Issues Report on Plastic Chemicals in Foods

Consumer Reports (CR) has published a report asserting that plastic chemicals such as bisphenols and phthalates are widespread in foods, based on its independent testing of nearly 100 food products. CR said it tested 85 foods, analyzing two or

three samples of each, looking for common bisphenols and phthalates, as well as the chemicals used to replace them. The samples included prepared meals, fruits and vegetables, milk and dairy products, baby food, fast food, meat and seafood—all packaged in cans, pouches, foil or other material.

CR said the results for bisphenol A (BPA) and other bisphenols was “somewhat reassuring,” finding that while they were detected in 79% of the tested samples, levels were notably lower than when CR last tested for BPA in 2009. CR said it found phthalates in all but one food, and the levels were much higher.

CR acknowledged that determining acceptable levels for these chemicals in food “is tricky,” noting that U.S. and European regulators have only set thresholds for BPA and a few phthalates. It said none of the foods it tested exceeded those limits.

“Many of these thresholds do not reflect the most current scientific knowledge, and may not protect against all the potential health effects,” Tunde Akinleye, the CR scientist who oversaw CR’s tests, said. “We don’t feel comfortable saying these levels are okay. They’re not.”