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LEGISLATION, REGULATIONS & STANDARDS

FDA Proposes Additional Traceability Requirements for “High Risk” Foods

The U.S. Food and Drug Administration (FDA) has [released](#) a proposed update to traceability recordkeeping requirements for foods considered “high risk” as sources of foodborne illness. The proposed rule would apply to entities that manufacture, process, pack or hold foods on the Food Traceability List and would require companies to “establish and maintain records containing information on critical tracking events in the supply chain for these designated foods, such as growing, shipping, receiving, creating, and transforming the foods.” The rule reflects the terms of a [settlement](#) FDA reached with the Center for Food Safety in a lawsuit intended to compel the agency to meet requirements set forth in the Food Safety Modernization Act.

“The availability of the traceability records that are set out in the proposed rule would also help limit the scope of recalls and in some instances, allow the FDA to better target consumer advice, avoiding blanket alerts on whole commodity sectors,” Deputy Commissioner for Food Policy and Response Frank Yiannas said in a [press release](#). “I am excited to continue collaborating with stakeholders as we work to finalize this rule, and further enhance traceability. We are encouraging you to be involved in this process by commenting on the proposed rule. We look forward to announcing public meetings to discuss this proposed rule with everyone interested in food safety and value input from all stakeholders during the comment period.” Comments on the rule will be accepted until January 21, 2021.

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Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information about Shook’s capabilities, please contact



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Health Advocacy Groups Submit Citizen Petition on Food Additives

Several advocacy groups, including the Environmental Defense Fund, American Academy of Pediatrics, Center for Food Safety and Consumer Reports, have submitted a citizen petition urging the U.S. Food and Drug Administration (FDA) to “define key terms essential to consider the cumulative effect of a food additive, food contact substance, generally recognized as safe substance, or color additive, taking into account any chemically- or pharmacologically-related substances in the diet, when assessing safety as required by law.” The petition asserts that “FDA and food manufacturers have not taken into account the many chemicals we consume in our daily diet that are similar in structure or affect similar function(s) of organs in the body when making safety determinations for new additives, despite the Congressional mandate and the agency’s own regulations.” The organizations argue that “one of almost 900 safety determinations conducted by food manufacturers and submitted to FDA for review as Generally Recognized as Safe (GRAS) notifications for human food considered the requirement in a meaningful way,” and they urge FDA to “revise the agency’s food and color additive regulations and associated guidance to ensure compliance with the requirements.”



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Berkeley Bans Soda and Candy Displays in Checkout Lanes

Berkeley, California, has reportedly passed an ordinance that will prevent grocery stores from displaying candy and soft drinks at the point of sale in an effort to encourage the consumption of food with more nutritional benefits, such as fruits and nuts. The ordinance, which applies to retailers with more than 2,500 square feet, states that products displayed in checkout aisles must have less than five grams of added sugars and less than 250 milligrams of sodium per serving. The ordinance will take effect March 1, 2021, with enforcement beginning in 2022.

FSIS Releases Updated Import Guidance

The U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) has announced the availability of updated guidance on importing meat, poultry and eggs into the United States. According to the announcement, “FSIS revised and reorganized a section on industry supply chain best practices; clarified

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

approaches to levels of reinspection; added information about generic labeling approvals, food defense, slaughter dates on import certification, and barcoding; and made minor editorial changes to improve the guidance’s clarity.” The announcement also directly responds to several comments received on the 2017 version of the guidance.

inspections, subject to FDA, USDA and FTC regulation.



LITIGATION

Hemp Trade Association Challenges DEA Cannabis Rule

The Hemp Industries Association and RE Botanicals Inc. have filed a lawsuit challenging the Drug Enforcement Administration’s (DEA’s) interim final rule implementing changes to the scope of the agency’s control over cannabis and tetrahydrocannabinol (THC). *Hemp Industry Ass’n v. DEA*, No. ___ (D.C. Cir., filed September 18, 2020). “The DEA’s interim final rule clarifies that all hemp derivatives or extracts exceeding 0.3% THC shall remain Schedule I controlled substances,” the industry group’s press release states. “This could be interpreted to include intermediate hemp derivatives that temporarily exceed 0.3% during processing, but contain less than 0.3% in final products. As such, it improperly establishes the DEA’s authority over legal hemp activities, which is contrary to the plain language and intent of the 2018 [F]arm [B]ill.” The plaintiffs argue that the DEA interim final rule was arbitrary and capricious and beyond the agency’s jurisdiction, and they urge the court to hold the rule to be unlawful on those grounds.

Arizona “Zero-Calorie” Beverage Contains Calories, Plaintiff Alleges

A consumer has alleged in a putative class action that the “zero-calorie” version of Arizona Beverages USA’s Arnold Palmer actually contained 15 calories per can. *Meyers v. Arizona Beverages USA LLC*, No. 20-5543 (N.D. Ill., E. Div., filed September 18, 2020). The complaint asserts that the U.S. Food and Drug Administration required Arizona Beverages to change the name of the product to “diet” because agency regulations only permit beverages with less than five calories per serving to list the calorie content as zero. The plaintiff, alleging that he would not have purchased the product had he known its true calorie content,

seeks damages and costs for allegations of consumer fraud and a violation of the Magnuson-Moss Warranty Act.

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