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FOOD & BEVERAGE LITIGATION UPDATE

SHOOK HARDY & BACON

LEGISLATION, REGULATIONS & STANDARDS

FDA Releases Plan for Reducing Infant Exposure to Heavy Metals

The U.S. Food and Drug Administration (FDA) has released "Closer to Zero," its action plan for reducing infants' exposure to heavy metals following a Congressional report on toxic elements in baby foods. "Although the FDA's testing shows that children are not at an immediate health risk from exposure to toxic elements at the levels found in foods, we are starting the plan's work immediately, with both short- and long-term goals for achieving continued improvements in reducing levels of toxic elements in these foods over time," the agency states. Under the plan, FDA will (i) "evaluate the scientific basis for action levels," (ii) "propose action levels," (iii) "consult with stakeholders on proposed action levels," and then (iv) "finalize action levels." The agency will then "establish a timeframe for assessing industry's progress toward meeting the action levels and recommence the cycle to determine if the scientific data support efforts to further adjust the action levels downward."

"We recognize that Americans want zero toxic elements in the foods eaten by their babies and young children," the FDA statement says. "In reality, because these elements occur in our air, water and soil, there are limits to how low these levels can be. The FDA's goal, therefore, is to reduce the levels of arsenic, lead, cadmium and mercury in these foods to the greatest extent possible. We are also sensitive to the fact that requiring levels that are not currently feasible could result in significant reductions in the availability of nutritious, affordable foods that many families rely on for their children. Our plan, therefore, outlines a multi-

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phase, science-based, iterative approach to achieving our goal of getting levels of toxic elements in foods closer to zero over time."

GAO Issues Report on Seafood Imports

The U.S. Government Accountability Office (GAO) has issued "Imported Seafood Safety: FDA Should Improve Monitoring of Its Warning Letter Process and Better Assess Its Effectiveness," finding that the U.S. Food and Drug Administration (FDA) was inconsistent in following key procedures and meeting goals for monitoring the importation of seafood. The report's recommendation is that FDA "(1) establish a process to monitor whether the agency is following the procedures and meeting the goals established for its warning letter process for imported seafood, and (2) develop performance goals and measures to assess how effective warning letters are at ensuring the safety of imported seafood."

Reintroduced Bill Would Change Alcohol Taxes on Kombucha

U.S. Sen. Ron Wyden (D-Ore.) and Rep. Earl Blumenauer (D-Ore.) have reintroduced legislation that would "ensure that kombucha beverages are exempt from excise taxes and regulations intended specifically for beer and other alcoholic beverages," according to a press release. The KOMBUCHA Act would increase the alcohol-by-volume level at which alcohol taxes would be applied to kombucha, "a nonintoxicating beverage made from a combination of tea, water, and a symbiotic culture of bacteria and yeast," to 1.25% rather than the existing standard of 0.5%.

"This amount of alcohol in kombucha is usually less than 0.5 percent alcohol, but because of the natural process of fermentation, the alcohol content may occasionally increase slightly, especially during transport or handling by third parties," the press release states. "Today, under the Internal Revenue Code, beverages with more than 0.5 percent alcohol-by-volume are subject to excise taxes intended for beer. But the reality is, consumers do not buy and drink kombucha because of its insignificant alcohol content. For example, a person would have to consume between five and 10 bottles of kombucha to equal the alcohol in just one beer."

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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

LITIGATION

Foods Grown Hydroponically Can Be Labeled "Organic," Court Affirms

The National Organic Program can continue to include foods grown through hydroponics following a ruling from a California federal court holding that the U.S. Department of Agriculture (USDA) acted reasonably in concluding that the statutory scheme does not exclude hydroponics. *Ctr. for Food Safety v. Perdue*, No. 20-1537 (N.D. Cal., entered March 18, 2021). The Center for Food Safety (CFS) had sought to limit foods labeled as "organic" to only foods grown in soil, but the USDA denied the advocacy group's petition.

"The petition denial should not be disturbed because USDA reasonably defends its determination that [the Organic Foods Production Act (OFPA)] does not compel the prohibition of hydroponics," the court held. "USDA's ongoing certification of hydroponic systems that comply with all applicable regulations is firmly planted in OFPA. It therefore provides the 'reasonable explanation' required on review, so its denial will not be vacated."

Court Issues Injunction on Prop. 65 Acrylamide Enforcement Through Lawsuits

A California federal court has ruled that the state "has not shown that the cancer warnings it requires are purely factual and uncontroversial" or "that Proposition 65 imposes no undue burden on those who would provide a more carefully worded warning." *Cal. Chamber of Com. v. Becerra*, No. 19-2019 (E.D. Cal., entered March 29, 2021). The California Chamber of Commerce filed a lawsuit seeking to enjoin new lawsuits from enforcing the Safe Drinking Water and Toxic Enforcement Act (Prop. 65) against foods that contain acrylamide. The court considered evidence on the toxicity of acrylamide, finding that "some evidence does support such an inference" that eating food with acrylamide will increase a person's risk of cancer, but "dozens of epidemiological studies have failed to tie human cancer to a diet of food containing acrylamide. Nor have public health authorities advised people to eliminate acrylamide from their diets. They have at most voiced concern."

"The problems posed by the safe harbor warning could have been avoided," the court held. "The State could allow businesses to explain that acrylamide forms naturally when some foods are

inspections, subject to FDA, USDA and FTC regulation.

prepared. It could permit businesses to say that California has listed acrylamide as a chemical that 'probably' causes cancer or is a 'likely' carcinogen or that the chemical causes cancer in laboratory animals. It could permit businesses to say that acrylamide is commonly found in many foods and that neither the federal government nor California has advised people to cut acrylamide from their diets."

"[T]he State has not shown that the safe-harbor acrylamide warning is purely factual and uncontroversial, and Proposition 65's enforcement system can impose a heavy litigation burden on those who use alternative warnings," the court ruled. Further, Prop. 65 "does not permit businesses to add information to the required warning at their discretion, and thus prevents them from explaining their views on the true dangers of acrylamide in food. That prohibition exacerbates the effect of the warning. It threatens to 'drown out' a business's 'messaging' addressing the claimed dangers of acrylamide in food."

"The court thus concludes the Chamber of Commerce is likely to show the acrylamide warning required by Proposition 65 is controversial and not purely factual." The court granted the California Chamber of Commerce's motion for a preliminary injunction and denied co-defendant Council for Education and Research on Toxics' motion for summary judgment.

FSIS Violated APA in Removing Pork Line Speed Limits, Court Rules

A Minnesota federal court has ruled that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) violated the Administrative Procedures Act (APA) when it adopted the New Swine Inspection System (NSIS), which eliminated line speed limits for pork processing. *United Food & Com. Workers Union, Local 663 v. USDA*, No. 19-2660 (D. Minn., entered March 31, 2021). The court found that the final rule establishing the NSIS "contains no discussion, analysis, or evaluation of the worker safety comments" that it received during the notice-and-comment period.

"The only response FSIS gave to the worker safety comments it solicited was to state that it lacked authority to regulate worker safety. In context, the agency appeared to suggest that it wanted to consider the comments but was not legally permitted to do so," the court held. "By offering its lack of legal authority and expertise on worker safety as its only response to the safety-related comments, FSIS gave the clear impression that it was rejecting the comments as legally impermissible considerations." Because FSIS

did have the authority to consider worker safety, the court held, the implication was misleading. “FSIS could not simply disregard important policy considerations it had previously identified because of a conclusion about the scope of its legal authority. FSIS had identified safety concerns in the Proposed Rule and had recently declined to increase poultry line speeds because of safety issues. Those concerns involved ‘important policy choices’ that the agency needed to address because it had flagged those choices as important considerations.”

“The agency’s rejection of worker safety concerns is not merely a technicality. It had wide-reaching implications for workers and pork plant operators. Many of these stakeholders submitted comments directly addressing the issue. As the comments to the Proposed Rule demonstrate, there are compelling arguments on all sides of the issue. Members of the pork industry advocated for the elimination of line speed limits because it would allow them to increase production and realize economic efficiencies. On the other hand, workers raised concerns about their physical health and safety in the absence of line speed limits. ‘Making that difficult decision was the agency’s job, but the agency failed to do it.’”

Ruling that FSIS acted arbitrarily and capriciously in violation of the APA, the court vacated the final rule establishing the NSIS and remanded the case to FSIS for further consideration.