ISSUE 743 | July 17, 2020

FOOD & BEVERAGE LITIGATION UPDATE

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SPOTLIGHT

FDA Enters New Phase of FSVP Enforcement

The U.S. Food and Drug Administration (FDA) has entered a new phase of enforcement for the Foreign Supplier Verification Program (FSVP) regulation, the legally required due diligence program to review and approve foreign suppliers of imported food. In May 2020, FDA placed two companies on Import Alert 99-41, which is essentially an import ban where an importer cannot import the food until they implement an appropriate FSVP to FDA's satisfaction.

This is not the first time FDA placed a company on Import Alert 99-41. However, the previous import alert listing concerned a company that imported food associated with a recall and foodborne illnesses. In this instance, there is no indication that the food caused any food illnesses or was otherwise non-compliant; rather, it appears that the only issue was the importers failed to comply with the FSVP requirement.

This inherently changes the tenor of an FSVP inspection because they now carry the threat of meaningful consequences (import refusals) for failing to comply, regardless of whether any evidence establishes that the food is unsafe or otherwise non-compliant. In addition to importers, this action affects those whose supply chains depend on imported food.

In June 2020, FDA refused the first food shipment because the U.S. importer did not comply with FSVP. This signals that the "education" phase of FSVP implementation is over and now FDA

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.

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will issue an import refusal for failing to comply with FSVP, even if there is no evidence that the food is non-compliant.

To learn more, contact Shook Of Counsel John F. Johnson for a white paper about this shift and what companies can do to avoid to the import alert.

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LEGISLATION, REGULATIONS & STANDARDS

USDA, HHS Release 2020 Dietary Guidelines Advisory Committee Report

The U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) has released the first print of the Scientific Report of the 2020 Dietary Guidelines Advisory Committee, which will be used to guide dietary recommendations. Changes include a reduced recommendation for the percentage of added sugars in an adult's diet and a section for children under two years old. The report also notes the effects of COVID-19 on its findings.

"As more is learned about infection by SARS-Co V-2 and the development of COVID19, it is clear that it has significant nutritional implications. These parallel epidemics, one noninfectious (obesity and diet-related chronic diseases) and one infectious (COVID-19), appear to be synergistic. Those at most risk for the most serious outcomes of COVID-19, including hospitalization and death, are people afflicted by diet-related chronic diseases (obesity, type 2 diabetes, and cardiovascular disease). Finally, throughout the world, the consequences of physical isolation and financial disruption by the threat of COVID-19 infection has led to significant increases in food insecurity and hunger, further increasing susceptibility to both infectious and diet-related chronic diseases. Thus, these interrelationships between chronic diseases, COVID-19, and social determinants of health, emphasize the critical importance of improving dietary patterns. These parallel epidemics demonstrate the central role of nutrition and healthy dietary patterns in susceptibility to both infections and diet-related chronic diseases and these relationships should be further examined in future dietary guidelines."

FDA to Resume Domestic Inspections

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

The U.S. Food and Drug Administration (FDA) has announced that it will resume domestic inspections of regulated facilities during the week of July 20, 2020, after pausing in March due to COVID-19. “To arm our investigators with the most reliable and accurate information, the FDA has developed a rating system to assist us in determining when and where it is safest to conduct prioritized domestic inspections,” the agency states. “The COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. We are also making the Advisory Level data available to our state partners who carry out inspections of FDA-regulated entities on the agency’s behalf under contract.”

The agency also announced that the inspections will be pre-announced. “The FDA has also determined that, for the foreseeable future, prioritized domestic inspections will be pre-announced to FDA-regulated businesses. This will help assure the safety of the investigator and the firm’s employees, providing the safest possible environment to accomplish our regulatory activities, while also ensuring the appropriate staff are on-site to assist FDA staff with inspection activities.”

FDA Announces New Era of Smarter Food Safety Blueprint

The U.S. Food and Drug Administration (FDA) has released a blueprint of plans to implement the Food Safety Modernization Act and a hub for the New Era of Smarter Food Safety. The blueprint focuses on four elements: (i) tech-enabled traceability; (ii) smarter tools and approaches for prevention and outbreak response; (iii) new business models and retail modernization; and (iv) food safety culture.

“This document represents the thinking of FDA food safety experts, consumers, the food industry, technology firms, federal and state regulatory partners, our regulatory counterparts in other nations, and academia,” the blueprint states. “Together, we envision a framework that will enable food to be traced to its source in seconds and will utilize new data analytical techniques to strengthen prevention of foodborne illnesses, alerting consumers in real time before contaminated or misbranded foods are consumed. We envision a framework in which education, communication, and democratization of data will enable industry, public health advocates, and government to work in concert to keep the food supply safe.”

inspections, subject to FDA, USDA and FTC regulation.

USDA Responds to Petition on COVID-19 in Meat and Poultry Plants

The U.S. Department of Agriculture (USDA) has issued a response to the Physicians Committee for Responsible Medicine's petition urging the agency to require meat and poultry processing plants to publish information about COVID-19 testing and infection rates at their facilities and to include on their product labels the statement "Warning: Workers in U.S. meat and poultry processing facilities have been sickened or killed by the SARS-CoV-2 virus, and this product has not been certified virus-free." USDA's Food Safety and Inspection Service states that it does not have the authority to require facilities to report on the health information of their workers.

The agency's response further notes that the proposed warning statement "is misleading because it inaccurately implies that meat and poultry products that have not been 'certified as virus-free' may transmit COVID-19 or are somehow unsafe. As discussed above, public health and food safety experts have found no evidence to support transmission of COVID-19 associated with meat or poultry products. Thus, we are denying your request to amend the safe handling labeling regulations because we believe the requested warning statement would cause meat and poultry products to be misbranded."

LITIGATION

Californians Can Buy Out-of-State Foie Gras, Court Rules

A California court has reportedly ruled that Californians can buy foie gras from out-of-state sellers and have it delivered within the state to avoid the state's ban on sales or gifts of foie gras. The ruling applies only to individual purchasers, as restaurants and retailers are still prohibited from selling foie gras, according to the *Associated Press*. "There is no principled way to distinguish between foie gras purchased out of state and transported into California by the purchaser and that which is delivered by a third party," the court reportedly held.

Second Circuit Rejects Barilla Class Certification

The U.S. Court of Appeals for the Second Circuit has sided with an objector to a class settlement in a lawsuit alleging that Barilla USA pasta boxes contained too much slack fill. *Berni v. Barilla S.p.A.*, No. 19-1921 (2nd Cir., entered July 8, 2020). The lawsuit asserts that Barilla reduced the amount of pasta in its box packaging but retained the same size of box, allegedly misleading consumers. The parties reached a settlement that included payments to class counsel and the named representative along with an agreement to update the packaging to include a "fill line" to indicate how much pasta the box contains. A class member objected to the settlement, arguing that the only relief the class received was injunctive relief, and a class of past purchasers could not be certified for injunctive relief.

The district court rejected the objector's assertion, but the Second Circuit disagreed with the lower court. "At a general level, we note that past purchasers of a consumer product who claim to be deceived by that product's packaging—like the purchasers of Barilla pasta here—have, at most, alleged a past harm. Such a past harm is of the kind that is commonly redressable at law through the award of damages, which, it should be noted, is what Plaintiffs primarily sought in their complaint. For several reasons, past purchasers of a product, like the Barilla purchasers, are not likely to encounter future harm of the kind that makes injunctive relief appropriate. In the first place, past purchasers are not bound to purchase a product again—meaning that once they become aware they have been deceived, that will often be the last time they will buy that item," the court held. "But even if they do purchase it again, there is no reason to believe that all, or even most, of the class members will incur a harm anew. Supposing that they have been deceived by the product's packaging once, they will not again be under the illusion that the boxes of the newer pastas are filled in the same way as the boxes of the older pastas. Instead, next time they buy one of the newer pastas, they will be doing so with exactly the level of information that they claim they were owed from the beginning. A 'fill-line' or some disclaimer language will not materially improve their position as knowledgeable consumers."

Holding that the class could not be certified, the appeals court reversed the district court's approval of the settlement and remanded the case for further proceedings.

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