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LEGISLATION, REGULATIONS AND STANDARDS

FDA Denies CSPI Petition for *Vibrio* Performance Standard in Shellfish

The U.S. Food and Drug Administration (FDA) has denied a February 9, 2012, petition filed by the Center for Science in the Public Interest (CSPI) that requested “a performance standard of non-detectable as determined by the best available method of detection for *Vibrio vulnificus* in molluscan shellfish intended for raw or processed raw consumption.”

Citing *V. vulnificus* as “the leading cause of seafood-associated deaths in the United States,” the petition notes that FDA already enforces a zero tolerance standard for *V. vulnificus* in ready-to-eat fish and a non-detectable standard of less than 30 most probable numbers per gram (MPN/g) for post-harvest processed shellfish. According to CSPI, the Food Safety Modernization Act directs the agency to set performance standards for significant foodborne contaminants.

In rejecting the petition, FDA notes that other strategies—including state adherence to and federal oversight of control measures designed to manage *V. vulnificus* risk—have effectively reduced oyster-associated *V. vulnificus* illnesses since 2013. In particular, the agency points to the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (NSSP Guide) adopted by FDA and the Interstate Shellfish Sanitation Conference (ISSC). Controls enacted under the NSSP Guide set “a risk-per-serving approach to be achieved through implementation of stringent post-harvest time-to-temperature controls,” among other measures. In addition, ISSC has focused on educating the immunocompromised population about the risks associated with the consumption of raw or undercooked shellfish; FDA has partnered with the National Oceanic and Atmospheric Administration to refine *V. vulnificus* risk forecasting; and a *Vibrio* Assessment Review Board provides research and technical assistance to states and industry.

“In sum, FDA continues to work on innovate ways to further improve *Vibrio* management,” writes FDA Director for the Office of Food Safety Nega Beru. “The risk assessments discussed... will help states craft *Vibrio* management plans tailored to the specific risk factors in their regions;

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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.

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such as whether illnesses arise early or late in the growing season. Understanding populations and predictive modeling will allow states to use resources more wisely and further reduce illnesses by minimizing post-harvest *Vibrio* growth.”

FDA Issues Guidance on the Use of Fruit and Vegetable Juices as Color Additives

Responding to food manufacturers' requests, the U.S. Food and Drug Administration (FDA) has published industry guidance to clarify when fruit and vegetable juices “may be used as color additives for foods without additional premarket review and approval from the agency under its color additive petition process.”

Under current regulations, the agency provides that “the safety of fruit juice and vegetable juice as color additives for use in food is assured by the fact that the fruit or vegetable from which the color additive is derived has been safely consumed as food, such that there would not be safety concerns in using the juice or water soluble color components from the fruit or vegetable as a color additive.” In particular, FDA clarifies what it means by the terms “fruit,” “vegetable,” “mature,” “fresh,” and “edible,” as well as “expressing the juice” and “water infusion of the dried fruit or vegetable.” The agency also states that the “only minimal processing methods may be used for the production of the color additives fruit juice and vegetable juice.”

“There may be circumstances under which a fruit or vegetable that is normally regarded as edible should not be used as a plant material for producing fruit juice and vegetable juice color additives,” notes the guidance. “For example, a plant material could contain a pesticide chemical that is unsafe within the meaning of section 408(a) of the FD&C Act (21 U.S.C. 346a(a)). In addition, the plant could be grown under environmental conditions which cause the plant to produce a deleterious substance which could cause detrimental health effects. Importantly, manufacturers are responsible for ensuring that their products meet all applicable FDA requirements before they are introduced into U.S. interstate commerce.”

USDA Revises Thinking About Date Labeling

Citing the need to help curb food loss and waste, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has announced new guidance that encourages food manufacturers and retailers to use the phrase “Best if Used by” on date labeling. Infant formula is the only

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product currently subject to mandatory date labeling under federal law. Date labeling for other food and beverage products is voluntary, and the variety of “Sell by” and “Use by” phrasing used to describe quality dates has apparently led to the early disposal of products that are still safe to consume. *See FSIS News Release*, December 14, 2016.

FTC Issues Agenda for PrivacyCon 2017

The Federal Trade Commission’s (FTC’s) second public forum targeting the privacy and security implications of emerging technologies will cover topics that include (i) the Internet of Things and big data, (ii) mobile privacy, (iii) consumer privacy expectations, (iv) online behavioral advertising, and (v) information security. Slated for January 12, 2017, at the FTC’s Constitution Center in Washington, D.C., the event will also be available via live webcast. Details about the agenda and a pre-conference networking event are available at [FTC's Website](#). *See FTC News Release*, December 16, 2016.

U.S. Codex Delegates Schedule Spices and Culinary Herbs Meeting

The U.S. Department of Agriculture’s Office of the Deputy Under Secretary for Food Safety and the Agricultural Marketing Service are convening a January 17, 2017, public meeting in Washington, D.C., to evaluate draft positions for consideration at the 3rd Session of the Codex Committee on Spices and Culinary Herbs (CCSCH) slated for February 6-10 in Chennai, India. Agenda items for the January 17 meeting include draft standards for cumin, thyme and oregano; a draft standard for black, white and green pepper; and sampling plans for cumin and thyme. *See Federal Register*, December 14, 2016.

LITIGATION

USDA Wins Summary Judgment in Foie Gras Dispute

A California federal court has granted the U.S. Department of Agriculture’s (USDA’s) motion for summary judgment in a case alleging the agency acted arbitrarily in denying a petition to prohibit foie gras produced from force-fed poultry. *Animal Legal Def. Fund v. USDA*, No. 12-4028 (C.D. Cal., order entered December 14, 2016). In the petition for rulemaking, several animal rights organizations and individuals argued force-feeding poultry caused hepatic lipidosis in the animals, rendering them unhealthy and unsafe for consumption; USDA’s Food Safety



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Inspection Service (FSIS) disagreed, finding that the buildup of fat from force-feeding did not make the liver unsafe to consume, unlike buildup related to disease.

The court first determined that the Animal Legal Defense Fund and other plaintiff organizations had standing to sue, but the plaintiff individuals did not. Turning to the merits of the case, the court considered the plaintiffs' three challenges to FSIS's decision: (i) "its explanation for why hepatic lipidosis does not render the liver unfit for human consumption is 'nonsensical and irrational'"; (ii) "its conclusion that there was insufficient evidence of a connection between consumption of force-fed foie gras and the onset of secondary amyloidosis in humans 'ran counter to the evidence before it'"; and (iii) "FSIS entirely failed to consider other bases purportedly included in the petition that support a finding that foie gras is unfit for human consumption."

In response to the first argument, the court found the distinction between disease and force-feeding as the causes of hepatic lipidosis was "eminently reasonable," given that the condition is one symptom of a disease that can also cause inflammation, hemorrhaging and a building of fibrin in the liver tissue. Because FSIS's reasoning "is not totally implausible," the court deferred to the agency's scientific conclusions.

The court also dismissed the second argument, finding that FSIS provided a reasonable scientific explanation for its determination that the evidence was insufficient to demonstrate a connection between human consumption of foie gras and the onset of secondary amyloidosis. Finally, the court agreed with FSIS's argument that the plaintiffs failed to properly present alternative bases for banning foie gras in their petition. "The petitioners made passing references to other ailments that the force-feeding process could cause (most of which were simply secondary to hepatic lipidosis), and did not mention any of the myriad regulations which Plaintiffs now cite," the court held, dismissing the plaintiffs' final argument.

California Court Dismisses Cookie Suit Involving PHO Claims

A California federal court has dismissed a lawsuit alleging Kellogg Co. misrepresents its Mother's[®] Cookies products as free of *trans* fats despite containing partially hydrogenated oil (PHO). *Hawkins v. Kroger Co.*, No. 15-2320 (S.D. Cal., order entered December 13, 2016). Details about the dismissal of a similar case involving the same plaintiff appear in Issue [592](#) of this *Update*.

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The court held that the plaintiff had standing to sue based on the health effects of inflammation and organ damage associated with the consumption of PHO, noting that Kellogg's response to the arguments focused on the insufficiency of speculative future risks for standing rather than the current effects. The court then turned to federal law governing the plaintiff's claims and found that because PHO is currently permitted in food until June 2018, the plaintiff could not plausibly allege that Kellogg violated federal law. Further, her state law claims were preempted by federal law. With no viable claims remaining, the court dismissed the action with prejudice.

Tradewinds Iced Tea Mislabeled "100% Natural," Putative Class Action Alleges

A consumer has filed a projected class action against Tradewinds Beverage Co. alleging the company's iced tea products are misleadingly labeled as natural despite containing caramel color. *Martin v. Tradewinds Beverage Co.*, No. 16-9249 (C.D. Cal., filed December 14, 2016). The plaintiff argues that she regularly paid a premium for Tradewinds Iced Tea products believing them to be made of all-natural ingredients. For alleged violations of California's consumer-protection statutes, she seeks a corrective advertising campaign, destruction of all misleading advertising materials, restitution, damages and attorney's fees.

Plaintiff in Herr Foods Litigation Seeks Disqualification for Defense Attorney

The plaintiff in a purported class action asserting that Herr Foods Inc. mislabels its packaged snacks as "natural" has filed a motion to disqualify defense counsel, alleging the attorney repeatedly made "extortionate threats" and committed professional misconduct. *Whitaker v. Herr Foods, Inc.*, No. 16-2017 (E.D. Penn., motion filed December 14, 2016). The plaintiff's motion follows Herr Foods' motion for summary judgment, which asserted that the plaintiff could not possibly have purchased the products he claimed and that he is "a wholly inadequate lead plaintiff" because of "his faulty memory," "his lengthy history of felony convictions involving theft and dishonesty and his potential mental health problems."

The plaintiff's motion for disqualification alleges the defense attorney told the plaintiff that Herr Foods directed him to file for sanctions and refer the plaintiff to the district attorney's office for an attempted crim-

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inal extortion investigation. “If you would like to talk about an agreement whereby you, your Firm, and your Client agree to withdraw the case with prejudice and further agree to never bring (or to facilitate, participate in, etc.) any type of claim ever again against Herr’s, I can have a discussion with my Client to see whether it would be willing to forego sanctions and referral to the DA,” the email apparently said. The plaintiff argues that this offer amounts to extortion and has asked the court to disqualify the attorney based on his conduct.

“Wine Ponzi Scheme” Perpetrator Sentenced to Six Years

John Fox, former owner of wine shop Premier Cru, has reportedly been sentenced to 6.5 years in prison after pleading guilty to wire fraud and defrauding investors out of at least \$45 million. As part of the scheme, Fox sold wine to customers around the world, embezzled the money, then used newer purchasers’ money to buy and ship the wine promised to earlier purchasers, an arrangement one prosecutor called a “wine Ponzi scheme.” Fox reportedly spent the money on luxury cars, personal credit cards and gifts for women he met online. He began serving his sentence immediately. *See Los Angeles Times*, December 15, 2016.

OTHER DEVELOPMENTS

Rudd Center Examines Food and Beverage TV Advertising to Children

The University of Connecticut’s Rudd Center for Food Policy and Obesity has released a study on TV food advertising viewed by preschoolers, children and adolescents, claiming that “food advertising exposure increased with age for both black and white youth, but black youth viewed approximately 50% or more ads than did white youth of the same age.” F. Fleming-Milici and J. L. Harris, “Television food advertising viewed by preschoolers, children and adolescents: contributors to differences in exposure for black and white youth in the United States,” *Pediatric Obesity*, December 2016. Based on Nielsen panel data gathered between 2008 and 2012, the study reports that “increases in food-ads-per-hour increased exposure for all youth,” but that greater TV viewing and higher rates of advertising “on youth- and black-targeted networks both contributed to black youth’s greater exposure.”

“Four product categories contributed almost 60% of food ads viewed by all youth in 2012: breakfast cereals, candy, fast-food and other restaurants,” notes the study authors. “Nearly one quarter of these ads

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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.



promoted fast-food restaurants, with white youth viewing two to four fast food ads per-day and black youth viewing four to six ads per-day. Although black youth viewed more ads than white youth viewed in every food and beverage category, the proportion of food ads viewed differed significantly for only two categories: candy represented a significantly higher proportion of ads viewed by black children as compared to white children, while breakfast cereals represented a significantly lower proportion.”

Slim-Fast Discontinues Snack Advertorial Content After Ad Board Ruling

Slim-Fast Foods Co. has ended its “100 Calories Snacks” advertisements appearing in *Star* magazine after the advertising industry’s self-regulation investigative unit, the National Advertising Division, determined that the format of the ads could mislead consumers into believing they were part of the publication’s editorial content. The cover of *Star* featured “what appeared to be an article on weight loss that claimed, ‘Joann LOST 40 lbs’ and ‘snack away the weight,’” which directed readers to a page with a piece titled “Snack Your Way to Slim” that detailed three women’s efforts to lose weight and how Slim-Fast snacks supposedly helped. Slim-Fast has reportedly agreed to discontinue the advertisements at issue as well as the advertising format.