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LEGISLATION, REGULATIONS AND STANDARDS

FDA Releases FSMA Final Rules on Produce Safety, Foreign Supplier Verification Programs and Accredited Third-Party Certification

The U.S. Food and Drug Administration (FDA) has **filed** three final rules under the Food Safety Modernization Act (FSMA) on **produce safety**, **foreign supplier verification programs** (FSVPs) and **accredited third-party certification**, all slated for publication in the November 27, 2015, edition of the *Federal Register*.

The agency will also hold a **webinar series** to discuss the new rules, which are intended to “establish enforceable safety standards for the production and harvesting of produce on farms and make importers accountable for the safety of the food they bring into the U.S.”

The produce safety rule addresses, among other things, (i) the quality and testing of agricultural water, (ii) biological soil amendments such as raw manure and stabilized compost, (iii) food safety requirements for sprouts, (iv) the management of domesticated and wild animals, (v) health, hygiene and worker training, and (vi) sanitation standards for equipment, tools and buildings. FDA also describes hazard analysis and supplier verification requirements for importers, as well as the accreditation procedures for third-party auditors. Effective 60 days after publication in the *Federal Register*, the rules establish final compliance dates ranging from one to three years depending on business size, type and other factors.

FDA Seeks Info and Comments About Use of the Term “Natural”

Citing Citizen Petition and federal court requests for the agency to define “natural” for use in food labeling and determine if food products containing genetically engineered ingredients and high-fructose corn syrup may be labeled as “natural,” the U.S. Food and Drug Administration (FDA) is **soliciting** information and comments about use of the term in the labeling of human food products.

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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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More specifically, FDA seeks responses to questions that include the following: (i) Should the agency define natural through rulemaking? (ii) Should the agency prohibit use of the term in food labeling? (iii) If the agency defines natural, what foods should be permitted to bear the term? (iv) Should certain production practices, e.g., salting, irradiating, be considered in defining the term? (v) Should natural be applied only to "unprocessed" foods? (vi) Should the way an ingredient is produced or sourced affect whether a product containing that ingredient be labeled natural? and (vii) Should natural be associated with a nutritional benefit? See *Federal Register*, November 12, 2015.

N.Y. Lawmaker Takes Aim at Caffeinated Food Products

U.S. Sen. Chuck Schumer (D-N.Y.) is urging the U.S. Food and Drug Administration (FDA) to investigate the increased availability of caffeinated foods in light of a new peanut butter product containing 150 mg of caffeine per 2-tablespoon serving.

"The FDA should take immediate action and investigate whether this caffeine product should be pulled from shelves," Schumer said. "To think that peanut butter, one of the snacks most closely associated with children, might have to be stored in the medicine cabinet as opposed to the kitchen cabinet should serve as a jolt to the FDA." See *Press Release of Sen. Chuck Schumer*, November 8, 2015.

According to the manufacturer's [website](#), STEEM Caffeinated Peanut Butter contains no artificial sweeteners and "as much caffeine as two cups of coffee, so stick with the normal serving suggestions for the best effect." The site cautions that feeding the product to domestic animals could "lead to SERIOUS health issues."

LITIGATION

Sales Data Deemed Inadmissible Hearsay in Gerber Litigation

A California federal court has remanded a putative class action against Gerber Products Co. on the labeling of its Gerber® Graduates® Puffs to state court and declined to admit sales data into evidence on hearsay grounds. *Gyorke-Takatri v. Nestle USA, Inc.*, No. 15-3702 (N.D. Cal., order entered November 6, 2015). The plaintiffs allege Gerber misleads consumers with its Graduates® Puffs marketing by implying the products are healthy with "vibrant images of fruits and vegetables on the outside of the Puffs' packaging."

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Gerber argued that the amount in controversy was more than \$5 million and thus sufficient to justify federal court jurisdiction. The plaintiffs argued that the court should not consider the total retail sales of Puffs, which Gerber says is well over the \$5-million threshold, because the data Gerber used to reach those numbers was gathered from Nielsen, a third party. The court agreed, finding that the third-party data was inadmissible as hearsay, and thus Gerber's argument for jurisdiction failed. Accordingly, the court remanded the case to state court.

Fruit and Vegetable Photos Not Misleading to Reasonable Consumer, Court Holds

A California federal court has dismissed a proposed class action against Plum Organics alleging that large photos of fruits and vegetables on the company's Mighty 4[®] Children's Food product packaging mislead consumers into believing the products contain significant amounts of those fruits and vegetables. *Workman v. Plum Inc.*, No. 15-2568 (N.D. Cal., filed November 2, 2015). The court refused to find that the mere inclusion of the pictures constituted misrepresentation.

"The products at issue do not display any affirmative misrepresentations," the court said. "They merely show pictures of featured ingredients contained in the puree pouch and fruit bars. No reasonable consumer would expect the size of the flavors pictured on the label to directly correlate with the predominance of the pictured ingredient in the puree blend."

In October 2015, Plum announced it would change its marketing, including product names, to better reflect the contents of its products. Additional information appears in Issue [582](#) of this *Update*.

Parties Reach \$1.5-Million Settlement in MSG Labeling Dispute

CJ America Inc., maker of Annie Chun's soup and noodle products, and a plaintiff have reached a settlement in a lawsuit alleging the company misled consumers by selling products with monosodium glutamate (MSG) while labeling the foods with the claims "No MSG Added" or "100 percent all natural ingredients." *Petersen v. CJ America Inc.*, No. 14-2570 (S.D. Cal., settlement agreement filed October 30, 2015).

Under the agreement, CJ America will pay \$1.5 million to a settlement fund distributed in \$1.50 increments to purchasers of each eligible product, with a limit of 10 claims for class members without proofs of purchase. Any remaining funds will be directed to the Mayo Clinic, Action for Healthy Kids and National Farm to School Network. CJ

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America will also remove “No MSG Added” from its product packaging for a minimum of three years. Attorneys for the plaintiff seek 25 percent of the settlement fund (\$375,000) as attorney’s fees.

Animal Legal Defense Fund Sues USDA for Undue Delay in Foie Gras Petition Response

The Animal Legal Defense Fund (ALDF) has filed a lawsuit against the U.S. Department of Agriculture (USDA) alleging a violation of the Administrative Procedure Act (APA) based on USDA’s lack of response to ALDF’s 2011 rulemaking petition requesting mandatory labeling on foie gras produced through the forced feeding of ducks or geese. *Animal Legal Def. Fund v. U.S. Dep’t of Agric.*, No. 15-5063 (N.D. Cal., San Francisco Div., filed November 5, 2015).

ALDF argues that force-fed foie gras products are mislabeled because USDA certifies them as “[i]nspected for wholesomeness” despite the fact that force-feeding “induces a metabolic disease and commonly results in the onset of all of the conditions mentioned in [USDA’s Poultry Products Inspection Act].” The organization seeks a declaration that USDA has violated the APA and an injunction compelling the agency to substantively respond to the petition.

“The USDA is responsible for ensuring that all poultry products that enter the food supply are from healthy animals,” ALDF Executive Director Stephen Wells said in a November 5, 2015, press release. “Despite the diseased origins of foie gras and the threat it poses to human health, the agency allows foie gras products to carry its official mark of inspection, which misleads consumers into thinking that they have been inspected for wholesomeness. This violates the Poultry Products Inspection Act.” More information about ongoing litigation concerning California’s overturned ban on foie gras appears in Issue [554](#) of this *Update*.

Proposed Class Action Against Safeway Challenges Slack Fill in Tuna Cans

A California consumer has filed a putative class action against Safeway Inc. alleging the grocery retailer’s tuna cans are under-filled by 10 to 20 percent based on federally mandated fill standards. *Soto v. Safeway Inc.*, No. 15-5078 (N.D. Cal., filed November 5, 2015). The plaintiff contends that U.S. National Oceanic and Atmospheric Administration (NOAA) testing indicates Safeway’s 5-ounce tuna cans contain an average of 2.29 ounces of pressed cake tuna despite federal standards requiring cans of that size to contain at least 2.84 ounces of product. This result

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was consistent across 97.9 percent (94 of 96) of the tuna cans analyzed, according to the complaint. The plaintiff alleges breach of warranties, fraud, unjust enrichment, negligent misrepresentation and violations of California's consumer protection statutes, and he seeks class certification, compensatory and punitive damages, an injunction and attorney's fees.

OTHER DEVELOPMENTS

Italian Police Investigate Alleged Olive Oil Fraud

Police in Turin, Italy, are reportedly investigating seven companies, including Bertolli, Carapelli and Santa Sabina—for allegedly selling “Extra Virgin” olive oils (EVOOs) that fail to meet E.U. standards to be labeled as such. The investigation was reportedly launched after consumer magazine *Il Test* notified the police of its taste-test results. The police then hired the Italian customs agency to test 20 of the most popular brands of EVOO in a laboratory, finding that nine brands from seven companies were lower quality oil.

“For months now we have been increasing quality controls. In 2014 our inspectors carried out 6,000 checks and confiscated oil worth 10 million euros,” Agriculture Minister Maurizio Martina told *The Telegraph*. “It’s vital to protect a sector as important as that of olive oil.” See *The Telegraph*, *The Guardian* and *The Local*, November 11, 2015.

SCIENTIFIC/TECHNICAL ITEMS

Microscopic Plastics Reportedly Detected in Table Salt

A study examining table salts sold in China has purportedly found that many brands contain microscopic plastic particles such as polyethylene terephthalate, polyethylene and cellophane. Dongqi Yang, et al., “Microplastic Pollution in Table Salts from China,” *Environmental Science & Technology*, October 2015. Relying on samples obtained from Chinese supermarkets, researchers report that microplastic content was highest in sea salts at 550–681 particles per kilogram, followed by lake salts at 43–364 particles/kg and rock salts at 7–204 particles/kg.

The authors link this contamination to the pollution of coastal and estuary waters with water bottles, cellophane wrappers and the microbead exfoliates found in cosmetics. They also raise questions about the salt processing, drying and packaging process. Based on World Health Organization guidelines for salt intake, the study estimates that adults

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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.



who maximize their sea salt consumption will ingest approximately 1,000 microplastic particles each year from table salt alone, in addition to the high microplastic concentrations found in mussels, fish and other seafood products.

“Due to the pollution of seawater, many contaminants have been found in sea salts, including plasticizers, such as di(2-ethylhexyl) adipate and benzyl butyl phthalate,” explain the authors. “Plastic might be the direct sources of these contaminants. However, plastics might absorb contaminants from the seawater and transfer them to the sea products. Therefore, the presence of marine microplastics in the sea salts might pose a threat to food safety.” See *American Chemical Society’s Chemical & Engineering News*, November 2, 2015.