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LEGISLATION, REGULATIONS AND STANDARDS

USDA Finalizes *Salmonella* and *Campylobacter* Standards for Poultry

The U.S. Department of Agriculture (USDA) has finalized standards that seek to reduce *Salmonella* and *Campylobacter* in ground chicken and turkey products, as well as raw chicken breasts, legs and wings. Part of the Food Safety and Inspection Service’s (FSIS’) effort to revamp the poultry inspection system, the new rules require routine sampling throughout the year rather than infrequent sampling on consecutive days, and authorize the agency to publicize facility results online.

“Over the past seven years, USDA has put in place tighter and more strategic food safety measures than ever before for meat and poultry products. We have made strides in modernizing every aspect of food safety inspection, from company record keeping, to labeling requirements, to the way we perform testing in our labs,” said USDA Secretary Tom Vilsack in a February 4, 2016, news release. “These new standards, in combination with greater transparency about poultry companies’ food safety performance and better testing procedures, will help prevent tens of thousands of foodborne illnesses every year, reaching our Healthy People 2020 goals.”

By updating its inspection schedule, testing at points closer to the final product and strengthening pathogen reduction performance standards, FSIS seeks to achieve at least a 30 percent reduction in *Salmonella*-related illnesses linked to chicken parts, ground chicken and ground turkey. For *Campylobacter*, it also expects to see a 32-percent reduction in illnesses linked to chicken parts and ground chicken, and a 19-percent reduction in illnesses linked to ground turkey.

Meanwhile, U.S. Reps. Rosa DeLauro (D-Conn.) and Louise Slaughter (D-N.Y.) criticized the standards for failing to address all incidences of foodborne illness. “While USDA’s initiative in issuing this plan is to be applauded, the substance falls short in addressing this important public health issue,” DeLauro was quoted as saying. “The Government Accountability Office recently identified major flaws in the proposed poultry slaughter program, so why is USDA proposing we expand the program?”

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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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Meat is continuing to leave these processing facilities contaminated with *Salmonella*. We should be fixing the source of the problem, not leaving it up to consumers to guess whether their dinner will send them to the hospital." See *Rep. DeLauro Press Release*, February 4, 2016.

Additional details about new poultry standards appear in Issues [532](#) and [552](#) of this *Update*.

CDC Declares End to *E. Coli* Outbreak as Chipotle Faces Widening Criminal Investigation

The Centers for Disease Control and Prevention has declared that two *E. coli* outbreaks linked to Chipotle Mexican Grill Inc. "appear to be over," but the agency has not identified a food source for the outbreaks.

"The epidemiologic evidence collected during this investigation suggested that a common meal item or ingredient served at Chipotle Mexican Grill restaurants was a likely source of both outbreaks," the agency said. "When a restaurant serves foods with several ingredients that are mixed or cooked together and then used in multiple menu items, it can be more difficult for epidemiologic studies to identify [sic] the specific ingredient that is contaminated."

Meanwhile, Chipotle faces a joint investigation by the U.S. Food and Drug Administration and U.S. Department of Justice into a 2015 norovirus outbreak in one of its California restaurants. The company has reportedly been served an additional subpoena requiring it to produce documents on company-wide food safety measures dating from 2013. Additional details about the probe appear in Issue [589](#) of this *Update*. See *Reuters*, February 2, 2016.

EFSA Seeks to Revise Consumer Exposure Estimates for Food Contact Materials

The European Food Safety Authority's (EFSA's) Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids (CEF Panel) has issued a scientific opinion recommending revisions to the safety assessments conducted for food contact materials (FCM). After considering scientific comments received during public consultation, the CEF Panel advocates new standards for estimating food intake and calculating the level of FCM migration into food. The scientific opinion also finds that genotoxicity testing for FCM substances should be mandatory even in low-exposure scenarios, and that nanomaterials used in FCM should be evaluated on a "case by case" basis.

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To address different consumption scenarios, the CEF Panel divided foods into four categories based on exposure data extrapolated from EFSA's Comprehensive European Food Consumption Database as well as "default water consumption figures set by the World Health Organization (WHO) for infants." For each of these food categories, the panel identified the "critical" age group with the highest consumption by body weight and set consumption figures accordingly.

Replacing Scientific Committee on Food guidelines that use a default consumption figure of 17 grams per kilogram body weight per day (g/kg bw per day), this system would establish consumption estimates for packaging substances in contact with the following food categories: (i) water and foodstuffs such as reconstituted infant milk, (ii) milk, milk products and other non-alcoholic drinks, (iii) foods specifically intended for infants and toddlers, and (iv) foods other than those covered by categories one, two or three. According to the opinion, infants have the highest consumption by body weight of water and reconstituted infant milk, with a consumption figure estimated at 150 g/kg bw per day, while toddlers have the highest consumption by body weight of foods in the other three categories, with consumption figures estimated at 80, 50 and 20 g/kg bw per day, respectively.

Intended for use in estimating FCM exposures, these consumption figures are "approximately 9, 5, 3 and 1.2 times higher than the current default for consumption." In addition, the CEF Panel advocates "a tiered approach to toxicity testing of substances migrating" from FCM, proposing three thresholds—1.5, 30 and 80 $\mu\text{g}/\text{kg}$ bw per day—that would trigger the need for additional toxicity data. The opinion adds that the migration of FCM substances resulting in exposures exceeding 80 $\mu\text{g}/\text{kg}$ bw per day would approach those seen with food additives and require a corresponding toxicological data set.

"The first level, 1.5 $\mu\text{g}/\text{kg}$ bw per day, is intended to be a general threshold for the investigation of potential toxic effects other than genotoxicity," explains the CEF Panel in January 26, 2016, press release. "In case a substance can be classified in Cramer class I (the less toxic class, i.e. the substance has a simple chemical structure and can be anticipated to be metabolized to innocuous products, suggesting low oral toxicity), a second level of 30 $\mu\text{g}/\text{kg}$ bw per day could be set instead of 1.5 $\mu\text{g}/\text{kg}$ bw per day as the threshold for the investigation of repeated-dose toxicity. A third exposure threshold [80 $\mu\text{g}/\text{kg}$ bw per day] is proposed as a trigger for additional toxicity studies beyond the core set of general toxicity data."

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After the European Commission and member state authorities review these recommendations and provide direction “on the necessary levels of protection for consumers,” EFSA will issue detailed guidance on applications for the safety assessment of FCM substances. As CEF Panel member Laurence Castle notes, “This opinion reflects both advances in science and our experience over the last decade in applying existing EU guidelines... [The scientific opinion] presents recent scientific developments that impact on the estimation of consumer exposure to substances migrating from food contact materials, the tiered approach to their safety assessment, toxicological data requirements and consideration of the migration of non-intentionally added substances (NIAS).”

Russian MP Proposes “Graphic” Warning Labels on “Junk Food” and Fast-Food Packaging

Russian MP Oleg Mikheyev has reportedly asked the government to require “graphic warning labels” on fast-food packaging in an effort to stop the spread of obesity and improve the health of Russian citizens. Mikheyev, who previously proposed a tax on “junk food,” also argued that producers of food products such as potato chips or soft drink be required to include photos of illnesses caused by excessive consumption of those products.

“People know that sugar can cause type-2 diabetes, but few of them actually know what the trophic ulcers look like. Same goes for kidney stones that appear because of excessive consumption of salty foods or cholesterol plaques,” Mikheyev reportedly wrote in a letter to Prime Minister Dmitry Medvedev. Russian politicians have discussed mandatory labeling for fast food and other food products in the past, including in a July 2015 bill that proposed restricting fast-food and alcohol ads. *See RT*, January 28, 2016.

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Ohio Court Affirms Dismissal of Kroger “Humanely Raised” Chicken Dispute

An Ohio appeals court has affirmed a lower court decision finding that two consumers’ mislabeling allegations against The Kroger Co. are preempted by the Poultry Products Inspection Act (PPIA). *Arnold v. Kroger Co.*, No. C-150291 (Ohio Ct. App., 1st App. D., Hamilton Cnty., order entered January 22, 2016). The consumers alleged Kroger’s chickens were not subjected to “a humane environment” as the company

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advertised and thus were not worth the premium the store charged. The trial court dismissed the claims as preempted by the PPIA, and the plaintiffs appealed.

The appeals court was unpersuaded by the plaintiffs' argument that the Food Safety and Inspection Service's (FSIS') inspection and approval of Kroger's slaughtered chickens were insufficient to determine whether the chickens were in a humane environment while alive. "FSIS has determined that humane treatment of poultry directly implicates its fitness for human consumption because 'under the PPIA, poultry products are more likely to be adulterated if, among other circumstances, they are produced from birds that have not been treated humanely,' which may result in poultry that is 'not acceptable for human food,'" the court found.

Court Overrides Jury Verdict in Heinz Lead-Tainted Baby Food Insurance Dispute

Contradicting an advisory jury verdict, a Pennsylvania federal court has allowed Starr Surplus Lines Insurance Co. to void its policy with H.J. Heinz Co. covering damages related to the manufacture and sale of lead-tainted baby cereal. *H.J. Heinz Co. v. Starr Surplus Ins. Co.*, No. 15-0631 (W.D. Penn., order entered February 1, 2016). Surplus sought to rescind the policy, and the jury agreed with its argument that Heinz had made material misrepresentations on its application for product contamination coverage. The jury concluded that the insurance company knew about the misrepresentations and sold the policy anyway, thus losing its grounds for rescinding the policy; the court disagreed, finding "Heinz did not prove by a preponderance of the evidence that Starr had sufficient knowledge of the misrepresented facts prior to issuing the policy." Accordingly, the court voided the policy. Additional information about the jury decision appears in Issue [588](#) of this *Update*.

PETA's Lawsuit Against Whole Foods Dismissed

A California federal court has dismissed a lawsuit brought by People for the Ethical Treatment of Animals Inc. (PETA) alleging Whole Foods Market Inc. falsely advertises its meat as ethically slaughtered. *PETA v. Whole Foods Mkt., Inc.*, No. 15-4301 (N.D. Cal., order entered January 29, 2016). The organization challenged Whole Foods' five-step Global Animal Partnership rating as misleading consumers because the assessments are allegedly insufficient. Details on PETA's complaint appear in Issue [579](#) of this *Update*.

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The court first found that PETA had standing to sue despite the organization's not being a customer of Whole Foods. The court then turned to Whole Foods' argument that PETA failed to plead its fraud allegations with the specificity required. The photos included with the complaint were insufficient to fulfill the requirement, the court found, because PETA did not clarify which aspects of the in-store displays were at issue. That vagueness also prevented the court from determining whether PETA's claims were preempted—while labels may be governed by federal law, advertisements are subject to California consumer-protection statutes. Accordingly, the court granted Whole Foods' motion to dismiss but granted PETA leave to amend the allegations.

Chinese Firms Fined for Spreading KFC "Mutant Chicken" Rumors

A Shanghai court has reportedly fined three Chinese technology companies for their part in spreading rumors that KFC fare is produced with "mutant chickens" with eight legs and six wings. KFC filed a lawsuit in June 2015 seeking damages for economic losses and damage to its reputation. The court reportedly ordered the companies to make an official apology and pay a total of \$91,191 (600,000 yuan) to KFC. Additional details about the lawsuit appear in Issue [567](#) of this *Update*. See *Reuters*, February 2, 2016.

Bacardi Files FOIA Request for "Havana Club" Trademark Determination

Bacardi Ltd. has reportedly filed a Freedom of Information Act request seeking information on the renewal of a trademark registration for "Havana Club" granted to Empresa Cubana Exportadora de Alimentos y Productos Varios ("Cubaexport"), a Cuban government-owned entity. Cubaexport had filed for a renewal in 2006, but the U.S. Treasury Department's Office of Foreign Assets Control (OFAC) refused to grant the license required to renew the trademark.

Cubaexport sold its rum recipe and the rights to "Havana Club" to Bacardi in 1994, 30 years after the United States prohibited the import of Cuban goods. Bacardi sold rum under the "Havana Club" name while disputing the rights to the mark with Pernod Ricard, which owns the rights to sell Havana Club worldwide. In January 2016, Cubaexport sought to renew its trademark in "Havana Club," arguing that it had obtained the necessary license from OFAC, and the U.S. Patent and

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Trademark Office (PTO) granted the registration. Bacardi now reportedly seeks relevant documents from the Treasury, OFAC, PTO, State Department, Executive Office of the President and the National Security Council. *See Bloomberg BNA*, February 2, 2016.

Vodka Sauce Allegedly Mislabeled as “All Natural”

A New York consumer has filed a putative class action against Victoria Fine Foods alleging the company falsely advertises its vodka sauce as “all natural” and free of preservatives despite containing citric acid. *Shmidt v. Victoria Fine Foods*, No. 16-0230 (E.D.N.Y., filed January 15, 2016). The complaint asserts that Victoria “sought to capitalize on consumers’ preference for natural products and the association between such products and a wholesome way of life.”

The plaintiff argues that the primary jurisdiction doctrine does not apply because the U.S. Food and Drug Administration (FDA) “has repeatedly declined to adopt formal rule-making that would define the word ‘natural,’ although she asserts that FDA “has loosely defined the term ‘natural’ as a product that ‘does not contain added color, artificial flavors, or synthetic substances.’” The complaint also cites the U.S. Department of Agriculture’s Food Standards and Labeling Policy Book, “which states that the term ‘natural’ may be used on labeling for products that contain processed ingredients only where such ingredients are subjected to ‘minimal’ processing and that relatively severe processes, e.g., solvent extraction, acid hydrolysis and chemical bleaching would clearly be considered more than minimal processing.” For alleged violations of New York consumer-protection statutes as well as negligent misrepresentation, unjust enrichment and breach of warranties, the plaintiff seeks class certification, restitution, damages, an injunction and attorney’s fees.

Viacom Pursues Alleged “Krusty Krab” Infringers

Viacom International Inc. has filed a lawsuit against IJR Capital Investments alleging that a restaurant owned by the company infringes on Viacom’s intellectual property in the “SpongeBob SquarePants” franchise. *Viacom Int’l Inc. v. IJR Capital Invs.*, No. 16-0257 (S.D. Tex., Houston Div., filed January 29, 2016). As the complaint explains, “The ‘Krusty Krab’ is owned by Eugene H. Krabs, a prominent and recurring character in the SpongeBob universe. SpongeBob SquarePants works at the ‘Krusty Krab’ as a fry cook, but he also performs a myriad of other duties, and once stated that his official title is ‘Vice Assistant General Manager in charge of certain things.’”

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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.

IJR operates The Krusty Krab in Texas and has filed for trademark registration. Viacom argues that IJR is “attempting to trade off of the goodwill and reputation of the ‘SpongeBob SquarePants’ media franchise’ and that consumers are likely to be confused by IJR’s use of “Krusty Krab.” Viacom seeks an injunction and damages for false designation of origin, unfair competition, dilution, and trademark infringement under the Lanham Act and Texas law. It also requests that the court determine that IJR cannot register “The Krusty Krab” as a mark.

