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LEGISLATION, REGULATIONS AND STANDARDS

CDC Proposes Adding Bird Flu Strains to List of Select Agents and Toxins

The Centers for Disease Control and Prevention (CDC) has **issued** a notice of proposed rulemaking that would add certain highly pathogenic avian influenza strains (HPAIs) to the Department of Health and Human Services' (HHS) list of select agents and toxins. In addition to listing any influenza virus that contains hemagglutinin (HA) from the Goose Guangdong/1/96 lineage, including wild-type viruses, CDC seeks to categorize as a Tier 1 select agent any virus containing HA from the HPAI H5N1 lineage "that were made transmissible among mammals by respiratory droplets in a laboratory."

As directed by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, HHS **maintains** "a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety." Tier 1 designates those agents and toxins that "present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety."

"We have determined that these influenza viruses have the potential to pose a severe threat to public health and safety," states CDC in the notice. In particular, the agency highlights the increased pathogenicity of the HA molecule found in these strains that allows the virus to replicate outside the respiratory tract in humans. As the notice explains, "Extrapulmonary dissemination of HPAI H5N1 virus has been documented among some fatal human HPAI H5N1 virus infections."

Recognizing the effect of listing man-made transmissible HPAI H5N1 on vaccine development, CDC has specifically requested comments "on criteria that could be used for the exclusion of vaccine reassortants such as those well-characterized vaccine strains or backbones (*e.g.*, PR8) that have been demonstrated to not pose a severe threat to public health and

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safety.” The agency will accept comments on the proposed rule until September 14, 2015. *See Federal Register*, July 16, 2015.

FDA Science Board to Tackle Robust Agenda at July 2015 Meeting

The U.S. Food and Drug Administration (FDA) has **announced** a public meeting of its Science Board for July 29, 2015, at the agency’s campus in Silver Spring, Maryland. Among other things, the 21-member **group** will hear updates by Center for Veterinary Medicine representatives about two scientific initiatives and provide feedback about implementation of certain directives in the National Strategy for Combating Antibiotic-Resistant Bacteria. The board will also discuss the 21st Century Cures Act and be provided a status update about the Office of Medical Products and Tobacco. *See Federal Register*, July 13, 2015.

UK Government Committee Recommends Halving Sugar Intake

The U.K. Scientific Advisory Committee on Nutrition (SACN) has **released** its final *Carbohydrate and Health* report recommending that “free sugars account for no more than 5% of daily energy intake.” Asked by the U.K. Department of Health and the Food Standards Agency to “examine the latest evidence on the links between consumption of carbohydrates, sugars, starch and fiber and a range of health outcomes,” the expert panel commissioned systematic reviews of evidence from prospective cohort studies and randomized controlled trials, in addition to considering comments submitted in response to its first draft report.

Based on these findings, the report concludes, among other things, that (i) “high levels of sugar consumption are associated with a greater risk of tooth decay”; (ii) “drinking high-sugar beverages results in weight gain and increases in BMI in teenagers and children”; and (iii) “consuming too many high-sugar beverages increases the risk of developing type 2 diabetes.” To mitigate these health effects, SACN not only urges consumers to minimize sugar-sweetened beverage consumption, but recommends that “the term free sugar is adopted, replacing the terms Non Milk Extrinsic Sugars (NMES) and added sugars.” The panel also revised the dietary intake guidelines for fiber as follows: (i) adults over age 16 should increase their fiber intake to 30 grams per day, (ii) children ages 11 to 15 years should consume 25 grams daily, (iii) children ages 5 to 11 years should consume 20 grams daily, and (iv) children ages 2 to 5 years should consume 15 grams daily.

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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“The evidence is stark—too much sugar is harmful to health and we all need to cut back. The clear and consistent link between a high-sugar diet and conditions like obesity and type 2 diabetes is the wake-up call we need to rethink our diet,” said SACN Carbohydrates and Health Chair Ian Macdonald. “Cut down on sugars, increase fibre and we’ll all have a better chance of living longer, healthier lives.”

LITIGATION

Court Finds Gerber Case Unaffected by Fourth Circuit Change in False Ad Standards

A California federal court has denied Gerber Products Co.’s attempt to dismiss a false advertising lawsuit about the company’s Good Start® Gentle based on the reasoning in a June 2015 Fourth Circuit decision that significantly changed the law. *Zakaria v. Gerber Prods. Co.*, No. 15-0200 (C.D. Cal., order entered July 14, 2015). The June decision found that, “so long as there is a ‘reasonable difference of scientific opinion’ as to the merits of a manufacturer’s health claim, the alleged actual falsehood of that health claim cannot be the basis for a cause of action under several consumer protection laws.” *In re GNC Corp.*, No. 14-1724 (4th Cir., order entered June 19, 2015).

After the court denied its motion to dismiss on June 18, Gerber filed for reconsideration, arguing that *In re GNC* “has changed the law of false advertising.” The court, noting that the Fourth Circuit decision was not binding on the states of the Ninth Circuit, found the reasoning of *In re GNC* unpersuasive for three reasons: (i) Gerber failed to cite any California cases consistent with the ruling; (ii) the plaintiff’s allegation did not rest on the opinions of experts, but rather on a factual argument that Good Start® Gentle does not contain the health benefit advertised on its label; and (iii) the plaintiff’s theories of liability go beyond the claim that Gerber knowingly made a false statement about its product. Accordingly, the court denied Gerber’s motion for reconsideration.

Halal Food Co. Executive Found Guilty of Making False Export Statements

An Iowa federal jury has found William Aosse, the former owner of Midamar Corp., guilty of making false export statements along with conspiracy and wire fraud stemming from the company’s misrepresenta-

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tion of the source of food exported to Malaysia and Indonesia. *U.S. v. Aossey*, No. 14-0116 (N.D. Iowa, jury verdict entered July 13, 2015). Aossey was indicted over claims that Midamar bought products from a slaughterhouse not certified to export meat to Indonesia and Malaysia, then removed the facility's federal establishment number with nail-polish remover and replaced it with the number of a certified facility. Additional charges alleging that the company's products do not meet halal standards are pending against Aossey's sons.

Actual Calories, Fat in Kraft Sour Cream Four Times the Label Listing, Lawsuit Alleges

A consumer has filed a putative class action against Kraft Foods Group, Inc. alleging that the company's Knudsen Hampshire Sour Cream is labeled as containing 60 calories with 3.5 grams of saturated fat per half-cup while the actual content is 240 calories with 14 grams of saturated fat. *Appel v. Kraft Foods Grp., Inc.*, No. BC587662 (Cal. Super. Ct., Los Angeles Cnty., filed July 9, 2015). The plaintiff further alleges that the listed sodium content of 10 milligrams and sugar content of one gram is incorrect because the sour cream actually contains 40 milligrams of sodium and four grams of sugar. The complaint does not provide the source of the plaintiff's quadrupled figures. He alleges that Kraft has violated California consumer-protection statutes and seeks class certification, compensatory and punitive damages, restitution, an injunction, and attorney's fees.

Foster Farms Targeted in Purported Class Action over "Humane" Labeling

A consumer has filed a putative class action against Foster Poultry Farms, Inc. alleging that the company's label misleads by displaying an American Humane Association (AHA) certification logo because that certification does not indicate a higher, more humane standard for raising chickens. *Leining v. Foster Poultry Farms, Inc.*, No. BC588044 (Cal. Super. Ct., filed July 13, 2015).

The complaint asserts that Foster Farms markets itself as a humane producer of chicken products and charges higher prices accordingly. The plaintiff believed that this marketing message communicated that the chickens at Foster Farms "lived a life without disease and discomfort and were afforded a quick and painless death." She argues, however, "the



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AHA certification standards permit practices throughout all phases of the production process that, if known, would not be considered humane either by the reasonable consumer or even under the AHA's own definition of humane meat production.”

The complaint details each of Foster Farms' alleged departures from the plaintiff's interpretation of humane treatment. AHA standards, she argues, allow certified producers to (i) force female chickens to molt by 10 to 14 days of food deprivation, which apparently causes the chickens to lose up to 25 percent of their body weight, (ii) grind live male chicks, (iii) trim up to one-half of the beak tips, (iv) remove roosters' combs without anesthesia, (v) pierce the nasal septa of young breeding roosters with a plastic stick, (vi) shackle the legs of chickens during preparation of slaughter, and (vii) submit the chickens to “near-starvation levels of food and water deprivation.” The plaintiff “does not reasonably consider any of these practices to be consistent with her understanding of the humane treatment signified by the American Humane® Certified label on the Foster Farms chicken packages that she purchased.” She also points to living conditions for the chickens as “inhumane and cruel,” including allowed tolerances for diseases and ambient ammonia concentrations.

The plaintiff alleges that these practices amount to unfair competition, negligent misrepresentation and breaches of warranty, and she seeks class certification, an injunction against further labeling of Foster Farms chicken as “humane,” restitution and damages, and attorney's fees.

OTHER DEVELOPMENTS

As You Sow Praises Pollinator Protection Policies

Shareholder advocacy group As You Sow has reportedly withdrawn a shareholder resolution after General Mills Inc. agreed to “consolidate and disseminate guidance to growers of key commodities such as corn and soy on how to protect and minimize the impact of neonicotinoids and other pesticides to pollinators.” According to a July 8, 2015, press release, the company will support the White House's Pollinator Health Task Force strategy by working with a non-profit conservation group and suppliers to craft policies meant to reverse the decline in honeybee populations.



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“Many of the crops that General Mills buys depend on pollinators,” said As You Sow’s Environmental Health Program Manager Austin Wilson. “By investing in supply-chain sustainability, General Mills is ensuring the future of its supply chain and its profitability.”

Salt-Reduction Strategies Focus of Upcoming Webinar

“Pass (on) the Salt: The Business Case for Sodium Reduction” is the title of a July 29, 2015, [webinar](#) organized by California-based law and policy group ChangeLab Solutions. Program faculty, including two ChangeLab staff attorneys, will reportedly discuss various institutional (e.g., state governments, hospitals) initiatives to limit the number of salty foods provided or available for purchase in the workplace and how such campaigns “can result in a positive return on investment.”

MEDIA COVERAGE

DOJ Warns of Criminal Prosecutions for Food-Safety Lapses

In a recent Associated Press (AP) interview, U.S. Associate Attorney General Stuart Delery warns that the Department of Justice (DOJ) will pursue criminal penalties against companies that sell poisoned food. AP cites the recent prosecution of Peanut Corp. of America executives along with actions against the producers of tainted cantaloupe and eggs as evidence of the federal government’s increased focus on criminal enforcement of food safety laws. Plaintiffs’ attorney Bill Marler reportedly told the news organization that the DOJ’s actions were especially notable because the company executives charged in the prosecutions often did not know that their food products were tainted.

“We have made a priority holding individuals and companies responsible when they fail to live up to their obligations that they have to protect the safety of the food that all of us eat,” Delery said. “The criminal prosecutions we bring should stand as a stark reminder of the potential consequences of disregarding danger to one’s customers in the name of getting a shipment out on time—of sacrificing what is right for what is expedient.” *See Associated Press*, July 13, 2015.

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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.



Politico Takes President Obama and Congress to Task over Food-Safety Reform

By failing to adequately fund and implement the Food Safety Modernization Act (FSMA), the “Obama administration and Congress have all but squandered an opportunity to give the anemic Food and Drug Administration, which is responsible for the safety of 80 percent of the nation’s food supply, a level of oversight the public long assumed it had,” according to a July 14, 2015, Politico **investigation**. The lengthy article details various delays in implementing the law and serious outbreaks of food-borne illnesses that might have been prevented had FDA been given the financial resources for inspections and other food-safety initiatives.