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LEGISLATION, REGULATIONS AND STANDARDS

Advocacy Groups Petition FDA for Ban on Chemicals Used in Food Contact Materials

The Natural Resources Defense Council (NRDC) has joined the Center for Science in the Public Interest and other consumer groups in petitioning the U.S. Food and Drug Administration (FDA) to remove several chemicals from food contact materials. The first **food additive petition** asks FDA to promulgate a new rule "prohibiting the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be used in food contact articles," and to amend existing regulations to ban the use of potassium perchlorate in food-container sealing gaskets. Citing "the well-recognized toxicity of perchlorate," the petition alleges that dietary exposure can impair fetal and infant development, especially when pregnant or nursing women do not consume enough iodine.

A <u>second petition</u> urges the agency to revoke approval for "the use of long-chain perfluorocarboxylate [PFC] oil and grease repellents in paper and paperboard." Noting that FDA has already asked some domestic manufacturers to stop using these chemicals in their food contact substances, the petition points to new studies that allegedly support this decision and raise questions about the effects of PFCs on pre- and post-natal development and reproductive health.

"We already know that perchlorate is both toxic and widespread in food and the bodies of virtually all Americans, so adding more to packaging that can get into food is especially risky. FDA should ban this chemical immediately from food uses to protect pre-natal and young children from potentially permanent brain damage," said NRDC Senior Strategic Director for Health and Food Erik Olson, adding that, "FDA should swiftly ensure that these risky PFCs, which it has already asked domestic producers to stop using, aren't sneaking into our food supply through pizza boxes or sandwich wrappers made overseas." See NRDC Press Release, October 16, 2014.



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SHB 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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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com);

U.S. Chamber and NAM Urge Congress to Suspend COOL Rule

Senior executives from the National Association of Manufacturers (NAM) and U.S. Chamber of Commerce have co-authored an October 14, 2014, Letter to members of Congress urging the lawmakers to "authorize and direct the Secretary of Agriculture to rescind elements of [country-of-origin labeling (COOL)] that have been determined to be noncompliant with international trade obligations by a final [World Trade Organization (WTO)] adjudication."

Citing Americans' jobs as a primary concern, the executives argue that the regulations requiring muscle cuts of meat to include COOL would harm the United States' relationship with its neighbors. "We are especially concerned that, should the WTO litigation conclude with a ruling of noncompliance by the United States, Congress would be unable to amend the statute prior to Canada and Mexico, our two largest export markets, instituting WTO-authorized retaliation against U.S. exports," the letter said. "The history is clear. Buyer supply chain needs result in export markets being lost even before retaliation is authorized. More damaging, once export markets are lost, it takes years to regain the market."

In August 2014, 110 members of Congress urged Secretary of Agriculture Tom Vilsack to rescind the COOL requirements if WTO rules against the United States. Further information about that letter appears in Issue <u>533</u> of this *Update*.

USDA Schedules Meeting of GIPSA Advisory Committee

The U.S. Department of Agriculture (USDA) has scheduled a November 4-5, 2014, public <u>meeting</u> of the Grain Inspection, Packers and Stockyards Administration (GIPSA) Advisory Committee at the National Grain Center in Kansas City, Missouri. Issues for discussion at the meeting will reportedly include the reauthorization status and standardization of user fees paid by official agencies; commodity inspection fees; and updates on quality assurance, compliance, science, and technology programs. *See Federal Register*, October 14, 2014.

Vermont Invites Public Comments on GMO-Labeling Rule Enforcement

Vermont Attorney General (AG) William Sorrell is inviting public comments on a <u>draft rule</u> intended to enforce the state's new law requiring the labeling of genetically modified organisms (GMOs) in food products. The proposed rule defines relevant terms such as "food," "genetic engineering" and "in vitro nucleic acid techniques," providing standards for retailers and food manufacturers about how to label and display the foods. In addition, the draft rule lists exemptions from the GMO-labeling requirement, including alcoholic beverages, food prepared for immediate consumption, medical food, and



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processed foods containing less than 1 percent genetically engineered materials. The AG's office is accepting comments by email and at hearings set for October 21, 22 and 24, 2014, in Burlington, Montpelier and Brattleboro, Vermont. Additional information about the law appears in Issue <u>521</u> of this *Update*, and a recent development on the lawsuit challenging the law appears in Issue <u>540</u> of this *Update*. *See Office of the Attorney General Press Release*, October 15, 2014.

GE Salmon Production Banned in California

California Governor Jerry Brown (D) recently signed a bill (A.B. 504) extending the prohibition of spawning, incubating or cultivating of genetically engineered (GE) salmon in the Pacific Ocean to all state waters. Hatchery production and stocking of transgenic fish is also prohibited. The legislation was sponsored by Assemblymember Wesley Chesbro (D-Arcata), who asserts that the specter of "frankenfish" escaping into California waters "could destroy our native salmonid populations through interbreeding, competition for food and the introduction of parasites and disease."

The new law also restricts medical or scientific research to that performed by "accredited California academic institutions or private entities for research only and not for commercial production," provided such activities are conducted in closed systems that reduce the "risk of escape of transgenic finfish species and any potential disease they may transmit." See Press Release of Assemblymember Wesley Chesbro, September 29, 2014.

WTO Rejects Indian Restrictions on U.S. Poultry Imports

A World Trade Organization (WTO) dispute settlement panel has <u>found</u> that a series of food safety restrictions imposed by the Indian government on imports of U.S. poultry products was based on the inaccurate proposition that U.S. poultry was more likely to carry bird flu. India failed to distinguish between high-pathogenic bird flu that had not been found in the United States since 2004 and a low-pathogenic strain that had appeared in the country, the WTO panel found, so it rejected the Agreement on Sanitary and Phytosanitary Measures. The United States initially challenged the import restriction in 2012 following complaints from chicken farmers accusing the Indian government of unfairly shielding its poultry producers from foreign competition. India has 60 days to challenge the panel's findings, and if it does, the WTO Appellate Body will have 90 days to issue a report on the dispute.



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LITIGATION

Gerber Probiotics False Advertising Putative Class Action Can Continue

A New Jersey federal court has refused to dismiss a lawsuit alleging that Gerber falsely advertises some of its products as providing immune system boosts and as being nearly equal to breast milk. In re Gerber Probiotics Sales Practices Litig., No. 12-835 (U.S. Dist. Ct., D.N.J., order entered October 6, 2014). The plaintiffs alleged that Gerber misleadingly advertised three products—Good Start Protect Infant Formula, Good Start 2 Protect Formula for 9 through 24 months and DHA & Probiotic Cereal—as boosting immunity with an "Immuniprotect" formula that includes trademarked Bifidus BL probiotic bacteria.

Gerber challenged the plaintiffs' fourth amended complaint for lack of standing, arguing that the complaint did not allege that a named plaintiff purchased the infant formula product, but the court found that the basis for the claims was the same in that Gerber advertised each product as "scientifically advanced" and superior through the inclusion of Bifidus BL. The court agreed with Gerber's argument that the plaintiffs had failed to allege an ascertainable loss because "they fail to name the identity of the alleged branded and private label products" to which they compared Gerber's products to assess the price difference, but because plaintiffs could plead that information with specificity, "the Court will grant a final opportunity to amend this claim insofar as they can insert the identities and prices of comparable products sufficient to allege ascertainable loss under the benefit of the bargain theory."

Claims Trimmed in Mott's "No Sugar Added" Putative Class Action

A California federal court has granted in part and denied in part a motion for summary judgment in a lawsuit alleging that Mott's violated the U.S. Food and Drug Administration's (FDA's) and California's Sherman Law standards on the use of "no sugar added" on food packaging. Rahman v. Mott's LLP, No. 13-3482 (U.S. Dist. Ct., N.D. Cal., order entered October 14, 2014). The plaintiff alleged that Mott's 100% Apple Juice included a "no sugar added" label but failed to follow the additional FDA regulations requiring "a statement that the food is not 'low calorie' or 'calorie reduced' (unless the food meets the requirement for a 'low' or 'reduced calorie' food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content."

Mott's moved for summary judgment on four grounds: the plaintiff (i) did not suffer damages as a result of purchasing the apple juice, (ii) lacked standing to seek injunctive relief, (iii) did not rely on the "No Sugar Added" label when choosing to purchase the product, and (iv) failed to show that the "No Sugar Added" label is misleading to a reasonable consumer. The court dismissed the first and third arguments, finding that the plaintiff had shown sufficient



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damages and that the issue of whether he relied on the label is a factual issue that cannot be decided by summary judgment. The court agreed with Mott's that the plaintiff did not have standing for injunctive relief because he "cannot plausibly prove that he will, in the future, rely on the 'No Sugar Added' statement to his detriment." Assessing the "reasonable consumer" standard, the court was not convinced by the plaintiff's expert witness, a professor who testified to how he could determine that consumers relied on the "No Sugar Added" label to make health-related and purchasing decisions but had not actually conducted such a study. It then dismissed the plaintiff's claims brought under California's False Advertising Law, Consumers Legal Remedies Act and the fraud and unfair prongs of the Unfair Competition Law (UCL) as well as the claim of negligent misrepresentation, but allowed the claims brought under the unlawful prong of the UCL and breach of quasi-contract to continue.

Court Says Texas Can Intervene in Lawsuit over "Alamo" Trademark

Adopting a magistrate judge's recommendation, a Texas federal court has ruled that Texas can intervene in a lawsuit brought by brewer Alamo Beer Co. alleging that Old 300 Brewing infringed Alamo Beer's trademark for using the silhouette of the Alamo building on its labels. *Alamo Beer Co. LLC v. Old 300 Brewing LLC*, No. 14-285 (U.S. Dist. Ct., W.D. Tex., order entered October 14, 2014). The state of Texas filed a motion to intervene in April 2014, asserting that its interests in the Alamo trademark were not adequately represented by either party. A magistrate judge issued a report on the matter in May recommending that Texas be allowed to join the lawsuit, and Alamo Beer argued to the court that the magistrate judge had failed to properly analyze two factors of mandatory intervention and that the state lacked the right to intervene under trademark law. Reviewing Alamo Beer's concerns, the court rejected its arguments and concluded "these objects are without merit." Further information on the state's motion to intervene appears in Issue 523 of this *Update*.

OTHER DEVELOPMENTS

CSPI Report Asserts Food and Beverage Options in Checkout Aisles Promote Obesity

The Center for Science in the Public Interest (CSPI) has released a <u>report</u> claiming that candy, energy bars, chips, and cookies constitute 90 percent of foods marketed in store checkout lanes, while sugar-sweetened beverages constitute 60 percent of the beverage options. According to the study, which examined 30 retailers in the Washington, D.C., area, 86 percent of non-grocery retailers displayed foods and/or beverages in checkout aisles, but only one



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food store abstained from marketing foods or beverages at the point of sale. In addition, the one retailer with a designated "family-friendly" aisle still marketed allegedly unhealthy foods and beverages in amounts and percentages similar to those found in regular checkout lanes.

Arguing that such practices promote obesity, the consumer watchdog is urging retailers to set "nutrition standards for their checkout offerings" by limiting the amount of calories, saturated and *trans* fats, added sugars, and sodium in food and beverage options. "In this age of diabetes and obesity, it's unethical for retailers to push people to buy and consume extra calories that will harm their health," opined CSPI Senior Nutrition Policy Counsel Jessica Almy in an October 16, 2014, press release. "Food stores should set nutrition standards for the foods at checkout and non-food retailers should get out of the junk-food business altogether."

SCIENTIFIC/TECHNICAL ITEMS

WHO Reviews Energy Drink Consumption in Europe

World Health Organization (WHO) researchers recently published an analysis of energy drink consumption in Europe that takes into account relevant scientific literature published through June 2014. Joao Breda, et al., "Energy drink consumption in Europe: a review of the risks, adverse health effects, and policy options to respond," Frontiers in Public Health, October 2014. Noting that most adverse events associated with energy drink consumption are caffeine-related, the study reports that some energy drinks contain "extreme caffeine levels much higher than mainstream brands as they try to establish themselves in the market."

"Consumption of energy drinks among adolescents is associated with other potentially negative health and behavioral outcomes such as sensation seeking, use of tobacco and other harmful substances, and binge drinking and is associated with a greater risk for depression and injuries that require medical treatment," suggest the study's authors. "There is an increasing amount of research linking energy drink consumption with high-risk behavior, particularly when combined with alcohol."

To mitigate the risk of caffeine overdose and other health effects, the study ultimately recommends setting an upper limit on the amount of caffeine contained in a single energy-drink serving. In addition, the authors advocate marketing and sale restrictions to reduce consumption among youth.

"Energy drink manufacturers aggressively market their products to children, adolescents, and young adults," concludes the report. "The absence of regulatory oversight in many countries has contributed to the aggressive marketing



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of energy drinks targeted primarily toward young males. Regulatory agencies should enforce industry-wide standards for responsible marketing of energy drinks and ensure that the risks associated with energy drink consumption are well known."

New Study Provides Basis for Fructose-Tolerance Test

Investigators with Beth Israel Deaconess Medical Center (BIDMC) have for the first time identified a hormone that, when stimulated by fructose ingestion, could serve as the basis for a reliable fructose-tolerance test. Jody Dushay, et al., "Fructose ingestion acutely stimulates circulating FGF21 levels in humans," *Molecular Metabolism*, October 2014. Known as Fibroblast Growth Factor 21 (FGF21), the hormone in question has been associated with obesity, insulin resistance and non-alcoholic fatty liver disease in both humans and animals. In this study, researchers reported that FGF21 levels increased by an average of 400 percent in healthy volunteers who consumed 75 grams of fructose. By comparison, the consumption of glucose had little immediate effect on FGF21 blood levels.

"This tells us that fructose actively regulates FGF21 in humans," explained one study author. "The hormone-like response of FGF21 to fructose ingestion suggests that FGF21 might play an unanticipated role in regulating fructose metabolism. We were totally surprised by this dramatic effect because, to date, there has been no way of assessing the body's acute metabolic response to fructose ingestion. We haven't had a simple quick test like we have for glucose." See BIDMC Press Release and The New York Times, October 13, 2014.

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FOOD & BEVERAGE LITIGATION UPDATE

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.

SHB 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.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.





