Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Bill Seeks to Block Mandatory GM Labeling

U.S. Rep. Mike Pompeo (R-Kansas) has introduced legislation (H.R. 4432) that would prohibit states from implementing labeling laws for foods that contain genetically modified (GM) ingredients. Titled the "Safe and Accurate Food Labeling Act," the bill would (i) require the U.S. Food and Drug Administration (FDA) to mandate GM labeling only if those foods "are found to be unsafe or materially different from foods produced without biotech ingredients"; and (ii) establish a federal labeling standard for foods with GM ingredients, giving FDA sole authority to require labeling on such foods if they are ever deemed unsafe or materially different from foods produced without GM ingredients.

According to news sources, Pompeo contends that state campaigns to label foods containing GM ingredients are intended to scare consumers, not inform them. GM crops have made "food safer and more abundant," Pompeo said. "It has been an enormous boon to all of humanity."

GM labeling advocates, however, reportedly refer to Pompeo's bill as the "Deny Americans the Right to Know" or "DARK" Act, arguing that GM labeling would allow consumers to make informed purchasing decisions. *See Reuters.com*, April 9, 2014; *Rep. Mike Pompeo News Release*, April 10, 2014.

FDA Issues Recordkeeping Rule and Guidance for Industry

The U.S. Food and Drug Administration (FDA) has issued a final rule adopting the interim final rule titled "Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements" for recordkeeping regulations under the Food Safety Modernization Act (FSMA). The amendments made under FSMA allow FDA access to records beyond those relating to specific suspect food articles if the agency believes that other food articles are likely to be affected in a similar manner. The amendments also permit FDA to access records relating to articles of food "for which there is a reasonable probability that the use of, or exposure to, the article of food will cause serious adverse health consequences or death to humans or animals." The expanded records-access authority is intended to improve FDA's ability to respond to and contain safety problems with the food supply for humans and animals.

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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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FDA has also issued two guidance documents, "FDA Records Access Authority under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act" and "What You Need to Know About Establishment, Maintenance, and Availability of Records—Small Entity Compliance Guide," which update previous versions. Comments on the guidance documents will be accepted at any time. *See Federal Register*, April 4, 2014.

FDA Releases Draft Honey Labeling Guidance

The U.S. Food and Drug Administration (FDA) has **issued** draft guidance concerning the proper labeling of honey and honey products to ensure that such products "are not adulterated or misbranded." In light of its earlier refusal to create a new standard of identity for honey, the agency developed the guidance to respond to labeling issues raised by a March 8, 2006, petition submitted by the American Beekeeping Federation and other honey-related associations.

According to FDA, the draft guidance (i) "summarizes FDA's legal authority over honey and honey products"; (ii) "provides a commonly used definition of honey"; (iii) "offers advice on labeling issues such as the floral source of honey, blends of honey and other sweeteners, and blends of honey and other ingredients, such as flavors"; and (iv) "describes some of the measures FDA takes to guard against honey adulterated with cane sugar, corn syrup, or residues of chloramphenicol or fluoroquinolones." The agency has requested comments on the draft guidance before June 9, 2014. *See CFSAN Constituent Update,* April 8, 2014; *Federal Register,* April 9, 2014.

EFSA Delays BPA Risk Assessment

The European Food Safety Authority (EFSA) has **extended** "the timeline to complete its full risk assessment of bisphenol A (BPA) to the end of 2014." After receiving nearly 250 comments in response to the second part of its draft risk assessment, EFSA has emphasized the need for "a full understanding of these comments before finalizing its risk assessment of BPA." Additional details about the draft risk assessment and an April 23, 2014, stakeholder meeting appear in Issues **511** and **515** of this *Update.*

OEHHA Intends to List Ethylene Glycol as Reproductive Toxicant

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **issued** a notice of intent to list ethylene glycol (EG) as known to the state to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

Used in the manufacture of polyethylene terephthalate resins (PET), which are used in bottling, the chemical has been reported for its potential human

reproductive and developmental effects by the National Toxicology Program in a 2004 monograph that "identifies EG as causing developmental toxicity in laboratory animals, and satisfies the formal identification criteria in the Proposition 65 regulations," according to OEHHA.

Public comments "as to whether ethylene glycol meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings" are requested by May 12, 2014. Companies making and selling products containing chemicals listed under Proposition 65 are required to disclose exposures to California consumers or face fines for failure to do so. *See OEHHA News Release*, April 11, 2014.

OEHHA to Webcast Prop. 65 Warnings Workshop

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) will **conduct** a pre-regulatory public workshop on Proposition 65 (Prop. 65) warnings on April 14, 2014, in Sacramento. The event will be Webcast. OEHHA Chief Counsel Carol Monahan-Cummings will discuss potential regulatory action, including clarifying questions and responses, discussion of proposed changes and public questions and answers, as well as next steps. Additional information about the proposed Prop. 65 warning changes appears in Issue **517** of this *Update*. *See OEHHA News Release*, April 7, 2014.

City Council in California Declares Hot Sauce Operations a Public Nuisance

The Irwindale, California, City Council has reportedly voted 4-0 to declare that Huy Fong Foods, the maker of Sriracha hot sauce, is maintaining a public nuisance. If the council adopts an official resolution during its next meeting, the company will have some 90 days to mitigate the odor, blamed by local residents for their burning eyes and throats. The council's action came despite assurances from the company's lawyer that it planned to submit an action plan within the next two weeks and fix the odor problem by June 1. The South Coast Air Quality Management District has been conducting tests at the facility and claims that the problems could be resolved with active carbon filters.

Irwindale has sued the popular hot sauce maker in superior court, claiming that the company breached its development agreement and created a public nuisance. The court granted the city's request for a preliminary injunction requiring Huy Fong Foods to cease emitting noxious or irritating odors and set a trial for November, but complaints about odors have persisted. During city council's April 9, 2014, hearing, council members apparently decided to designate the facility a public nuisance as insurance in the event that Huy Fong Foods fails to install mitigation measures. The council also claimed that it has the authority to enter the factory, make the needed changes and assess costs to the owner, a news source said.

State Sen. Ed Hernandez, speaking to the council through a representative, called the company one of the "shining stars" in the local business community and offered to help it find a new base of operations in another city. *See Irwindale, California, Notice and Call of Special Meeting Agenda,* April 3, 2014; *Los Angeles Times*, April 9, 2014.

LITIGATION

D.C. Circuit Orders *En Banc* Rehearing in AMI Challenge to COOL Rules

The D.C. Circuit Court of Appeals has vacated a panel's March 28, 2014, denial of the motion for preliminary judgment filed by meat producer interests in litigation challenging U.S. Department of Agriculture (USDA) regulations requiring retailers of "muscle cuts" of meat to list the countries of origin and production (country-of-origin labeling or COOL) as to each step of production—born, raised or slaughtered. *Am. Meat Inst. v. USDA*, No. 13-5281 (D.C. Cir., order entered April 4, 2014). Additional information about the March 28 decision appears in Issue **518** of this *Update*.

A court majority voted to rehear the case before the full court on May 19 and ordered the parties to brief a supplemental issue: "Whether, under the First Amendment, judicial review of mandatory disclosure of 'purely factual and uncontroversial' commercial information, compelled for reasons other than preventing deception, can properly proceed under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985), or whether such compelled disclosure is subject to review under *Central Hudson Gas & Electric v. PSC of New York*, 447 U.S. 56 (1980)." Supplemental briefs must be filed by April 21.

ECJ Case Dismissed Following Notice of Pending FDA Review

A federal court in California has granted beverage manufacturer Santa Cruz's motion to dismiss a putative class action alleging that the "evaporated cane juice" (ECJ) listed on its beverage labels is merely sugar, thus violating the Food and Drug Administration's (FDA's) required use of an ingredient's "common or usual name." *Swearingen et al. v. Santa Cruz Natural Inc.*, No. 13-4291 (U.S. Dist. Ct., N.D. Cal., order entered April 2, 2014).

Finding that FDA had primary jurisdiction over the matter, the court cited a March 5, 2014, notice that the agency has reopened the comment period on its draft industry guidance pertaining to the use of the term ECJ on food labels. Details about FDA's action appear in Issue **516** of this *Update*. According to the court, this notice clearly indicates that FDA is currently engaged in "active rulemaking on the issue" and intends to resolve the matter. Citing FDA's superior resources to determine whether ECJ is sugar and the likelihood that the pending FDA decision would affect the outcome of the

case, the court dismissed the lawsuit without prejudice. The decision joins a spate of other cases on the subject of ECJ and food labels, some of which have had different outcomes.

Court Allows "No Sugar Added" Claims to Proceed

A federal court in California has denied the motion to dismiss putative class claims that Mott's LLP deceives consumers by placing "No Sugar Added" on its 100% Apple Juice label. *Rahman v. Mott's LLP*, No. 13-3482 (U.S. Dist. Ct., N.D. Cal., order entered April 8, 2014). Information about the court's prior decision dismissing without prejudice most of the claims in the plaintiff's first amended complaint appears in Issue 511 of this *Update*.

As to the plaintiff's second amended complaint, the court disagreed with the defendant's argument that an ongoing U.S. Food and Drug Administration (FDA) rulemaking pertaining to Nutrition Facts label disclosures about the presence or absence of added sugars required dismissal of the action under the primary jurisdiction doctrine. While the court agreed that food regulation is within FDA's purview, it stated, "plaintiff's claims do not concern statements made on the apple juice's Nutrition Facts label; rather, plaintiff's claims relate to nutrient content claims made on the product's front label." Thus, the court determined that the claims "are not implicated by the March 3, 2014, proposed rule." The court refused, as well, to speculate whether FDA would finalize the rule and if that action would require rulemaking as to other parts of a food product label.

The court also found that the plaintiff had alleged sufficient facts to show that a reasonable consumer would be deceived by Mott's "No Sugar Added" labeling. According to the court, the plaintiff had "remedied the defects identified by the Court" as to his first amended complaint. In the new complaint, the plaintiff alleges that "while shopping, he observed that the label of one of Mott's competitor apple juices, Treetop, did not contain a 'No Sugar Added' claim [and] that this difference between the labels caused him to believe that Mott's 100% Apple Juice contained less sugar and was healthier than Treetop's apple juice." He also identified additional competitor products lacking the "No Sugar Added" claim and containing "approximately the same amount of sugar and calories per ounce as Mott's 100% Apple Juice."

The court further determined that the plaintiff had sufficiently alleged injury and damages despite indicating that he intended to purchase the company's product in the future, albeit less of it. According to the court, "plaintiff alleges that he entered into more transactions and parted with more money than he would have absent the misrepresentations. 'That increment, the extra money paid, is economic injury and affords the consumer standing to sue.'" The plaintiff's negligent misrepresentation claim will also proceed, with the court finding that the plaintiff adequately pleaded justifiable reliance.

Suit Against Safeway for Failure to Warn of Food Recalls May Proceed

A federal court in California has determined that a consumer case alleging that Safeway was negligent for failing to notify customers of food recalls may proceed. *Hensley-MacLean v. Safeway, Inc.*, No. 11-01230 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., order entered April 7, 2014). According to the court, Safeway failed to justify a post-sale exception to California's negligence law, which imposes a general duty of care.

The plaintiffs claim that Safeway should—and could easily—notify customers of food recalls after they have purchased the recalled products because Safeway collects contact information from its loyalty card customers. Safeway argued that it had no duty to warn customers after they have taken the products out of the store. Rejecting the company's argument, the court observed that Safeway could clearly foresee that its customers would consume the products purchased at its stores. The court also identified a number of previous decisions holding that the manufacturer's duty extends beyond the point of sale, as well as a decision implying that a seller's duty may also extend beyond that point. Without any justification for establishing a post-sale, no-duty rule, the court denied Safeway's motion for summary judgment.

Theft of Yogurt Trade Secret Alleged in Chobani Ownership Dispute

The former wife of billionaire Chobani, Inc. CEO Hamdi Ulukaya has alleged that he "boasted on occasions that he had obtained the formula for the Chobani brand of yogurt from [competitor] Fage by bribing a former employee of Fage. He traveled to Europe and bribed this individual with 30,000 Euros." *Giray v. Ulukaya*, No. 652838-2012 (N.Y. Sup. Ct., N.Y. Cnty., memorandum filed April 3, 2014). She made the allegation in a memorandum of law filed in support of her motion for injunctive relief in litigation seeking a determination that she is a 53 percent shareholder in defendant Euphrates, Inc., the assets of which, she claims, were used to create Chobani.

Plaintiff Ayse Giray, a New York physician, also claims that she financed the formation of Euphrates "and is merely claiming what was acknowledged by defendants in writing. The yogurt was based upon a recipe he stole from a competitor, Fage. He defrauded his angel investors by selling in excess of 100% of the shares of Euphrates in addition to his own. Each of them had to sue him to enforce their agreements or at least get their money back. He lied to his banks and the USDA by misrepresenting his assets and by concealing the true ownership of Euphrates to avoid the need for a personal guarantee. He kept the factories' doors open by reducing expenses through tax fraud and bypassing sewage meters." Giray seeks an order enjoining the defendants from taking any action diminishing her rights and compelling them to provide her with all agreements "in connection with the prospective sale of any interest in Chobani or Euphrates which would dilute, adversely affect or diminish Plaintiff's shareholder interest."

The court has reportedly refused to issue a temporary restraining order. *Bloomberg Businessweek*, April 4, 2014.

OTHER DEVELOPMENTS

NRDC Claims GRAS Process Is Flawed

The Natural Resources Defense Council (NRDC) has **issued** a report claiming that the U.S. Food and Drug Administration's (FDA's) generally recognized as safe (GRAS) process for identifying food additives not required to undergo premarket approval is flawed and calling for legislation to change the process.

According to NRDC, minimal FDA supervision and "a gaping loophole that allows companies to simply declare as safe hundreds of chemicals added to our foods—without any notification to the FDA or the public," mar the U.S. food safety protection system.

Under federal law, substances added to food are deemed food additives subject to FDA's premarket approval unless they are considered GRAS by qualified experts or otherwise excluded from the food additive definition. While food companies can notify the agency that experts have made a GRAS determination, the law does not required them to do so. NRDC claims that it has identified "275 chemicals from 56 companies [that] appear to be marketed as GRAS and used in many food products based on companies' safety determinations that, pursuant to current regulations, did not need to be reported to the FDA or the public," and cites instances in which "companies have sometimes certified their chemicals as safe for use in food despite potentially serious allergic reactions, or adverse reactions in combination with common drugs." *See NRDC Press Release*, April 7, 2014.

SCIENTIFIC/TECHNICAL ITEMS

New Research Targets Role of Parental Obesity in Autism Spectrum Disorders

A study examining the link between parental body mass index (BMI) and autism spectrum disorders (ASDs) has reportedly claimed that paternal obesity "is an independent risk factor for ASDs in children." Pal Suren, et al., "Parental Obesity and Risk of Autism Spectrum Disorders," *Pediatrics,* April 2014. Noting that previous research focused only on the role of maternal pre-pregnancy obesity in neurodevelopmental disorders, the study's authors relied on data from 92,909 children enrolled in the Norwegian Mother and Child Study to estimate the relative risk of ASDs using logistic regression models.

The results evidently showed that "maternal obesity (BMI ≥30) was only weakly associated with ASD risk, whereas paternal obesity was associated with an increased risk of autistic disorder and Asperger disorder." In particular, the study reported that (i) the risk of autistic disorder was 0.27 percent in children of obese fathers and 0.14 percent in children of normal-weight fathers, and (ii) the risk of Asperger disorder was 0.38 in children of obese fathers and 0.18 percent in children of normal-weight fathers. These findings also suggested that "a dose-response relationship may be present, so that the risks of these [two] disorders increase by increasing paternal BMI," raising questions about the public health implications "if the associations were found to have a causal relation."

"We were very surprised by these findings because we expected that maternal obesity would be the main risk factor for the development of ASD. It means that we have had too much focus on the mother and too little on the father," the lead author was quoted as saying. "This probably reflects the fact that we have given greater focus to conditions in pregnancy, such as the growth environment for the fetus in the womb than both environmental and genetic factors before conception." *See Norwegian Institute of Public Health Press Release,* April 7, 2014.

Cereal Box Characters Allegedly See Eye-to-Eye with Consumers

Researchers with Cornell University and the Yale Rudd Center for Food Policy and Obesity have reportedly found that eye contact with cereal box spokes-characters "increased feelings of trust and connection to the brand, as well as choice of the brand over competitors." Aviva Musicus, et al., "Eyes in the Aisles: Why is Cap'n Crunch Looking Down at My Child?," *Environment and Behavior*, 2014.

After analyzing 65 cereals in 10 grocery stores, the study's authors claimed that cereals marketed to children were generally placed on the bottom two shelves and displayed characters featuring "a downward gaze at an angle of 9.67 degrees," while those marketed to adults were generally placed on the top two shelves and displayed characters featuring a slightly upward gaze at an angle of 0.43 degrees. In addition, the study reported that participants asked to evaluate sample cereal boxes were more likely to choose one brand over another if the character on the box appeared to make eye contact with them.

Noting that they don't believe spokes-characters "are deliberately designed to direct their gaze downward in order to make eye contact with children," the researchers nevertheless suggested that "spokes-characters making eye contact can thus serve as a useful advertising tool to draw in both adults and children." In particular, they argued that such tactics could be used to market healthier options.

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"Cereals marketed towards adults generally have lower sugar and higher fiber levels than cereals marketed towards children," concludes the study. "Such healthier cereal could be made to feature more spokes-characters that not only gaze at adults but also make eye contact with children, enhancing the chance children would choose such cereal, and consequently encouraging healthier choices and consumption. Since eye contact appears to produce positive effects for adults as well as children, eye contact from spokes characters can be used to promote healthier choices among adults as well."

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