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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

GE Labeling Bills Introduced in U.S. House and Senate

U.S. Sen. Barbara Boxer (D-Calif.) and Rep. Peter DeFazio (D-Or.) have introduced companion bills (S. 809; H.R. 1699) that would amend the federal Food, Drug, and Cosmetic Act to require the makers of genetically engineered (GE) foods and foods with GE ingredients to include this information on their labels. Noting that the Food and Drug Administration stated in 1992 that such labels were unnecessary because GE foods were not "materially" different from other foods, Boxer characterized this approach as antiquated and said, "Common sense would indicate that GE corn that produces its own insecticide—or is engineered to survive being doused by herbicides—is materially different from traditional corn that does not. Even the U.S. Patent and Trademark Office has recognized that these foods are materially different and novel for patent purposes."

One Republican representative has agreed to co-sponsor the legislation; the remaining support is from Democratic senators and representatives. According to Boxer, 64 countries require GE food labels, and her "Genetically Engineered Food Right-to-Know Act" is supported by a number of organizations, including the Center for Food Safety, Environmental Working Group, Center for Environmental Health, Ben & Jerry's, Clif Bar & Co., Lundberg Family Farms, and Nature's Path. *See U.S. Sen. Barbara Boxer Press Release*, April 24, 2013.

Food Trade Groups Urge Congress to Reject Proposed FSMA Fees

Several dozen trade associations representing the interests of food and beverage producers, processors, shippers, and retailers have submitted their concerns about the Obama administration's proposed 2014 Food and Drug Administration (FDA) budget, which includes $59 million in food facility registration and inspection fees to fund FDA activities under the Food Safety Modernization Act (FSMA). In their April 17, 2013, letter to the chair and ranking member of the Senate Appropriations Subcommittee for Agriculture,

Rural Development, Food and Drug Administration, and Related Agencies, the industry groups call for FDA to submit requests for FSMA implementation funding through the appropriations process, "rather than seeking authorization of new regulatory taxes, which Congress has repeatedly rejected."

Federal Agencies Prepare Draft Positions for Codex Alimentarius Meeting

The U.S. Department of Agriculture and Food and Drug Administration have **announced** a June 18, 2013, public meeting in Washington, D.C., to provide information and receive public comments on agenda items and draft U.S. positions for discussion at the 36th Session of the Codex Alimentarius Commission in Rome on July 1-5. Agenda items include (i) a report by the chair of the 68th session of the executive committee; (ii) revocation of existing Codex standards and related texts; (iii) "Amendments to the Codex Standards and Related Texts"; (iii) "Financial and Budgetary Matters"; and (iv) chair and vice chair elections and coordinator appointments. *See Federal Register,* April 23, 2013.

Brazilian Regulator Fines McDonald's over Happy Meal® Promotion

The consumer regulatory agency of Sao Paulo, Brazil, has reportedly fined McDonald's US$1.6 million for allegedly marketing to children. Procon SP has claimed that franchisee Arcos Dorados Holdings Inc. violated the state's consumer code by using children's characters and toys to promote Happy Meals®. "This is not an isolated case," a Procon SP lawyer was quoting as saying. "There's no need to appeal as they do to children without the maturity or the rationality to enter the market as consumers."

In 2011, the Brazilian Consumer Defense Foundation fined the fast-food corporation US$1.8 million after a nonprofit organization complained that Happy Meal® incentives encouraged "unhealthy eating habits" among children. A McDonald's spokesperson has since told media sources that the company plans to appeal the latest ruling. Additional details about the Consumer Defense Foundation matter appear in Issue **420** of this *Update. See Law360* and *Reuters,* April 23, 2013.

Denmark Repeals Beverage Tax

Citing the loss of millions of euros, the Danish government is reportedly abandoning its 80-year tax on soft drinks because consumers are crossing the border to shop in Germany instead.

"This decision is the result of concerted efforts to highlight the negative impact of the tax," said Niels Hald, secretary general of the Danish soft drinks association, Bryggeriforeningen. "In taking this step the Danish government acknowledged the regressive nature of the tax, its negative impact

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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on regional jobs close to the borders and the adverse environmental consequences of border trade."

Removal of the tax will reportedly take place in two stages, with a 50-percent reduction as of July 1, 2013, and full elimination as of January 1, 2014. The decision comes months after the Danish government repealed a similar tax on foods with high concentrations of saturated fat and stopped a proposed sugar tax last year. *See UNESDA News Release,* April 22, 2013; *euvoice.eu*, April 24, 2013.

Following Court Mandate, OEHHA Removes BPA from Prop. 65 List

After a state court in California granted the American Chemistry Council's (ACC's) request for preliminary injunction and ordered Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) to remove bisphenol A (BPA) from the list of chemicals known to the state to cause reproductive toxicity, **OEHHA did so**. OEHHA had argued that ACC's request to enjoin OEHHA from "listing, or taking any further action in listing" BPA was moot because the Proposition 65 (Prop. 65) listing action took effect April 11, but the court said it had the authority to order OEHHA to remove the chemical from the list.

According to the court, ACC demonstrated that it had a reasonable probability of prevailing on the merits of its claim that the National Toxicology Program report on which OEHHA relied for its listing did not identify BPA as causing reproductive toxicity. "[T]here was no definitive statement that BPA is a developmental toxicant and could adversely affect development or a statement indicating that it was reasonable to assume that the rodent data was relevant to humans," the court stated. "Moreover, the Report reiterates on a number of occasions that there is insufficient evidence and more research must be conducted to understand the effects on humans. Indeed, the Report specifically states that the 'current literature cannot yet be fully interpreted for biological or experimental consistency or for relevance to human health.'"

The court also determined that ACC adequately demonstrated that its members would be irreparably harmed by BPA's listing. In this regard, the court quoted an ACC expert's declaration that this "unprecedented" listing would affect "'all consumer products containing BPA, rather than a narrow range of specific products.' The listing 'will cause widespread and irreversible consumer deselection of products made from BPA . . . ; retailers will remove products from store shelves and stop selling such products . . . ; and consumer product manufacturers will move to reformulate their products . . . which will adversely and irreparably impact members of the ACC, other chemical manufacturers, wholesalers and retailers involved with BPA related products, and the public, which will be deprived of the highly beneficial properties of polycarbonate and epoxy resins.'"

OEHHA has also **withdrawn** its January 25, 2013, proposal to establish a maximum allowable dose level for BPA. *See OEHHA News Releases*, April 19, 2013.

LITIGATION

Court Declares Missed Food-Safety Rule Deadlines an FSMA/APA Violation

A federal court in California has determined that the Food and Drug Administration (FDA) has violated the Food Safety Modernization Act (FSMA) and Administrative Procedure Act (APA) by failing to promulgate, within FSMA deadlines, food-safety rules that implement the law. *Ctr. for Food Safety v. Hamburg*, No. 12-4529 (U.S. Dist. Ct., N.D. Cal., decided April 22, 2013). According to the court, Congress "intended that the implementing regulations be promulgated and finalized by a date certain. The dates set for completion of the regulations in the seven areas identified in the complaint have passed. However, that does not mean that the FSMA now should be interpreted as granting the FDA total discretion in deciding when to finalize the regulations. . . . Thus, the court finds that the imposition of an injunction imposing deadlines for finalization of the regulations would be consistent with the underlying purposes of the FSMA."

Still, agreeing with FDA "that the purpose of ensuring food safety will not be served by the issuance of regulations that are insufficiently considered, based on a timetable that is unconnected to the magnitude of the task set by Congress," and in the hope that the parties could "arrive at a mutually acceptable schedule," the court ordered them to meet and confer and, by May 20, 2013, prepare a "joint written statement setting forth proposed deadlines, in detail sufficient to form the basis of an injunction."

In the April 26 *Federal Register*, FDA published notices extending the deadlines for public comment on its proposed FSMA implementation rules relating to "**Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**" and "**Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**." Comments on these proposals and the agency's "**Draft Qualitative Risk Assessment of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm**" are now requested by September 16, 2013.

Honey Farmers Bring RICO Actions Against Importers

According to news sources, several U.S. beekeeping companies have filed lawsuits under the federal Racketeer Influenced and Corrupt Organizations Act (RICO), alleging that the defendant companies illegally imported honey from China thus evading millions of dollars in anti-dumping duties and

depressing the price for domestic honey. *Moore v. Groeb*, No. 13-2905 (U.S. Dist. Ct., N.D. Ill., filed April 17, 2013); *Adee Honey Farms v. Groeb Farms, Inc.*, No. 13-2922 (U.S. Dist. Ct., N.D. Ill., filed April 18, 2013).

Among other things, the complaint alleges that some of the imported honey contained adulterated antibiotics, was not actually honey and was falsely represented to government authorities as honey from countries other than China. The plaintiffs reportedly cite a February 2013 agreement between defendant Groeb Farms and the federal government indicating that the company's "unlawful actions 'caused losses to the United States of no less than $78,866,216' in the form of unpaid antidumping duties" during a four-year period. As part of the agreement, Groeb Farms purportedly paid a $2-million fine. *See Courthouse News Service*, April 22, 2013; *The National Law Journal*, April 23, 2013.

LEGAL LITERATURE

Legal Issues Raised If Sugar Is Deemed "Addictive"

In a recently published article, psychology and law professors discuss research tending to show that the low-cost, highly refined, widely available sugars consumed by Americans may fit the developing definition of an addictive substance and consider whether such a finding would justify a range of legal and regulatory responses. Ashley Gearhardt, et al., "If Sugar Is Addictive … What Does It Mean for the Law?," *Journal of Law, Medicine & Ethics*, Spring 2013. Noting that the understanding of addiction and public perceptions shifted when nicotine was declared an addictive substance despite its lack of mind-altering properties and relatively weak withdrawal symptoms, the authors report that the new addiction criteria include an inability to successfully cut down or abstain from a substance, "continued use despite negative consequences," and diminished control over consumption.

The authors compare the concentration of the coca leaf, with minimal addictive potential, into crack cocaine, which "'hijacks' the reward system for at-risk individuals," to sugar's refinement from a raw fruit, which also contains fibers and water, into an ingredient in "unnaturally high-sugar food," whose addictive potential "is enhanced by the cheapness, accessibility, and heavy marketing of these products, thus increasing the public health burden." The authors also explore research on lab animals showing a preference for sugar and claim that "this field is growing rapidly."

The article asks, "If the goal of sugar-addiction research is to lessen the consumption of sugar, then what should be the response of law? . . . What legal tools should be employed?" Without providing definitive answers, the authors suggest that the food industry could respond with self-regulation or that government could respond with regulatory tools, such as labeling

requirements, advertising restrictions, taxes, product bans or restrictions, reductions in farm subsidies and sugar programs, and the development of education programs. Class action litigation is also mentioned as a potential regulatory tool. The article concludes by raising the issues that must be considered if sugar meets, for example, the criteria that justify the regulation of alcohol, including "whether there are possible negative aspects of prohibiting sugary products (i.e., soda ban in California schools); whether civil liberties might be violated by proposed regulations; and how regulations might impinge on traditional values of personal responsibility."

Public Health Law Fellow Calls for BPA Ban to Encompass All Infant-Contact Products

Arguing that bisphenol A (BPA) exposure is particularly harmful for young children, infants and fetuses "because they lack mature systems of bodily detoxification," a public health law and policy fellow at the Arizona State University Sandra Day O'Connor College of Law has called for governmental entities at every level to prohibit the chemical in any product "meant to be consumed or used by a young child, infant, or pregnant woman." Leila Barraza, "A New Approach for Regulating Bisphenol A for the Protection of the Public's Health," *Journal of Law, Medicine & Ethics*, Spring 2013. Part of a public health law conference symposium, this article discusses the mixed results of litigation against companies that use BPA in food and beverage contact materials and the failure of legislative initiatives that would restrict its use to take hold at the federal and state levels.

The author calls on the Food and Drug Administration and Environmental Protection Agency to take action to regulate BPA, although she acknowledges that "suitable alternatives" are not readily available. She also calls for future regulation modeled on Connecticut's "aggressive" law, "which included not only reusable food and beverage containers, but also extended to thermal receipt paper. This should be further expanded to include disposable food and beverage containers, tableware, pacifiers, teethers, food container lids, canned foods and beverages, toys, and medical devices."

OTHER DEVELOPMENTS

Pediatricians Issue Warning over "Cinnamon Challenge"

A recent *Pediatrics* "Perspectives" article **warns** physicians and parents about the increasing number of children and adolescents who have attempted the "Cinnamon Challenge," an impossible prank made popular on the Internet that apparently entails "swallowing a tablespoon of ground cinnamon in 60 seconds without drinking fluids." Amelia Grant-Alfieri, et al., "Ingesting and Aspirating Dry Cinnamon by Children and Adolescents: The 'Cinnamon Challenge,'" *Pediatrics,* April 2013. According to the authors, the challenge has

already led "to dozens of calls to poison centers, emergency department visits, and even hospitalizations for adolescents requiring ventilator support for collapsed lungs."

In particular, the article reports that the American Association of Poison Control Centers fielded 178 calls related to the "Cinnamon Challenge" during the first six months of 2012 and that "[a]t least 30 participants nationwide have required medical attention." Based on these incidents as well as animal studies involving pulmonary exposure to cinnamon, the authors caution that inhalation "can cause pulmonary inflammation, predisposing airways to epithelial lesions and scarring," in addition to posing a greater health risk to "persons allergic to cinnamon or with brocho-pulmonary diseases, including asthma."

"The Cinnamon Challenge is a behavioral phenomenon, a popular dare fueled by peer pressure that along with competition, often instigates risk-taking behaviors among adolescents," they conclude, noting that increased Internet and social media chatter around the prank has been augmented "by celebrities and even government officials posting their own Cinnamon Challenge videos… Although we cannot make a strong statement on documented pulmonary sequelae in humans, it is prudent to warn that the Cinnamon Challenge has a high likelihood to be damaging to the lungs."

Avian Influenza (H7N9) Deemed "One of the Most Lethal" by WHO Leader

The World Health Organization (WHO) recently **released** the results of its preliminary investigation into a new strain of avian influenza A (H7N9), which WHO Assistant Director-General for Health Security Keiji Fukuda reportedly described as "one of the most lethal influenza viruses we have seen so far." First identified in China and linked to live poultry markets, the disease has sickened more than 100 people to date and caused at least 20 deaths, according to the latest WHO reports. Additional details about the global response to H7N9 appear in Issue **479** of this *Update*.

Speaking on behalf of the research team assessing the outbreak, Fukuda told reporters that WHO experts will continue to work closely with Chinese health officials to monitor the virus's spread and to determine whether human-to-human transmission has occurred. To this end, the assistant director-general has urged continued surveillance in both human and animal populations throughout China as well as international cooperation with the ongoing investigation. "The risks of such an outbreak situation are shared in a globalized world where we are all interconnected. This underlines the importance of the example set by China in following the International Health Regulations," said Fukuda, praising the work of authorities in tracking the new virus. "The response reflects earlier and strong investments in health and preparedness made by China." *See WHO Press Release and Opening Statement by Dr. Keiji Fukuda,* April 24, 2013.

Hispanic Institute Criticizes Food and Beverage Industry in New Report

The Hispanic Institute has published a **report** advocating regulation of sugary drinks and processed foods to "help reduce alarmingly high rates of obesity among Hispanics." Titled "Obesity: Hispanic America's Big Challenge," the report claims that 40.4 percent of Mexican Americans and 39.1 percent of Hispanics overall are obese, raising concerns about the rising health care costs associated with diabetes, heart and kidney disease, stroke, and other obesity-related conditions.

In particular, The Hispanic Institute blames rising obesity rates on the "intentional actions" of food and beverage manufacturers, citing Michael Moss's *Salt Sugar Fat* (2013) to support its argument that industry seeks "to 'optimize' the flavors and textures of foods and beverages in order to make them irresistible to consumers." Comparing the current opposition to food and beverage regulation to that which initially stymied anti-smoking efforts, the report also faults marketing efforts that allegedly target "young people, Hispanics and African Americans especially," as well as corporate support for minority organizations that have a stake in regulating the sale of products such as sugar-sweetened beverages.

"If the minority organizations' past behavior with big tobacco companies is any indication of how they will approach their relationship with sugary drink manufacturers in the future, it is likely they will turn away from those donations and support regulation—but not until there is some incentive for them to change," concludes the report. "The negative effects of sugary drinks, other bad food choices and lack of regular exercise on the health of the fastest growing group in America will continue until Hispanics use their considerable political clout to influence public policymaking and their economic strength to influence purveyors of those products." *See The Hispanic Institute Press Release,* April 24, 2013.

Apples Top EWG List of Most Contaminated Produce

The Environmental Working Group (EWG) has **issued** its *2013 Shopper's Guide to Pesticides in Produce,* which "ranks pesticide contamination on 48 popular fruits and vegetables, based on an analysis of more than 28,000 samples tested by the U.S. Department of Agriculture [USDA] and federal [Food and Drug Administration]."

This year's "Clean Fifteen™" list—fruits and vegetables with the least pesticide load—includes corn, onions, pineapples, avocados, cabbage, frozen sweet peas, papayas, mangoes, asparagus, eggplant, kiwi, grapefruit, cantaloupe, sweet potatoes, and mushrooms. Topping the "Dirty Dozen™" list of the "most pesticide-contaminated produce" are apples, followed by strawberries, grapes and celery.

According to EWG, this is the second year in a row that the group "has expanded the Dirty Dozen™ with a Plus category to highlight two crops—domestically-grown summer squash and leafy greens, specifically kale and collards." Evidently, these crops "did not meet traditional Dirty Dozen™ criteria but were commonly contaminated with pesticides exceptionally toxic to the nervous system." *See Environmental Working Group News Release,* April, 22, 2013.

SCIENTIFIC/TECHNICAL ITEMS

New Study Examines Role of Gut Bacteria in Link Between Lecithin and Cardiovascular Disease

A recent study investigating the link between dietary phosphatidylcholine (lecithin) and the production of trimethylamine-*N*-oxide (TMAO), "a proatherosclerotic metabolite," has concluded that "the production of TMAO from dietary phosphatidylcholine is dependent on metabolism by the intestinal microbiota." W.H. Wilson Tang, et al., "Intestinal Microbial Metabolism of Phosphatidylcholine and Cardiovascular Risk," *The New England Journal of Medicine,* April 2013. During the first phase of the study, researchers administered a dietary phosphatidylcholine challenge (two hard-boiled eggs and 250 mg of deuterium [d9]-labeled phosphatidylcholine) to 40 healthy adults, then analyzed participants' plasma and urinary TMAO levels as well as their plasma choline and betaine levels. The study's authors also performed the same analyses after six participants took a week-long course of antibiotics to suppress their gut microbiota and after the effects of the antibiotics had worn off.

According to the study, the researchers not only observed "time-dependent increases in levels of both TMAO and its d9 isotopologue, as well as other choline metabolites," following the dietary phosphatidylcholine challenge, but found that "plasma levels of TMAO were markedly suppressed after the administration of antibiotics and then reappeared after withdrawal of antibiotics." In addition, the second part of the study examined "the relationship between fasting levels of TMAO and incident major adverse cardiovascular events" during three years of follow-up in 4,007 adults undergoing elective coronary angiography. The results evidently revealed that, even in low-risk cohorts, "fasting plasma TMAO levels predict the risk of incident major adverse cardiovascular events independently of traditional cardiovascular risk factors and the presence or extent of coronary artery disease."

"Our findings suggest that pathways that are dependent on the intestinal microbiota may contribute to the pathophysiology of atherosclerotic coronary artery disease and suggest potential therapeutic targets," concluded the study's authors. "The ability of oral broad-spectrum antibiotics to temporarily suppress the production of TMAO is a direct demonstration that intestinal microorganisms play an obligatory role in the production of TMAO from phosphatidylcholine in humans." Additional details about a similar study on the role of intestinal bacterial in producing TMAO from carnitine appear in Issue **479** of this *Update*. *See NEJM Editorial,* April 25, 2013.

Researchers Claim Industry Policy Submissions Are Unreliable

British-based researchers who closely examined alcohol industry submissions to a 2008 Scottish government consultation on "Changing Scotland's relationship with alcohol" have **distilled** the arguments presented and contend that they misrepresent the scientific evidence and should not be considered persuasive. Jim McCambridge, et al., "Industry Use of Evidence to Influence Alcohol Policy: A Case Study of Submissions to the 2008 Scottish Government Consultation," *PLOS Medicine*, April 2013.

Observing that industry actors "consistently oppose[] whole-population approaches, . . . favouring instead targeted interventions that focus on a supposedly problematic minority of drinkers and emphasising the role of individual responsibility," and faulting their use of relevant research literature, the authors "suggest that the public interest is not served by industry actors' involvement in the interpretation of research evidence" and that "[c]ommercial conflicts of interest should be made explicit." They further warn policy makers to "treat industry actors' interpretation of research evidence with extreme caution."

Special Issue of *Biological Psychiatry* Focuses on Food Addiction

The Society of Biological Psychiatry has dedicated the May 1, 2013, edition of its flagship journal, *Biological Psychiatry,* to the debate over whether "food is, or can be addictive." According to its introduction, the special issue explores (i) whether food and drugs of abuse share common neurobiological mechanisms; (ii) whether the addiction model can "reasonably" be adopted for binge eating; (iii) the possibility of shared vulnerabilities, such as stress, that can affect "the likelihood of a relapse for drug addiction and obesity"; and (iv) the key differences between food and drug addiction models. To this end, it includes articles that address the theories, concepts and evidence behind food addiction models; addiction risk factors and susceptibility; neural adaptations and reward circuits; and the prevalence of binge eating disorder, among other topics.

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Additional details about commentary authored by Ashley Gearhardt and Kelly Brownell for this special edition appear in Issue 450 of this *Update*. Additional details about National Institute on Drug Abuse Director Nora Volkow's contributions appear in Issue 470 of this *Update*.

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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.