Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

CSPI Urges FDA to Ban Caramel Colorings Made with Ammonia

The Center for Science in the Public Interest (CSPI) has filed a **regulatory petition** with the Food and Drug Administration (FDA), asking the agency to prohibit two types of caramel coloring used in cola, beer, soy sauce, and other foods. According to CSPI, "the artificial brown coloring in colas and some other products is made by reacting sugars with ammonia and sulfites under high pressure and temperatures," resulting in "the formation of 2-methylimidazole [2-MI] and 4-methylimidazole [4-MI], which in government-conducted studies caused lung, liver, or thyroid cancer or leukemia in laboratory mice or rats."

The consumer watchdog is thus urging FDA to prohibit Caramel III and Caramel IV food colorings because both are made with ammonia. Experts with ties to the National Toxicology Program (NTP) have also penned a **letter** in support of this request, citing several NTP animal studies finding "'clear evidence' for carcinogenicity" of both 2-MI and 4-MI. "[T]he phrase 'caramel coloring' is misleading when used to describe colorings made with ammonia or sulfite," concludes CSPI in a February 16, 2011, press release. "The terms 'ammonia process caramel' or 'ammonia sulfite process caramel' would be more accurate, and companies should not be allowed to label any products that contain such colorings as 'natural.'" *See Reuters,* February 16, 2011.

Meanwhile, a coalition of industry organizations has submitted a **letter** to California Governor Jerry Brown (D) to express concerns about actions taken by the Office of Environmental Health Hazard Assessment (OEHHA) as former Governor Arnold Schwarzenegger (R) left office. According to the February 11, 2011, letter, "These actions cast doubt on OEHHA's use of best available science [and] signal a bias toward selective use of scientific methodologies, data and assumptions that yield the lowest possible health reference levels, yet are unlikely to provide any real-world public health benefits."

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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The coalition includes groups such as the California Chamber of Commerce, California Restaurant Association and American Chemistry Council. They ask Brown to suspend all pending OEHHA decisions until "necessary appointments are made and the appropriate administration staff can engage in discussions with OEHHA, Cal/EPA and other affected agencies to evaluate whether these actions are truly based on the best available science, and how best to mitigate the impacts that would follow from their incorporation in state environmental regulatory decisions."

OEHHA administers the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) under which consumers must be notified about products containing known carcinogens or reproductive toxins. Among the issues specifically raised in the letter is a recently adopted final Prop. 65 listing of 4-MI as a carcinogen that would require colas and other products containing the coloring to bear a cancer warning label. According to the coalition, "No other government on earth currently requires or recommends product warnings for [4-MI]."

The coalition suggests that the timing of this and other OEHHA actions could indicate "a desire by OEHHA to avoid executive oversight," and appear to "contribute significantly to the counter-productive regulatory environment you cited during the gubernatorial campaign."

GAO Continues to Include Food Safety in High-Risk Series Report

The Government Accountability Office (GAO) has issued an **update** to its "High-Risk Series" report in which it attempts to "focus attention on government operations that it identifies as high risk due to their greater vulnerabilities to fraud, waste, abuse, and mismanagement or the need for transformation to address economy, efficiency, or effectiveness challenges." Among other matters, the report continues to call for revamping federal oversight of food safety.

Citing the nationwide 2010 *Salmonella*-tainted egg recall as an example, GAO contends that fragmented federal oversight has created food-safety challenges. While the Food Safety Modernization Act has expanded Food and Drug Administration oversight authority, GAO recommends that Congress "also consider enacting comprehensive, uniform, and risk-based food safety legislation [and] commissioning a detailed analysis of alternative organizational structures for food safety."

APHIS Deregulates GE Corn for Ethanol Production

The U.S. Department of Agriculture's (UDSA's) Animal and Plant Health Inspection Service (APHIS) has **issued** a determination of nonregulated status for a corn variety genetically engineered (GE) to facilitate ethanol production.

Developed by Syngenta Seeds, Inc., Event 3272 or Enogen™ corn produces a microbial enzyme that, according to the petition for deregulation, is "unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340." After reviewing the scientific data and soliciting public feedback on a draft environmental assessment, APHIS has agreed that this variety of GE corn "should be granted nonregulated status" as of February 15, 2011. *See Federal Register,* February 15, 2011.

Meanwhile, corn millers and other food industry interests have reportedly criticized the decision, telling *The New York Times* that cross-pollination with food-grade corn "could lead to crumbly corn chips, soggy cereal, loaves of bread with soupy center and corn dogs with inadequate coatings." Because Enogen™ corn is designed to break down corn starch into sugar—a process previously handled at ethanol plants—the variety is intended "solely for industrial purposes." But the North American Millers' Association (NAMA) has raised concerns that any co-mingling "will have significant adverse impacts on food product quality and performance," as well as disrupt exports. "USDA has failed to provide the public with sufficient scientific data on the economic impacts of contamination on food production, or information on how USDA will ensure Syngenta's compliance with a stewardship plan," NAMA President Mary Waters was quoted as saying. *See North American Millers' Association Press Release* and *The New York Times,* February 11, 2011.

These objections have since caught the attention of consumer advocates such as the Center for Food Safety (CFS), which has already threatened legal action. "The resemblance to StarLink is uncanny," stated CFS Science Policy Analyst Bill Freese in a February 11, press release referencing a 2000 incident in which unapproved GE corn entered the human food supply. "Much like StarLink, Syngenta's biofuels corn poses allergy concerns and is not meant for human food use. It's hard to believe that USDA has forgotten the substantial harm StarLink caused to farmers and the U.S. food industry, but apparently it has."

Commerce Department, NOAA Issue Draft Aquaculture Policies

The U.S. Department of Commerce (DOC) and National Oceanic and Atmospheric Administration (NOAA) have **solicited** public comment on complementary draft policies aiming "to enable the development of sustainable marine aquaculture." According to NOAA, these policies apply to "the farming of marine organisms such as shellfish, finfish, and algae for food, habitat restoration, and rebuilding of wild fish stocks," and outline how the agency plans "to fund research into innovative aquaculture technologies, work with partners to create job initiatives that encourage the growth of the industry, and grant access to favorable sites for aquaculture facilities."

To this end, the NOAA draft policy specifically offers "a national approach for supporting sustainable commercial production, expanding restoration aqua-

culture, and researching and developing new technologies." It also includes principles meant to guide the regulation of aquaculture in federal waters, with an emphasis on (i) ecosystem compatibility, (ii) compatibility with other uses, (iii) the best available science and information, (iv) social and economic benefits, (v) goals for industry collaboration, (vi) transparency, and (vii) public education. DOC and NOAA will accept comments on both policies until April 11, 2011. *See NOAA Press Release,* February 9, 2011.

Meeting Slated for Codex Committee on Food Contaminants

The U.S. Department of Agriculture, Food and Drug Administration, Office of the Under Secretary for Food Safety, and U.S. Department of Health and Human Services have **announced** a February 22, 2011, public meeting in College Park, Maryland, to provide information and receive public comments on draft U.S. positions to be discussed at the 5th session of the Codex Committee on Contaminants in Foods (CCCF) on March 21-25 in The Hague, The Netherlands. Among other things, CCCF "establishes or endorses permitted maximum levels of contaminants, and where necessary revises existing guidelines for contaminants and naturally occurring toxicants in food and feed."

Agenda items include proposed draft maximum levels for melamine in liquid infant formula, deoxynivalenol and its acetylated derivatives in cereals and cereal-based products, and total aflaxtoxins in dried figs. Topics for discussion papers include mycotoxins in sorghum, arsenic in rice, ochratoxin A in cocoa, and furan. *See Federal Register,* February 15, 2011.

Health Canada Strengthens Food Allergen and Gluten Source Labeling

Canada Minister of Health Leona Aglukkaq has announced **revisions** to food allergen labeling regulations with the aim of reducing the number of food recalls and adverse reactions. The revisions strengthen the requirements by adding gluten sources to the list of allergens that must be disclosed on product labels and specifying in plain terms what food makers must say about their ingredients, including "hidden" allergens, gluten sources and sulphites. According to Health Canada, the changes will take effect August 4, 2012, to allow the industry time to implement them. The agency claims that the revisions will "provide a clearer ingredient label so that consumers can better avoid foods that contain the ingredient to which they are allergic or sensitive," and will ensure that allergens, gluten sources and sulphites "will be labelled in a systematic and consistent manner." *See Health Canada Press Release*, February 14, 2011.

EFSA to Hold Workshop on Draft Guidance for GMO Plant Comparators

The European Food Safety Authority (EFSA) has announced a preliminary program for a consultative workshop on draft guidance on the selection of comparators, or controls, for the risk assessment of genetically modified organism (GMO) plants. Scientists and risk assessors from European Union (EU) member states, industry and non-governmental organizations are expected to attend the March 31, 2011, workshop in Brussels.

According to EFSA's Website, agenda items include (i) "Principles of risk assessment in the EU legal framework"; (ii) "GMO risk assessment: pros and cons of different approaches"; (iii) "Specific food and feed/molecular characterization and environmental needs for selection comparator"; and (iv) "Risk assessment when no comparator is available."

Meanwhile, EU's Standing Committee on the Food Chain has reportedly "returned no definitive opinion" on whether to approve or veto the use of three GMOs for maize and cotton. According to a news source, the inconclusive vote could thwart other forms of food biotechnology where consensus does not exist, such as growth hormones and nanotechnology. The committee's non-decision will be forwarded to the Council of EU Farm Ministers, which has not supported increased use of GMOs in the past. If the council fails to reach an agreement, the European Commission will make the decision. *See Meatingplace.com,* February 15, 2011.

EFSA Rejects Probiotic Cheese Heart Claims

The European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies has **rejected** an article 13.5 application submitted by Piimandusühistu E-Piim, the manufacturer of a probiotic cheese, claiming that its product "helps to maintain the cardio-vascular system/heart health through reduction of blood pressure." The applicant evidently submitted 38 publications and four proprietary reports related to the maintenance of normal blood pressure and the *Lactobacillus plantarum* TENSIA™ bacteria found in its "semi-hard Edam-type" Harmony™ "heart cheese."

EFSA ruled, however, that "none of these publications addressed the effects of *L. plantarum*," while three of the four unpublished proprietary reports were uncontrolled and therefore inadmissible. The fourth study, according to EFSA, "was a randomised, double-blind, placebo-controlled, cross-over human intervention," but ultimately failed "to show an effect of *L. plantarum* TENSIA™ on blood pressure." The panel therefore concluded that "a cause and effect relationship has not been established between the consumption of *Lactobacillus plantarum* TENSIA™ in the semi-hard Edam-type 'heart cheese' of Harmony™ and maintenance of normal blood pressure."

California Lawmakers Propose Ban on Possession, Sale of Shark Fins

California State Assemblymen Paul Fong (D-Cupertino) and Jared Huffman (D- San Rafael) have introduced a **bill** (A.B. 376) that would prohibit the possession, sale, trade, and distribution of shark fins. Apparently in demand for shark fin soup, "the ingredient is very high in mercury and the FDA warns that it could be dangerous to consumers' health," according to a joint press release issued by the lawmakers.

Calling shark finning "a senseless act" in which fins and tails are cut from living sharks with the remainder of the fish thrown back in the ocean, Huffman noted that the practice "can seriously destabilized the food chain" because of sharks' predatory status "in ocean ecosystems around the world." Although shark finning is illegal under federal and California statutes, Fong called those laws "insufficient when we have species of sharks depleted up to 90 percent. The demand for shark fin is growing and the worldwide shark population is depleting to extinction rates. I say it is time to remove shark fin from the menu."

California State Senator Leland Yee (D-San Francisco) has opposed the bill, calling it "the wrong answer to a legitimate problem." Although concerned about overfishing of sharks, Yee said that the "proposed state law to ban all shark fins from consumption—regardless of species or how they were fished or harvested—is the wrong approach and an unfair attack on Asian culture and cuisine. Some sharks are well-populated and many can and should be sustainably fished." *See Fong/Huffman* and *Yee Press Releases,* February 14, 2011.

LITIGATION

Public Health Group Sues USDA and HHS over Dietary Guidelines

The Physicians Committee for Responsible Medicine (PCRM), an organization devoted to preventive medicine, a vegan diet and animal rights, has sued the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS), claiming the agencies used deliberately obscure language in their 2010 Dietary Guidelines regarding the foods consumers should avoid.

While the guidelines specifically call for increased consumption of vegetables, fruits and whole grains, PCRM contends that the agencies "hide the food Americans should eat less of. The Guidelines use biochemical terms, such as 'saturated fat' and 'cholesterol' instead of specific food terms 'meat' and 'cheese.'" According to PCRM, the guidelines are written this way due to "the USDA's close ties to the meat and dairy industries, including fast-food companies such as McDonald's." The organization also apparently blames

USDA's dual mission of giving nutritional advice to Americans and promoting American agricultural products for the use of language better understood by scientists, biochemists and Nobel Laureates.

The lawsuit asks the court to order the agencies to "withdraw those portions of the Dietary Guidelines that use vague or ambiguous language to hide the ill effects of consuming meat and dairy products and reissue such portions with healthful recommendations based on the preponderance of current scientific and medical knowledge." PCRM's nutrition education director said, "Americans need straightforward health advice, not bureaucratic mumbo jumbo designed to protect agribusiness." The complaint also reportedly asks the court to find that the agencies violated the Administrative Procedure Act by failing to respond to PCRM's March 2010 petition calling on USDA and HHS to withdraw their MyPyramid food diagram and replace it with PCRM's "power plate" diagram.

The Center for Consumer Freedom (CCF), which refers to PCRM as a "phony 'medical' group," has called the lawsuit another in a long line of efforts by the organization to "ram its anti-meat agenda," down consumers' throats. According to the center, "In recent years we've seen PCRM tying up the court system from coast to coast, seeking to remove eggs, milk, meat, and seafood from the American diet." *See The Washington Post*, February 15, 2011; *CCF Common Sense Daily*, February 16, 2011; and *PCRM Press Release*, February 17, 2011.

Salad Dressing Maker Sued Again for Understating Fat, Calorie, Salt Content

Galeos, LLC has been sued in a federal court in California for misrepresenting the nutritional content of its miso-based salad dressings, purportedly advertised on the weight-loss TV show "The Biggest Loser" and promoted as beneficial to health. *Healey v. Galeos, LLC*, No. 11-00240 (U.S. Dist. Ct., C.D. Cal., filed February 11, 2011). Details about a previous suit with similar allegations filed in the same court appear in **Issue 376** of this *Update*. The plaintiff contends that independent laboratory testing has shown that the label for the company's Miso Caesar Dressing® understates the calories by 430 percent, the fat by 550 percent and the sodium content by 350 percent.

Seeking to certify a nationwide class of consumers, the plaintiff alleges violations of California's unfair competition and false advertising laws, breach of express warranty and negligent misrepresentation. She also seeks an injunction requiring the publication of corrective nutritional values, compensatory and punitive damages, as well as restitution, interest, attorney's fees, and costs. According to a news source, a company representative has indicated that testing by two different laboratories confirmed the accuracy of its calorie and fat counts, while the carbohydrate and sodium levels were apparently misstated. The company also reportedly claims that its dressings have been awarded a Best Low-Fat Dressing award from Gourmet Foods and are

endorsed by Weight Watchers International, Inc. *See Product Liability Law 360*, February 11, 2011.

Diabetic Sues Sushi Restaurant, Can't Eat All-You-Can-Eat Rice

A diabetic man has reportedly filed a lawsuit in Los Angeles County Superior Court, seeking at least $4,000 in mental anguish damages from a Studio City sushi restaurant that requires those patrons paying an all-you-can-eat price to eat all of the food served and not just the fish. *Martin v. A Ca-Shi Sushi*, No. n/a (Cal. Super. Ct.). David Martin alleges that restaurant owner Jay Oh is discriminating against diabetics by requiring them to eat the rice along with the sashimi, which Martin picked out and consumed, leaving the rice behind. According to a news source, Oh offered to prepare two orders of sashimi alone for Martin at a cost of $3 less than the all-you-can-eat sushi deal, but Martin refused.

Instead, he filed a lawsuit and said he would be willing to settle for $6,000. Oh is reportedly going to fight the litigation even if his legal costs exceed that amount. "The rice is part of the all-you-can-eat sushi," according to Oh. "if you only eat the fish, I would go broke." The next court hearing has apparently been scheduled for February 25, 2011. Oh's counsel has filed a motion to dismiss, but expects the dispute to go to trial later this year. *See The Los Angeles Times*, February 17, 2011.

Preliminary EU Ruling Says Honey with GMO Is Not Authorized

According to an advocate general opinion, which is not binding on the European Union (EU) Court of Justice, honey that contains genetically modified organisms (GMOs) due to the proximity of the hives to experimental GMO maize fields is considered a food produced from a GMO and therefore cannot be marketed unless authorized. *Heinz Bablock v. Freistaat Bayern*, Case No. C-442/09 (Advocate General's Opinion, issued February 9, 2011).

The case was referred from a German administrative court considering the claim of a beekeeper who alleged that the state of Bavaria had rendered his apicultural products unfit for marketing or consumption by growing the experimental GMO maize near his hives. The maize DNA was apparently detected in samples of his honey.

While the advocate general determined that pollen from GMO maize is "no longer viable and is thus infertile" and as such "cannot be regarded as a GMO," still its presence renders the honey a food "produced from GMOs." His opinion concluded that "food containing material from a genetically modified plant, whether that material is included intentionally or not, must always be regarded as food produced from a GMO." The GMO maize and a number

of food products derived from the maize were authorized in the EU, but the honey was not and could not therefore be sold. The EU Court of Justice is now considering the matter. *See EU Court of Justice Press Release No 5/11*, February 9, 2011.

OTHER DEVELOPMENTS

DOJ Asked to Indict Peanut Company Executive for *Salmonella* Outbreak

According to a news source, the families of those who died or became ill from consuming *Salmonella*-tainted peanut products scheduled a February 11, 2011, press conference to call for the Department of Justice (DOJ) to bring criminal charges against the man who headed the bankrupt Peanut Corp. of America, to which the contamination was allegedly traced. More than 700 people were said to have experienced ill effects during the 2008-2009 outbreak and at least nine died. Former Peanut Corp. CEO Stewart Parnell invoked the Fifth Amendment when called to testify before Congress, and, despite a two-year investigation by the U.S. attorney's office, no charges have yet been filed.

The press conference coincided with a food safety seminar at the American University Washington College of Law at which some of the family members were scheduled to speak along with plaintiffs' lawyer William Marler, who has represented a number of those allegedly affected by the tainted peanut butter. Oregon resident Karen Andrew, who claims that the ill effects she experienced lingered for a year, was quoted as saying, "Something should be done. [Parnell] hasn't paid a price." Parnell's lawyer said he and Parnell, who now works as an industry consultant, hoped the government would agree that "there's no basis for prosecution."

Meanwhile the Governmental Accountability Project, a whistleblower protection organization, also participated in the seminar to bring to the food industry's attention new Food Safety and Modernization Act provisions that protect workers who report safety violations in plants regulated by the Food and Drug Administration. The new law reportedly protects workers from retaliation if they report violations of the food safety act or refuse to perform work they believe is illegal. The Department of Labor and the courts will have the authority to reinstate fired whistleblowers and award back pay with interest, attorney's fees and other damages. *See Government Accountability Project Press Release*, February 9, 2011; *Oregon Live*, February 10, 2011; and *Bloomberg Businessweek*, February 11, 2011.

SCIENTIFIC/TECHNICAL ITEMS

Research Warns Against Teen Energy Drink Consumption

A scientific literature review has reportedly warned against routine energy drink use, claiming that these beverages have been associated with reported "serious adverse events, especially in children, adolescents, and young adults with seizures, diabetes, cardiac abnormalities, or mood and behavioral disorders or those who take certain medications." Sara Seifert, et al., "Health Effects of Energy Drinks on Children, Adolescents, and Young Adults," *Pediatrics*, February 2011. Using PubMed and Google resources "to identify articles related to energy drinks," researchers apparently estimated that energy drinks "are consumed by 30% to 50% of adolescents and young adults," and raised concerns about the effects on those with cardiovascular conditions, ADHD, eating disorders, and diabetes.

"Energy drinks have no therapeutic benefit, and both the known and unknown pharmacology of various ingredients, combined with reports of toxicity, suggest that these drinks may put some children at risk for serious adverse health effects," reported the reviewers, who speculated that "youth-aimed marketing and risk-taking adolescent developmental tendencies combine to increase overdose potential."

The study's authors therefore urge pediatricians to "screen for consumption" and educate patients as to "the potential adverse effects of energy drinks." They have also recommended that long-term research "should aim to better define maximum safe doses, the effects of chronic use, and effects in at-risk populations," as well as provide better documentation and tracking systems.

"Unless research establishes energy-drink safety in children and adolescents, regulation, as with tobacco, alcohol and prescription medications, is prudent," concludes the literature review. "This approach is essential for reducing morbidity and mortality, encouraging research, and supporting families of children and young adults at risk for energy-drink overdose, behavioral changes, and acute/chronic health consequences."

Teenagers Reportedly Disregard Calorie Counts

A recent study claims that teenagers notice but ultimately disregard calorie counts on fast-food menu boards, ordering the same number of calories as they did before New York City's mandatory labeling laws took effect. B. Ebel, et al., "Child and adolescent fast-food choice and the influence of calorie labeling: a natural experiment," *International Journal of Obesity,* February 2011. In a follow-up to a 2009 study, New York University researchers collected survey and receipt data from "349 children and adolescents aged 1–17 years who visited the restaurants with their parents (69%) or alone (31%) before or after labeling was introduced."

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The findings evidently showed "no statistically significant differences in calories purchased before and after labeling," although 9 percent of the subjects reported that calorie information influenced their purchasing decisions. In addition, 70 percent said that taste, followed by cost, was the most important factor in their choices, and the majority underestimated the energy content of their selections by up to 466 calories. As the study authors concluded, "Adolescents in low-income communities notice calorie information at similar rates as adults, although they report being slightly less responsive to it than adults. We did not find evidence that labeling influenced adolescent food choice or parental food choices for children in this population." *See The New York Times,* February 15, 2011.

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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.