Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Canadian Agency Issues Draft Model for Food Inspection Modernization

The Canadian Food Inspection Agency (CFIA) has **issued** a draft food inspection model as part of its *Inspection Modernization: Optimizing Confidence in Food Safety* plan. According to CFIA, the modernized approach to food inspection will apply to both imported and domestic commodities and, in addition to the inspection model, rely on modern science, improved data collection and better training and tools for CFIA inspectors.

The new draft model apparently favors a risk-based approach to regulatory oversight and covers the following components: (i) licensing and registration, (ii) CFIA oversight, (iii) inspection, (iv) compliance and enforcement, and (v) system performance. In particular, food and beverage manufacturers would need to develop "preventative control plans scalable to the size and complexity of their operation" that "mitigate all sources of food safety risk and demonstrate that the measures effectively meet regulatory requirements." CFIA would in turn determine the level of required oversight—enhanced, normal or reduced—based on risk factors in the domestic- and imported-food sectors, as well as implement a systems approach to inspection that "assesses the regulated parties' plans and processes to ensure that food is prepared safely and complies with regulations."

Under these proposed measures, CFIA would ultimately be responsible for communicating industry requirements and "using risk and science-based tools to determine that industry's controls are effective and acceptable," while regulated parties would need to demonstrate compliance and provide evidence "that their controls and operating processes result in safe food." In the event of non-compliance, CFIA would determine "the most appropriate response" based on the circumstances, potential for harm, intent of the regulated party, and previous performance. Such responses could include the issuance of corrective action requests, letters of non-compliance or import alerts; the detainment, forfeiture, disposal, or recall of products; a refusal to certify a product; suspension of licensing; or prosecution. The agency has also proposed a system performance review designed to "assess [the] overall

effectiveness of the food inspection system," "identify gaps and trends," and "create accountability and provide feedback to support continuous improvement." Additional details about the inspection modernization plan appear in Issue 442 of this *Update*.

LITIGATION

Dole Asks Court to Dismiss "Assembly-Line" False Labeling Suit

Dole Food Co. has filed a motion to dismiss or strike claims in a putative class action alleging that its food product labels mislead consumers. *Brazil v. Dole Food Co., Inc.*, No. CV12-01831 LHK (U.S. Dist. Ct., N.D. Cal., San Jose Div., motion filed August 13, 2012). Identifying the plaintiff as a "repeat class representative" who recently received an incentive award in another lawsuit, Dole argues that his claims are preempted under federal law, he lacks standing because he has not been injured, the claims are not plausible, and he has failed to state a claim under California law. The company also notes that the case is "one of 24 (and counting) nearly identical 'misbranding' class action cases filed during a 15-week blitz by nine law firms from six different states," thus making it an "assembly-line" complaint that follows "a common recipe."

In summary, Dole contends, "By this lawsuit, Plaintiff seeks colossal damages, punitive damages, and a nationwide injunction asking the Court to redesign Dole's product labels. These are matters that FDA [the Food and Drug Administration] already oversees. Plaintiff is saying, in effect, 'Never mind, FDA, I get to do the mandating.' But a '*Brazil* label'—named after this case—is both unwarranted and unnecessary." The original complaint was nearly doubled in size after Dole moved to dismiss it and now apparently involves six products and one product line with multiple alleged violations pertaining to (i) use of the word "fresh," (ii) preservatives, (iii) nutrient content and antioxidant claims, (iv) "sugarless" labeling, (v) "low calorie" claims, and (vi) "health" claims. According to Dole, under recent Ninth Circuit decisions, private enforcement of FDA requirements is barred.

Organic Farmers Seek to Stop GM Canola Crops in Oregon

A non-profit family farming organization, the Center for Food Safety and several seed companies have sued the Oregon Department of Agriculture seeking court review and a stay of a temporary rule that would open 1.7 million acres to genetically modified (GM) canola plants. *Friends of Family Farmers v. Or. Dep't of Agric.*, No. n/a (Or. Ct. App., filed August 15, 2012). The plaintiffs claim that opening formerly protected acreage to GM crops in the Willamette Valley without imposing appropriate buffers would harm them through cross-pollination, seed crop contamination, increased pests and disease, and escaped canola weeds.

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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They claim that the rule was adopted under the agency's temporary rule-making authority which does not include opportunity for public notice, review and comment. "The critical prerequisite for adopting a temporary rule is the requirement to demonstrate that an agency's failure to act promptly will result in 'serious prejudice' to the public interest or the parties concerned." According to the plaintiffs, "the rule is invalid because it was adopted without compliance with applicable rulemaking procedures and exceeds the statutory authority" of the agency. In its statement of findings, the department apparently states, "Failure to adopt temporary rules governing the planting of these crops could result in serious prejudice to the agricultural industry in the protected districts." The plaintiffs contend that the agency was required to find that failure to act promptly *will* result in serious prejudice.

Center for Food Safety attorney George Kimbrell reportedly said, "[The agency's] rushed, backroom deal cutting is the textbook way agencies act when they know they're doing wrong. This irresponsible and unlawful approval of unprecedented canola planting gambles with the stability of Oregon's agricultural crown jewel, and all for some GE [genetically engineered] canola biofuel speculation." *See Law360*, August 15, 2012.

State AG Seeks Information from Energy Beverage Co.

According to the quarterly Securities and Exchange **filing** of Monster Beverage Corp., an unnamed state attorney general (AG) subpoenaed company records in July 2012 regarding its energy beverages. The subpoena apparently concerns "the Company's advertising, marketing, promotion, ingredients, usage and sale of its Monster Energy® brand of energy drinks." The company further notes, "As the investigation is in an early stage, it is unknown what, if any, action the state attorney general may take against the Company, the relief which may be sought in the event of any such proceeding or whether such proceeding could have a material adverse effect on the Company's business, financial condition or results of operations."

News sources indicate that Monster had a 35-percent share of the energy drink market in 2011, and at least one financial analyst understands that others in the industry may also be targeted in the probe. While the caffeine in energy drinks is less than that contained in a cup of brewed coffee, the beverages typically contain three times more caffeine than soft drinks. Senator Richard Durbin (D-Ill.) **communicated** earlier this year with the Food and Drug Administration, calling on the agency to regulate the beverages and citing a report that showed emergency room visits involving consumption of energy drinks increased 10 times from 2005 to 2009 with some 13,000 visits most recently recorded. Durbin and Senator Richard Blumenthal (D-Conn.) introduced legislation in 2011 to strengthen warnings on product labels; the bill has stalled in Congress. *See Associated Press*, August 10, 2012.

PCRM Failed to Investigate Grilled Chicken Claims, Court Dismisses Prop. 65 Warning Suits

A California court has reportedly dismissed claims filed by the Physicians Committee for Responsible Medicine (PCRM) against fast-food chains, finding that the group failed to investigate its allegations before suing under Proposition 65 (Prop. 65). *PCRM v. McDonald's Corp.*, No. BC383722; *PCRM v. KFC Corp.*, No. BC457193 (Cal. Super. Ct., Los Angeles Cnty., decided August 15, 2012). Filed in 2008 and 2011, the suits alleged that the restaurants failed to warn consumers that their grilled chicken menu items contain PhIP, a chemical known to the state to cause cancer. Yet, PCRM did not apparently visit the restaurants until February 2012 to take pictures of the posted warnings. The restaurants reportedly post notices that some of their products contain cancer-causing chemicals and refer customers to nutritional brochures for additional details. They contend that their warnings comply with Prop. 65.

Information about similar litigation filed in San Francisco County appears in Issue **320** of this *Update*. PCRM represents the interests of vegetarians and advocates on behalf of animal rights. *See Law360*, August 15, 2012.

Prop. 65 Proceedings Initiated Against Bay Area Candy Retailers

Claiming that lead levels in candies imported from China, Taiwan and Hong Kong exceed Proposition 65 (Prop. 65) limits, the Center for Environmental Health has reportedly initiated legal proceedings against eight retailers and distributors in San Francisco's Bay Area. The organization has apparently urged the companies to remove the products from store shelves after testing showed that typical serving sizes would expose consumers to 10 times or more lead than state and federal standards. One candy allegedly contained nearly 100 times more lead than the Prop. 65 limit. According to Center Executive Director Michael Green, "It is especially worrisome when we find lead in candy, since consumers are ingesting the lead with every bite. This candy may be very dangerous, particularly for children or pregnant women." *See Center for Environmental Health News Release*, August 7, 2012.

False Ad Suits Filed in Israel Against Yogurt Makers

According to a news source, putative class actions have been filed against Strauss Group Ltd. and Tnuva Food Industries Ltd., alleging that their yogurt products, marketed as "yogurt with granola nuts" and "yogurt with granola fruit," respectively, mislead consumers because they contain so little nuts or fruit. Seeking NIS 72 million (US$17.8 million) from Strauss, which has a 42-percent market share, and NIS 142.5 million (US$35.3 million) from Tnuva, the petitioners reportedly claim that the products should be labeled as "flavored" with the ingredients. *See Middle East North Africa Financial Network*, August 12, 2012.

OTHER DEVELOPMENTS

CSPI Calls on Welch Foods to Cease Making Deceptive Health-Benefit Claims

Welch Foods, Inc. is the most recent recipient of a **letter** from the Center for Science in the Public Interest (CSPI) warning the company that, if not otherwise resolved, the watchdog's claims that Welch is making deceptive health-benefit representations about its fruit snacks, spreads and juices will be taken to court for injunctive relief. According to the August 14, 2012, letter, the types of matters about which CSPI is most concerned are (i) "Welch Foods claims that its 100% Fruit Juice product line is heart-healthy and may promote overall health"; (ii) "Welch Foods claims that its Fruit Snacks, Fruit Juice Cocktails, Spreads, and 100% Fruit drinks 'Reward Your Heart' and are heart-healthy products"; and (ii) "Welch Foods claims that its Fruit Snacks products are nutritious and healthful to consume."

CSPI contends that, to the contrary, the products contribute to "insulin resistance and obesity, and may thus promote heart disease and diabetes," the claims lack substantiation, and the company's "Fruit Snacks contain added sugars and artificial food dyes, lack significant amounts of real fruit, and contain no dietary fiber." The letter warns that if Welch fails to respond, CSPI will initiate litigation seeking a permanent injunction prohibiting the company from these types of promotions and claims as well as disgorgement of company profits. CSPI Litigation Director Steve Gardner said, "It takes a heroic amount of chutzpah to tell consumers that these fruit snack candies will reward anyone's heart." *See CSPI News Release*, August 14, 2012.

Commentary Explores Policy Impact of Food Addiction Model

Researchers with the University of Michigan and Yale University's Rudd Center for Food Policy and Obesity have authored commentary in *Biological Psychiatry* about the policy implications of an addiction model for food. Ashley Gearhardt & Kelly Brownell, "Can Food and Addiction Change the Game?," *Biological Psychiatry,* August 2012. Gearhardt and Brownell argue that scientific efforts to establish whether certain foods or ingredients "have addictive potential" "will be more important to policy and social change than emphasizing the individual difference variables or investigating how obese and nonobese individuals differ." In particular, they claim that such research will need to emphasize the effects of potentially addictive foods "on the many rather than just the few" to maximize the impact on public policy.

"Scientific enquiries into how addictive substances are capable of hijacking the brain has reduced stigmatization of addicted individuals and led to more substance-focused policy approaches (e.g., taxation of cigarettes, restrictions in marketing)," write the authors. "In the case of tobacco, these substance-based strategies have created significant changes in the environment, altered

public opinion about the addictive products and the companies that sell them, and generated widespread improvements in public health."

Alleging that the food industry "will likely use any inconsistency in the food-addiction literature to plant doubt, attack scientists' credibility, or fund negative studies," Gearhardt and Brownell also highlight several policy concerns unique to food addiction that researchers should consider when designing their studies. As they note in the case of early childhood addiction, "If ultraproccessed foods are found to have an addictive potential, the case for more aggressive policy initiatives to protect children will likely be warranted, such as restricting children's exposure to calorie-dense food advertisements, reducing access points (e.g., vending machines), and increasing prices."

"If certain foods do have an addictive potential but this reality is ignored, it is likely that both treatment and policy progress will be stalled," opine the authors. "Imagine if tobacco research had stopped at the time that cigarettes were considered habit forming but not addictive. Policy initiatives might have focused solely on education and attempts to strength the resolve of those with a bad smoking habit… If scientific evidence identifies that certain foods are also capable of hijacking the brain in an addictive manner, it would likely be a landmark change that would support bold policy approaches that focus on improving the food environment."

RAND Researchers Say Alcohol-Control Policies Could Be Useful to Address Obesity

A peer-reviewed **article** appearing in *Preventing Chronic Disease* explores how five alcohol-control policies could hold promise in addressing the obesity epidemic if used to regulate access to low-nutrient foods. Deborah Cohen & Lila Rabinovich, "Addressing the Proximal Causes of Obesity: The Relevance of Alcohol Control Policies," *Preventing Chronic Disease*, May 2012. The policy interventions discussed include (i) limitations through zoning and licensing on the density of food outlets; (ii) displays and sales restrictions that focus on controlling impulse buying; (iii) regulations on portion sizes; (iv) pricing strategies, i.e., higher taxes on foods high in calories and low in nutritional value; and (v) strategic use of warning labels and ads that discourage people from over-eating or consuming too many foods lacking nutritive value. According to lead author and RAND researcher Deborah Cohen, "Just as regulating alcohol accessibility has been effective in reducing problem drinking, regulating food accessibility is promising for controlling unhealthy eating habits." *See RAND News Release*, August 15, 2012.

Will Plain Cigarette Packs in Australia Lead to Similar Food-Packaging Restrictions?

In the wake of an Australian High Court ruling validating regulations requiring cigarettes to be sold in plain packages, some commentators are speculating whether other products, such as alcoholic beverages and fast food, will be subject to the same types of restrictions. The opinion, penned by Patrick Carlyton, suggests that because alcoholism and obesity also purportedly have deleterious effects, government may consider imposing taxing and packaging rules on the other industries. While he questions whether these types of restrictions actually affect consumption—"will plain packaging work in reducing smoking rates? No one knows. It hasn't been tried before"—he concludes, "One thing is certain. Plain packaging for unhealthy foods in supermarket aisles would certainly constitute a relief for every parent, and this would have nothing to do with the health benefits." *See News Limited Network*, August 16, 2012.

Documentary Targets GM Agriculture

The Institute for Responsible Technology (IRT) has released a new documentary, *Genetic Roulette: The Game of Our Lives,* that accuses the U.S. government of permitting "untested genetically modified (GM) crops into our environment and food supply." Based on IRT founder Jeffrey Smith's book of the same title, the film alleges that "the same serious health problems found in lab animals, livestock, and pets that have been fed GM foods are now on the rise in the U.S. population."

"Gastrointestinal disorders, allergies, inflammatory disease, and infertility are just some of the problems implicated in humans, pets, livestock, and lab animals that eat [GM] soybeans and corn," opines IRT, which ultimately urges consumers to refrain from eating GM ingredients in an effort to ward off "the deteriorating health of Americans, especially among children."

SCIENTIFIC/TECHNICAL ITEMS

Second Butter Flavoring Implicated in Bronchiolitis Obliterans

A recent study has allegedly linked a second artificial butter flavoring—2,3-pentanedione (PD)—to respiratory toxicity in animals, raising concerns about the diacetyl replacement's potential effects on factory workers. Ann Hubbs, et al., "Respiratory and Olfactory Cytotoxicity of Inhaled 2,3-Pentanedione in Sprague-Dawley Rats," *The American Journal of Pathology,* September 2012. After exposing rats to either PD, diacetyl or air for six hours, researchers reported that those inhaling PD "developed necrotizing rhinitis, tracheitis, and bronchitis comparable to diacetyl-induced injury." The study's authors then investigated PD's delayed toxicity on the animals, concluding that the

substance caused "respiratory epithelial injury in the upper nose…, which progressed through 12 to 14 hours after exposure," as well as the loss of olfactory neurons and altered gene expression in the brain.

"Our study demonstrates that PD, like diacetyl, damages airway epithelium in laboratory studies. This finding is important because the damage is believed to be the underlying cause of bronchiolitis obliterans," said lead author Ann Hubbs of the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health."Our study also supports established recommendations that flavorings should be substituted only when there is evidence that the substitute is less toxic than the agent it replaces."

In particular, the study notes that even though PD is classified "as generally recognized as safe under its normal use when consumed in food," "a chemical with a long history of being eaten without any evidence of toxicity[] can still be an agent with respiratory toxicity." To this end, the findings seek to identify the shared features of short-chain diketones like diacetyl and PD that could contribute to their apparent cytotoxicity. "Thus, our study suggests several intriguing potential mechanisms for the toxicity of inhaled volatile α-diketones, demonstrates mRNA changes in the brain, documents olfactory neurotoxicity, and clearly demonstrates that the remarkable airway toxicity is shared with its close structural relative, PD," conclude the authors. *See American Journal of Pathology Press Release,* August 13, 2012.

Study Praises State Restrictions on Competitive Foods in Schools

A recent study has reportedly concluded that school children in states with strong restrictions on competitive food sales gained less weight than their counterparts in states with weaker restrictions. Daniel Taber, et al., "Weight Status Among Adolescents in States That Govern Competitive Food Nutrition Content," *Pediatrics,* September 2012. After identifying states with strong, weak or no competitive food laws, researchers analyzed data from 6,300 students in 40 states in both fifth and eighth grade (2004 and 2007). The findings evidently showed that "students exposed to strong laws at baseline gained, on average, 0.25 fewer BMI [body mass index] units… and were less likely to remain overweight or obese over time than students in states with no laws."

"Laws that regulate competitive food nutrition content may reduce adolescent BMI change if they are comprehensive, contain strong language, and are enacted across grade levels," concluded the study's authors. "Our results suggest that competitive food laws had a relatively weak association with BMI change if they contained diluted nutrition standards that were nonspecific or not required. Consistency of competitive food standards is critical, given that competitive food policies tend to be weaker at higher grade levels. Based on our results, elementary school laws may have a limited impact unless reinforced by strong codified laws at higher grade levels."

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BPA Exposure Associated with Coronary Artery Disease

U.K. researchers have allegedly identified raised urinary bisphenol A (uBPA) concentrations in 591 study participants "with intermediate or severe stenoses compared to those graded as having no coronary artery disease [CAD]," suggesting that "associations between uBPA and CAD may be specific to coronary artery stenosis." **David Melzer, et al., "Urinary Bisphenol A Concentration and Angiography-Defined Coronary Artery Stenosis," *PLoS One*, August 2012**. According to the authors, their results apparently supported the associations between uBPA and CAD reported in three previous studies but "effectively ruled out reverse causation, strengthening the evidence for causal inference."

"The mechanism by which BPA ingestion and metabolism influences vascular function and risk of cardiovascular disease has not been elaborated… We recently suggested plausible mechanisms by which BPA might increase the risk of cardiovascular disease, including reduced nitric oxide bioavailability, altered vascular reactivity to endothelin-1, oxidative stress and inflammation," concluded the researchers, who recommended further work to determine the underlying relationship between BPA and CAD. "In our relatively small sample of patients investigated for ischemic heart disease referred for coronary angiography, BPA exposure… was higher in those with severe coronary artery stenoses compared to those with no vessel disease. Larger studies are needed to estimate true dose response relationships."

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