Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Senators Continue Crusade to Keep GE Salmon Out of U.S. Markets

Alaska's U.S. Senators Mark Begich (D) and Lisa Murkowski (R) have introduced two new bills as part of their ongoing campaign to prevent the federal government from allowing the sale of genetically engineered (GE) salmon. Information about related legislative proposals they sponsored in January 2011 appears in Issue 380 of this *Update*.

One new proposal (S. 1717) would make it unlawful for anyone to "ship, transport, offer for sale, sell, or purchase genetically altered salmon or other marine fish, or a product containing genetically altered salmon or other marine fish, in interstate or foreign commerce." The other proposal (S.A. 751), offered as an amendment to a House appropriations bill (H.R. 2112), would preclude the Food and Drug Administration (FDA) from spending any funds to approve an application for the approval of GE fish. One such application is pending before the agency.

According to Begich, "There is just too much at risk here. The public has expressed serious concerns about the introduction of Frankenfish into the nation's food supply, including potential threats to the environment and public health, and economic impacts on producers of sustainable wild salmon." Echoing his concerns, Murkowski said, "Frankenfish could pose serious risks to wild populations of many fish. While these modified fish are supposed to be sterile, 5 percent of the fish could remain fertile, and escaped stock could breed with wild stocks, introducing hazardous mutations to a currently healthy and hygienic wild stock." *See Senator Mark Begich Press Release*, October 17, 2011.

U.S. Senate Adopts Amendment to Keep Spuds in Schools

The U.S. Senate has reportedly adopted an amendment to the Fiscal Year 2012 Senate Agriculture Appropriations bill that would prevent the U.S. Department of Agriculture (USDA) from reducing the amount of potatoes and other starches in school meals. According to Senator Susan Collins (R-Maine), who

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authored the bipartisan measure, USDA earlier this year "proposed a rule that would limit servings of a certain category of vegetables that includes white potatoes, green peas, lima beans, and corn, to a total of one-cup per week in the National School Lunch Program," while also prohibiting "this category of vegetables from the School Breakfast Program altogether."

The amendment blocks USDA from eliminating these vegetables but keeps the requirement "that school meals be consistent with the most recent Dietary Guidelines for Americans." As a result, USDA and schools will reportedly retain the flexibility to regulate cooking methods and make "reasonable and suitable substitutions among affordable fresh and nutritious food options."

"I am delighted that my colleagues in the Senate have accepted our amendment," said Collins, who noted that USDA had estimated the rule's cost at $6.8 billion over five years. "This means USDA cannot proceed with a rule that would impose unnecessary and expensive new requirements affecting the servings of healthy vegetables, such as white potatoes, green peas, corn, and lima beans." *See Senator Susan Collins Press Release* and *The New York Times,* October 18, 2011.

Consumer Interests Seek FTC Investigation of Digital Youth Marketing; Doritos® Targeted

Several consumer advocacy organizations have filed a **complaint** with the Federal Trade Commission (FTC) based on a **report** that "identifies, analyzes, and documents a set of digital marketing practices that pose particular threats to children and youth, especially when used to promote foods that are high in fat, sugars, and salt, which are known to contribute to child and adolescent obesity." The complaint specifically targets PepsiCo and Frito-Lay, focusing on promotions for Doritos®.

According to the complainants, "Frito-Lay has infiltrated the lives of teens by developing covert advertising campaigns centered on things teens love—video games, music, horror, sports, contests, and social networking." They further contend that (i) "Frito-Lay disguises its marketing campaigns as entertaining video games, concerts, and other immersive forms of entertainment, thus making it more difficult for teens to recognize them as marketing and to be skeptical about the messages they present"; (ii) "Frito-Lay claims to protect teens' privacy but fails to do so. The campaigns also collect and use teens' personal information without meaningful notice and consent"; and (iii) "Frito-Lay uses viral marketing in ways that violate the FTC endorsement guidelines."

Seeking an FTC investigation into their allegations, the complainants argue that "teens are uniquely vulnerable to the kinds of deceptive techniques used by Frito-Lay because of certain physiological and psychological traits associated with adolescence." They claim that the marketing campaigns are

affecting purchasing decisions, "evident from both the increased sales of Doritos and the fact that to play the game or enjoy the concert, the consumer is often required to purchase Doritos."

The report released with the complaint was prepared by the National Policy & Legal Analysis Network to Prevent Childhood Obesity. Titled "Digital Food Marketing to Children and Adolescents," the report addresses "five categories of digital marketing techniques that are used routinely by fast food, snack food, and soft drink companies to target children and adolescents." They purportedly include (i) "Augmented reality, online gaming, virtual environments, and other immersive techniques that can induce 'flow,' reduce conscious attention to marketing techniques, and foster impulsive behaviors"; (ii) "Social media techniques that include surveillance of users' online behaviors without notification, as well as viral brand promotion"; (iii) "Data collection and behavioral profiling designed to deliver personalized marketing to individuals without sufficient user knowledge or control"; (iv) "Location targeting and mobile marketing, which follow young peoples' movements and are able to link point of influence to point of purchase"; and (v) "Neuromarketing, which employs neuroscience methods to develop digital marketing techniques designed to trigger subconscious, emotional arousal."

The organizations filing the FTC complaint are the Center for Digital Democracy, Consumer Action, Consumer Watchdog, and Praxis Project.

FDA Sets Allowable Level for DEHP in Bottled Water

The Food and Drug Administration (FDA) has **announced** changes to its bottled water quality standard "by establishing an allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP)." Effective April 16, 2012, the final rule establishes "in § 165.110(b)(4)(iii)(C) (21 CFR 165.110(b)(4)(iii)(C)), which includes allowable levels for pesticides and other synthetic organic chemicals, an allowable level for DEHP at 0.006 mg/L." It also requires manufacturers to monitor their products "for DEHP at least once each year under the current good manufacturing practice (CGMP) regulations" and to monitor their source water "as often as necessary, but at least once every year unless they meet the criteria for source water monitoring exemptions under the CGMP."

According to FDA, the amended rule brings bottled water standards in line with those set by the Environmental Protection Agency (EPA) for public drinking water. The two comments opposing the rule change evidently did not provide enough evidence to challenge FDA's finding "that long-term, chronic exposure to DEHP above the MCL [maximum contaminant level] of 0.006 mg/L may have the potential to cause health effects in humans including damage to liver and testes, reproductive effects, and cancer."

"By finalizing the allowable level for DEHP in the bottled water quality standard, FDA is meeting the requirement in the [Food, Drug, and Cosmetic

Act] to amend its regulations for bottled drinking water in response to EPA's establishment of an MCL for DEHP," states the October 20, 2011, *Federal Register* notice. "Although DEHP is not expected to be found in bottled water in levels above the standard, FDA concludes that this rule is protective of public health because it will ensure that, should current conditions change, such as new sources of water or new manufacturing practices, the level of DEHP will remain low."

IOM Recommends "Fundamental Shift" in FOP Labeling

The Institute of Medicine (IOM) has released the **second** of its two-phase report on front-of-package (FOP) rating systems and symbols for food products, advocating a "fundamental shift" in labeling strategy. While its first phase, released in October 2010, analyzed nutrition rating systems and the scientific research that underlies them, the new 231-page assessment examines consumers' use and understanding of FOP systems. Details of the first phase were featured in **Issue 368** of this *Update*.

Concluding that "it is time for a move away from front-of-package systems that mostly provide nutrition information on foods or beverages but don't give clear guidance about their healthfulness," IOM recommends that the Food and Drug Administration allow only four items on any FOP system—calories, saturated and *trans* fat, sodium, and sugar. It suggests the agency develop, test and implement a single, standard point system from zero to three—designated by a simple icon like check marks or stars—indicating the products' levels of saturated and *trans* fats, sodium, and added sugars. According to IOM, "The more points a food or beverage has, the healthier it is. This system would encourage food and beverage producers to develop healthier fare and consumers to quickly and easily find healthier products when they shop." IOM also recommends that a new FOP system feature a "multi-stakeholder, multi-faceted awareness and promotion campaign that includes ongoing monitoring, research, and evaluation."

Center for Science in the Public Interest Executive Director Michael Jacobson called IOM's proposal "eminently sensible" and "far preferable" to the voluntary "Facts Up Front" labeling program the grocery industry has endorsed. "A simple icon with 3, 2, 1, or zero check marks would give shoppers at-a-glance information about nutritional booby traps lurking inside packaged foods," he said. Still, the approach "has holes that the FDA would have to address," he noted. "For instance, it gives no consideration to foods' vitamin, mineral, fiber, or protein content. Also, white bread, whole wheat bread, broccoli, artificially sweetened soft drinks, and artificially colored and flavored diet Jell-O would all have top scores of 3."

Meanwhile, the Grocery Manufacturers Association (GMA) called IOM's proposal an "untested, interpretive approach," and praised the Facts Up Front

labeling system as a "real-world program that delivers real value to consumers in real time." The group noted that "consumers have said repeatedly that they want to make their own judgments rather than have government tell them what they should and should not eat." *See News from the National Academies, CSPI News Release* and *GMA News Release,* October 20, 2011.

EC Adopts "Nanomaterial" Definition

The European Commission (EC) has **adopted** a recommendation defining "nanomaterials" as materials "whose main constituents have a dimension of between 1 and 100 billionth of a meter." According to an October 18, 2011, press release, this definition considers only "the size of the constituent particles of a material, rather than hazard or risk." As such, it describes nanomaterials as "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm."

The definition apparently relies on input from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Joint Research Centre (JRC), whose draft recommendations were covered in **Issue 355** of this *Update*. The EC hopes that the adopted version clearly defines "which materials need special treatment in specific legislation" and "brings coherence to the variety of definitions that are currently in use in different sectors." The commission also plans to review the definition in 2014 "in the light of technical and scientific progress."

"I am happy to say that the EU is the first to come forward with a cross-cutting designation of nanomaterials to be used for all regulatory purposes," said European Environment Commissioner Janez Potočnik in describing the consultation process. "Industry needs a clear coherent regulatory framework in this important economic sector, and consumers deserve accurate information about these substances. It is an important step towards addressing any possible risks for the environment and human health, while ensuring that this new technology can live up to its potential."

California Agency Extends Comment Period on Change to 4-MEI No Significant Risk Level

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **extended** the deadline for public comment on a proposal to increase the no significant risk level (NSRL) for 4-methylimidazole (4-MEI) to November 7, 2011. The action was taken in response to a request from the American Beverage Association and International Technical Caramel Association. The chemical has been identified as a by-product of fermentation, heating or roasting in certain foods and beverages, such as coffee, some carbon-

ated beverages, beer and wine, soy sauce, molasses, and crackers. The new proposed NSRL is 29 micrograms per day, an increase from the 16 micrograms per day level that OEHHA proposed in January.

Philadelphia Seeks Exemption from Preemption for Menu Labeling Ordinance

The Food and Drug Administration (FDA) recently opened a **docket** pertaining to a petition filed by Philadelphia seeking to exempt from preemption a menu labeling ordinance that requires chain restaurants and retail food facilities in the city to provide calorie, fat and sodium information for the food and beverage products they sell.

According to the petition, the ordinance meets three requirements under the Federal Food, Drug, and Cosmetic Act allowing FDA to grant an exemption from preemption: the ordinance "was designed to address a particular local need for information which need is not met by the requirements" of federal labeling law, the exemption from preemption "would not unduly burden interstate commerce," and the exemption "would not cause any food to be in violation of any applicable requirement under federal law."

Philadelphia contends that while Congress required uniformity in chain restaurant menu labeling as part of the Patient Protection and Affordable Care Act of 2010, 21 U.S.C.S. § 343-1(a), it "specifically left untouched subsection (b) which provides that the Secretary of Health and Human Services may exempt any state or local requirement from subsection (a) if the aforementioned three factors are met."

LITIGATION

Seventh Circuit Dismisses Non-Natural Fiber Claims with Prejudice

The Seventh Circuit Court of Appeals has dismissed with prejudice consumer protection claims filed against two companies that make snack bars with extra fiber, finding the claims preempted under federal law. ***Turek v. General Mills, Inc.*, No. 10-3267 (7th Cir., decided October 17, 2011)**.

According to the court, "The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars are not identical to the labeling requirements imposed on such products by federal law, and so they are barred." The plaintiff had sought the inclusion of information on chewy bar product labels indicating that inulin derived from chicory root "produces fewer health benefits than a product that contains only 'natural' fiber," and that "inulin from chicory root should not be consumed by pregnant or lactating women."

Additional details about the complaint and the district court's ruling dismissing the claims appear in Issues 327 and 364 of this *Update*.

Among other matters, the Seventh Circuit explained the desirability of uniform federal rules relating to food products, stating "It is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy."

CSPI Alleges Fruit Roll-Ups® Maker Deceives Consumers

The Center for Science in the Public Interest (CSPI) is representing a California woman who has sued General Mills, Inc. on behalf of a putative nationwide class of consumers who purchased the company's Fruit Roll-Ups®, Fruit by the Foot® and Fruit Gushers® products, claiming that the company deceptively markets them as healthy and wholesome. ***Lam v. General Mills, Inc.* No. 11-5056 (U.S. Dist. Ct., N.D. Cal., filed October 14, 2011)**. According to CSPI, "General Mills is basically dressing up a very cheap candy as if it were fruit and charging a premium for it."

Product labeling purportedly refers to the snacks as "fruit flavored," "naturally flavored," "good source of Vitamin C," "low fat," and "gluten free." The complaint alleges that these claims are misleading because the snacks actually contain *trans* fat, added sugars, and artificial food dyes. The plaintiff also alleges that the products lack "significant amounts of real, natural fruit" and have no dietary fiber. No personal injury is alleged; instead, the plaintiff claims "that she would not have purchased the Products for herself and her children at a premium price had these misrepresentations not been made."

While the complaint indicates that the products' nutrition panels set forth detailed information about the actual ingredients, the plaintiff contends that "it is hard for a reasonable consumer to tell that the Fruit Roll-Ups Strawberry product does not actually contain any strawberries." The plaintiff also takes issue with the defendant's "various promotional gimmicks," including the opportunity to "win a laptop and give another one to a child in Africa" and to earn cash for school via a "box top for education." The complaint refers to a package promotion that "directs consumers to a website that contains online games and activities for children," but does not indicate in what way these promotions are misleading.

Alleging violation of Minnesota's Uniform Deceptive Trade Practices Act, California Consumers Legal Remedies Act and California's "Sherman Law," as well as fraudulent business acts and practices, misleading and deceptive advertising, breach of express warranty, breach of implied warranty of merchantability, and unjust enrichment, the plaintiff seeks restitution;

disgorgement; compensatory, statutory and punitive damages; injunctive relief; attorney's fees; and costs. *See CSPI News Release*, October 14, 2011.

Overstated Protein Content Claims Settled with Free Protein Bars for Class Members

General Nutrition Centers Inc. and the company that makes 2:1 Protein Bars® have settled class claims filed in California alleging that the companies misbranded four flavors in the product line by "allegedly overstat[ing] their protein content and understat[ing] their sugar and carbohydrate content." *Cagle v. Anti-Aging Essentials, Inc.*, No. 11-02940 (U.S. Dist. Ct., C.D. Cal., motion for preliminary approval of proposed settlement filed October 17, 2011).

While the companies apparently reformulated the bars and labels before the lawsuit was filed, they have agreed to comply with federal labeling laws in the future and to provide three free protein bars to class members who have been identified through online purchase records or their use of customer loyalty cards. Consumers who can prove their purchases with receipts will receive free replacement bars under the proposed settlement, if the court approves it. Consumers without proof of purchase would be able to receive buy-one-get-one-free coupons for the products. The named class representatives would receive $5,000 each as an incentive award under the proposal. The defendants have also agreed not to oppose up to $165,000 in attorney's fees and costs.

OTHER DEVELOPMENTS

"All Natural" Lawsuits Proliferate, But Recovery Could Be Elusive

According to legal commentators, including Shook, Hardy & Bacon Agribusiness & Food Safety Practice Co-Chair **Madeleine McDonough**, while the floodgates have opened on litigation against food and beverage makers accusing them of misleading consumers with "All Natural" labels, proving that each plaintiff relied on the representation to purchase a given product may ultimately doom this recent class action trend. In a *Law360* article titled "'All Natural' Class Action Wave May Be Short-Lived," even plaintiffs' lawyers concede that consumers expecting "all natural" products to provide some undefined quality will have difficulty proving that everyone relied on the representation when purchasing the product.

Noting that the Food and Drug Administration has not placed a priority on defining the term in conjunction with foods and beverages, which makes it a fertile ground for litigation, McDonough also said that plaintiffs face the hurdle of proving a concerted effort to defraud them. In her experience, however, "product manufacturers are trying to be careful, and they are aware of litigation threats." She contends that while companies consider the litigation to be a "tempest in a teapot," they have been conservative about product

claims to avoid the considerable costs of defending putative class actions. *See Law360*, October 19, 2011.

Natural Food Store Launches GM-Free Labeling

A natural foods co-op in Durango, Colorado, has reportedly rolled out a new labeling initiative for products free of genetically modified organisms (GMO) to recognize "October's designation as national non-GMO month." According to an October 19, 2011, article in *The Durango Herald,* the local co-op displays two labels on shelves to indicate products certified by the Non-GMO Project and those verified by manufacturers as containing no GMOs.

"Normally, consumers would have to do the research or call manufacturers themselves if they wanted that information," the store's marketing manager told the *Herald* while noting that the co-op itself is also a member the National Cooperative Growers Association, Just Label It Campaign and Non-GMO Project. As another natural grocer apparently elaborated, "Without GMO labeling, the only way to know if products contain genetically engineered foods is if they are made with 100 percent USDA-certified organic ingredients."

The manager of a third area store, however, cautioned that such labeling programs are still expensive despite gaining momentum. "It's a huge job for us to chase down where corn came from and how it is handled in every bag of chips and every box of cereal. We are letting the bigger guys in the industry take it on before we step into it," she said.

MEDIA COVERAGE

NYT Covers California's "Adieu to Foie Gras"

An October 15, 2011, *New York Times* article has covered the impending ban on foie gras sales in California, where several chefs are apparently staging swan-song dinners in honor of the fatty fare. According to the *Times*, a law signed eight years ago will in eight months make California the first state to criminalize foie gras, fining violators up to $1,000 per day for serving the delicacy to patrons. As a result, chefs like Ludo Lefebvre recently announced "You Gotta Fight for Your Right to Foie!" events for fans to overindulge on duck and goose livers one last time.

"I want people to have the freedom to eat what they want. Animal rights people would turn everyone into a vegan if they could," Lefebvre told the paper. "Foie gras is one of the greatest ingredients, a French delicacy. I was born and raised with foie gras. It's like if you took kimchi away from Korean people."

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While noting that a similar ban in Chicago survived only two months before being overturned, the *Times* did not anticipate diners defeating the popular measure anytime soon. But the law has apparently raised questions among nationally recognized names like New York University Professor of Food Studies and Public Health Marion Nestle, who questioned the logic behind the ban.

"What's being regulated here?," she was quoted as asking. "You are denying people the food that people in some countries have been eating for generations. They don't believe the process of fattening up the ducks or geese is painful to the ducks or geese. I've seen the videos, and everyone says the same thing: they all seem to run up to be fed. The question is whether you believe that the killing of animals for food for people is acceptable. It's a moral judgment. You have an ethical slippery slope here."

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