Shook, Hardy & Bacon L.L.P.

ISSUE 403 | JULY 29, 2011

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

Legislation, Regulations and Standards

Lawmakers Urge FDA to Finalize Gluten-Free Labeling Rules 1

Industry Coalition Seeks Regulatory Exemption for Packaged Foods Storage 1

Consumer Groups Urge FDA to Regulate Heavy Metals in Fruit Juice 2

NIOSH Seeks Comments on Criteria for Setting Occupational Diacetyl Exposure Limit 2

EPA Requests Feedback on BPA Toxicity Testing Plan 3

FSIS Proposes New Labeling for Injected Raw Meat, Poultry 3

EU to Tighten Bacon Labeling Rules 4

OEHHA Requests Input on Prioritizing BPA Under Prop. 65 Procedures 4

Litigation

Putative Class Claims Fraud in Muscle Milk® Advertising 5

Texan Alleges Four Loko® Caused His Stroke 6

Other Developments

NAD & CARU Announce 2011 Annual Conference 6

IOM Publishes Summary of Food Technology and Obesity Workshop 6

Media Coverage

Mark Bittman, "Irradiation and the 'Ick Factor,'" *The New York Times*, July 26, 2011 7

Scientific/Technical Items

Fast-Food Customers Who Read Calorie Postings Make Lower-Calorie Selections 7

LEGISLATION, REGULATIONS AND STANDARDS

Lawmakers Urge FDA to Finalize Gluten-Free Labeling Rules

Two U.S. senators have asked the Food and Drug Administration (FDA) to finalize standards for a 2007 proposed rule for gluten-free food labels. In a **letter** to FDA Commissioner Margaret Hamburg, Senators Ron Wyden (D-Ore.) and Patrick Leahy (D-Vt.) claim the delay is "creating unnecessary confusion for consumers and uncertainty for agricultural producers." Included as part of the Food Allergen Labeling and Consumer Protection Act of 2004, the proposed gluten-free labeling rule represents the last time "any significant action on this has been taken," the lawmakers wrote, adding that "regulatory uncertainty surrounding FDA's inaction has led to a proliferation of 'gluten free' standards and labels provided by 3rd party groups."

Wyden also issued a July 21, 2011, press release asserting that "accurate and standard" labeling on gluten-free products is essential for those with Celiac disease—"a painful disorder stemming from the inability to properly digest the gluten found in breads."

Industry Coalition Seeks Regulatory Exemption for Packaged Foods Storage

The American Bakers Association and a number of other industry trade associations have submitted a **citizen petition** to the Food and Drug Administration (FDA) seeking regulations that would exempt those businesses engaged in storing packaged foods from hazard analysis and prevention controls applicable to food producers and processors.

The petition notes that under the Food Safety Modernization Act (FSMA) Congress allowed FDA to implement its food safety provisions "in a manner that acknowledges the difference in risk posed by various types of operations." Claiming that "storage facilities themselves pose a very limited, if any, food-safety risk," the petition notes that any potential hazards in warehouses are already addressed through existing good manufacturing practices governing warehousing and distribution facilities.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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The petitioners, including the Grocery Manufacturers Association, International Bottled Water Association, and Snack Food Association, seek a rule that would state, "A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 of the Federal Food, Drug, and Cosmetic Act if the facility complies with the requirements set forth at 21 C.F.R. § 110.93."

According to American Frozen Food Institute (AFFI) President and CEO Kraig Naasz, speaking in support of the petition, "Food safety is the highest priority throughout the frozen food industry supply chain. The FSMA provisions requiring warehouse facilities that store packaged frozen foods to implement the same preventive controls required of food producers are overly burdensome, duplicative and unnecessary, and would lead to increased costs for the warehouse community and, ultimately, consumers." *See AFFI Press Release*, July 25, 2011.

Consumer Groups Urge FDA to Regulate Heavy Metals in Fruit Juice

Consumer advocacy organizations have **written** to Food and Drug Administration (FDA) Commissioner Margaret Hamburg to report the results of tests conducted on apple juice, showing arsenic levels above federal tolerance levels for drinking water.

The organizations, Food & Water Watch and the Empire State Consumer Project, urge FDA to "establish tolerance levels for arsenic in food" and "to focus its import surveillance resources on imported juice concentrate as a product of concern and increase its testing of those imported products." One apple juice sample apparently contained 55 parts per billion (ppb) of arsenic; the U.S. Environmental Protection Agency's drinking water tolerance level for arsenic is 10 ppb. According to the groups' letter to FDA, the agency has admitted that it has "established a 'level of concern' when arsenic levels exceed 23 parts per billion, but has no actionable levels for regulatory purposes." *See Food & Water Watch News Release*, July 21, 2011.

NIOSH Seeks Comments on Criteria for Setting Occupational Diacetyl Exposure Limit

The National Institute for Occupational Health and Safety (NIOSH) will hold a **public meeting** August 26, 2011, to solicit public input on a draft document titled "Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione." Diacetyl is a butter-flavoring chemical widely used in baked goods and microwave popcorn. Numerous lawsuits have been filed against flavoring manufacturers by workers and others alleging that inhaling the substance caused their bronchiolitis obliterans, a debilitating lung condition. Pentanedione is also a constituent of synthetic flavoring agents.

NIOSH will make the draft document available online by August 12, and those wishing to participate in the public meeting must notify the NIOSH docket office no later than August 19. Public comments must be submitted by October 14.

With limited meeting space, NIOSH will give priority to those who register to provide oral comments; 10 minutes will be allotted to each presenter. Among the matters that will be discussed are hazard identification, risk estimation, health effects, basis for recommended exposure limit, locations and individuals most at risk of exposure, and current control strategies. If time permits, others registered on a first-come basis to attend the meeting will have an opportunity to present their comments. The meeting will open with a presentation by federal officials. *See Federal Register*, July 25, 2011.

EPA Requests Feedback on BPA Toxicity Testing Plan

The U.S. Environmental Protection Agency (EPA) has issued an advance notice of proposed rulemaking (ANPRM) related to bisphenol A (BPA) toxicity testing and the study of its potential environmental impacts. The agency has requested comments by September 26, 2011, on (i) requiring toxicity testing "to determine the potential for BPA to cause adverse effects, including endocrine-related effects, in environmental organisms at low concentrations," and (ii) monitoring for BPA in surface water, ground water, drinking water, soil, sediment, and landfill leachate "to determine whether environmental organisms may currently be exposed to concentrations of BPA in the environment that are at or above levels of concern for adverse effects, including endocrine-related effects."

According to a July 26, 2011, EPA press release, the ANPRM builds on a March 2010 action plan meant to strengthen the agency's chemical management program and "assure the safety of chemicals that many American encounter in their daily lives." Although the latest effort is directed only toward "the environmental presence and environmental effects of BPA," EPA is also working with the Department of Health and Human Services on potential human health issues. Additional details about the action plan appear in Issue 344 of this *Update*.

FSIS Proposes New Labeling for Injected Raw Meat, Poultry

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has issued a proposed rule that would require raw meat and poultry products that contain injected marinades or solutions to be named in a way that clearly distinguishes them from 100 percent meat or poultry products. According to FSIS, consumers are likely unaware that "enhanced products" may contain increased levels of sodium because current labels are unclear as to whether a solution has been added. For example, under current rules, 100 percent

chicken breasts and products containing 60 percent chicken and 40 percent solution may both be called and labeled "chicken breast." The latter product must indicate that a solution has been added, but manufacturers have been doing so in typefaces and fonts that can be difficult to read.

To avoid misbranding, FSIS proposes that the labels feature (i) as the product's "name" an accurate description of the product with the percent of added solution, such as "chicken breast – 40% added solution of water, teriyaki sauce, and salt"; (ii) the added solution's ingredients; and (iii) a consistent font, size and color on a contrasting background easily visible to consumers. FSIS considered but rejected use of the term "enhanced," because it could "imply a judgment about the value of the product." Requesting comments by September 26, 2011, the agency anticipates that the finalized rules will take effect January 1, 2014. See *USDA Press Release*, July 21, 2011; *Federal Register*, July 27, 2011.

EU to Tighten Bacon Labeling Rules

The European Union (EU) has reportedly introduced new rules that would halve the percentage of added water allowed in bacon products labeled as such. According to media sources, current laws set the added water limit for bacon at 10 percent, but the updated measure would require bacon containing more than 5 percent added water to be renamed "bacon with added water." If adopted by the European Council this fall, the regulations would apparently take effect in 2015.

The plan has since drawn feedback from both bacon retailers and aficionados, as well as government agencies like the U.K. Department for Environment, Food and Rural Affairs, which said that the stricter requirements would "make it clearer to shoppers exactly what they are buying." The British Retailers Consortium (BRC), however, was less sanguine, telling reporters that reducing the added water content would make bacon "less moist, less succulent and less tender when it was cooked." As one BRC spokesperson explained, "We are concerned the nature of the product could change significantly and that any change could be confusing for consumers who perhaps wouldn't understand that they were buying the same product that now just had an 'added water' label." *See The Parliament.com* and *The Telegraph,* July 25, 2011; *Yorkshire Post,* July 26, 2011; *The Guardian's Word of Mouth Blog,* July 27, 2011.

OEHHA Requests Input on Prioritizing BPA Under Prop. 65 Procedures

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **announced** that its Carcinogen Identification Committee will discuss whether 39 chemicals should be prioritized "for possible preparation of hazard identification materials" during the committee's October 12-13, 2011, meeting.

While no decision will be made at this meeting about adding the chemicals to California's Proposition 65 (Prop. 65) list of substances known to the state to cause cancer, the process OEHHA is following could ultimately lead to their inclusion. Public comments on the 39 listed chemicals are requested by September 20, 2011.

Among those chemicals under consideration is bisphenol A (BPA). According to OEHHA's supporting materials, which include references to numerous carcinogenicity and genotoxicity studies, billions of pounds of BPA are produced each year in the United States, and most human exposure occurs "through the diet." Other chemicals under consideration are those used in agriculture, such as the fungicides chloropicrin, dicloran, fluazinam, and thiophanate methyl. Also on the list are the insecticide flonicamid and broad spectrum antifungal agents known as triazoles, used in pesticides. N-nitroso-n-methylaniline, a chemical found in smoked meat and used in rubber manufacturing, will also be considered. *See OEHHA News Release*, July 22, 2011.

LITIGATION

Putative Class Claims Fraud in Muscle Milk® Advertising

A California woman has filed a putative nationwide class action against the company that makes Muscle Milk® beverages and protein bars, alleging that promotions touting the products as "high performance" and "nutritious snacks" are false and misleading because they contain as much fat and calories as Krispy Kreme® doughnuts. *Delacruz v. Cytosport, Inc.*, No. 11-3532 (U.S. Dist. Ct., N.D. Cal., filed July 18, 2011). The company apparently markets the products as "a 'meal replacement' to provide 'healthy sustained energy'" and allegedly "suggests that these fat-filled Products will help people lose weight, telling consumers, among other things, that the Products will help people 'Go from cover it up to take it off.'"

According to the complaint, the named plaintiff purchased the products for six months and consumed them "before workouts, after workouts, in between meals as a snack, and sometimes as a meal replacement." She contends that she did so in reliance on the company's product representations, believing "the Products to be healthy, nutritious foods that she could eat to help her live an active lifestyle, meet her nutritional goals, and lose weight." Seeking to certify a class of all U.S. residents who purchased the products since 2007, the plaintiff alleges violations of the Consumers Legal Remedies Act, Unfair Business Practices Act and False Advertising Law; fraud; negligent misrepresentation; and unjust enrichment. She requests compensatory and punitive damages, restitution and disgorgement, declaratory and injunctive relief, corrective advertising, interest, attorney's fees, and costs.

Texan Alleges Four Loko® Caused His Stroke

A 33-year-old man has filed a personal injury lawsuit in a Texas federal court against companies that made and sold the Four Loko® that allegedly caused the stroke he had in October 2010 immediately after consuming two cans of the caffeinated alcohol beverage. *Villa v. Phusion Projects, LLC*, No. n/a (U.S. Dist. Ct., S.D. Texas, McAllen Div., filed mid-July 2010). According to the complaint, the plaintiff continues to experience health problems, including slurred speech and lack of balance. Alleging negligence and products liability, the plaintiff seeks damages in excess of $75,000, punitive damages, attorney's fees, and costs.

OTHER DEVELOPMENTS

NAD & CARU Announce 2011 Annual Conference

The National Advertising Division (NAD) of the Council of Better Business Bureaus and the Children's Advertising Review Unit (CARU) have **announced** the agendas for their joint 2011 annual conferences slated for October 3-5, 2011, in New York. The two-day NAD conference, "What's New in Advertising Law, Claim Support and Self-Regulation," will include keynote remarks by David Vladeck, director of the Federal Trade Commission's (FTC's) Bureau of Consumer Protection, as well as sessions on online behavioral advertising, claim substantiation, mobile marketing, litigation and FTC enforcement priorities, and the future of advertising self-regulation. Immediately following the NAD session, CARU will host a one-day conference focused on privacy and digital issues in youth marketing, with expert panels dedicated to new FTC regulations, multimedia and social media advertising to children, and responsible food marketing to children.

IOM Publishes Summary of Food Technology and Obesity Workshop

The Institute of Medicine (IOM) recently **released** the summary of a November 2-3, 2010, public workshop titled "Leveraging Food Technology for Obesity Prevention and Reduction Effort," which addressed how the food industry "can continue to leverage modern and innovative food processing technologies to influence energy intake." According to IOM, "Eating is impacted not only by the biological responses that occur when the presence of food or even the smell of food triggers physiological chain reactions but also by societal norms and values around portion size and other eating behaviors." Workshop organizers invited behavioral scientists, food scientists and other experts from multiple sectors to discuss "evidence-based associations between various eating behaviors and weight gain and considered the opportunities and challenges of altering the food supply—both at home and outside the home (e.g., in restaurants)—to alleviate overeating and help consumers with long-term weight maintenance."

In particular, the workshop attendees explored four general categories of eating behavioral challenges: (i) the association between increased portion size and

increased energy intake; (ii) the association between decreased energy density and decreased energy intake; (iii) the effects of increased satiety on energy intake; and (iv) the unpredictable behaviors of consumers toward "improved" food products and foods with health claims. They also noted the regulatory, economic and product reformulation challenges facing manufacturers who wish to avail themselves of new food technologies to help consumers prevent or manage weight gain. "Several participants asserted that there is no 'magic bullet' food product, or type of product, to serve as an obesity prevention or reduction tool," concluded the IOM summary. "There was also a call by participants for a more systematic analysis of obesity in America—that is, research aimed at teasing apart not only behaviors that lead to excess energy consumption but also behaviors that lead to insufficient energy expenditure."

MEDIA COVERAGE

Mark Bittman, "Irradiation and the 'Ick Factor,'" *The New York Times,* July 26, 2011

"The big question is this: How do we get the safest and most ethical food system possible while adequately feeding ourselves?," asks *New York Times* columnist Mark Bittman in this latest opinion piece supporting "a massive overhaul of the food system." Discussing recent *E. coli* outbreaks in Europe, Bittman concedes that the controversial process known as irradiation "could be a useful tool" in controlling bacteria and other foodborne illnesses, but warns that it should not be viewed as a panacea or replacement for other measures. "The answer will come in steps," he writes. "[B]etter regulation and inspection of food production; stricter labor laws; more rigorous testing for pathogens, to name just a few—and eventually those steps may lead to a point where irradiation is unnecessary."

Bittman urges lawmakers to adequately fund the Food and Drug Administration's Food Safety Modernization Act, even while citing "the ironies" inherent in a system that insists on labeling safely irradiated products but not labeling "meat from animals routinely fed antibiotics," genetically modified ingredients or produce raised with chemical pesticides. "If irradiation were called 'cold pasteurization'—as it sometimes is—it wouldn't have the 'ick factor,' and we might be more accepting of it," Bittman concludes. "People just don't like the sound of it—it's not going to get re-labeled cold pasteurization—and it's expensive. (Still, if there were another massive *E. coli* outbreak here, there could be a groundswell)."

SCIENTIFIC/TECHNICAL ITEMS

Fast-Food Customers Who Read Calorie Postings Make Lower-Calorie Selections

The *British Medical Journal* has published a **study** that sought to "assess the impact of fast food restaurants adding calorie labeling to menu items on the energy content of individual purchases."

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 403 | JULY 29, 2011

According to the researchers, including an independent consultant and a city official, the more than 8,400 adults interviewed in 2009 did not overall purchase foods lower in calories after New York City implemented regulations requiring calorie posting, but among the one in six lunchtime customers who used the calorie information provided, lower calorie choices were made. Significant variations were apparently found in the data collected from different chains, a matter attributed to customer purchasing patterns and changes in menu options and promotions.

More than 7,300 lunchtime customers at 275 fast-food locations, representing 13 chains, were interviewed in 2007 and provided their register receipts so researchers could verify their self-reported purchases. The same method was used to compare and assess the purchases made in 2009. Women and customers in wealthier neighborhoods apparently used the calorie information more often than men or customers in the poorest neighborhoods, and the youngest customers evidently "were the least likely to report using calorie information." According to the data, "Customers who reported using the calorie information after regulation purchased 106 fewer calories, on average, compared with customers who didn't see or didn't use the information."

Among the study's limitations were time constraints on the amount of information that could be collected and variability in the number of fast-food meals consumed ("customers may be eating fast food more or less often; which would not be captured in this study design"). Certain types of customers with different dietary motivations may also be attracted to certain chains, another matter not accounted for. The study authors also note, "This analysis does not attempt to distinguish between the multiple potential mechanisms by which calorie labeling could affect the energy content of purchases, such as changes in menu offerings, more informed consumer choice, or differences in pricing or promotion."

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