Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Lawmakers Introduce Bill Addressing Nanotech Product Risks

U.S. Senators Mark Pryor (D-Ark.) and Benjamin Cardin (D-Md.) have introduced a bill (S. 1662) that focuses on the potential risks of products containing nanomaterials. The Nanotechnology Regulatory Science Act of 2011 would establish a Food and Drug Administration (FDA) program to conduct the scientific research needed to evaluate the health and safety of common nanotech products and develop safety practices for companies using the technology. The measure would authorize $48 million for the program over three years starting in fiscal year 2013; the lawmakers said the FDA laboratories and research facilities suited to conduct the studies are located in their states.

The senators claim that more than 800 commercial uses of nanotechnology are currently known and more than 1,300 consumer nanotechnology products, including cell phones, MP3 players and food packaging, are available on the market. The National Science Foundation estimated in 2010 that new nanotechnology-based products would create 2 million jobs and add $1 trillion in revenue to the global economy by 2015.

"From new cancer treatments to stain-resistant pants, nanotechnology offers hundreds of promising applications and jobs," Pryor said. "As these products are developed and used, we should assess potential risks to human health, safety, or the environment." Introduced on October 6, 2011, the bill has been referred to the Senate Committee on Health, Education, Labor, and Pensions. *See Sens. Mark Pryor* and *Benjamin Cardin Press Releases,* October 6, 2011.

Agency Reps Reveal Watered-Down Youth-Marketing Principles in Committee Testimony

The House Energy & Commerce Committee held a **hearing** on October 12, 2011, to consider "Food Marketing: Can 'Voluntary' Government Restrictions Improve Children's Health?" Speaking for the committee, Chair Fred Upton (R-Mich.) concluded that an interagency working group tasked with

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

developing standards for marketing food to children and teenagers had taken what appeared to be "a first step toward Uncle Sam planning our family meals." Agency witnesses, such as Federal Trade Commission (FTC) Bureau of Consumer Protection Director David Vladeck, then testified that the proposed voluntary standards released in spring 2011 are undergoing "significant revisions" to allay the concerns of industry stakeholders.

Among other matters, the FTC has determined that (i) "with the exception of certain in-school marketing activities, it is not necessary to encompass adolescents ages 12 to 17 within the scope of the covered marketing"; (ii) "philanthropic activities, charitable events, community programs, entertainment and sporting events, and theme parks are, for the most part, directed to families or the general community and do not warrant inclusion with more specifically child-directed marketing"; and (iii) FTC staff "does not contemplate recommending that food companies change the trade dress elements of their packaging or remove brand equity characters from food products that don't meet nutrition recommendations," that is, the government will no longer suggest that cartoon characters be removed from the packaging of foods without nutritional value marketed to children.

Testifying on behalf of the U.S. Department of Agriculture, Robert Post indicated that a voluntary self-regulation program, involving 17 food manufacturers and restaurant chains, appeared to be moving in a positive direction in terms of "getting healthier products marketed to children" by agreeing "to follow a unified set of nutrition criteria."

Public health advocacy interests responded with concerns about an apparent weakening of what were already voluntary government guidelines. Center for Science in the Public Interest Nutrition Policy Director Margo Wootan said, "What an unseemly spectacle it is to see panicked junk-food advertisers running to Congress to help fending off the innocuous, voluntary guidelines for food marketed to children proposed by the Interagency Working Group." Noting that the industry was apparently playing the "national nanny card," Wootan also said, "I suppose if you're in the business of convincing young children to want to eat Cocoa Puffs, Cookie Crisps, Kool-Aid, and fake 'fruit' snacks, it makes perfect sense that you'd try to change the conversation away from nutrition and health."

Meanwhile, industry opponents of the marketing guidelines reportedly testified that the government should scrap them entirely, calling them "backdoor regulations" that would result in the loss of thousands of U.S. jobs and accomplish little in addressing childhood obesity. According to a spokesperson for the Association of National Advertisers, "These are unprecedented and extreme proposals [that] need to be formally withdrawn and taken back to the drawing board." Some congressional representatives apparently agreed that the recommendations be withdrawn, critical of what they viewed as the

Obama administration's failure to consider potential economic impacts of the guidelines and concerned over opening the door to consumer lawsuits. *See Advertising Age* and *CSPI News Release*, October 12, 2011.

Chemical Industry Seeks BPA Ban, FDA Inclined to Adopt One

According to a news source, the Food and Drug Administration (FDA) is poised to prohibit the use of bisphenol A (BPA) in baby bottles and sippy cups in response to a petition filed by the American Chemistry Council. A council spokesperson apparently stated during an October 7, 2011, press briefing that while scientific data and government assessments have declared the chemical safe and U.S. manufacturers ceased making these products with the plasticizer in response to market demand, the council took the action because of "quite a bit of legislative activity around a product that doesn't exist" and "[c]onfusion about these products has become an unnecessary distraction to consumers, legislators and state regulators."

An environmental advocate reportedly characterized the council's petition as a "stunning reversal," noting that the "industry spent millions this year fighting efforts in California and other states to ban BPA in baby bottles and sippy cups." The Environmental Working Group called on the industry to "drop any further objections to phasing out BPA in baby formula containers and other canned food." *See American Chemistry Council News Release*, October 7, 2011; *BNA Product Safety & Liability Reporter*, October 11, 2011.

Meanwhile, California Governor Jerry Brown (D) has signed a bill (**A.B. 1319**) that places limits on bisphenol A (BPA) in children's products. The legislation was intended to prohibit the chemical's use in baby bottles and sippy cups, but extends to other products as well.

The new law, enacted on October 4, 2011, will be known as the "Toxin-Free Infants and Toddlers Act." It mandates that after July 1, 2013, any bottles or cups that are "intended to be filled with any liquid, food, or beverage intended primarily for consumption from that bottle or cup by children three years of age or younger," cannot contain BPA at a detectable level above 0.1 parts per billion. BPA, found in many plastic food and beverage containers, is widely considered an endocrine disrupter, which means that it can act like an artificial hormone when it enters the human body.

The new law excludes any container intended to contain liquid, food or beverages for consumption by the general population, as well as medical devices. It does not, however, preclude the Department of Toxic Substances Control from prioritizing or taking "action on any products containing bisphenol A in order to limit exposure to or reduce the level of hazard posed by bisphenol A." Manufacturers are required to use the least toxic alternative when replacing BPA in regulated products, and they "shall not" replace BPA with any toxins that may cause "birth defects, reproductive harm or developmental harm," or

are included on the list of chemicals known to cause cancer or reproductive toxicity. The new law will be codified at California Health and Safety Code sections 108940 and 108941.

For further information about the California law, please contact SHB San Francisco Partners **Keith Casto** (**kcasto@shb.com**) or **Kevin Haroff** (**kharoff@shb.com**).

FDA Declares Preemption Language in Regulation Preambles Not Legally Supportable

The Food and Drug Administration (FDA) has **determined** that text included in the preambles to three regulations adopted over the past 10 years and purporting to preempt state law "are not legally justified." The agency reviewed all of its regulations in response to President Barack Obama's (D) May 20, 2009, memorandum outlining the administration's preemption policy. The three affected regulations involve labeling rules for prescription drugs, biological products and medical devices.

FDA also clarified the preemption language in other regulations, including those on food labeling and specifically cited "74 FR 2443, January 15, 2009," which proposed amending the labeling for yogurt products.

According to the agency, the preamble, which discusses the rule's "pre-emptive effect, in that it would preclude states from issuing any … requirements … that are not identical to those required by the final rule," failed to "acknowledge the applicability limitation set forth in section 6 (c) (2) of the Nutrition Labeling and Education Act." According to FDA, that section, which provides that 403A of the Food, Drug, and Cosmetic Act "shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides for a warning concerning the safety of the food or component of the food," should have been included in the preamble's preemption discussion. *See Federal Register*, October 5, 2011.

U.S. Agencies Convene Public Meeting to Target Ways of Reducing Sodium Consumption

The Food and Drug Administration (FDA), Centers for Disease Control and Prevention, Food Safety and Inspection Service (FSIS), Agricultural Research Service, and Center for Nutrition Policy and Promotion have **announced** a public meeting to discuss approaches to reduce sodium consumption. The November 10, 2011, public meeting in Silver Spring, Maryland, will provide a forum for the agencies to hear directly from interested parties and will help inform possible future regulation. Comments are requested by November 29.

FDA and FSIS had previously requested "comments, data, and evidence relevant to the dietary intake of sodium as well as current and emerging

approaches designed to promote sodium reduction." Additional details about the open dockets on dietary sodium intake appear in Issue 409 of this *Update*. *See Federal Register,* October 12, 2011.

FDA Submits Plan to Study Risk Perceptions of Food Recalls

The Food and Drug Administration (FDA) has **submitted** a proposed information collection to the Office of Management and Budget (OMB) to conduct an experimental study designed to evaluate the public's risk perceptions after a foodborne-illness-related recall. Produce growers, food retailers and consumers will be asked to participate in the study "to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections about consumers' attitudes."

Using a hypothetical fresh spinach recall, the study will test whether "'attribution error'—the tendency people have of overestimating others' negative response to situations compared to their own response"—contributes to unnecessarily prolonging the economic effects of a food recall. The study will involve 900 participants (180 growers, 180 retailers and 540 consumers) assigned to either an "anger" scenario, "fear" scenario or "control" scenario. After reading a news article about the recall, participants will complete a questionnaire assessing their "emotional response; appraisals, attribution of responsibility; perceptions about the safety of the affected produce; intentions to grow, sell or buy the affected produce; perceived probability of a repeat event; and a measure of their innate ability to effectively respond to the information in the article." Comments are requested by November 10, 2011. *See Federal Register,* October 11, 2011.

European Commission Faces Backlash over Proposed CAP Reforms

The European Commission (EC) recently **released** 12 legal proposals designed to update the Common Agricultural Policy (CAP) by 2013, a move which has apparently elicited a strong response from environmentalists over reforms meant to "strengthen the competitiveness and the sustainability of agriculture" throughout the region. According to the EC, the proposals would simplify CAP while addressing nine additional points, including (i) "better targeted income support," (ii) more responsive and effective crisis management, (iii) "green" payments for "preserving long-term productivity," (iv) additional investment in research and innovation, and (v) "a more competitive and balanced food chain."

For example, as *The Guardian's* environmental blog explains, the CAP reforms would "move away from historical payments to a flat-rate payment scheme," limit payments to the largest enterprises, and provide additional assistance to young and organic farmers. Yet the October 13, 2011, blog post also notes

that the proposals have drawn swift criticism from organizations such as the Royal Society for the Protection of Birds (RSPB) and Greenpeace, which warned that some aspects of the reform amount to little more than "green washing."

"Handing out €435bn of taxpayers' money over the next 10 years to some of the most destructive corporations and richest individuals in Europe— as millions of people across the continent lose their jobs— is crass," opines *Guardian* Environmental Editor John Vidal. "There is to be no rethink of the export subsidy system which is unfair to developing countries, and no new obligation on farmers to protect rivers or biodiversity. The overall cut in funding for agri-environment schemes spells disaster."

EFSA Issues Opinion on Labeling Lysozyme in Wine

The European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies (NDA) has issued a **scientific opinion** on the use of egg-derived lysozyme in wine manufacturing after the Oenological Products and Practices International Association (OENOPPIA) applied to permanently exempt the anti-microbial stabilizer from labeling requirements. According to NDA, which was tasked with assessing the likelihood of allergic reaction to lysozyme-treated wine, the additive is approved for use in some foods to control lactic acid bacteria but "must follow purity specifications set forth in European legislation." Because it can evidently be used "at different stages of wine production and at different doses," lysozyme was detected in some wines at residual amounts "considered sufficient to trigger allergic reactions in susceptible individuals."

OENOPPIA had apparently argued that lysozyme is not only "the weakest allergen among the four major egg white proteins," but unlikely to cause a clinical reaction in egg-allergic individuals when consumed orally. NDA, however, disagreed with this conclusion, countering that (i) allergic sensitization to lysozyme "is common among egg allergic individuals," (ii) "residual amounts of lysozyme considered sufficient to trigger allergic reactions in susceptible individuals have been demonstrated in wines treated with lysozyme," and (iii) "a number of clinical reports… described clinical allergic reactions to lysozyme." As a result, the panel concluded that "wines treated with lysozyme may trigger adverse allergic reactions in susceptible individuals under the conditions of use proposed by the applicant."

Health Canada Outlines New Energy Drink Rules

Health Canada recently announced **new measures** that would reclassify energy drinks as food instead of a natural health product (NHP), thus requiring each can to bear a nutritional facts table. According to an October 6, 2011, press release, the new rules would also direct energy drink manu-

facturers to (i) limit caffeine content to 180 milligrams per single serving; (ii) indicate caffeine amounts on product labels and identify groups, such as children, "for whom high levels of caffeine are not recommended"; (iii) declare ingredients, nutrition and allergens; (iv) ensure that "types and levels of vitamins and minerals are within safe levels"; and (v) warn consumers not to mix the product with alcohol.

The proposed approach would bring energy drinks under the purview of the Canadian Food Inspection Agency, while compelling producers to report any consumer complaints to Health Canada as well as submit information about consumption and sales. The agency intends to work with industry to complete the transition over the next six months, with compliance expected within 18 to 24 months.

"I firmly believe that it's up to individuals and parents to make their own decisions when it comes to what they eat and drink," Canadian Minister of Health Leona Aglukkaq said of the proposal, which more closely reflects the system used in the United States. "I believe today's changes will be especially helpful to the parents of teenagers who regularly consume energy drinks."

French Health Minister, National Assembly Support BPA Ban

French Health Minister Xavier Bertrand has become the second cabinet member to publicly **declare** his support for legislation recently adopted by the National Assembly that would prohibit bisphenol A (BPA) in all food packaging as of January 1, 2014. According to an October 7, 2011, press statement issued by Bertrand, the bill—if passed by the Senate later this year—would also require packaging that contained BPA to bear warning labels directed at pregnant women and children younger than age 3.

In particular, Bertrand cited a recent government report that highlighted the alleged risks associated with low-level exposure to BPA, rendering the "precautionary" bill "legitimate and even necessary." The minister also called for an intermediary measure that would prohibit BPA in food containers designed for children younger than age 3 by 2013.

"I have always said that if we had new evidence, we would assume responsibility," Bertrand was quoted as saying. "With this new law, France is the first country in Europe and among the first in the world to go so far in the precaution against Bisphenol A." *See FoodProductionDaily.com,* October 10, 2011; *ENDS Europe,* October 13, 2011.

LITIGATION

JPML Consolidates Wesson Oil Actions Before Multidistrict Litigation Court

The U.S. Judicial Panel on Multidistrict Litigation (JPML) has consolidated six actions questioning the "100% Natural" claims for Wesson oil products before a multidistrict litigation (MDL) court in California. ***In re: Wesson Oil Mktg. & Sales Practices Litig.*, MDL No. 2291 (JPML, transfer order filed October 13, 2011)**. The defendant requested the transfer, and while the California, Florida and New Jersey plaintiffs supported consolidation, they disagreed on the transferee district. According to the court, centralization "in the Central District of California will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."

The court found, "All actions contain similar allegations against ConAgra and share factual questions regarding the labeling and marketing of Wesson oils as '100% Natural' when the oils purportedly contain genetically modified plants or organisms. Little litigation activity has occurred in the actions, which were all filed within the past few months, and plaintiffs seek to represent overlapping classes of consumers. Centralization will eliminate duplicative discovery and prevent inconsistent pretrial rulings, particularly with respect to class certification." Additional details about two of the cases appear in Issues **400** and **401** of this *Update*.

Purely Economic Injury Sufficient for *Trans* Fat Suit Against Quaker Oats to Continue

A federal court in Illinois has determined that a plaintiff claiming that he would not have paid a premium for a product advertised as "heart healthy," "0 grams trans fat" and "wholesome" had he known it actually contained *trans* fats, has standing to pursue his false advertising claims under state law. *Askin v. The Quaker Oats Co.*, No. 11 CV 111 (U.S. Dist. Ct., N.D. Ill., E. Div., decided October 12, 2011). Citing a recent Seventh Circuit decision in which the court found standing under similar circumstances, that is, an affirmative product representation and allegations that consumers paid more for the product than they would have had they known of its purported risks, the court ruled that alleged economic harm alone is redressable and confers standing.

The court deferred ruling on the defendant's argument that the named plaintiff in this putative class action cannot file a lawsuit under Illinois law because he is a resident of and purchased the products in New York. Noting that this is a merits-based argument and not a matter of standing, the court indicated that it would reserve ruling on the issue until it resolves the defendant's motion to dismiss under the first-to-file rule. Apparently, Quaker Oats has also urged the court to dismiss the claims on the ground that they are duplicative of claims filed earlier in California. The named plaintiffs from the California

actions have moved to intervene to file their own motion to dismiss under the first-to-file rule.

Failure-to-Warn Claims Against Tuna Co. Not Preempted, Says Federal Court

Granting the defendants' motion to dismiss in part, a federal court in New York has allowed further proceedings on most of the claims filed by a man who alleged that consuming one to two cans of tuna daily for more than two years caused his mercury poisoning. *Porrazzo v. Bumble Bee Foods, LLC*, No. 10-4367 (U.S. Dist. Ct., S.D.N.Y., decided September 30, 2011). So ruling, the court agreed with the Third Circuit Court of Appeals that the Food and Drug Administration's failure to adopt a regulation on the alleged risks of mercury in fish or warnings about that risk does not preclude the states from imposing a duty to warn. Additional information about that case appears in **Issue 272** of this *Update*.

According to his complaint, the plaintiff purchased and consumed 10 six-ounce cans of tuna fish each week from January 2006 to October 2008, at a time when the manufacturing defendant "promoted its tuna fish as an 'excellent and safe source of high quality protein, vitamins, minerals and Omega-3 fatty acids, as well as being low in saturated fats and carbohydrates[,] and touted its product as being 'heart healthy,'" without disclosing that it contained mercury. The plaintiff allegedly began experiencing chest pains, heart palpitations, sweatiness, dizziness, and lightheadedness several times each week, which led him to seek medical attention for what he believed was a heart condition. His primary care physician ordered a heavy metals blood test after numerous other tests failed to reveal the cause of his symptoms, and the test purportedly revealed that he had more than double the normal mercury level in his blood. Thereafter, the N.Y. State Department of Health advised the plaintiff to stop eating tuna fish, and within a few weeks, his blood mercury level had returned to normal, and his symptoms disappeared.

In addition to finding that the plaintiff's claims were not preempted, the court determined that (i) he had plausibly alleged an injury and that the defendants' conduct was the proximate cause of his injury; (ii) his claims for emotional distress and punitive damages could be pursued as elements of his damages but not as causes of action; (iii) his daily tuna consumption could not be said, as a matter of law, to be unreasonable; (iv) it was too early to say that the "dangers of mercury poisoning from consumption of canned tuna fish are open and obvious, and that an ordinary consumer would necessarily be aware that canned tuna fish contains high levels of methylmercury"; and (v) he adequately alleged strict liability failure to warn as to both defendants.

The court determined that the plaintiff could not pursue a negligent failure to warn claim or a claim for breach of implied warranty of merchantability against the retailer under state law. The court also ruled that some of the

plaintiff's claims could be pursued under the state's Agriculture and Markets Law, but that others, involving claims of added deleterious substances, unfit food, the product of a diseased animal, or inferiority to other like products on the market, failed. The court indicated that it would not *sua sponte* allow the complaint to be amended, noting that the plaintiff did not request leave to file a second amended complaint or demonstrate how further amendment would cure the deficiencies in his pleadings.

OTHER DEVELOPMENTS

Cornucopia Institute Claims "Natural" Is Often Meaningless Marketing Hype

The Cornucopia Institute has published a **report** titled "Cereal Crimes: How 'Natural' Claims Deceive Consumers and Undermine the Organic Label—A Look Down the Cereal and Granola Aisle." Noting that, with one exception, no government agency has defined what the term "natural" means on food packages, the organization explains how companies that make cereal products exploit consumer confusion over the difference between "organic" and "natural" products, charging a premium for "natural" products that actually contain ingredients containing pesticides or ingredients grown and processed with genetically engineered (GE) organisms.

The report, accompanied by an "online scorecard with nearly 50 cereal and granola brands, available on the Cornucopia website," (i) details current legal requirements that distinguish organic from "natural" claims; (ii) discusses individual company definitions of "natural" to demonstrate "how vastly different they can be"; (iii) summarizes the results of consumer polling showing that many "erroneously believe that the 'natural' label has merit, such as signifying that the food is free of pesticides and genetically engineered ingredients"; (iv) reveals how "natural" companies intentionally blur the distinction between their products and organic products; (v) names the companies that offer certified organic product lines and those that used to but no longer do after purchase by large food corporations; (vi) addresses product pricing indicating that "natural" products, which are conventionally produced and processed, are often "priced at a premium, closer to organic prices"; (vii) asserts that "natural" company practices are undercutting organic farmers; (viii) describes environmental-impact differences between organic and conventional farming methods; and (ix) shows how consumers wishing to avoid GE products would do best to avoid certain "natural" brands found to contain, on the basis of laboratory testing, 50-100 percent GE ingredients. The report also includes a summary of studies suggesting that GE ingredients and pesticides pose purported risks to health.

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The Cornucopia Institute, which promotes sustainable and organic agriculture, concludes by calling on "natural" breakfast cereal companies "to become organic as a service to their customers." According to the institute, "consumers care about claims such as 'no pesticides' and 'no GMOs.' The only way to assure this is by being certified organic. 'Natural' claims may be profitable, but they are misleading and disingenuous unless the product is certified organic."

IOM Obesity Prevention Workshop Slated for October 20

The Institute of Medicine's (IOM's) Food and Nutrition Board has announced an October 20, 2011, public workshop in Washington, D.C., titled "Alliances for Obesity Prevention: Finding Common Ground." Funded by the Robert Wood Johnson Foundation and hosted by IOM's Standing Committee on Childhood Obesity, the event will include discussion of ways to engender dialogue and develop new alliances among obesity-prevention allies. Speakers will include Susan Linn of Campaign for a Commercial-Free Childhood.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400