Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Warns Company Making and Selling "Inhalable" Caffeine Product

The Food and Drug Administration issued a warning letter to Breathable Foods, Inc., which makes AeroShot Energy®, an "inhalable" caffeine product, on March 5, 2012. According to the agency, the AeroShot product is misbranded because it is labeled as intended for inhalation while the company's Website indicates that the product is intended for ingestion. "Your labeling is false and misleading because your product cannot be intended for both inhalation and ingestion," states the letter. FDA also notes that the product label fails to include a domestic address or phone number through which reports of serious adverse events associated with the product may be received. The letter further informs the company that FDA has "safety questions about the possible effects of your product."

FDA expresses concerns regarding "contradictory messages" about use of the product "in combination with alcohol. On the one hand, your website includes a posting of a news interview in which the inventor of your product, David Edwards, states that he is not encouraging the mixing of AeroShot with alcohol. On the other hand, your website includes clips of news videos related to AeroShot, as well as links to news articles related to the product. Several of these news items refer to the use of your product in combination with alcohol or as a 'party drug.'"

Additional information about the product and calls for an FDA investigation is included in Issue 428 of this *Update*.

Meanwhile, Breathable Foods CEO Tom Hadfield reportedly said that the company would cooperate with FDA to resolve the issues raised in the warning letter. He was quoted as saying, "We plan to work closely with the FDA to meet their requests for information and labeling changes to ensure compliance with dietary supplement requirements. AeroShot delivers a mix of B vitamins and caffeine to the mouth for ingestion and is not 'inhaled' into the lungs." He also reportedly denied that the product was marketed as a "party drug" for youths younger than 18. "AeroShot is not recommended or

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marketed to persons under 18 or for use with alcohol," Hadfield said. According to the product's inventor, other products relying on the delivery technology will be added to the marketplace in coming months; they include vitamins and minerals, confections and products related to oral health care. *See Foodnavigator-usa.com*, March 7, 2012.

FDA Issues Industry Guidance on Testing Procedures for *Salmonella*

The Food and Drug Administration (FDA) has **released** industry guidance addressing the testing procedures for *Salmonella* species "in human foods and direct-human-contact animal foods."

Applicable to firms that manufacture, process, pack, or hold these products for distribution to consumers, institutions or food processors, the **guidance** also discusses the interpretation of test results when the presence of *Salmonella* "in the food may render the food injurious to human health." The guidance excludes egg producers and others covered under different FDA food-safety rules. The agency will accept comments at any time. *See Federal Register,* March 8, 2012.

FDA Releases Guidance on Veterinary Medicines

The Food and Drug Administration (FDA) has **announced** the availability of industry guidance concerning drugs for veterinary care. The **guidance** provides "recommendations on what documentation to submit to support the CMC [Chemistry, Manufacturing, and Controls] information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use."

Noting that a variety of products are manufactured from fermentation processes, such as "competitive exclusion products" that consist of one or more microorganisms intended to prevent harmful bacteria like *Salmonella* from colonizing, FDA has requested comments on the guidance at any time. *See Federal Register,* March 8, 2012.

FSIS Seeks Comments on Guidance for Selecting Food-Safety Testing Labs

The Food Safety and Inspection Service (FSIS) has **issued** policy guidance that provides criteria for federally inspected establishments to select commercial or private laboratories to analyze testing samples. Created for businesses that prepare meat, poultry or processed egg products, the **document** attempts to ensure that "microbiological testing performed on their behalf meets their food safety needs."

FSIS encourages federally regulated establishments, which are required to produce commercial products that are safe and not adulterated or misbranded, to select labs that provide accurate, reliable test results by maintaining Quality

Control or Quality Assurance practices. The establishments may undergo microbiological testing for reasons such as "fulfilling regulatory requirements, supporting ongoing verification of HACCP [Hazard Analysis & Critical Control Points] plans, supporting decisions made in the establishment's hazard analysis, evaluating the effectiveness of the establishment's sanitation program, or complying with purchase specifications or requirements." FSIS requests comments by May 7, 2012. *See Federal Register,* March 8, 2012.

UN Special Rapporteur Urges Regulation, Taxation to Abate "Nutritional Crisis"

The U.N. Special Rapporteur on the Right to Food Olivier De Schutter recently presented a **report** before the U.N. Human Rights Council, calling for governments to enact five priority actions to curb malnourishment, micronutrient deficiency and obesity in populations worldwide. In particular, De Schutter has urged policy makers to consider (i) "taxing unhealthy products"; (ii) "regulating foods high in saturated fats, salt and sugar"; (iii) "cracking down on junk food advertising"; (iv) "overhauling misguided agricultural subsidies that can make certain ingredients cheaper than others"; and (v) "supporting local food production so that consumers have access to healthy, fresh and nutritious foods."

According to a March 6, 2012, press release, the independent expert told the council that in 2010 "U.S. companies spent $8.5 billion advertising food, candy and non-alcoholic beverages, while $44 million was budgeted for the U.S. government's primary standing healthy eating program." He also reportedly pointed to "the abundance of processed food as a major threat to improving nutrition," with developed countries "now exporting diabetes and heart disease to developing countries."

"We have deferred to food companies the responsibility for ensuring that a good nutritional balance emerges. Voluntary guidelines and piecemeal nutrition initiatives have failed to create a system with the right signals, and the odds remain stacked against the achievement of a healthy, balanced diet," De Schutter was quoted as saying. "Heavily processed foods lead to diets richer in saturated and trans-fatty acids, salt and sugars. Children become hooked on the junk foods targeted at them. In better-off countries, the poorest population groups are most affected because foods high in fats, sugar and salt are often cheaper than healthy diets as a result of misguided subsidies whose health impacts have been wholly ignored."

EU Directive Bans Fruit Juices with Added Sugar

The Council of the European Union (EU) has adopted a **directive** banning the use of added sugars in any fruit juices sold in Europe. According to a March 8, 2012, Council press release, the new directive "incorporates the current industry practice of not adding sugars to fruit juices" and will phase out "no

added sugars" labeling after a transitional period, at the end of which "all fruit juices present on the market are not allowed to contain added sugars anymore."

The directive also addresses labeling for fruit nectars, which evidently cannot be made without added sweeteners; adds tomatoes "to the list of fruits used for fruit juice production"; and confirms that product names must indicate the fruits included in the juice. Expected to take effect by the beginning of June, the directive gives member states 18 months after enactment to transpose its provisions into national law. "The new rules will apply to all fruit juices marketed in the EU, irrespective of their origin," concludes the Council's press release. "This ensures an equal treatment between fruit juices produced within the EU and imported from third countries."

UK Advertising Watchdog Censures Kellogg's for Sugar Claims

The U.K.'s Advertising Standards Authority (ASA) has **censured** Kellogg Marketing and Sales Co. (UK), Ltd. for falsely claiming on its Website, in relation to promotions for children's breakfast cereals, that "A panel of world health experts recently reviewed all the scientific evidence and concluded that a high sugar intake is not related to obesity, or the development of diseases such as heart disease, diabetes, high blood pressure or cancer."

ASA acknowledged that Kellogg's had based the claim on "credible scientific evidence and review," but noted that the company's wording, without qualifiers, did not account for contrary evidence and "implied there was absolute certainty about the claims being made," which is not the case. Because Kellogg's had "referred in particular to a high sugar intake," ASA concluded that the claim was misleading given the number of authoritative government cautions about limiting the quantity of sugary foods consumed. The company apparently assured the authority that it would remove the claims from its Website.

Series of Celebrity Tweets Ending with Tweet About Candy Not in Violation of UK Ad Code

The U.K.'s Advertising Standards Authority (ASA) has **determined** that a series of tweets from Rio Ferdinand and Katie Price that culminated in messages specifically referencing and showing a photo of these personalities with Snickers® bars did not violate the U.K. Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (Code).

The initial tweets did not contain any indication that they were sponsored by Mars Chocolate UK Ltd. The final tweets, with the Snickers® content, included "#spon" to indicate they were sponsored and the "strap line 'you're not you when you're hungry.'" According to Mars, the strap line was intended to tie

into the earlier tweets, "because their content would not usually be associated with the celebrity tweeters."

The company also indicated that it believed only the final tweets were marketing communications and that the earlier tweets did not require identification as marketing communications. In the alternative, the company explained that "the campaign could be regarded as one marketing communication, rather than as five separate tweets, but that the circumstances meant it became a marketing communication only when the final tweets were posted." ASA concluded that, because the initial tweets, sent in quick succession, were intended as "teasers" and did not include marketing content while the final tweets did so and were identified as such, "it was acceptable that the first four tweets were not individually labelled as being part of the overall marketing communications. We therefore concluded that the ads did not breach the Code."

Comment Period on Potential Prop. 65 Chemicals Extended Again

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **extended** until April 6, 2012, the public comment period for several chemicals, including benzophenone, a substance used in plastic packaging as a UV blocker, that the agency is considering adding to the list of chemicals known to the state to cause cancer (Prop. 65) under the Labor Code mechanism. An interested party apparently requested the extension. Because these are "ministerial listings," OEHHA has indicated that comments should be limited "to whether the International Agency for Research on Cancer has identified the specific chemical or substance as a known or potential human or animal carcinogen."

LITIGATION

Donning and Doffing Class Certified; U.S. Supreme Court Declines to Review Compensation Ruling

A federal court in Arkansas has reportedly certified a class of poultry-processing plant workers who allege that the company has violated federal and state employment laws by failing to compensate them for the time they spend donning, doffing and sanitizing required gear and equipment, as well as walking to and from the production floor and performing other job-related duties. *Garner v. Butterball, LLC*, No. 10-01025 (U.S. Dist. Ct., E.D. Ark., decided February 22, 2012). The plaintiffs apparently demonstrated that their claims met all of the class certification requirements, although the court modified the class definition to account for statutes of limitations applicable to claims filed under the Federal Labor Standards Act and Arkansas Minimum Wage Act. Thus, the class has been defined as hourly production employees who worked

at two Butterball plants "at any time since October 1, 2006, through the date of final judgment in this action."

Meanwhile, the U.S. Supreme Court has denied a petition to review a Fourth Circuit Court of Appeals ruling that time spent donning and doffing poultry-processing safety gear at the beginning and ending of work shifts is compensable. *Mountaire Farms, Inc. v. Perez*, No. 11-497 (U.S., decided February 27, 2012). The Fourth Circuit held that donning and doffing protective gear at meal breaks was not compensable, however, and also determined that because the company's violations were not willful, the two-year statute of limitations would apply to back-pay claims. *See Mealey's Class Actions*, March 2, 2012.

Federal Court Narrows Claims in Tomato Recall Suit Against FDA

A federal court in South Carolina has dismissed three of four claims in a lawsuit filed by a family farming operation that claims the Food and Drug Administration's (FDA's) 2008 tomato recall, which later proved unnecessary as the agency conceded that tomatoes were not the source of the *Salmonella* contamination, caused the farm substantial economic harm. *Seaside Farm, Inc. v. United States*, No. 11-1199 (U.S. Dist. Ct., D.S.C., Beaufort Div., decided March 6, 2012). Further details about the litigation appear in **Issue 395** of this *Update*.

The court dismissed the plaintiff's Takings Clause claim, the claim that FDA violated the South Carolina Unfair Trade Practices Act and the defamation claim. The plaintiff's negligence claim will, however, proceed. While the court suggested that this may actually be a claim for defamation and thus may also be subject to dismissal under the Federal Tort Claims Act, because the defendant did not seek to dismiss on this ground, the court declined "to dismiss the negligence claim on this ground at this time."

The court gave the parties 60 days to conduct discovery as to certain jurisdictional issues and gave the government the opportunity to again challenge subject matter jurisdiction. "At that time, both parties should also be prepared to discuss whether the plaintiff's claim for negligence is actually a defamation claim."

Batali and Bastianich Settle Wage Claims for $5.25 Million

Restaurateurs Mario Batali and Joseph Bastianich have apparently agreed to settle for $5.25 million wage-related claims in a class action filed by waitstaff at their New York City restaurants including Babbo, Bar Jamon, Casa Mono, Del Posto, Esca, Lupa, Otto, and Tarry Lodge. *Capsolas v. Pasta Resources Inc.*, No. 10-5595 (U.S. Dist. Ct., S.D.N.Y., motion for preliminary approval of settlement filed March 5, 2012). Additional information about the suit appears in **Issue 361** of this *Update*.

If approved, the settlement would cover attorney's fees (one-third of the total) and costs, class members' awards, service payments to the named plaintiffs, and the claim administrator's fees. The class, consisting of captains, servers, waiters, bussers, runners, back waiters, bartenders, and/or barbacks, will receive a proportional share of the settlement fund "based on the number of hours they worked, the Restaurant at which they worked, the percentage of total tips received during their employment, and whether they opted in to the collective."

LEGAL LITERATURE

FDA Regulation of Nanotechnology (ABA 2012)

Part II of the American Bar Association's (ABA's) Nanotechnology Project, this recently released **book** comprehensively considers, by product category, how the Food and Drug Administration (FDA) reviews nanotechnology-based products.

Shook, Hardy & Bacon Agribusiness & Food Safety Attorney **James Andreasen** was among those practitioners contributing to the work. Among the chapters are "Color Additives," "Food Additives and Related Substances," "Dietary Supplements," "Food and Animal Feed Products," and "Biological Products." They address "how FDA can, and to some extent, has, regulated nanomaterials in products falling under its multiple areas of responsibility," and (i) identify "products that already feature nanomaterials"; (ii) review "FDA's regulatory program for the specific product category (such as particular pre-market and post-market controls)"; and (iii) discuss "how that program might apply to nanomaterials."

OTHER DEVELOPMENTS

Study Outlines Challenges for Nanotechnology Use in Foods and Agriculture

A recent *Food Policy* article titled "Implications of nanotechnology growth in food and agriculture in OECD countries" describes how nanomaterials and ingredients are currently being used in foods, food packaging and agriculture in Organization for Economic Co-operation and Development (OECD) countries and outlines potential challenges that could affect the industry's growth, health and safety issues and public acceptance.

In Canada, commercially available nano products include diet and nutritional supplements, energy drinks and food storage containers. Israeli companies are using nanotechnology to produce canola oil and calcium- and vitamin D- fortified milk. South Korean consumers can purchase their food in nano-silver food containers and can also find nanomaterials used in baby bottles, cutting boards, frying pans, salad bowls, water purifiers, and produce cleaners. In the United States, nanoparticles can be found in fortified fruit juice, diet beverages, food

storage, health supplements, bottles, and water purifiers. Nano-herbicides, nano-pesticides and "nonporous zeolites to slow the release and increase efficiency of fertilizers" are also apparently in use in OECD countries.

The author identifies as challenges (i) maintaining the sector's growth and move toward commercialization, (ii) health and environmental risks, and (iii) public acceptance. As to the latter, the article calls for "public participation and a well-designed risk communication strategy" to increase acceptance, noting that the rejection of genetically modified (GM) foods and crops in OECD countries "provides an illustration of what needs to be avoided." With public awareness of nanotechnology still limited, researchers have apparently emphasized delivering appropriate messages, responding to consumer concerns and using the right messenger: "a message from a distrusted authority may increase consumer aversion." Some have also called for the industry to "proactively communicate transparently on the use of nanotechnology in food." Still, blanket labeling is seen as something to be avoided.

Soft Drink Makers Change Caramel Coloring to Reduce 4-MEI

After the Center for Science in the Public Interest (CSPI) **informed** Food and Drug Administration (FDA) Commissioner Margaret Hamburg that laboratory analyses of soft drinks revealed high levels of 4-methylimidazole (4-MEI) in certain caramel colored beverages, the major soft drink manufacturers reported that they were changing the way they manufacture the caramel coloring to address the issue. California added 4-MEI to its list of chemicals known to the state to cause cancer (Prop. 65), and the companies had already apparently reformulated products sold there to avoid the need for a Prop. 65 cancer exposure warning.

The changes will be expanded throughout the national market even though an FDA spokesperson reportedly indicated in response to CSPI's claims that a person would have drink in excess of 1,000 cans of soda a day to achieve the levels to which rats were exposed in studies purportedly showing an association with cancer. The American Beverage Association reportedly called CSPI's claims "outrageous" and little more "than scare tactics." FDA is apparently reviewing CSPI's 2011 petition seeking to revoke the generally recognized as safe designation for these chemicals and to prohibit products containing them from being labeled "natural." CSPI's March 5, 2012, letter to the FDA commissioner was an amendment to that petition and complained about FDA's lack of action, while attempting to "clarify the risk posed by caramel colorings in soft drinks." *See CSPI, American Beverage Association Press Releases* and *Reuters,* March 5, 2012; *Associated Press*, March 8, 2012.

Consumer Interest Organization Questions Privatization of Poultry Inspections

Based on documents obtained from the U.S. Department of Agriculture (USDA) under the Freedom of Information Act, Food & Water Watch has **urged** the agency not to expand its pilot HACCP-based inspection project, contending that inspections conducted by poultry processing plant employees miss many defects. While USDA hopes to expand the program, claiming it will save the federal government $90 million and eliminate more than 800 inspector positions over three years, Food & Water Watch asserts that consumer health would be compromised by any such expansion.

According to the consumer watchdog, USDA's pilot project, launched in 1998 and involving two dozen slaughter facilities, relies on untrained plant employees to inspect carcasses for food safety and other consumer protection issues. Many of the pilot plants have apparently been granted line speed waivers and have sped up their lines to 200 birds per minute. In plants where USDA inspectors still conduct conventional inspections, the plants operate at line speeds of 35 birds per minute. Verification sampling of 20 to 80 birds per slaughter line during an eight-hour shift under the pilot program reportedly showed that the highest error rate involved contamination with feathers, lungs, oil glands, trachea, and bile. Average error rates in this category were 64 percent in chicken facilities and 87 percent in turkey facilities. The data also apparently showed no consistency across the industry and that "[t]he overwhelming number of non-compliance records filed for the 14 plants was for fecal contamination found on the carcasses" that had been missed by company employees watching the line. *See Food & Water Watch Press Release*, March 7, 2012.

SCIENTIFIC/TECHNICAL ITEMS

Study Likens Ice Cream Consumption to Drug Addiction

A recent study has claimed that frequent ice cream consumption parallels "the tolerance observed in drug addiction" by reducing "activation in reward-related brain regions (e.g., striatum)." Kyle Burger and Eric Stice, "Frequency ice cream consumption is associated with reduced striatal response to receipt of an ice cream-based milkshake," *American Journal of Clinical Nutrition,* March 2012. Researchers apparently used functional magnetic resonance imaging (fMRI) on 151 healthy-weight adolescents to assess their neural responses upon receipt of a milkshake or a tasteless solution. The results evidently indicated that "milkshake receipt robustly activated the striatal regions," although the fMRIs of youths who indulged in frequent ice cream consumption showed "a reduced response to milkshake receipt in these reward-centered brain regions."

"These findings suggest that intake of energy-dense foods may contribute to down-regulation of reward circuitry, echoing the effects of frequent drug use," concluded the study authors, who noted "reduced striatal activation" in subjects who reported frequent ice cream consumption, as opposed to consumption of other energy-dense foods such as chocolate candy. As a result, the authors also suggested that "sensory aspects of the eating experience"—including food texture, form and temperature—"play a role in neural adaption and imply a learning explanation for this effect."

"This tolerance is thought to increase use, or eating, because the individual [is] trying to achieve the previous level of satisfaction," explained one study author in a March 5, 2012, *Telegraph* article. "Repeated, overconsumption of high-fat or high-sugar foods may alter how the brain responds to these foods in a way that perpetuates further intake."

Researchers Examine BPA Exposure and Supposed Cardiovascular Risk

A recent study has allegedly backed previous research suggesting that higher exposures to bisphenol A (BPA) may elevate the risk for coronary artery disease (CAD). David Melzer, et al., "Urinary Bisphenol A: A Concentration and Risk of Future Coronary Artery Disease in Apparently Healthy Men and Women," *Circulation,* February 2012. Relying on data from the European Prospective Investigation of Cancer—Norfolk, U.K., researchers evidently compared the urinary BPA concentrations of 758 "initially healthy" participants who later developed CAD, with the BPA measures of 851 participants who did not develop cardiovascular disease. Their findings apparently suggested that respondents with the highest urinary BPA concentrations at the outset were more likely to develop CAD over a 10-year follow-up period, with each 4.56 nanogram per milliliter (ng/Ml) increase in urinary BPA concentration associated with a 13 percent rise in CAD risk.

According to the study, these results parallel the "cross-sectional findings in the more highly exposed NHANES [National Health and Nutrition Examination Survey] 03/04 and 05/06 study respondents." The researchers have thus called for further studies to determine the exact relationship between BPA dose and CAD, as well as to establish the underlying mechanism. "This study strengthens the statistical link between BPA and heart disease, but we can't be certain that BPA itself is responsible," one author was quoted as saying. "It is now important that government agencies organize drug style safety trials of BPA in humans, as much basic information about how BPA behaves in the human body is still unknown." *See Peninsula College of Medicine & Dentistry Press Release,* February 23, 2012.

Data Analysis Questions Food Coloring Link to ADHD

A meta-analysis of recent scientific literature has questioned data alleging a link between synthetic food colors approved by the Food and Drug Administration (FDA) and attention-deficit/hyperactivity disorder (ADHD). Joel Nigg, et al.,

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"Meta-Analysis of Attention-Deficit/Hyperactivity Disorder or Attention-Deficit/Hyperactivity Disorder Symptoms, Restriction Diet, and Synthetic Food Color Additives," *Journal of the American Academy of Child & Adolescent Psychiatry,* January 2012. Researchers evidently assessed 24 articles on synthetic food colors and 10 additional studies on dietary restriction, but ultimately found that several effects observed for food color additives were subject to publication bias or other flaws.

In particular, the study authors noted that, while a restriction diet appears "to benefit some children with ADHD," reports based on information from parents or teachers/observers were not wholly reliable or consistent even "after quality of measure was taken into account." The analysis also revealed that "nearly all studies examined combinations of colors, with too little consistency in their mixtures for us to test comparative effect sizes of different mixtures or individual compounds." The have thus recommended further efforts to "quantify comparative effects of individual colors and additives or competing specific mixtures," as well as additional research restricted to FDA-approved food colors only.

"These gaps reflect a complete absence of modern studies on this topic in the United States since the early 1990s. The literature remains limited by lack of validation of blinding in many studies, and wide variety in methodology which would be best addressed by a pooled analysis of individual data across studies—not possible with the old literature," concluded the authors. "In short, despite 35 years of research and evidence of an effect of food colors on objective measures of attention, the database that would confirm this possibility and generalize it for contemporary use is woefully out of date with regard to policy or clinical decisions in the United States." *See FoodProductDesign.com,* March 2, 2012.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.