Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 495 | AUGUST 23, 2013

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FTC Seeks Comments on Children's Online Privacy Protection Rule

The Federal Trade Commission (FTC) has **issued** a request for comments concerning a proposed parental consent method submitted by AssertID, Inc. under the Voluntary Commission Approval Processes provision of the Children's Online Privacy Protection Rule. Amended December 19, 2012, and effective July 1, 2013, the Children's Online Privacy Protection Rule requires certain Websites to post privacy policies and obtain verifiable parental consent before collecting, using or disclosing personal information from children younger than age 13 and provides approved methods for obtaining the consent. Interested parties may, however, submit requests for commission approval of additional consent methods.

Regarding AssertID, Inc.'s proposal, the commission seeks comment on the following questions: (i) is this method already covered by existing methods listed in Section 312.5(b)(1) of the rule; (ii) does the proposed method meet the requirements for parental consent laid out in 16 C.F.R. § 312.5(b)(1)—is it reasonably calculated to ensure that the person providing consent is the child's parent; and (iii) does the proposed method pose a risk to consumers' personal information, and if so, is that risk outweighed by the benefit to consumers and businesses? Comments will be accepted until September 20, 2013. *See Federal Register,* August 21, 2013.

FDA Public Meeting to Discuss FSMA Changes

The Food and Drug Administration (FDA) has **announced** an upcoming public meeting slated for September 19-20, 2013, in Washington, D.C., to discuss regulations proposed under the Food Safety Modernization Act (FSMA) that would establish Food Supplier Verification Programs as well as new rules for accrediting third-party auditors and certification bodies. Intended to ensure "that imported food meets the same safety standards as food produced domestically," the proposed rules would (i) require importers "to verify that their foreign suppliers are implementing the modern, prevention-oriented food safety practices called for by [FMSA]," and (ii) "strengthen the quality,

objectivity, and transparency of foreign food safety audits on which many U.S. food companies currently rely." FDA will accept advanced registrations from individuals who wish to participate in person by September 10, 2013. Additional details about the proposed rules appear in Issue 492 of this *Update*. *See Federal Register,* August 16, 2013.

FDA to Prepare EIS for Proposed Produce Standards

The Food and Drug Administration (FDA) has **announced** plans to prepare an environment impact statement (EIS) for a proposed rule that would establish standards for the growing, harvesting, packing, and holding of produce for human consumption. According to an August 16, 2013, FDA press release, the agency determined that an EIS was necessary based on public feedback and its own analysis, and will now begin a scoping process "designed to determine relevant issues that will influence the scope of the environmental analysis." FDA will accept comments on the EIS scoping process until November 15, 2013. Additional details about the proposed produce standards appear in Issue 466 of this *Update*. *See Federal Register,* August 19, 2013.

FDA to Collect Information on Consumer Studies of Nutrient Content Claims on Fortified Foods

The Food and Drug Administration (FDA) has apparently signaled its intent to proceed with an experimental study of consumer responses to nutrient content claims on fortified foods by issuing a **notice** of the proposed collection of information to the Office of Management and Budget. First announced in the August 15, 2012, *Federal Register,* the study would involve 7,500 adults asked to complete a 15-minute Web-based survey designed to gauge their responses "to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy."

"The study is a part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets," concludes FDA, which has estimated the total burden of this information collection at 3,099 hours. "Results of the study will be used primarily to inform the Agency's understanding of how claims on the packages of fortified food may affect how consumers perceive a product or a label, which may in turn affect their dietary choices." *See Federal Register,* August 22, 2013.

Petition Proposes Expanding Safe Uses of Vitamin D_2 and Vitamin D_3

The Food and Drug Administration (FDA) has apparently **filed** a petition submitted by the Dean Foods Co. and the WhiteWave Foods Co. "proposing that the food additive regulations be amended to provide for the expanded safe uses of vitamin D_2 and vitamin D_3 as nutrient supplements in food." In particular, the petition seeks to amend (i) 21 C.F.R. 172.39 "to provide for the

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.

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.

safe use of vitamin D_2 as a nutrient supplement in edible plant-based food products intended for use as alternatives to milk and milk products," and (ii) 21 C.F.R. 172.80 "to provide for the safe use of vitamin D_3 as a nutrient supplement in milk at levels higher than those currently permitted." FDA has also noted that because the action will not have any significant effect on the human environment, there is no need to undertake an environmental assessment or prepare an environmental impact statement. *See Federal Register,* August 16, 2013.

NOP to Modify Rules Governing Use of Substances in Organic Crop Production and Processing

The U.S. Department of Agriculture's National Organic Program (NOP) has **issued** a proposed rule that would amend the National List of Allowed and Prohibited Substances to permit the use of biodegradable biobased mulch film in organic crop production and the use of *Citrus hystrix* and curry leaves in organic processing. NOP has also proposed removing two nonorganic agricultural products from the National List—hops (*Humulus lupulus)* and unmodified rich starch—"as their use exemptions expired on January 1, 2013, and June 21, 2009, respectively."

According to NOP, biodegradable biobased mulch film is a synthetic substance "used as an alternative to petroleum-based plastic mulches that do not biodegrade," while the leaves and fruit of *Citrus hystrix* are traditional ingredients in Lao, Thai and other Southeast Asian cuisines, and curry or sweet neem leaves are an important ingredient in Indian, Sri Lankan, Malay, and other Southeast Asian cuisines. The agency will accept comments on the inclusion of these substances in organic crop production and processing until October 21, 2013. *See Federal Register,* August 22, 2013.

Visa Delays Affecting FDA Inspections in China

According to a news source, U.S. Food and Drug Administration (FDA) personnel have experienced significant delays in obtaining visas from China to staff food and drug inspection offices in that country. One staff member reportedly withdrew his application after waiting nine months for approval to work in China. The delays are seen as a setback for the agency's efforts to improve supply chain safety; FDA planned to use $10 million in additional appropriations to increase its food inspection staff from two to nine and its drug inspection unit from just one to 11. FDA currently has three offices in the country—in Beijing, Shanghai and Guangzhou—staffed with eight U.S. civil servants and five Chinese nationals. An FDA spokesperson said, "We believe that timely issuance of visas for FDA staff will be beneficial to both the U.S. and China, and that it's in China's best interest to issue these visas and move on to our next stage of collaboration." *See Pharmalot*, August 20, 2013.

OEHHA Provides Tracking Table for Potential Additions to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has published a **table** providing information on the status of chemicals considered for addition to the Proposition 65 (Prop. 65) list under the authoritative bodies mechanism. "The table lists the authoritative body, the document or documents providing the basis for the possible listing, the endpoint (toxic effect) relevant to the possible listing, and the next step in the listing process. OEHHA will update this table on a regular basis."

The chemicals subject to a notice of intent to list in 2014 if criteria are met include pulegone (a flavoring agent), emissions from high-temperature unrefined rapeseed oil (used in animal feed and as a vegetable oil), nitrite in combination with amines or amides (present in foods), atrazine (a herbicide) and its metabolites, genistein (an isoflavone in soybean foods), and ethylene glycol (used in bottling). Styrene, which is used in food containers, may be subject to a notice of intent to list in 2015 if criteria are met. Substances added to the Prop. 65 list are those identified as known to the state to cause cancer or reproductive risk. Companies using the chemicals in products sold in California must provide warnings to consumers. *See OEHHA News Release*, August 20, 2013.

LITIGATION

COOL Dispute Intensifies Before D.C. Court and WTO

A federal court in the District of Columbia will consider on August 27, 2013, whether to issue a preliminary injunction to stop the U.S. Department of Agriculture (USDA) from implementing country-of-origin labeling (COOL) program changes required by a 2011 World Trade Organization (WTO) determination that, as initially drafted, the rules gave less favorable treatment to cattle and hogs imported from Canada and Mexico. *Am. Meat Inst. v. USDA*, No. 13-1033 (filed July 8, 2013). Information about the revised COOL rule appears in Issue **485** of this *Update*.

A number of meat-processing interests, including the American Meat Institute, Canadian Cattlemen's Association, Confederación Nacional de Organizaciones Ganaderas, National Cattlemen's Beef Association, and National Pork Producers Council, challenged the new rule alleging that it violates First Amendment rights under the U.S. Constitution, exceeds USDA's authority and violated the Administrative Procedure Act.

In early August, the U.S. Cattlemen's Association (USCA), National Farmers Union, American Sheep Industry Association, and Consumer Federation of America sought to intervene in the lawsuit, and the court granted that motion. These opposition ranching and consumer interests contend that if

the court enjoins the rule's enforcement, the United States will once again be deemed in violation of WTO requirements. They also claim that the plaintiffs' alleged economic harms are overstated and based on uncertain assumptions about future market behavior.

Meanwhile, Canada has asked WTO to establish a compliance panel to re-examine the U.S. COOL program, as amended, claiming that the amendments were inadequate and would make matters worse. In a joint statement, Canada's Minister of International Trade Ed Fast and Minister of Agriculture and Agri-Food Gerry Ritz said, "We had hoped to avoid having to again resort to the WTO to resolve this matter. However, despite consistent rulings by WTO, the U.S. government continues its unfair trade practices, which are severely damaging to Canadian industry and jobs. We believe that the recent amendments to the COOL measure will further hinder the ability of Canadian cattle and hog producers to freely compete in the U.S. market."

Explaining the Canadian initiative to its members, USCA South Dakota Director and COOL Committee Chair Danni Beer noted that once the WTO compliance panel is established, arguments and briefings will be brought before it. "If the compliance panel's findings are not satisfactory to either side in the dispute, the decision can be appealed to the WTO Appellate Body. Canada's request for a compliance panel is the first step in this process. If the U.S. is found to be in compliance, then Canada has no right to retaliation, which must be authorized by the WTO. If the U.S. is found not to be in compliance, then Canada can pursue retaliation, but a specific amount of retaliation must be requested and is subject to arbitration."

Beer also observed that this compliance panel request is separate from the litigation pending in Washington, D.C., in which it intervened. He claimed, "The defense of COOL has unified producers across this country who believe that a successful, viable future for the U.S. cattle industry means maintaining the identity of the U.S. cattle herd and differentiating U.S. beef from foreign beef." *See USCA Press Releases*, August 9, 20 and 21, 2013; *Canadian Ministers Fast and Ritz Statement*, August 19, 2013.

Consumer Fraud Claims Against Tetley USA Dismissed

A federal court in California has dismissed a putative statewide class action alleging that Tetley USA misleads consumers by making "antioxidant, nutrient content, and health claims" for certain of its tea products; the statutory warranty claims were dismissed with prejudice, and the remaining claims were dismissed with leave to amend the complaint to comply with the plausibility pleading standard. *De Keczer v. Tetley USA, Inc.*, No. 12-2409 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered August 16, 2013).

According to the court, while the plaintiff acknowledged that the products at issue were consumables under the Song-Beverly Consumer Warranty Act,

he "appears to argue that the product labels constitute express warranties and that the products in question therefore fall under the provisions of section 1793.35, which provides for the enforcement of express warranties on consumables. The Court rejects this argument because food labels, like the ones at issue, do not constitute express warranties against a product defect. Labels on product packaging and websites are 'product descriptions rather than promises that [a food product] is defect-free or guarantees of specific performance levels.'" The court dismissed the Magnuson-Moss Warranty Act claim for the same reason.

As to whether the pleadings were sufficient, the court observed that the complaint used the term "Misbranded Food Products" "no less than eighty times." Because the term was defined as "including but not limited to" five of the company's products, none of which precisely mirrored the products that the plaintiff alleged purchasing, the court found that "the Amended Complaint does not provide a clear and unambiguous account of the allegedly fraudulent, deceptive, misrepresentative, or otherwise unlawful statements." The plaintiff was given 15 days to file an amended pleading.

Court Dismisses Consumer Fraud Claims Against Hain Celestial Group

A federal court in California has dismissed putative nationwide class claims against The Hain Celestial Group alleging that the company's food and beverage product labels and Website mislead consumers because they (i) list the ingredient "Evaporated Cane Juice" or "Organic Evaporated Cane Sugar Juice," (ii) are falsely labeled "All Natural" or "Only Natural," and (iii) falsely claim to have "No Trans Fat" or other nutrient content claims. *Smedt v. The Hain Celestial Group, Inc.*, No. 12-3029 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered August 16, 2013). The court dismissed the statutory warranty claims with prejudice on the grounds that the food products are consumables and not covered under the state and federal laws and because food and beverage labels "do not constitute express warranties against a product defect."

The court dismissed the fraud-related claims with leave to amend within 15 days, finding that the amended complaint failed to "unambiguously specify the particular products that have violated the particular labeling requirements, the allegedly unlawful representations that were on the products, and the particular statements Plaintiff allegedly relied on when making her purchases." The court found that the complaint "contains the same deficiencies as did the pleadings in similar food product labeling lawsuits that were recently dismissed by this Court. Like in those cases, here, Defendant—as well as the Court—would have to draw its own inferences about the products at issue and alleged mislabeling based on the equivocal assertions contained in the Amended Complaint. Drawing such inferences about the particular misconduct that is alleged to constitute fraud, deception, or misrepresentation is something the heightened Rule 9 pleading standard seeks to avoid."

Brewery Worker Claims Free Beer Was Part of Regular Base Pay

A former non-exempt Anheuser-Busch brewery worker in California has filed a putative class action against the company alleging that it violated the state labor code by failing to include the value of free or discounted beer—termed "incentive pay"—in employees' regular pay rates and thus undercompensated them by calculating overtime pay on the basis of pay rates that were too low. *Controulis v. Anheuser-Busch, LLC*, No. BC518518 (Cal. Super. Ct., Los Angeles Cnty., filed August 16, 2013). The plaintiff also claims that the company failed to timely provide a final paycheck when employees were discharged or quit. According to the complaint, the plaintiff was terminated during the year preceding the complaint's filing while he was on a leave of absence.

Seeking to certify several classes of California employees, the plaintiff alleges failure to pay overtime wages, wage statement violations, waiting time penalties, unfair competition (that is, by underpaying its employees, the defendant had an unfair advantage over its competitors), and "Private Attorneys General Act." As to the latter, the plaintiff claims that he may recover civil penalties under the Labor Code for the company's alleged transgressions. He requests compensatory, consequential, general, and special damages; statutory penalties; statutory waiting time penalties; injunctive relief and restitution; civil penalties calculated per employee per pay period; interest; attorney's fees; and costs.

OTHER DEVELOPMENTS

Rudd Center/RWJF Target Youth-Focused Food and Beverage Marketing Expenditures

Yale University's Rudd Center for Food Policy and Obesity and the Robert Wood Johnson Foundation's (RWJF's) Bridging the Gap research program recently published a study in the *American Journal of Preventative Medicine* concluding that the food and beverage industry "still spends the bulk of its money to promote unhealthy products" to children and teens. Lisa Powell, et al., "Food Marketing Expenditures Aimed at Youth: Putting the Numbers in Context," *American Journal of Preventative Medicine,* August 2013. Seeking to contextualize a Federal Trade Commission (FTC) report that found food and beverage companies spent less on youth-focused marketing in 2009 than in 2006, the study suggests that the expenditure trends highlighted by FTC ultimately fail to account for changes in the marketing landscape that allegedly negate the overall decrease in spending.

In particular, according to a concurrent issue brief, Rudd Center and Bridging the Gap researchers reported that "the vast majority of youth-directed ads promote unhealthy foods and drink, such as fast-food products, carbonated beverages, and cereals, candies, and other items that are high in sugar, fat,

or sodium." They also noted that (i) "nearly 40 percent of the reduction [in marketing expenditures directed at youths ages 2 to 17] was attributed to a drop in expenditures on fast-food restaurant premiums, such as toys"; (ii) TV ads also decreased in cost during this time while remaining "the dominant platform for advertising to youths"; and (iii) "increased spending on new media raises unique concerns because such marketing strategies cost far less than traditional media."

Based on these findings, the study's authors recommended that the Children's Food and Beverage Advertising Initiative revisit its nutrition criteria for foods and beverages marketed to children, as well as close alleged loopholes to cover product packaging, in-store promotions, and other forms of child-targeted marketing. "The current analysis highlighted the lack of progress in existing industry-initiated actions and demonstrated that stronger self-regulatory efforts are needed to noticeably reduce youth exposure to unhealthy food marketing," concludes the study. "Continued monitoring of expenditures, exposure, and nutritional content is needed, and policy actions by federal, state, and local governments and regulatory agencies may be required." *See Rudd Radar Press Release,* August 15, 2013.

Advocacy Groups Seek Global Ban on Animal Drugs

The Center for Science in the Public Interest, Consumers Union and Food Animal Concerns Trust have sent a **letter** urging U.S. delegates to an upcoming U.N. food standards agency meeting about residues of veterinary drugs in food to ask other countries to stop using drugs that have long been prohibited for use in the United States due to "human health concerns, particularly carcinogenicity and mutagenicity." The drugs in question include carbadox, nitrofural, furazolidone, chlorpromazine (thorazine), stilbenes (e.g. diethylstilbestrol, DES), olaquindox, dimetridazole, ipronidazole, metronidazole, and ronidazole, and according to Food Animal Concerns Trust Director Steven Roach, they are "not needed for animal health" and most countries have adopted safer alternatives. "We urge the U.S. delegation to insist on a recommendation that other countries prohibit use of these drugs, as the U.S. itself does," said Roach. *See Consumerist,* August 21, 2013.

Energy Drink Makers Target New Demographic

Although the typical energy drink user is reportedly young and male, a recent news source indicates that a new demographic is emerging as a top consumer of these beverages—busy, young mothers. Recent data from Nielsen reveal that busy mothers and their households—categorized as "Young Bustling Families"—are more likely to drink energy drinks than the average U.S. household, with a purchasing index of 150, higher than both "Young Transitionals" or young adults just out of college, and "Independent Singles" in their 20s and 30s.

In response to these new consumption patterns, some energy drink makers have developed "women-friendly" energy drinks, including a pink lemonade-flavored beverage from which a portion of sales are donated to the Avon Foundation Breast Cancer Crusade, and a beverage with no sugar or calories that apparently features a sweeter, more refreshing flavor, and is packaged in a white can with "feminine design elements." *See Convenience Store News,* August 16, 2013.

MEDIA COVERAGE

NYT Reports "Shipping Continued After Computer Inspection System Failed at Meat Plants"

A recent *New York Times* report has claimed that the failure of a new computer system used by meatpacking and processing plant inspectors did not stop untested shipments of beef, poultry, pork, and lamb from reaching consumers. According to an August 17, 2013, article by Ron Nixon, the U.S. Department of Agriculture (USDA) acknowledged the August 8, 2013, system failure but "played down the threat to public safety and insisted that the breakdown of the $20-million computer system had not compromised the nation's meat supply."

Designed to speed up the inspection process, which involves sending meat samples to laboratories to test for *E. coli* and other contaminants, the new computer system is an important piece of USDA's plan "to provide real-time information about the conditions at meat processing plants and make it easy for the agency to track food safety problems before they led to outbreaks." But Nixon notes that ongoing glitches—some of which USDA's Office of Inspector General apparently disclosed in a March 2013 report—have increasingly frustrated inspectors who claim that the system's daily problems are as "potentially dangerous as the larger failures." As the OIG report reportedly revealed, auditors found that some plants had not properly sampled millions of pounds of ground beef for months at a time due to issues with the computerized inspection process.

"I was one of the testers on the system in 2010 when it was still in the development phase," one inspector told Nixon. "I sent reports in every day about issues we were having. Today the same problems are still happening."

SCIENTIFIC/TECHNICAL ITEMS

Study Examines BPA and Chronic Disease Risk Factors in Children

A recent study has reportedly claimed that higher levels of urinary bisphenol A (BPA) "were associated with a higher odds of obesity… and abnormal waist

circumference-to-height ratio" in children. Donna Eng, et al., "Bisphenol A and Chronic Disease Risk Factors in US Children, *Pediatrics,* September 2013. Using data from 3,000 children ages 6 to 18 who were enrolled in the National Health and Nutrition Examination Survey 2003-2010, University of Michigan researchers evidently sought to evaluate cross-sectional associations between urinary BPA "and multiple measures of adiposity, cholesterol, insulin, and glucose."

The results suggested that although urinary BPA was associated with an increased risk of obesity, "there were no associations found between BPA and laboratory measures of cardiovascular disease and diabetes risk," an outcome that apparently contrasted with previous adult studies. "Our findings suggest the need for longitudinal analysis to elucidate temporal relationships between BPA exposure and the development of obesity and chronic disease risk factors in children, to inform future policy regulating children's consumer products," concludes the study.

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
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400