Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Warns Against Use of Powdered Pure Caffeine Products

Following the recent death of an Ohio teenager whose autopsy reportedly revealed blood levels of more than 70 micrograms of caffeine per milliliter, the Food and Drug Administration (FDA) this week issued "consumer advice" warning parents that powdered pure caffeine is a "powerful stimulant and very small amounts may cause accidental overdose." Such products are unregulated and sold as dietary supplements. According to the agency, a teaspoon of pure caffeine is "roughly equivalent" to the amount contained in 25 cups of coffee. FDA is encouraging the public as well as health care providers to report any adverse events related to consumption of powdered pure caffeine to the agency. *See Associated Press*, July 19, 2014; *FDA Consumer Advice on Powdered Pure Caffeine*, July 21, 2014.

Federal Nanotechnology Research Focus of Upcoming Webinar

The National Nanotechnology Coordination Office will host a July 31, 2014, Webinar to discuss research undertaken by U.S. government National Nanotechnology Initiative (NNI) agencies. NNI's six core research areas include nanomaterial measurement infrastructure; human exposure assessment; human health; environment; risk assessment and risk management methods; and informatics and modeling. *See Federal Register*, July 22, 2014.

Codex Alimentarius Commission Adopts Standards for Lead in Baby Formula and Arsenic in Rice

Representatives of more than 170 countries, the European Union and governmental and non-governmental organizations convened in Geneva, Switzerland, on July 14-18, 2014, for the annual meeting of the Codex Alimentarius Commission. Delegates reportedly adopted a recommendation that no more than 0.01 mg/kg of lead be allowed in infant formula and that raw materials be sourced from geographical areas where lead is less prevalent, citing the particular vulnerability of infants and young children to developmental health effects from lead exposure. Codex also set a maximum allowable level for arsenic in rice of 0.2 mg/kg because long-term exposure to the naturally occurring chemical has been linked to the development of cancer, heart disease and diabetes.

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Other **decisions** made during the annual meeting related to restricting the use of eight veterinary drugs (chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquinadox) in food-producing animals to prevent any residual quantities in meat, milk, eggs, and honey; quality and safety standards for scallops, passion fruit, okra, and durian; maximum allowable levels of fumonisins in corn; maximum use levels for additives in food; maximum residue levels for pesticides in food and feed; and a code of hygienic practice for spices and dried aromatic herbs. *See FAO News Release*, July 17, 2014.

EU Publishes Draft Directive Allowing Member States to Ban GMOs

At the request of 13 member states, the Council of the European Union (EU) has adopted a draft directive granting its member states "more flexibility to decide whether or not they wish to cultivate genetically modified organisms (GMOs) on their territory." In a July 23, 2014, press release, the council states that it sought "to provide a sound legal basis in the related EU legal framework in order to allow member states to restrict or prohibit the cultivation, in all or part of their territory, of GMOs that have been authorised or are under authorisation at the EU level." The measure was originally proposed in 2009 but stalled after a 2011 draft; in June 2014, the EU Environmental Council reached a political agreement that led to this draft directive, which the council projects will be adopted in 2015. *See Law360*, July 23, 2014.

EU and Southern Africa Agree to Protect Unique Food Names

The European Union (EU) and the Southern African Development Community (SADC)—Botswana, Lesotho, Mozambique, Namibia, South Africa, and Swaziland—have agreed to protect each other's geographical indication (GI) names on agricultural products. The EU lists 251 GIs it seeks to protect for a variety of products, focusing especially on dairy products like cheese, while South Africa's 105 GIs are primarily wine-related. As a result of the agreement, the countries will allow the labeling of a product as the GI only if it originated from a designated area, but they will respect previously registered trademarks. "[GIs] are a key tool to protect the know-how of farmers and develop added value in quality agricultural products," said EU Agricultural Commissioner Dacian Ciolos. *See Law360*, July 22, 2014.

Health Canada Revises Nutrition Labels to Emphasize Added Sugars

Health Canada has **proposed** nutrition labeling changes as part of an ongoing effort to make food and beverage labels easier for consumers to read. Based on a **public consultation**, the conclusions of Canadian Food Inspection Agency's **Food Labelling Modernization Initiative** and a technical review of current labels, the amendments would revise the Nutrition Facts table, ingredient list and suggested Daily Values to take into account "the most up to date scientific information and consumption habits."

In particular, the proposed changes would (i) adjust serving sizes to reflect "the amounts of food that Canadians actually eat in one sitting," (ii) update the Daily Values and nutrients displayed in the Nutrition Facts table; (iii) refresh the appearance of the Nutrition Facts table and ingredient list to emphasize calories, added sugars and other nutrients of concern to Canadian consumers, and (iv) create "an optional information box highlighting the presence of certain bioactive components, such as caffeine."

Health Canada has also recommended grouping together "all sugar-based ingredients added directly to a food," so that ingredient lists would place each individual sugar type (e.g., "sugar, glucose-fructose, honey, fancy molasses") in parentheses after the common name "Sugars." In addition, the Nutrition Facts table would highlight the amount of added sugar as well as establish a Daily Value for total sugar consumption at 100 grams.

"These changes will make it easier to read and understand labels and help Canadians make healthy food choices. Over the coming months, we'll be conducting face-to-face and online consultations to gather information about what Canadians think about the new proposed food labels," said Minister of Health Rona Ambrose in a July 14, 2014, statement. The agency will accept comments on the proposal until September 11, 2014.

CFIA Adopts Monetary Penalties for Meat Safety Violations

The Canada Food Inspection Agency (CFIA) has **announced** new administrative monetary penalties (AMPs) for businesses that fail to meet the requirements laid out in the Meat Inspection Act (MIA) and Meat Inspection Regulations, 1990 (MIR). According to a July 16, 2014, press release, the agency is amending the Agriculture and Agri-Food Administrative Monetary Penalties Regulations to "allow CFIA inspectors to issue an AMP for non-compliance with 84 provisions of [MIA] and [MIR]," which include items related to both food safety and non-safety issues such as labeling.

"AMPs are an additional tool that will support the CFIA in delivering its mandate for food safety, explained Chief Food Safety Officer for Canada Martine Dubuc. "AMPs do not replace existing inspection and enforcement tools, but instead offer additional flexibility in addressing meat-related violations."

UK Ad Watchdog Backs Teabag Claims

The U.K. Advertising Standards Authority (ASA) has dismissed a competitor's complaint alleging that Unilever UK Ltd.'s commercial for its pyramid-shaped teabags "exaggerated the capability and performance of the advertised product." Tata Global Beverages reportedly argued that (i) the visual demonstration used in a TV commercial for PG Tips tea was misleading, (ii) Unilever's claim that "the tea has more room to move freeing the great fresh taste" could not be substantiated, and (iii) "the comparison with a round teabag denigrated [ ] Tata's brand 'Tetley' because they believed that they were an identifiable competitor and that the ad portrayed the brand in a negative light."

According to ASA, Unilever not only countered that the visual demonstration in question "imitated consumer behavior when making tea," but noted that the claims reflected the results of product testing and mathematical modeling supplied to ASA for review. Denying that the ad made a direct comparison to Tetley, the company apparently targeted round teabags because this design currently reflects 30.8 percent of the market. In addition, Clearcast—the non-governmental organization that approves TV advertising in the United Kingdom—concurred that Unilever "had evidence to show that the tea moved more freely" and "did not believe the ad denigrated the Tetley brand[ ] for the reasons outlined by Unilever."

Concluding that the commercial did not exaggerate the performance of PG Tips' pyramid-shaped teabag, ASA specifically held that consumers "would interpret the visual demonstration to be a representation of a simple consumer experiment and would not interpret it as a representation of a detailed scientific test." In addition, the agency ruled that "consumers would not immediately identify a round teabag as being a Tetley teabag," and declined to find the ad in violation of the U.K. Code of Broadcast Advertising.

In a related development, ASA also dismissed a complaint against Greene King Brewing and Retailing Ltd. for its use of puppets in a TV ad for Old Speckled Hen beer. Although "Henry the Fox" had been the voice of the beer brand since 1994, the complaint challenged whether the ad was irresponsible for featuring a fox puppet and a man in a white rabbit costume because these characters might appeal to children. Rejecting the allegations, ASA agreed with Greene King Brewing that the commercial's "intelligent, highbrow humor and dry wit" was clearly intended to engage adult audiences only.

"The ASA acknowledged that talking puppets were often used in programs and films that were targeted towards children," states the ruling. "However, we considered that, in this instance, the fox character's behavior, dress and appearance were aimed towards adults. We noted that the voice of the fox clearly sounded like an older man, and that the character's language and deadpan delivery were unlikely to appeal to children."

LITIGATION

FDA Not Required to Hold Hearings on Antibiotics Bans, Second Circuit Says

The Second Circuit has reversed a district court's decision that ordered the U.S. Food and Drug Administration (FDA) to initiate hearings responding to a livestock antibiotics challenge from the Natural Resources Defense Council (NRDC) based on a 1977 agency finding that the use of growth antibiotics for healthy animals was unsafe. *NRDC v. FDA*, No. 12-2106 (2d Cir., order entered July 24, 2014). Two judges were "firmly persuaded that Congress has not required the FDA to hold hearings whenever FDA officials have scientific concerns about the safety of animal drug usage," that FDA has discretion on proceedings to withdraw approval of animal drugs, and that the law requires "withdrawal of approval of animal drugs or particular uses of such drugs only when the FDA has made a final determination, after notice and hearing, that the drug could pose a threat to human health and safety."

In 1977, FDA planned to limit the use of growth antibiotics in animals by pulling them from the market, but following the agency's formal rejection of the plan in 2011, environmental groups sued FDA to force the implementation of the plan. Agreeing with the groups, as led by NRDC, a district court ordered FDA to initiate hearings on the controversial use of antibiotics. Additional information about the district court's ruling appears in issue **432** of this *Update*.

In reversing the district court, the Second Circuit held that the lower court could not force FDA to restart its plan because FDA has discretion on when it holds hearings or begins the process of withdrawing approval for the drugs. In addition, the 1977 FDA conclusion about the use as unsafe does not bind the agency to pursue the withdrawal of approval because the conclusion was not a final determination.

In a dissent, the chief judge warned, "Today's decision allows the FDA to openly declare that a particular animal drug is unsafe, but then refuse to withdraw approval of that drug. It also gives the agency discretion to effectively ignore a public petition asking it to withdraw approval from an unsafe drug."

Heinz "Dip & Squeeze" Case Revived by Third Circuit

The Third Circuit has reversed a Michigan district court's dismissal in a case alleging that H.J. Heinz Co. stole the idea for the "Dip & Squeeze" ketchup packet from plaintiff David Wawrzynski, an inventor who had proposed the idea to the company in 2008. *Wawrzynski v. H.J. Heinz Co.*, No. 13-4100 (3d Cir., order entered July 21, 2014).

Wawrzynski owned a 1997 patent for a condiment packet that allowed users to dip food into it. From that idea, he developed a "separate and distinct" condiment packet that he called the Little Dipper, which allowed users to either dip food into it or squeeze out the contents. He met with Heinz in 2008 and discussed the possibility of selling the idea to the company, but they never reached a deal. Later, Heinz released its Dip & Squeeze ketchup packet, which allows users the option of dipping food directly into it or tearing off a small corner to squeeze out the ketchup. Wawrzynski sued Heinz in 2011 for stealing the idea, and the lawsuit mentioned his 1997 patent for the earlier but distinct product but did not allege infringement of the patent. The district court granted Heinz's motion for summary judgment based on preemption by federal patent law and for declaratory judgment that Heinz did not infringe Wawrzynski's patent.

In assessing the case, the Third Circuit found that the district court had misunderstood the claims in Wawrzynski's complaint by believing them to be for patent infringement when, in fact, they were for damages "arising from Defendants' failure to pay Mr. Wawrzynski for his concepts and ideas regarding new condiment packaging and marketing for new condiment packaging." His claims concerned his second idea, which was distinct from the idea in the patent, so "because his claims are not inconsistent with the federal patent scheme, Wawrzynski's claims are not preempted by patent law." As a result, the Third Circuit held that the district court erred in issuing the declaratory judgment because it had no subject-matter jurisdiction to rule on the issue of patent infringement without a case or controversy, and it remanded the case back to the district court.

Eleventh Circuit Dismisses Colombia War Crimes Claims Against Chiquita

Finding no U.S. jurisdiction, the Eleventh Circuit has dismissed multidistrict litigation against Chiquita alleging the company was liable for aiding and abetting torture and war crimes by paying a paramilitary group for security. *Cardona v. Chiquita Brands Int'l*, No. 12-14898 (11th Cir., order entered July 24, 2014). Relatives of alleged victims of the paramilitary group filed actions against Chiquita in 2010 and 2011. Additional information on the litigation appears in Issues **342**, **345** and **387** of this *Update*.

A district court denied Chiquita's motion to dismiss but the Eleventh Circuit has reversed this decision, relying on the U.S. Supreme Court's decision in *Kiobel v. Royal Dutch Petroleum*, 133 S. Ct. 1659 (2013). As in *Kiobel*, "[t]here is no allegation that any torture occurred on U.S. territory, or that any other act constituting a tort in terms of the [Alien Tort Statute (ATS)] touched or concerned the territory of the United States with any force." As a result, the court had no jurisdiction to rule on the case, and thus erred by not granting Chiquita's motion to dismiss.

In a dissent, one judge argued that "it is a fundamental principle of international law that every State has the sovereign authority to regulate the conduct of its own citizens, regardless of whether that conduct occurs inside or outside of the State's territory." Because the case concerns an American national—Chiquita—the court has jurisdiction over its actions, albeit to a limited extent, when the national aids and abets overseas torts from within the United States, she argued.

Claims Trimmed in Case Against Bigelow for Allegedly Inflating Health Benefits of Tea

A California federal court has dismissed fraud claims against R.C. Bigelow in a putative class action accusing the company of advertising that its tea "delivers healthful antioxidants" when the levels of antioxidants are too low to benefit the consumer. *Victor v. R.C. Bigelow*, No. 13-2976 (U.S. Dist. Ct., N.D. Cal., order entered July 18, 2014). The court allowed to proceed the plaintiff's claim that Bigelow's antioxidants assertion on its packaging violated California's Unfair Competition Law (UCL) based on the "unlawful" prong, but it dismissed with prejudice his claims that Bigelow had violated the "fraud" prong of the UCL.

Despite arguing the importance of the word "deliver," the plaintiff failed to prove that the phrase "delivers healthy antioxidants" represented that the product contained a high enough level of antioxidants to provide health benefits to the tea drinker; as the court had previously allowed the plaintiff to amend his complaint, the claims relating to fraudulent and misleading labeling were dismissed with prejudice.

The sole remaining claim accuses Bigelow of making unlawful claims about its tea's antioxidants levels. "While federal food labeling laws and regulations require a manufacturer to use only approved nutrient claims on a food label, none of Bigelow's tea products contain an antioxidant nutrient accepted by regulation; thus the use of 'antioxidant' on its product labels violates labeling rules." The court also noted that the products "do not conform with regulations specifically governing antioxidants and terms such as 'healthful.'" In addition, the antioxidant claims could subject purchasers to criminal liability because "'unlikely' as it is that a California consumer would be subject to jail time and a criminal fine for possessing misbranded food, California does

criminalize the possession of misbranded goods." Finding this potential criminal liability sufficient to support the unlawful claim, the court denied Bigelow's motion to dismiss.

Putative Class Actions Accuse Whole Foods and Breyers of "All Natural" Mislabeling

According to a putative class action removed to Arkansas federal court, Whole Foods mislabels several of its 365 Everyday Value brand products as "organic" or "all natural" despite containing synthetic ingredients. *Stafford v. Whole Foods Market Cal.*, No. 14-420 (U.S. Dist. Ct., E.D. Ark., removed July 22, 2014). Originally filed in Arkansas state court in June, the complaint accuses several products of mislabeling—for example, the plaintiff says, the 365 Everyday Value soft drink contains carbon dioxide, citric acid, tartaric acid, and caramel coloring despite its "all natural" label. Whole Foods argued to the state court that the potential class contains more than 100 people who seek over $5 million in damages, so the case was removed to federal court. Alleging that Whole Foods violated Arkansas labeling laws and breached warranties, the plaintiff seeks class certification, damages and interest.

A similar case filed in New Jersey state court alleges that Breyers, a subsidiary of Unilever United States, falsely labels its ice cream as "all natural" while including cocoa processed with alkali (Dutch-process cocoa), which contains the artificial ingredient potassium carbonate. *Jefferson v. Conopco*, No. L-7025-14 (Super. Ct. N.J., Bergen Cnty., filed July 16, 2014). The plaintiff accuses Breyers of violating the New Jersey Consumer Fraud Act and the Truth in Consumer Contract for labeling its ice cream as "all natural" despite its inclusion of cocoa that has been alkalized, which the complaint argues the U.S. Food and Drug Administration (FDA) recognizes as a non-natural process and requires the statement "processed with alkali" or the more common name of the specific alkali ingredient. The plaintiff seeks class certification, statutory and compensatory damages, interest, and attorneys' fees.

SCIENTIFIC/TECHNICAL ITEMS

High-Salt Diet Linked to Doubled CVD Risk in People with Diabetes

A recent study has allegedly concluded that high dietary sodium intake doubles the risk of cardiovascular disease (CVD) in patients with type-2 diabetes. Chika Horiakwa, et al., "Dietary Sodium Intake and Incidence of Diabetes Complications in Japanese Patients with Type 2 Diabetes–Analysis of the Japan Diabetes Complications Study (JDCS)," *Journal of Clinical Endocrinology & Metabolism,* July 2014. Researchers with the University of Niigata Prefecture analyzed food frequency questionnaires and disease incidence data for more than 1,500 people with type-2 diabetes who participated in the

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Japan Diabetes Complications Study (JDCS) during eight years of follow-up. Their results evidently showed that although sodium intake was not associated with overt nephrology, diabetic retinopathy or all-cause mortality, participants "who consumed an average of 5.9 g of sodium per day had about a 2-fold higher risk of CVD than those who consumed an average of 2.8 g/d."

"The study's findings provide clear scientific evidence supporting low-sodium diets to reduce the rate of heart disease among people with diabetes," the study's lead author was quoted as saying. "Although many guidelines recommend people with diabetes reduce their salt intake to lower the risk of complications, this study is among the first large longitudinal studies to demonstrate the benefits of a low-sodium diet in this population." *See The Endocrine Society Press Release,* July 22, 2014.

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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.