

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

FDA Denies Citizen Petitions Seeking Aspartame Ban

The U.S. Food and Drug Administration (FDA) has denied two citizen petitions asking the agency to prohibit the use of aspartame as a non-caloric sweetener. Dated July 16, 2002, the first petition argued that the Public Health Security and Bioterrorism Preparedness Response Act authorizes FDA to recall dangerous chemicals without manufacturer approval. Citing studies conducted by the European Ramazzini Foundation (ERF), the second petition urged FDA to revoke approval for the sweetener under the Delaney Clause in section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act, which provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

Responding to these claims, FDA **reasoned** that the first petition and subsequent comments contained "no substantive scientific evidence demonstrating that aspartame's use presents a public health risk or that this sweetener is adulterated or misbranded." The agency also **found** that the second petition failed to include adequate data from the ERF studies or demonstrate that consumer exposure to aspartame exceeds the acceptable daily intake.

As the agency concluded, "The safety of aspartame has been reviewed repeatedly, not only by FDA, but by other regulatory authorities, including those of Canada, the United Kingdom, Australia, Europe, and Japan. All these authorities agree that aspartame is safe for the general population except for individuals with phenylketonuria."

EPA Flags BPA, Phthalates for Chemical Assessment

The Environment Protection Agency (EPA) has updated its **Toxic Substances Control Act (TSCA) Work Plan for Chemical Assessments** to include bisphenol A (BPA), seven phthalates and 15 other substances. Designed to help the Office of Pollution Prevention and Toxics identify chemicals with "the highest potential for exposure and hazard," the TSCA Work Plan in 2012 flagged 83 chemicals as part of an ongoing initiative to expedite assessments for substances believed to have reproductive, developmental or neurotoxic

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effects, as well as those that are “probable or known carcinogens” or “persistent, bioaccumulative and toxic.” The plan also targets substances used in children’s products and those that have been detected in biomonitoring programs.

This latest update to the TSCA Work Plan removes 15 chemicals and adds 23 new ones, bringing the total list to 90 chemicals. In addition to BPA, the chemicals added to the updated list include dibutyl phthalate, butyl benzyl phthalate, di-(2-ethylhexyl) phthalate, di-n-octyl phthalate, di-isononyl phthalate, di-isodecyl phthalate, and di-isobutyl phthalate. At the same time, however, EPA removed mercury and mercury compounds from the TSCA Work Plan “because their hazards are already well characterized and EPA has a strong risk reduction effort in place.” The agency also declined to add benzidine dyes, long-chain perfluorinated chemicals, methylene diphenyl diisocyanate, toluene diisocyanate and short chain chlorinated paraffins, reasoning that these chemicals either had low exposure or toxicity risk or had already been removed from commerce.

“EPA notes that identification of a chemical on the TSCA Work Plan for Chemical Assessments does not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment,” states the TSCA Work Plan summary. “Rather, identification of a chemical on the TSCA Work Plan for Chemical Assessments indicates only that the Agency intends to consider it for assessment. The Agency believes that identifying these chemicals early in the review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency’s attention to further inform the assessment.”

In a related development, EPA has [rejected](#) a petition for rulemaking on polyvinyl chloride (PVC), vinyl chloride and phthalates used as plasticizers. Submitted by the Center for Biological Diversity (CBD) under TSCA section 21, the petition alternatively requested additional toxicity testing of these chemicals. Though still reviewing a separate petition seeking action under the Resource Conservation and Recovery Act, EPA declined to initiate rulemaking because the first petition did not (i) “specify what risk management action it is requesting,” (ii) “set forth sufficient facts to establish that the disposal of PVC, vinyl chloride, or phthalates used as plasticizers presents or will present an unreasonable risk,” or (iii) “explain why action under TSCA would be preferable to action under other statutory authorities.” *See Federal Register*, October 31, 2014.

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FDA Seeks Comments on Expanding the Redbook

The U.S. Food and Drug Administration (FDA) will host a [public meeting](#) and is soliciting public input on whether to expand the products included in its guidance, titled “Toxicological Principles for the Safety Assessment of Food Ingredients”—also known as the “Redbook.”

The agency is apparently considering this expansion “to include chemical safety assessments for all products over which FDA’s Center for Food Safety and Applied Nutrition (CFSAN) has statutory authority including regulatory contexts such as food additives, food contact substances, dietary supplement ingredients, food contaminants, and cosmetics.” According to FDA, “The Redbook would describe toxicological principles which apply across regulatory categories while still providing specific guidance for applying these principles within each particular context. The safety of foods containing microbial contaminants will continue to remain outside of the scope of the Redbook.”

The meeting will take place December 9, 2014, in College Park, Maryland, and those wishing to participate in person must register by December 2. Those wishing to make oral presentations must submit their requests by November 21, and written comments are requested by February 9, 2015. *See Federal Register*, October 30, 2014.

FAO/WHO Committee Issues Report on Veterinary Drug Residues in Food

The World Health Organization (WHO) has issued a [technical report](#) from a joint Food and Agriculture Organization/WHO Expert Committee tasked with evaluating the safety of certain veterinary drugs and recommending maximum residue limits (MRLs) in food.

Among other things, the report addresses toxicological and residue data on various anthelmintic, antiparasitic, antifungal, and antibacterial agents and attendant MRLs in minor species, honey and fish.

LITIGATION

Court Denies Molasses Supplier Dismissal in Tainted Licorice Case

A California federal court has rejected in part and granted in part Total Sweeteners Inc.’s motion for summary judgment in a case alleging that the molasses supplier sold American Licorice Co. shipments tainted with lead that American Licorice then used to create Red Vines black licorice candy, resulting in a costly recall. *Am. Licorice Co. v. Total Sweeteners Inc.*, No. 13-1929 (U.S. Dist. Ct., N.D. Cal., order entered October 22, 2014). Additional details about the case appear in Issue [494](#) of this Update.

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American Licorice argued that, under the sales contract, Total Sweeteners was obliged to provide molasses that complied with state and federal regulations; Total Sweeteners asserted that American Licorice knew that molasses has some naturally occurring lead and should have tested for it upon receipt. The court focused on the contract, agreeing with Total Sweeteners that the sales contract between the parties, and not a subsequent purchase order with terms favorable to the licorice maker, governed American Licorice's purchases. The court also determined that a contractual limitation on consequential damages applied to the claims. The court refused, however, to rule as a matter of law that American Licorice had waived its rights under the contract by failing to notify Total Sweeteners about any problems within 45 days of receiving the product. According to the court, whether the 45-day time limit was reasonable presented a genuine issue of material fact. The court also found that the sales contract did not, as Total Sweeteners argued, effectively disclaim express and implied warranties.

Federal Court Dismisses Olive Oil Owners from False-Labeling Class Action

A federal court in New York has granted the motion for summary judgment filed by the owners of Kangadis Food Inc., a company that declared bankruptcy when faced with class claims that it falsely labeled its products as pure olive oil when they actually contain an industrially processed substance. *Ebin v. Kangadis Family Mgmt. LLC*, No. 14-1324 (U.S. Dist. Ct., S.D.N.Y., order entered October 24, 2014). Additional information about the litigation appears in [Issue 539](#) of this *Update*.

According to the court, the "plaintiffs have failed to adduce competent evidence from which any reasonable juror could conclude that defendants used their alleged domination of Kangadis Food Inc. as a means to accomplish the fraud here alleged." Counsel for the defendants reportedly surmised that the court agreed that the plaintiffs' "derivative claims are nothing more than a desperate attempt to extract some value from the defendants, individuals and a separate entity with perceived deep pockets." An opinion elaborating the ruling "will issue in due course"; until then, the proceedings are stayed and the court's reasons for granting the relief remain unspecified. In September, the court dismissed direct claims against the company owners, but found that claims could proceed against them under veil piercing and alter ego theories. *See Law360*, October 24, 2014.

Restaurant Chain Settles Kobe Beef Putative Class Action

A California state court has approved the settlement of a putative class action alleging that Barney's Worldwide Inc., owner of the Barney's Beanery restaurant chain, falsely advertised its beef as Kobe beef when a U.S. Department of Agriculture (USDA) ban on the import of beef from Kobe, Japan, was in effect. *Nalbantian v. Barney's Worldwide Inc.*, No. BC493145 (Cal. Super. Ct., Cty. of Los

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Angeles, approval entered October 23, 2014). The plaintiff had alleged that Barney's advertised its menu as containing Kobe beef—which the plaintiff said indicates that the beef comes from Wagyu-breed cattle raised and slaughtered in Kobe, Japan—despite a USDA ban imposed due to fears of disease in May 2010. Under the settlement, the restaurant chain will use "Kobe beef" on its menu only if it is listed as "American Kobe beef" and will pay up to \$220,000 in \$10 gift certificates to any class member who submits a claim and \$15 gift certificates to class members who submit proof of their purchase, such as a receipt or credit-card statement. Information about the settlement in a similar Kobe-beef case appears in Issue [525](#) of this *Update*.

Diamond Foods Agrees to \$2.75-Million Settlement in "All Natural" Class Actions

Diamond Foods, Inc. has agreed to settle the consumer-fraud class-action suits filed by plaintiffs in California and Florida alleging that the company falsely labels its Kettle Brand® chip products as "All Natural," when they contain artificial, synthetic or genetically modified ingredients, or as "Reduced Fat" while referencing non-comparable foods. *Klacko v. Diamond Foods, Inc.*, No. 14-80005 (U.S. Dist. Ct., S.D. Fla., motion for preliminary approval filed October 22, 2014). Details about one of two similar California lawsuits appear in Issue [510](#) of this *Update*. Under the agreement, the company would establish a \$2.75-million fund for class member claims, pay the costs of class notice and administration up to \$300,000 and agree not to oppose attorney's fees, expenses and costs of \$775,000.

Class members with proof of purchase would be able to recover up to \$20, representing \$1.00 for up to 20 purchases; those without proof of purchase would recover up to \$10. Any residual amount would be applied toward the retail value of the company's food products, which would be donated to Feeding America. Under the injunctive relief component of the agreement, the company would provide "natural promise" criteria to ingredient suppliers and require that they verify their ingredients comply with the promise. The company would also "create and maintain a database to track ingredients and ingredient suppliers," conduct annual audits to ensure compliance, and "employ reasonable efforts to obtain Non-GMO [genetically modified organism] Project approval for all Products where eligibility for Non-GMO Project approval is practical." Regarding "Reduced Fat" and "___% Less Fat" products, the company would "place the requisite comparison statement at the location on the packaging where the applicable claim is most prominently displayed."

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FTC Seeks to Enjoin Gerber Claims About Infant Formula and Allergies

The U.S. Federal Trade Commission (FTC) has filed a complaint in a New Jersey federal court against Gerber Products Co., alleging that since 2011 the company has falsely promoted its Good Start Gentle infant formula as a product that can prevent or reduce the risk of a child developing allergies. [FTC v. Gerber Prods. Co., No. 14-6771 \(U.S. Dist. Ct., D.N.J., filed October 29, 2014\)](#). The formula is apparently made with partially hydrolyzed whey proteins (PHWPs) that Gerber purportedly claims make the product easier to digest than formula made with intact cow's milk protein. Product stickers and ads compare the product to breastfeeding as a way to naturally protect a baby from allergies and claim that the formula is the "1st and ONLY" "TO REDUCE THE RISK OF DEVELOPING ALLERGIES."

The company also allegedly claims that the formula "is the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." According to FTC, the U.S. Food and Drug Administration (FDA) twice rejected Gerber's requests to make a health claim for its infant formula with PHWPs, finding "no credible" evidence to support the relationship between PHWP infant formula and a reduced risk of food allergy and "little scientific evidence" of a reduced risk for atopic dermatitis in infants. FDA would have allowed Gerber "to make a highly qualified health claim that 'the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship.'" Gerber has allegedly eschewed such language, using instead gold seals on formula canisters "emblazoned with '1st and Only' in the center, 'Meets FDA' in the top perimeter, and 'Qualified Health Claim' in the bottom perimeter."

Alleging a false or unsubstantiated allergy claim and false FDA approval claim, FTC seeks preliminary and permanent injunctive relief to prevent future violations of federal law, as well as "rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies," and costs. FTC's Bureau of Consumer Protection director reportedly said, "Parents trusted Gerber to tell the truth about the health benefits of its formula, and the company's ads failed to live up to that trust. Gerber didn't have evidence to back up its claim that Good Start Gentle formula reduces the risk of babies developing their parents' allergies." See *FTC News Release*, October 30, 2014.

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Lucasfilm Challenges Brewery's "Empire Strikes Bock" Trademark Application

Lucasfilm Ltd. has filed a notice of opposition to Walton Street Brewing Corp.'s application to the U.S. Patent and Trademark Office (USPTO) to register "Empire Strikes Bock" as a mark. Lucasfilm argues that the name will cause confusion with and dilute goods related to its *The Empire Strikes Back* 1980 film, which, as *Bloomberg BNA* notes, is not associated with any active trademarks but may be famous enough to be protected under common law. The production company also claims that granting the "Bock" trademark will cause confusion with its existing mark—Skywalker Vineyards—in the alcohol industry. In an irreverent video response, Walton Street's owner [explains](#) that the brewery has sold "Bock" on tap at its pub for several years and now intends to bottle it, and it never intended to cause any confusion with its "parody" beer. In the background, a person in a Stormtrooper costume appears to stir beer with a lightsaber, and the video concludes with the director of brewing operations appearing to speak "Wookiee," while the assertion that USPTO approved the trademark's registration in June 2014 is displayed below. *See Bloomberg BNA*, October 29, 2014.

Food Groups Claim AquaBounty Fined for Environmental Violations

Food & Water Watch and the Center for Food Safety (CFS) have reported that AquaBounty Technologies has been fined US\$9,500 for violating environmental regulations in Panama and call for the U.S. Food and Drug Administration (FDA), which is assessing the safety of the company's genetically engineered (GE) salmon, to terminate its review and deny AquaBounty's pending application to sell GE fish in the United States.

The Panamanian National Environmental Authority apparently [ruled](#) on October 23, 2014, that AquaBounty failed to secure the permits needed for water use and water discharge before commencing operations. The decision came in response to a complaint filed in 2013 by the environmental organization Centro de Incidencia Ambiental. CFS senior attorney George Kimbrell said, "AquaBounty has not been able to follow the law, because it lacks the capacity, sophistication, will, or all of the above. This decision is also even further proof that FDA is dangerously out of touch with the facts on the ground, advancing AquaBounty's application based on its promises, not reality."

A Friends of the Earth spokesperson said, "AquaBounty's days of hiding in the highlands of Panama are over. This is even more evidence that the FDA should deny approval of AquaBounty's application for genetically engineered salmon. Once these fish escape, it is impossible to retrieve them. And it may be extremely difficult to contain the negative environmental impacts of escaped fish." *See Food & Water Watch and Center for Food Safety News Releases*, October 28, 2014.

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OTHER DEVELOPMENTS

Sazerac Recalls Fireball Whiskey Containing Propylene Glycol at Levels Exceeding European Restrictions

Sazerac Co. has recalled its Fireball Cinnamon Whiskey from Sweden, Norway and Finland because some batches contain levels of flavoring chemical propylene glycol that exceed European limits. The company says that it mistakenly shipped batches to Europe that were intended for the United States, where the U.S. Food and Drug Administration (FDA) allows higher levels for the Generally Recognized As Safe ingredient. The recall drew media attention to the regulation discrepancy, with many noting that industrial-grade propylene glycol is used in antifreeze.

The company clarified October 29, 2014, that it uses food-grade propylene glycol, which it says is also used in many other consumable products, including salad dressing, beer, ice cream, and cake. Sazerac called the ingredient "ideal for use in a large variety of flavors to give most of today's food and beverages their distinctive taste. Flavor companies use it to carry flavor ingredients through to the final product, to preserve the integrity of the flavor and to ensure it is shelf stable." The company also explained that it has different recipes for Europe and North America, but prefers the North American recipe and adapted it to sell the product in Europe. "Both recipes are completely safe; one is not safer than the other," according to the press release. *See Los Angeles Times*, October 29, 2014; *CBS News*, October 30, 2014.

United States and Mexico Reach Deal on Sugar Imports

Hours before U.S. regulators were poised to penalize Mexican sugar imports, the United States and Mexico reached an agreement to set a price floor on imported sugar and to suspend anti-dumping and anti-subsidy duties. The dispute began in April 2014 when the U.S. Department of Commerce initiated an investigation following petitions from the U.S. sugar industry complaining of unfair pricing and government subsidies on Mexican sugar.

Under the agreement, Mexico will reportedly be allowed to meet any demand for sugar in the United States after U.S. producers and other countries with fixed quotas have exhausted their supplies. Mexican producers will sell their sugar for no less than \$0.2075 per pound for raw and \$0.2357 per pound for refined.

"We believe these Agreements, which work in concert with the U.S. sugar program, effectively address the market-distorting effects of any unfairly traded sugar," Assistant Secretary of Commerce for Enforcement and Compliance Paul Piquado said in an October 27, 2014, International Trade Administration press release. In response, the Sweetener Users Association (SUA) issued a statement reflecting concerns that the agreement will lead to

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market uncertainty, which may in turn lead to unfairly high sugar prices for consumers and food and beverage manufacturers. Citing the North American Free Trade Agreement, SUA said that “there has been free trade in sugar since early 2008. Entering into a managed trade agreement would not only set a bad precedent for our bilateral trade relationship, it would move America’s already protectionist sugar policy in the wrong direction, farther away from a free market approach.” Information about a letter submitted by U.S. senators urging the Commerce Department not to impose quotas on Mexican sugar imports appears in Issue [532](#) of this *Update*. See *International Trade Association Press Release*, October 27, 2014.

EWG Unveils “Food Scores” Database

The Environmental Working Group (EWG) has released a [database](#) and mobile app that score some 80,000 food products using three criteria—nutrition, ingredient concerns and processing—to inform consumers that “popular brands in many categories are not so much food as they are conveyances for excessive amounts of sugar, salt and preservatives.”

According to an October 27, 2014, EWG press release, the average product rated in the Food Scores database contains 14 ingredients and 446 mg of salt per 100 g, and it has a 58 percent chance of containing added sugar, 46 percent chance of artificial or natural flavor and 14 percent chance of artificial coloring. The guide allows consumers to search by product name, company or category and provides examples of comparable products with different scores. EWG’s press release specifically calls out stuffing and stuffing mixes as products with the highest likelihood of containing added sugars. According to *Bloomberg Businessweek*, 18 percent of the rated products earned a green (best) score and 25 percent were ranked red (worst), with most products falling somewhere in the middle. See *Bloomberg Businessweek*, October 27, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Study Links Sugar-Sweetened Beverages to Accelerated Aging

A recent study has purportedly linked sugar-sweetened beverage (SSB) consumption to accelerated cell aging, estimating that “daily consumption of a 20-ounce soda was associated with 4.6 years of additional biological aging.” Cindy Leung, et al., “Soda and Cell Aging: Associations Between Sugar-Sweetened Beverage Consumption and Leukocyte Telomere Length in Healthy Adults From the National Health and Nutrition Examination Surveys,” *American Journal of Public Health*, October 2014. University of California, San Francisco (UCSF) researchers apparently analyzed stored DNA from more than 5,000 adults enrolled in the 1999-2002 National Health and Nutrition Examination Surveys, which included 24-hour dietary recall assessments.

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According to a UCSF press release, the study authors reported that “telomeres—the protective units of DNA that cap the ends of chromosomes in cells—were shorter in the white blood cells of survey participants who reported drinking more soda.” Although this effect paralleled the telomere shortening allegedly seen in smokers, the consumption of 100 percent fruit juice “was moderately associated with longer telomeres.”

“Regular consumption of sugar-sweetened sodas might influence disease development, not only by straining the body’s metabolic control of sugars, but also through accelerated cellular aging of tissues,” one of the authors was quoted as saying. “This is the first demonstration that soda is associated with telomere shortness... Telomere shortening starts long before disease onset. Further, although we only studied adults here, it is possible that soda consumption is associated with telomere shortening in children, as well.” See *UCSF Press Release*, October 16, 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.

