

## FOOD & BEVERAGE LITIGATION UPDATE



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## LEGISLATION, REGULATIONS AND STANDARDS

### EU Council Asks Member States to Combat Antimicrobial Resistance

The Council of the European Union has issued a "One Health" perspective [document](#) recognizing that antimicrobial resistance (AMR) "is accelerated by excessive and inappropriate use of antimicrobial agents" and asking member states to "develop and implement national strategies or action plans for countering AMR." According to the perspective document, which underlined the need for "an active holistic approach" to combating AMR, "some practices in human and in animal healthcare including the possible incentives deriving from the prescription and subsequent sale of antimicrobial agents may lead to inappropriate use and overuse of antimicrobial agents." In particular, the Council has advocated restrictions on both the human and veterinary use of critically important microbials (CIAs) and newly developed microbials "with the aim in the future to reserve CIAs as much as possible for human use."

To this end, the Council has requested that member states curb the prophylactic use of all antimicrobials while limiting CIAs to cases "where no other type of antibiotics will be effective." It has also recommended, among other things, that member states (i) implement national guidelines "on the treatment of humans and animals with antimicrobial agents"; (ii) crack down on illegal sales of antimicrobials, "including illegal sales over the Internet"; (iii) limit the use of antimicrobials in the herd treatment of animals to cases where a veterinarian has assessed that there is a clear clinical justification to treat all animals; and (iv) collect data on the "sale and use of antimicrobials in animals."

Meanwhile, the Council has urged the European Commission to not only cooperate with member states on these goals but to expand the existing food and veterinary working group on AMR and to implement several "concrete initiatives" designed to address the use of antibiotic veterinary products such as medicated feed. "AMR is a growing European and global health problem in both humans and animals, leading to limited or poor options for treatment whilst diminishing the quality of life and to important economic consequences in terms of augmenting healthcare costs and productivity losses," stressed the Council, which has called for international cooperation,

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additional surveillance and increased public awareness as to "the importance of effective preventive and hygienic measures" to reduce the overall need for antibiotics.

### European Commission to Enforce Rules on Laying Hen Cages

The European Commission has apparently sent "a reasoned opinion" to 10 member states "that have failed to correctly implement Directive 1994/74EC which introduces a ban on the use of un-enriched cages for laying hens," according to a June 21, 2012, EU press release. The Commission has given Belgium, Greece, Spain, France, Italy, Cyprus, Hungary, the Netherlands, Poland, and Portugal two months to ensure compliance with the directive before referral to the EU Court of Justice. These countries apparently still permit the use of "un-enriched cages" for laying hens "despite the ban which came into force in January 2012 for which they have had 12 years to prepare."

Under the directive, "all laying hens must be kept in 'enriched cages' with extra space to nest, scratch and roost," or in systems with at least 750 square centimeters of cage area as well as "a nest-box, litter, perches and claw-shortening devices, allowing the hens to satisfy their biological and behavioral needs." As the Commission argued, however, member states that have failed to enforce these rules despite repeated warnings have put businesses that invested in the new infrastructure at a competitive disadvantage. "To demonstrate compliance, member states will need to show that all those establishments still using un-enriched cages, have either been transformed or closed," concluded the Commission.

### Indian Food Safety Authority to Regulate Energy Drinks

After two years of deliberation, the Food Safety and Standards Authority of India (FSSAI) has reportedly agreed to issue draft regulations that would require energy drink manufacturers to rebrand their products as "caffeinated beverages." Based on the findings of an expert panel convened to study caffeine and energy drink consumption in India, the draft regulations would apparently set an upper caffeine limit of 320 milligrams per liter or 320 parts per million (ppm) in caffeinated beverages, as well as prohibit any nutritive claims and the use of the word "energy" as a descriptor. FSSAI has also proposed that all energy drinks bear safety labels warning that such products (i) are "not recommended for children, pregnant or lactating women, persons sensitive to caffeine and sportspersons," (ii) should not be consumed in excess of two cans per day, and (iii) contain a "high caffeine content."

"We had been considering the standards for some time now. These drinks will have to put the label defining the limit and the warnings. The aim was to regulate the limit. The draft standards have now been sent to the health ministry for their notification," FSSAI Chair Sh. K. Chandramouli was quoted as saying. See *The Daily Mail*, June 24, 2012; *Decan Chronicle*, June 29, 2012.

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### OEHHA Proposes Maximum Allowable Dose Level for Sulfur Dioxide in Dried Fruits

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) is seeking public comments on its [proposal](#) to establish a Proposition 65 maximum allowable dose level for sulfur dioxide of 220 micrograms per day. Comments should be submitted by August 20, 2012. Requests for a public hearing must be made no later than August 6.

Sulfur dioxide preserves the color and flavor of dried, light-colored fruits, such as golden raisins and dried apricots, peaches, apples, pineapple, papaya, and mango, and acts as an antimicrobial agent. According to OEHHA's draft interpretive guideline, a warning for exposure to sulfur dioxide from consumption of dried fruit is not required under Proposition 65 because reasonably anticipated rates of exposure "will be below the proposed Maximum Allowable Dose Level." Sulfur dioxide was added to the list of chemicals known to the state to cause reproductive toxicity in July 2011; the particular type of toxicity found was "intrauterine growth restriction." See *OEHHA News Release*, June 29, 2012.

## LITIGATION

### Neither Wrigley nor Cadbury Infringed the Other's Menthol Chewing Gum Patent

The Federal Circuit Court of Appeals, in a divided ruling, has determined that Wrigley's 2000 patent for menthol chewing gum was invalid because prior patents made Wrigley's claimed invention obvious; thus, the court determined that Cadbury did not infringe Wrigley's patent when it reformulated its chewing gum to include the compound claimed in Wrigley's patent. [Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC, Nos. 2011-1140, -1150 \(Fed. Cir., decided June 22, 2012\)](#). The court also determined that Wrigley did not infringe Cadbury's 1989 patent for menthol chewing gum because the compound used by Wrigley is not the equivalent of the compound described in Cadbury's patent.

A dissenting judge argued that the majority applied the incorrect legal standard and improperly shifted the burden of proving the validity of Wrigley's patent to Wrigley and erred in how it assessed the evidence of commercial success and copying by others in its determination of obviousness. According to the dissenter, substantial evidence, "much of it from Cadbury's records," showed that the compound used by Wrigley produced superior results and was a commercial success that Cadbury then copied to reverse its loss of sales to the new Wrigley gum. Insisting that these "secondary indicia of nonobviousness must be considered in deciding whether a prima facie case of

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obviousness has been presented," the dissenting judge would have concluded that Wrigley's patent was not obvious and thus valid.

### NRDC Seeks FDA Documents Assessing Risks of Antibiotics in Livestock Production

The Natural Resources Defense Council (NRDC) has filed a lawsuit against the Food and Drug Administration (FDA) and the Center for Veterinary Medicine (CVM) alleging that they have failed, in response to a Freedom of Information Act (FOIA) request, to produce documents pertaining to risk assessments for antibiotics used in livestock production. *NRDC v. FDA*, No. 1:12-cv-4757 (U.S. Dist. Ct., S.D.N.Y., filed June 18, 2012).

Seeking a declaration that the defendants violated FOIA and an order that they disclose "all responsive, non-exempt records to plaintiff within fifteen days," NRDC refers to industry guidance that FDA issued in 2003 on "assessing the safety of antimicrobial new animal drugs with regard to the microbiological effects on bacteria of human health concern" and actions the defendants have taken since then relying on the guidance.

After FDA acknowledged in a December 2011 *Federal Register* notice that it had begun "to look at the safety of some . . . already approved drugs" due to the "antimicrobial resistance risks associated with their use," NRDC filed a FOIA request for "the results of any qualitative microbial food safety risk assessments of specific animal drug products that CVM has conducted since 2003" and all communications relating to these risk assessments. NRDC contends that FDA and CVM were required to respond to the request by June 8, 2012.

### Kraft Calls Wheat Thins® Labeling Challenge a "Lawyer-Concocted Class Action"

Kraft Foods and its subsidiary have asked a federal court in California to dismiss claims that they mislead consumers by labeling Wheat Thins® crackers as "100% whole grain," contending that the theory of the case does not meet the plausibility pleading standard and the state law-based claims are preempted under federal law. *Garcia v. Nabisco, Inc.*, No. 2:12-cv-04272 (U.S. Dist. Ct., C.D. Cal., motion filed June 22, 2012). According to the defendants' motion, this is nothing but a "lawyer-concocted class action lawsuit" and reasonable consumers understand that the "100% whole grain" representation "merely indicates that the only type of *grain* used in the crackers is 'whole grain' as opposed to non-whole grains used in enriched flours," not that the crackers contain nothing but whole grains. "Common sense dictates that processed crackers are not made with *only* a stalk of whole grain and that they are made with the help of processing agents, baking aids, and seasonings." In any event, say the defendants, all of the ingredients appear on the packaging ingredient list "in accordance with federal law."

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### Whole Foods Claims Lack of Control over Retail Stores in Motion to Quash *Skinny Girls* Subpoena

According to a news source, Whole Foods Market Inc. is seeking to stop its deposition in consumer fraud litigation filed against Skinny Girl Cocktails LLC, arguing that it does not own or operate Whole Foods retail stores nor does it “decide which suppliers, food brokers or distributors are to be used by Whole Foods Market retail locations.” *Greene v. Skinny Girl Cocktails LLC*, 1:12-mc-00550 (U.S. Dist. Ct., W.D. Tex., motion to quash filed June 22, 2012). A number of putative class actions alleging that the defendants falsely market margaritas as “all natural” were filed in district courts around the country after Whole Foods stores pulled the product from their shelves upon learning that it contains sodium benzoate as a preservative. An effort to have the actions consolidated before a multidistrict litigation court failed; additional details about that ruling appear in [Issue 422](#) of this *Update*. See *Law360*, June 25, 2012.

### Wajert Published in *Law360* on Legal Duties for Makers of Caffeinated Alcoholic Beverages

SHB Partner [Sean Wajert](#) has authored an article on the failure of a duty-to-warn claim in a case involving a caffeinated alcoholic beverage and a fatal motorcycle accident. Titled “No Duty to Warn for ‘Nonconventional’ Alcohol Beverages,” the article appeared in the June 27, 2012, issue of *Law360*. Wajert discusses the court’s dismissal of such claims in *Cook v. MillerCoors LLC*, and explains why “the court was reluctant to make an exception to the rule” that “the dangers inherent in alcohol consumption are well-known to the public.” With “hundreds of alcohol-containing products that are not ‘conventional’ in one way or another, by taste, ingredients, color, manufacturing process, advertising . . . To shift responsibility from the person who over-consumes one of these and then drives impaired is to send the absolutely wrong policy message.” To read the article, please click [here](#).

## OTHER DEVELOPMENTS

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### Rudd Center Publishes Report on Cereal Marketing to Children

Yale University’s Rudd Center for Food Policy and Obesity has issued a [report](#) claiming that cereal companies “have improved the nutritional quality of most cereals marketed directly to children, but they have also increased advertising to children for many of their least nutritious products.” Titled *Cereal F.A.C.T.S. Food Advertising to Children and Teens Score*, the report analyzes the nutritional quality of more than 100 brands and nearly 300 individual varieties of cereal marketed to children, families and adults while examining industry advertising on TV, the Internet and social media sites.

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According to the report, while nutritional quality improved for 22 cereal brands advertised to children in both 2008 and 2011, total media spending to promote child-targeted cereals increased by 34 percent during that same time period. Among its findings, the report concludes that (i) "Children viewed fewer TV ads for 7 of 14 child-targeted brands, including Corn Pops and Honeycomb"; (ii) "Children viewed more TV ads for the remaining seven child-targeted brands, including Reese's Puffs, Froot Loops, and Pebbles"; (iii) "Post launched a new Pebbles advergaming website, and General Mills launched new sites for Honey Nut Cheerios and Cinnamon Toast Crunch"; (iv) "Kellogg nearly doubled banner advertising on children's websites, such as Nickelodeon.com and Neopets.com, for its child-targeted brands. General Mills also increased banner advertising for four child-targeted brands, including Honey Nut Cheerios and Lucky Charms"; and (v) "Kellogg introduced the first food company advergaming for mobile phones and tablets targeted to children for Apple Jacks."

The study concluded that even though companies "offer more nutritious and lower-sugar cereals for children, like regular Cheerios and Frosted Mini-Wheats," those cereals are marketed to parents, not children. "While cereal companies have made small improvements to the nutrition of their child-targeted cereals, these cereals are still far worse than the products they market to adults," said co-author Marlene Schwartz. "They have 56 percent more sugar, half as much fiber, and 50 percent more sodium. The companies know how to make a range of good-tasting cereals that aren't loaded with sugar and salt. Why can't they help parents out and market these directly to children instead?" See *Yale News*, June 22, 2012.

### WTO to Field Dispute over India's Restrictions on U.S. Poultry

The World Trade Organization (WTO) recently agreed to convene a [dispute settlement](#) panel to investigate India's restrictions on the importation of U.S. poultry, eggs and other agriculture products purportedly due to concerns over avian influenza. The U.S. Trade Representative (USTR) apparently requested the panel after failing to resolve the dispute during an April 16-17, 2012, consultation with the Indian government, which has restricted the importation of various agricultural products from "those countries reporting Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza)." According to USTR, however, these restrictions violate several provisions of the Sanitary and Phytosanitary Measures Agreement as well as the General Agreement on Tariffs and Trade 1994, in part "because India's avian influenza measures are not applied only to the extent necessary to protect human or animal life or health, are not based upon scientific principles, and are maintained without sufficient scientific evidence." As a result, the trade delegation has argued that India's measures "appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements."

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Meanwhile, the National Chicken Council, National Turkey Federation and USA Poultry & Egg Export Council have estimated that the elimination of these trade barriers would net the industry an additional \$300 million annually in product exports. “Unfortunately, the government of India did not lift its unwarranted restrictions on U.S. poultry after consultations with the United States at the WTO in Geneva,” the groups said in a May 11, 2012, press release praising the complaint. “However, we are pleased that USTR is taking the next step. We support the dispute settlement process moving forward as soon as possible with the formation of this panel.”

### Law Blogger Focuses on Vegetable References in Health-Care Reform Ruling

Cornell Law School Professor Michael Dorf has observed in his blog that each of the three main opinions in the U.S. Supreme Court’s ruling on the “Affordable Care Act” “discussed the consumption of vegetables.” In his opinion upholding much of the law as a valid exercise of congressional authority, Chief Justice John Roberts stated “[M]any American do not eat a balanced diet. That group makes up a larger percentage of the total population than those without health insurance. The failure of that group to have a healthy diet increases health care costs, to a greater extent than the failure of the uninsured to purchase insurance. . . . Congress addressed the insurance problem by ordering everyone to buy insurance. Under the Government’s theory, Congress could address the diet problem by ordering everyone to buy vegetables.”

Justice Ruth Bader Ginsburg apparently responded in her dissenting and concurring opinion that the concept of Congress imposing a “vegetarian state” by prohibiting “the purchase and home production of all meat, fish, and dairy goods, effectively compelling Americans to eat only vegetables,” is a “hypothetical and unreal possibility.” According to Dorf, who is a vegetarian, the U.S. Supreme Court has thus expressly described the failure to eat plant-based foods as unhealthy eating that “imposes greater costs on our health care system than the enormous costs imposed by people going uninsured,” to which he says “Amen brother Roberts.” See *Dorf on Law*, June 28, 2012.

### UK Lobby Group Calls for Ban on Caramel-Coloring Ingredient

The United Kingdom’s (UK’s) Children’s Food Campaign (CFC) has reportedly urged the Ministry of Health to prohibit use of the chemical 4-Methylimidazole (4-MEI), a byproduct of fermentation often found in soy sauce, roasted coffee and the caramel coloring added to colas and beer. In January 2012, California EPA’s Office of Environmental Health Hazard Assessment adopted a no significant risk level for 4-MEI, with Proposition 65 cancer warnings unnecessary for exposures at or below 29 micrograms per day. The development was covered in [Issue 424](#) of this *Update*.

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According to news sources, CFC's effort was prompted by test results indicating that colas sold in Britain contain 135 micrograms of 4-MEI per can. Malcolm Clark, CFC campaign coordinator, asserts that only caramel colorings "free of known cancer-causing chemicals" should be used worldwide. See *Daily Mail*, June 25, 2012.

### SCIENTIFIC/TECHNICAL ITEMS

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#### *PLoS Medicine* Continues "Big Food" Series

This week's issue of *PLoS Medicine* includes an [article](#) in its "Big Food" series titled "Manufacturing Epidemics: The Role of Global Producers in Increased Consumption of Unhealthy Commodities Including Processed Foods, Alcohol, and Tobacco." According to the authors, "market data on commodity sales from EuroMonitor Passport Global Market Information database 2011 edition" show a "significant penetration by multinational processed food manufacturers such as Nestle, Kraft, PepsiCo, and Danone into food environments" in low- and middle-income countries. They suggest that this penetration coincides with a growth in the consumption of unhealthy commodities that is reaching and even exceeding "a level presently observed" in high-income countries.

Comparing data on global trends in tobacco and alcohol commodities, the authors claim that "population consumption of unhealthy *non-food* commodities such as tobacco and alcohol are strongly correlated with unhealthy food commodity consumption. In other words, in countries where there are high rates of tobacco and alcohol consumption, there is also a high intake of snacks, soft drinks, processed foods, and other unhealthy food commodities. The correlations of these products with unhealthy foods suggest they share underlying risks associated with the market and regulatory environment."

According to the authors, their research shows that "[s]ubstantial increases in consumption of unhealthy commodities are not an inevitable consequence of economic growth"; they also purportedly "found some evidence that free-trade agreements with the US are linked to greater consumption of soft drinks, even after correcting for the trading partner's level of income per capita. Free-trade agreements typically limit trade and market restrictions on imports of unhealthy commodities and such non-tariff measures as licensing, quotas, prohibitions, bans, and other restrictions having equivalent effect."

The article observes that regulatory interventions, such as increased prices for "non-healthy" commodities and limitations on the "availability of unhealthy products are among the most effective and low-cost strategies for preventing their consumption." The authors call for further studies "to test current and prior population-level experiments of trade and capital market integration,



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the spread of unhealthy commodities, and their links to adverse [noncommunicable disease] outcomes." See *PLoS Medicine*, June 26, 2012.

### Low-Glycemic, Low-Carb Diets Allegedly Burn More Calories Than Low-Fat Regimes

A recent study analyzing the effects of three weight-loss maintenance diets has purportedly concluded that subjects who adhered to either a low-glycemic or very low-carbohydrate diet burned more calories than those on low-fat diets. Cara Ebbeling, et al., "Effects of Dietary Composition on Energy Expenditure During Weight-Loss Maintenance," *Journal of the American Medical Association*, June 2012. According to a June 26, 2012, Boston Children's Hospital press release, researchers analyzed data on total energy expenditure from 21 adult participants who first lost 10 to 15 percent of their body weight and then completed each of the following three diets in random order for four weeks at a time: (i) a low-fat diet comprising "60 percent of daily calories from carbohydrates, 20 percent from fat and 20 percent from protein"; (ii) a low-glycemic-index diet comprising "40 percent of daily calories from carbohydrates, 40 percent from fat and 20 percent from protein"; and (iii) a low-carbohydrate diet comprising "10 percent of daily calories from carbohydrates, 60 percent from fat and 30 percent from protein."

The results evidently showed that the very low-carbohydrate diet produced "the greatest improvements in metabolism" but also increased participants' C-reactive protein and cortisol levels, "which can lead to insulin resistance and cardiovascular disease." By comparison the low-fat diet reportedly "caused the greatest decrease in energy expenditure, an unhealthy lipid pattern and insulin resistance," whereas the low-glycemic-index diet appeared to have "qualitatively similar, although smaller, metabolic benefits to the very low-carbohydrate diet, possibly without the deleterious effects."

"In addition to the benefits noted in this study, we believe that low-glycemic-index diets are easier to stick to on a day-to-day basis, compared to low-carb and low-fat diets, which many people find limiting," said one of the study's authors. "Unlike low-fat and very-low carbohydrate diets, a low-glycemic-index diet doesn't eliminate entire classes of food, likely making it easier to follow and more sustainable."

### New Study Claims BPA Exposure Lasts for Generations

A recent study has reportedly claimed that the first generation of mouse offspring exposed to bisphenol A (BPA) before birth "displayed fewer social interactions as compared with control mice, whereas in later generations... the effect of BPA was to increase these social interactions." Jennifer Wolstenholme, et al., "Gestational Exposure to Bisphenol A Produces Trans-generational Changes in Behaviors and Gene Expression," *Endocrinology*,

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June 2012. After feeding BPA-laced chow to female mice during mating and pregnancy, researchers evidently noted that the brains of embryos exposed to BPA “had lower gene transcript levels for several estrogen receptors, oxytocin, and vasopressin as compared with controls,” with decreased vasopressin mRNA persisting into the fourth generation, “at which time oxytocin was also reduced but only in males.”

According to the authors, their results “demonstrated for the first time... that a common and widespread EDC [endocrine-disrupting chemical] has trans-generational actions on social behavior and neural expression of at least the genes for vasopressin and oxytocin. Because exposure to BPA changes social interactions at a dose within the reported human levels, it is possible that this compound has transgenerational actions on human behavior.”

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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.

