ISSUE 426 | FEBRUARY 10, 2012

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Federal Lawmakers Introduce Bill to Limit Arsenic, Lead in Fruit Juice

U.S. Representatives Frank Pallone Jr. (D-N.J.) and Rosa DeLauro (D-Conn.) have proposed **legislation** (H.R. 3984) that would require the Food and Drug Administration (FDA) to establish standards for arsenic and lead in fruit juices within two years. Titled the "Arsenic Prevention and Protection from Lead Exposure in Juice Act of 2012," or the "APPLE Juice Act of 2012," the proposal is designed to "protect children from harmful health effects of significant juice consumption," the lawmakers said in a joint press release.

Calling for lead and arsenic to be as strictly regulated in juice as they are in bottled water, the lawmakers said the bill came in response to a *Consumer Reports* investigation revealing "alarmingly high levels" of the toxins in apple and grape juice in New Jersey, New York and Connecticut. "We must ensure that the juices our children drink are safe, particularly when 70 percent of the apple juice we consume comes from China," DeLauro said.

In November 2011, FDA announced that it was evaluating current allowable levels of inorganic arsenic in apple juice in response to consumer groups' demands for tighter restrictions. Details about this and related matters were featured in **Issue 419** of this *Update*. *See Press Release of Representatives Pallone and DeLauro*, February 8, 2012.

House Legislation Would Prohibit Taxpayer-Funded "Attack Ads" on Food, Beverage Companies

U.S. Representative Scott DesJarlais (D-Tenn.) has introduced a **bill** (H.R. 3848) that would prohibit federal money from being used in any advertising campaign "against the use of a food or beverage that is lawfully marketed under the Federal Food, Drug, and Cosmetic Act." DesJarlais told a news source that the legislation, titled the "Protecting Foods and Beverages from Government Attack Act of 2012," responds to New York City's recent anti-obesity ad campaign featuring a poster of a diabetic man with an amputated leg with the tagline, "Cut Your Portions, Cut Your Risk." DesJarlais claims the

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campaign encouraging subway riders to reduce their portions of food and sugary drinks was funded with federal stimulus money targeted for anti-obesity efforts.

"Our top priority should be restarting the economy and creating jobs—not funding scare campaigns against perfectly safe and legal products," he said in a press release. "At a time when our nation faces high unemployment, it makes absolutely no sense that federal and city agencies would aggressively advertise against American products made by American workers." *See Press Release of Representative Scott DesJarlais,* February 1, 2012; *FoxNews.com*, February 3, 2012.

Consumer Advocacy Groups Ask FDA to Review GE Salmon Under Food Additive Rules

Three consumer advocacy organizations have filed a **petition** with the Office of Food Additive Safety of the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition requesting that ABT Technologies' application to approve genetically engineered (GE) salmon be reviewed under the food additive provisions of the Food, Drug, and Cosmetic Act. The company's new animal drug application for the GE salmon is currently pending before the agency's Center for Veterinary Medicine.

According to Food & Water Watch, Consumers Union and the Center for Food Safety, the company's GE process "significantly alters the salmon's composition . . . in a way that is reasonably expected to alter its nutritive value or concentration of constituents, and the new substance raises safety concerns. Under the Agency's regulations and guidelines, such a substance must be treated as a food additive and the Agency must make a closer inquiry into the safety of its consumption, including, but not limited to, subjecting it to extensive pre-market testing."

The petitioners also ask the office to (i) review the gene expression product (GEP) of the recombinant DNA construct of the GE salmon as a food additive, (ii) render the GEP "an added substance under the Act's adulteration provisions," and (iii) find that neither the GE salmon nor the GEP used to create it are generally recognized as safe for human consumption. They claim that FDA "[m]ust find that the GEP is an added substance because it is a hormone removed from Chinook salmon meant to increase the speed at which Atlantic salmon grows to maturity. It is artificially added to Atlantic salmon." To support their argument, the petitioners describe in detail how the salmon has been created and provide an overview of FDA's food additive regulations. They also contend that the food additive review is the only way to bring the agency's safety analysis into compliance with Codex Alimentarius Commission guidelines and that the company "did not provide adequate or well-controlled studies."

NOP Addresses Synthetic Methionine Use in Organic Poultry

The U.S. Department of Agriculture's National Organic Program (NOP) has **issued** a proposed rule that would regulate the use of synthetic methionine in organic poultry production after a current interim final rule expires on October 1, 2012.

According to a February 6, 2012, *Federal Register* notice, the rule would amend the National List of Allowed and Prohibited Substances (National List) to permit the following maximum levels of synthetic methionine per ton of feed: (i) two pounds for laying and broiler chickens; and (ii) three pounds for turkey and all other poultry. NOP has requested public comments on the proposed rule by April 6.

The National List currently classifies methionine "as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability." The substance occurs naturally in feed sources that include blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal, but can also be produced synthetically as "a colorless white crystalline powder that is soluble in water." If adopted in 2012, the amended methionine listing would require a sunset review by the National Organic Standards Board by 2017.

CDC Report Says 90 Percent of Americans Consume Too Much Sodium

The Centers for Disease Control and Prevention (CDC) has dedicated its February 2012 issue of ***Vital Signs*** to reducing population salt intake, claiming that nine out of 10 Americans ages 2 years or older consume more sodium than recommended for a healthy diet. Noting that too much dietary sodium can result in high blood pressure leading to an increased risk of heart disease and stroke, CDC reports that the average adult consumes approximately 3,300 milligrams daily, some 1,000 mg more than the recommended amount for adults.

According to *Vital Signs*, approximately 65 percent of dietary sodium comes from processed foods bought in retail stores and approximately 25 percent from foods prepared in restaurants. More than 40 percent is reportedly linked to "breads and rolls, cold cuts and cured meats such as deli or packaged ham or turkey, pizza, fresh and processed poultry, soups, sandwiches such as cheese-burgers, cheese, pasta dishes [not including macaroni and cheese, which is its own category], meat mixed dishes such as meat loaf with tomato sauce, and snacks such as chips, pretzels, and popcorn." Observing that different brands of the same foods may have different sodium levels, the report calls for food producers and restaurants to offer more low-sodium options.

Codex Meeting to Target Food Contaminants

The U.S Department of Agriculture's Food Safety and Inspection Service, the Food and Drug Administration and the U.S. Department of Health and Human Services have **announced** a February 23, 2012, public meeting in College Park, Maryland, to provide information and receive public comments on draft U.S. positions to be discussed at the 6th Session of the Codex Committee on Contaminants in Food (CCCF) on March 26-30 in Maastricht, The Netherlands. CCCF is responsible for establishing or endorsing maximum levels "for contaminants and naturally occurring toxicants in food and feed." Agenda items will include draft maximum levels for melamine in liquid infant formula, arsenic in rice, and deoxynivalenol and its acetylated derivatives in cereals and cereal-based products. *See Federal Register*, February 3, 2012.

OEHHA Considers Adding Flavorings to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **proposed** adding two food and beverage flavorings, as well as a fungicide and an herbicide contaminant to the list of chemicals known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65).Comments are requested by April 10, 2012.

The chemicals are beta-Myrcene and Pulegone, which are components of certain essential oils used to flavor foods and beverages and also used as a fragrance in cosmetics, soaps, detergents, and herbal medicines, and Isopyrazam, a fungicide used in Central and South America on bananas, and 3,3′,4,4′-Tetrachloroazo-benzene, a contaminant and degradation product of certain herbicides. OEHHA has proposed the action under the authoritative bodies listing mechanism, citing the National Toxicology Program and the U.S. Environmental Protection Agency as institutions that have found the chemicals to be carcinogens or "likely to be carcinogenic."

LITIGATION

Class Certification Denied in Energy Beverage Litigation

A federal court in California has denied a motion for class certification filed by a plaintiff who alleged that Vital Pharmaceuticals, Inc. misled consumers by claiming their energy drinks, marketed under the brand name Redline®, were safe and effective for enhancing energy and promoting weight loss. *Aaronson v. Vital Pharms., Inc.*, No. 09-1333 (U.S. Dist. Ct., S.D. Cal., decided February 3, 2012). The plaintiff allegedly became shaky and his heart raced when he consumed the product, so he claimed that the company failed to adequately inform consumers about its risks.

According to the court, the plaintiff failed to establish typicality, adequacy of representation and predominance. As to typicality, he apparently admitted that he never read the product's warning labels, thus subjecting him to "unique defenses that are not applicable to the class members who read the labels." As to adequacy of representation, the court found, "The record confirms that Aaronson and/or his counsel have consistently failed to follow court orders, abide by court deadlines, and vigorously litigate the case." The court also noted that some of his "moving papers venture off into a half-coherent and irrelevant discussion." And common issues do not predominate, said the court, given that Aaronson alleged "a number of misrepresentations related to the drink's safety, energy-boosting effects, and weight-loss benefits. As a result, different class members may have relied on different representations in purchasing the product."

Seafood Company Sentenced to $1 Million in Fines and Community Service Payments

A California-based seafood company has reportedly been sentenced in federal court for knowingly selling mislabeled frozen fish fillets. *United States v. Seafood Solutions, Inc.*, No. 11-00297 (U.S. Dist. Ct., C.D. Cal., sentencing February 6, 2012). Seafood Solutions, Inc. agreed to plead guilty to the charge in July 2011, as part of a federal investigation into companies that had been selling Asian catfish imports under other labels to avoid anti-dumping duties. Under the terms of the agreement, the company was fined $700,000 and will pay an additional $300,000 to the National Fish and Wildlife Foundation. Two California men also pleaded guilty in connection with the scam and are apparently scheduled for sentencing on February 12, 2012. *See Law360*, February 7, 2012.

NRDC Seeks Documents Pertaining to GM Deregulation

The Natural Resources Defense Council (NRDC) has filed a complaint in a New York federal court seeking an order that would require the U.S. Department of Agriculture (USDA) to respond to the organization's request under the Freedom of Information Act (FOIA) for documents on "the agency's proposed deregulation of herbicide-resistant crops." *NRDC v. USDA*, No. 12-0795 (U.S. Dist. Ct., S.D.N.Y., filed February 6, 2012). According to the complaint, USDA "is currently considering petitions to deregulate several herbicide-resistant varieties of corn and soybeans, which, if granted, would significantly increase usage of the herbicides to which those genetically modified [GM] crops are resistant."

NRDC apparently submitted a FOIA request to USDA in October 2011, seeking records concerning the proposed agency action, as well as a "fee waiver on the grounds that disclosure of the requested information is in the public interest." The deadline for a response, according to NRDC, was November 15, but USDA has not yet allegedly responded nor has it made a determination

on the fee waiver request. The organization seeks a declaration that USDA has violated FOIA, an injunction ordering USDA to provide the requested records, the grant of its request for a fee waiver, and an award of costs and attorney's fees.

UK Group Files Complaints About Online Ads Targeting Kids

A U.K.-based public interest charity has filed 54 separate complaints with the Advertising Standards Authority (ASA) contending that the subject companies, including Cadbury and Pringle's, are promoting food products high in sugars, fat or salt to children online. Described by the Children's Food Campaign (CFC) as a "super complaint," the case reflects the findings of a **report** the charity released in December 2011 claiming that food advertisers use brand characters, animations, games, competitions, and videos online and through social media to heavily market junk food to children. It calls for the U.K. government to close a loophole allowing ads for products that cannot be aired during children's programming to be freely promoted online.

According to CFC spokesperson Malcolm Clark, youth marketing standards applicable to TV should be matched online. The existing code apparently states, "marketing communications must not condone or encourage poor nutritional habits or an unhealthy lifestyle in children."

When CFC corresponded with Minister for Culture, Communications and Creative Industries Ed Vaizey about its report, he purportedly indicated that the ASA will take concerns over irresponsible food advertising seriously and that the advertising industry body, established to apply voluntary codes of practice and avoid regulation, encourages complaints when advertising rules are believed to have been broken. CFC hopes to force the oversight body to define vague terms in its standards. *See Sustainweb.org, Foodnavigator.com, The Telegraph, Channel 4 News*, February 9, 2012.

Plaintiff's Counsel Seeking Plaintiffs for Potential Action Against Gerber over Marketing Claims

A California-based attorney is apparently considering filing a class action lawsuit against Gerber on behalf of consumers purportedly misled by the company's promotions for its baby food products. According to Ronald Marron, "Gerber claims that NutriProtect™ is 'Nutrition for Healthy Growth & Natural Immune Support.' But a close review of the ingredients, in tiny letters on the back, reveals that NutriProtect™ advertising is deceptive, leading parents to believe the Products are healthier and more nutritious than they actually are." Marron claims that some of the products "contain high amounts of sugar, salt, and high fructose corn syrup." He also indicates that Gerber is adding substances such as DHA to its products at a price premium, when parents could simply add a few drops of tuna oil to their baby's food to obtain the same purported health effects. Also cited as a questionable practice is the company's addition of prebiotics and probiotics to baby food. *See Topclassactions.com*, February 7, 2012.

LEGAL LITERATURE

Article Explores Intersection of Junk Food Ads Targeting Children and First Amendment

In an article supported, in part, by the Robert Wood Johnson Foundation, authors Jennifer Harris and Samantha Graff suggest that the findings of psychological research about the subliminal effects of food advertising on young people should be considered when advertisers defend their practices by invoking the First Amendment's commercial speech doctrine. Harris, who is affiliated with Yale University's Rudd Center for Food Policy, and Graff, with Public Health Law & Policy in Oakland, California, contend that U.S. Supreme Court First Amendment jurisprudence is premised on the understanding that consumers use the free flow of commercial information to make logical decisions. "The commercial speech doctrine is built on a rational choice theory of behavior," they claim.

But because advertisers often resort to newer forms of advertising using "implicit messages" intended to "covertly" influence behavior and because young people are purportedly unable to resist food advertising or consider the content rationally, the authors contend, "[i]t is difficult to understand why advertising designed to persuade without consumers' awareness or developed to appeal to young people's unique vulnerabilities should be afforded commercial speech protection." They call for policymakers "at all levels of government [to] consider testing the limits of the current, inadequate body of First Amendment case law and advancing a constitutional interpretation that accords with scientific reality."

The article, titled "Protecting Young People from Junk Food Advertising: Implications of Psychological Research for First Amendment Law," also observes that (i) "state and local governments have many options to regulate locally based food sales and promotion," (ii) "[t]hey also have significant flexibility under the First Amendment to limit advertising in schools," and (iii) "state and local government attorney's offices could file lawsuits alleging that techniques used by food advertisers violate state consumer protection laws." *See American Journal of Public Health*, February 2012.

OTHER DEVELOPMENTS

ISAAA Reports 2011 Growth in GM Crop Acreage

The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) has **released** its annual report on the global status of genetically modified (GM) crops, claiming that in 2011 "a record of 16.7 million farmers, up 1.3 million or 8 percent from 2010, grew biotech crops." According to ISAAA, these gains reflected increased plantings by developing countries, which apparently grew "close to 50 percent" of all global biotech crops, and among "small resource-poor farmers," who constituted 90 percent or 15 million of those planting GM crops.

"Developing countries… for the first time are expected to exceed industrial countries hectarage in 2012," notes the report. "[T]his is contrary to the prediction of critics who, prior to the commercialization of the technology in 1996, prematurely declared that biotech crops were only for industrial countries and would never be accepted and adopted by developing countries."

Meanwhile, Food & Water Watch (FWW) Europe has issued a February 2012 **issue brief** contesting the report's methodology and accusing ISSAA of inflating its statistics " to 'demonstrate' the alleged popularity of GM crops." In particular, FWW Europe's executive director, Wenonah Hauter, took issue with the report's decision to rely on "trait acres" that count one acre of crop "with six stacked GM traits in it" as "6 hectares of GM." As she opined in a February 7 press statement, "Our own analysis… reveals they derive their figures from reliance on biased data sources, overstating the benefits of GM for farmers and ignoring figures that don't support their preconceived pro-GM position…The only way the GM industry and their supporters can make GM look good is if they cook the books. The only way they can sell their product is in unlabeled packages so consumers don't know where it is. This smacks of desperation, not success."

CSPI to Present "Sugary Drinks Summit" in June 2012

The Center for Science in the Public Interest (CSPI) has **announced** "a national advocacy conference to motivate and strengthen national, state, and local initiatives, both public and private, to reduce sugary-drink consumption in the United States." Scheduled for June 7-8, 2012, in Washington, D.C., the meeting is apparently designed for "researchers, government officials, state and local legislators, health professionals, low-income and minority advocates, youth activists, consumer groups, faith-based organizations, health insurers, and business leaders" to "strategize to improve public health" and "add momentum to a growing public health movement."

SCIENTIFIC/TECHNICAL ITEMS

Meta-Analysis Allegedly Links Salt Intake to Increased Risk of Gastric Cancer

A meta-analysis of prospective studies has reportedly concluded that "dietary salt intake was directly associated with a risk of gastric cancer…, with progressively increasing risk across consumption levels." Lanfranco D'Elia, et al., "Habitual Salt Intake and Risk of Gastric Cancer: A Meta-analysis of Prospective Studies," *Clinical Nutrition,* January 2012. Researchers apparently conducted a pooled analysis using seven adult-population studies that provided data from 10 cohorts, as well as additional analyses on "the effect of salt-rich foods on the rate of gastric cancer." The meta-analysis overall involved information from dietary questionnaires completed by 268,718 participants from four countries.

According to researchers, their findings indicated "a graded positive association between salt consumption and incidence of gastric cancer," with "high" and "moderately high" salt intake associated with 68 percent and 41 percent "greater risk of gastric cancer, respectively, compared with 'low' salt consumption." In addition, the meta-analysis purportedly revealed "a statistically significant positive association between the consumption of selected salt-rich foods"—such as processed meat—"and rate of gastric cancer."

Noting that these results "do not conclusively prove a causal relationship between excessive salt intake and risk of gastric cancer," the study authors nevertheless highlighted decreased salt consumption "as a global priority for a highly cost-effective prevention of the epidemic of cardiovascular disease both in developed and developing countries." As a result, they concluded, "future research should focus on deeper evaluation of the mechanisms of the observed association and of its actual strength in non oriental populations."

Diet Soft Drinks Reportedly Associated with Increased Vascular Risk

A recent study has allegedly linked diet soft drink consumption with an increased risk of vascular events. Hannah Gardener, et al., "Diet Soft Drink Consumption Is Associated with an Increased Risk of Vascular Events in the Northern Manhattan Study," *Journal of General Internal Medicine,* February 2, 2012. Researchers evidently collected data from 2,564 adults in the Northern Manhattan Study for a mean follow-up of 10 years, controlling for a variety of factors such as age, race/ethnicity, smoking, BMI, and physical activity. Compared with those who did not consume diet soft drinks, participants who reported drinking diet soft drinks on a daily basis apparently exhibited "an increased risk of vascular events, and this persisted after controlling further for the metabolic syndrome, peripheral vascular disease, diabetes, cardiac disease, hypertension, and hypercholesterolemia."

The study authors noted, however, that many individuals "may consume diet soft drinks in an effort to reduce calories and sugar and lose weight to compensate for an underlying risk of vascular disease." Therefore, they emphasized the need for further research, including large prospective studies and randomized trials, to rule out "reverse confounding, or indication bias, such that people at increased risk of vascular events due to preexisting vascular conditions may be advised to switch from regular to diet soft drinks."

"Future studies in younger populations in which diet soft drink consumption is more prevalent are particularly important, as are studies examining the associations between all beverages, including other non-soft drink sugar-sweetened and diet beverages, and vascular events," the study concludes. "In addition, further study is needed on the potential mechanisms by which diet soft drinks may affect the risk of vascular events."

Researchers Allege "Modest Positive Association" Between Soda Consumption and Risk of Pancreatic Cancer

A recent pooled analysis from 14 prospective cohort studies has reportedly confirmed "a suggestive, modest positive association" between sugar-sweetened carbonated beverage (SSB) consumption and increased pancreatic cancer risk. Jeanine Genkinger, et al., "Coffee, Tea and Sugar-Sweetened Carbonated Soft Drink Intake and Pancreatic Cancer Risk: A Pooled Analysis of 14 Cohort Studies," *Cancer, Epidemiology, Biomarkers & Prevention,* February 2012. After examining data from 317,827 men and 536,066 women, the study purportedly found that (i) "coffee consumption was not associated with pancreatic cancer risk overall"; (ii) "no statistically significant association was observed between tea intake and pancreatic cancer"; and, (iii) for modest intakes of SSBs, "there was a suggestive and slightly positive association… which reached statistical significance in certain subgroups of participants (e.g., nondiabetics, nondrinkers of alcohol)." These results evidently confirmed one Japanese cohort study as well as the Singapore Chinese Health Study covered in **Issue 337** of this *Update*.

According to the February 2012 analysis, which noted having to compensate for the small number of cases "who consumed at least 355 g (~12 oz) of SSBs" per day, its findings were nevertheless "consistent with the idea that factors that raise insulin and glucose levels, and promote obesity and diabetes, such as SSBs, may be positively associated with pancreatic cancer risk, particularly in certain 'low risk' subgroups (e.g., normal weight, nondrinkers)… Thus, these results are in accordance with the WCRF/AICR [World Cancer Research Fund/ American Institute for Cancer Research] recommendation to limit consumption of SSBs."

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Researchers Find Titanium Nanoparticles in Food and Personal Care Products

U.S., Swiss and Norwegian researchers have analyzed an array of consumer products sold in the United States to determine how much titanium dioxide they contained by weight in a first-ever human exposure analysis and concluded that food sources likely account for most of the titanium nanoparticles released into the environment. Alex Weir, et al., "Titanium Dioxide Nanoparticles in Food and Personal Care Products," *Environmental Science & Technology*, February 8, 2012.

Noting that the substance is a common additive, the study showed that foods with the highest content of titanium dioxide (up to 360 mg per serving) are candies, sweets and chewing gum, and that personal care products, such as toothpaste and select sunscreens, can contain up to 10 percent titanium by weight. The research also showed that approximately 36 percent of the particles are nano-sized. The researchers conclude that children have the highest exposures due to their consumption of sweets and lower body weights. They also suggest that titanium dioxide's widespread use and disposal down the drain and eventually to wastewater treatment plants requires further study.

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