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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

CDC Reports First Cases of Highly Pathogenic Avian Influenza

According to the February 3, 2015, issue of the Centers for Disease Control and Prevention's (CDC's) *Morbidity and Mortality Weekly Report*, the U.S. Department of Agriculture has reported the first cases of highly pathogenic avian influenza A (HPAI) in wild or domestic birds found in the United States. Of the 14 recorded incidents, seven were associated with H5N2, six with H5N8 and one with H5N1. The detections occurred in the northwestern states of California, Idaho, Oregon, Utah, and Washington and involved five domestic "backyard" flocks, two captive wild birds and seven wild aquatic birds.

"Until more is known about these viruses, CDC is taking a cautious approach, and recommendations are largely consistent with guidance for influenza viruses associated with severe diseases in humans," notes CDC. "State health departments are encouraged to investigate all possible human infections with HPAI H5 virus and should notify CDC promptly when testing for influenza in persons with [influenza-like illness] who have been exposed to birds possibly infected with these viruses."

FDA Extends Closing Date for Food Advisory Committee Nominations

The Food and Drug Administration (FDA) has **extended** until February 27, 2015, the deadline for submitting materials related to (i) nominations for a non-voting industry representative to serve on the Food Advisory Committee and (ii) statements from organizations interested in participating in the selection process for the non-voting committee member.

The Food Advisory Committee evaluates data and makes recommendations on such matters as food ingredient safety, food and cosmetic labeling, nutritional issues, and exposure limits for food contaminants. *See Federal Register*, February 2, 2015.

FDA Extends Deadline for Comments on Expanding the Redbook

The U.S. Food and Drug Administration (FDA) has **extended** the deadline for public comments about 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." Comments may now be submitted until May 11, 2015. *See Federal Register*, February 2, 2015.

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com).

ICE and CDP Seize Chinese Honey Worth $2.45 Million

U.S. Immigration and Customs Enforcement (ICE) and Homeland Security Investigations and Customs and Border Protection (CBP) officers have reportedly confiscated since October 2014 about 450,000 pounds of honey produced in China but falsely declared to be from Latvia on import documents.

Chinese honey has been subject to a high import tax—currently 221 percent—since 2001, when the U.S. Department of Commerce found that Chinese producers were dumping honey on the market by selling it for lower than production costs. An assistant special agent in charge of Homeland Security Investigations in Houston reportedly identified the city as a "key point of entry" into the United States; in November 2013, agents there seized Chinese honey worth $4.2 million that was falsely labeled as Malaysian and Indian.

Chinese honey was also the subject of a 2002 U.S. Food and Drug Administration warning after concerns that it was adulterated with the antibiotic Chloramphenicol, which is not approved for use in the product. *See ICE News Release* and *Houston Chronicle*, January 28, 2015; *Modern Farmer*, February 3, 2015.

European Ombudsman Censures EFSA over Conflict of Interest Rules

The European Ombudsman has **issued** a January 28, 2015, decision directing the European Food Safety Authority (EFSA) to revise its conflict-of-interest rules after the agency "failed to ensure that those experts who work in academia declare all relevant information to EFSA." Stemming from a complaint filed by GeneWatch, the decision focused on an EFSA working group on genetically modified (GM) insects that included an academic expert whose employer has financial ties to a biotechnology company that "promotes genetically modified insects."

In particular, the European Ombudsman dismissed the agency's reasoning that "employment by a university has never been considered a conflict of interest at EFSA," as such a prohibition would disqualify the most qualified

individuals from working groups. The decision instead places the onus on EFSA to gather additional information about the nature of the university's financial relationships and the mechanisms in place "to prevent communication and instructions from the investment arm of the university influencing the academic arm."

"EFSA has an obligation to ensure that the outside experts who advise it are of the highest quality possible," states the decision. "It also has an obligation to ensure that these experts are, and are also seen to be, independent of any third party influence that might unduly affect their ability and willingness to give the best advice possible. The Ombudsman underlines that the independence of such advice, and the appearance of such independence in the eyes of EU citizens, are vital to building trust in the important work of EFSA."

LITIGATION

California to Appeal Federal Ruling Overturning Foie Gras Ban

The office of California Attorney General Kamala Harris will appeal the January 2015 decision overturning the state's ban on foie gras, according to a notice of appeal filed in California federal court. *Association des Éleveurs de Canards et d'Oies du Québec v. Harris*, No. 12-5735 (U.S. Dist. Ct., C.D. Cal., notice of appeal filed February 4, 2015).

The prohibition was found to impose "[m]arking, labeling, packaging, or ingredient requirements" that interfered with the free flow of poultry products in violation of the federal Poultry Products Inspection Act. The AG's 1-page notice of appeal cited no arguments supporting its challenge. Additional details about the district court decision appear in Issue **550** of this *Update*.

"Natural Source of Antioxidants" Not a Nutrient-Content Claim, Court Says

An Arkansas federal court has dismissed with prejudice a putative class action alleging that Twinings North America, Inc. mislabeled its tea by including the statement that the product is a "natural source of antioxidants" on its packaging. *Craig v. Twinings North Am., Inc.*, No. 14-5214 (U.S. Dist. Ct., W.D. Ark., Fayetteville Div., order entered February 5, 2015). The plaintiff had argued that under the Arkansas Food, Drug, and Cosmetic Act (AFDCA), an act identical to the food labeling regulations of the U.S. Food and Drug Administration (FDA), Twinings' tea failed to meet the nutrient level threshold—10 percent or more of the recommended daily intake—required for a claim about the nutrient content of a product.

Twinings argued that the Arkansas law claims were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) and could impose liability inconsistent with federal law. To assess the preemption argument, the court considered whether the statement "natural source of antioxidants" is a nutrient-content

claim within the purview of the statute. Express nutrient-content claims make direct statements about the level of a nutrient in the product—like a specific calorie amount—and implied claims describe a product "in a manner that suggests that a nutrient is absent or present in a certain amount (e.g. 'high in oat bran'); or suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an *explicit* claim or statement about a nutrient (e.g., 'healthy, contains 3 grams (g) of fat')," the court noted. The statement on Twinings' tea did not fall into either category, the court found.

Twinings also argued that tea and coffee are exempt from some FDA labeling requirements if they "contain insignificant amounts" of the nutrients and food components required to be detailed in the nutrition information as long as the product does not contain any nutrient-content claims. Finding no express or implicit nutrient-content claims, the court deemed the tea exempt from the labeling requirements.

Accordingly, the court determined that Twinings' label statement did not constitute misbranding, and "[e]ven if Twinings' labels contain nutrient-content claims, the product labels do not violate the FDA's labeling requirements because they do not characterize the level of antioxidants as required by [the statute]. Because Craig's allegations do not violate the FDCA, any related state law claims arising from the same facts are preempted. If allowed to proceed, the state law claims would impose liability inconsistent with the FDCA." The common law claims of breach of express and implied warranty of merchantability as well as unjust enrichment were also dismissed on the same grounds.

Plaintiffs alleging similar violations were certified in California as a statewide injunctive relief class in April 2014 after a court determined that the plaintiff failed to present an appropriate damages model. Details about the class certification appear in Issue **521** of this *Update*.

Federal Court Reopens and Stays Attune ECJ Case

A California federal court has granted plaintiffs' motion to vacate the judgment and reopened a proposed class action against Attune Foods Inc., finding that the delay in guidance from the U.S. Food and Drug Administration (FDA) on whether "sugar" is the "common or usual name" for "evaporated cane juice" (ECJ), an ingredient that appears on Attune's labels, could unfairly disadvantage the plaintiffs' case. *Swearingen v. Attune Foods Inc.*, No. 13-4541 (U.S. Dist. Ct., N.D. Cal., Oakland Div., order entered January 28, 2015).

Citing the primary jurisdiction doctrine, the court had dismissed the case without prejudice in May 2014 to await FDA guidance after the agency reopened the comment period in March of that year to determine whether sugar and ECJ are materially different substances. After the plaintiffs sought relief from the judgment, the court has now determined that FDA's delay

could unfairly disadvantage the plaintiffs if the statute of limitations prohibits their claims by the time the agency issues the guidance. Accordingly, the court granted the motion for relief from judgment, reopened the case and entered a stay.

Additional details about other ECJ cases dismissed without prejudice or stayed awaiting FDA guidance are available in Issues **524**, **529** and **544** of this *Update*.

Putative Class Action Challenging Source and Quality of Olive Oil to Continue

A California federal court has dismissed two claims and allowed four to continue in a putative class action alleging that (i) Salov North America Corp. mislabeled its Filippo Berio olive oils as "Imported from Italy" despite using olives grown and pressed in other countries and (ii) its extra virgin olive oils do not meet the high standards required to qualify as "extra virgin," partly due to inefficient bottling and transportation. *Kumar v. Salov North Am. Corp.*, No. 14-2411 (U.S. Dist. Ct., N.D. Cal., order entered February 3, 2015).

The court first assessed Salov's challenge to the plaintiff's standing and found that it could not, as a matter of law, determine that a reasonable consumer would not interpret "Imported from Italy" to mean that the product was made exclusively of Italian olives. Salov also asserted that the plaintiff must have seen the statement on the label that informed consumers that the product was "Packed in Italy with select extra virgin olive oils from Italy, Spain, Greece & Tunisia" because she alleged that she read the "best by" date, which appears near the statement on the back label of the product. The court found that, as a matter of law, it could not determine whether the plaintiff saw those statements.

The court also dismissed Salov's arguments against granting an injunction barring the use of the label. The company asserted that the plaintiff could not "demonstrate a 'real or immediate threat' that she will be misled in the future.'" If the court agreed with that argument, it said, it "would lead to the result that a class action plaintiff alleging mislabeling or false advertising could never seek injunctive relief on behalf of the class. [] The possibility of future injury is alleged sufficiently if the plaintiff would encounter the same statements today and could not be any more confident that they were true."

Salov also challenged the plaintiff's standing to claim that the bottle of extra virgin olive oil was not of extra virgin quality when she purchased it. The plaintiff alleged that she had bottles of the extra virgin olive oil tested, and a lab found that the product did not meet extra virgin standards; Salov asserted that the bottle tested was not the bottle the plaintiff purchased. The court dismissed the challenge, finding that the plaintiff's theory of the claim "does not require that she prove the particular bottle of oil she purchased had, in fact, degraded to the point of not being extra virgin. Whether some bottle of olive oil might not have degraded, despite the mixing, packaging, and shipping defects alleged, does not defeat the claim." The court also dismissed

arguments against the plaintiff as the representative of a class to be appropriate for the later certification stage rather than the pleading stage.

The court denied Salov's motions to dismiss the plaintiff's allegations that the Filippo Berio packaging violates California's Consumer Legal Remedies Act, False Advertising Law and Unfair Competition law as well as the claim of fraud. It dismissed the plaintiff's breach of contract and breach of covenant of good faith and fair dealing claims, finding that she failed to allege the existence of a contract with the company.

Former Diamond Foods CFO to Pay $125,000 in Walnut Fraud Case

Steven Neil, the former CFO of Diamond Foods Inc., has agreed to pay $125,000 to settle a U.S. Securities and Exchange Commission (SEC) lawsuit alleging that he directed his employees to underreport the amount of money paid to walnut growers to ensure that the company hit quarterly targets for earnings per share. *SEC v. Diamond Foods, Inc.*, No. 14-122 (U.S. Dist. Ct., N.D. Cal., order entered February 2, 2015). According to SEC, Diamond falsely reported some of its payments to walnut growers as advances for crops not yet delivered to exclude the amounts from year-end financial statements, and after an investigation into the company's accounting practices began, Neil allegedly gave independent auditors false and incomplete information about the payment scheme.

Diamond and its former CEO, Michael Mendes, reached a deal with SEC in January 2014 to pay a $125,000 penalty along with returning more than $4 million that Mendes had received in bonuses and other benefits. Additional details on the case appear in Issues 464 and 509 of this *Update*.

OTHER DEVELOPMENTS

Consumer Reports Touts Mandatory GMO Labeling

Citing increased demand for food and beverage products that do not contain genetically modified organisms (GMOs) as ingredients, the March 2015 issue of ***Consumer Reports*** magazine features an article intended to help consumers "sift through the facts" about the purported health and environmental effects of GMOs. The column describes recent attempts by individual states to require GMO labeling, as well as voluntary "Non-GMO Project Verified" certification programs. It claims that "the vast majority of corn, soy, canola, and sugar beets grown in the U.S. are now genetically engineered" even though the Food and Drug Administration does not follow the joint safety assessment guidelines established by the World Health Organization and Food and Agriculture Organization.

"In an interesting twist, some food companies that expressed strong opposition to such mandatory labeling are the same ones turning out new non-GMO products," opines *Consumer Reports*. "Those in favor of mandatory labels—

including Consumers Union, the advocacy arm of Consumer Reports—argue that even if the jury is still out on the health impact of GMOs, shoppers have a right to know what's in their food."

The article concludes that mandatory labeling schemes would add "less than a penny a day" to most grocery bills, dismissing studies that put the estimated cost increase for a family of four at $400 to $800 per year. As *Consumer Reports* argues, "[I]n countries where GMO labeling is required—including many where American food companies sell their products—food prices haven't increased as a result of mandatory labeling. And as our recent GMO testing showed, food products don't have to contain all-organic ingredients to qualify as non-GMO."

French Court Forbids "Nutella" Baby Name

A French court has reportedly rejected a couple's choice of name for their baby, "Nutella," and renamed her "Ella" because "the name 'Nutella' given to the child is the trade name of a spread" and "it is contrary to the child's interest to be wearing a name like that" because it "can only lead to teasing or disparaging thoughts."

French parents have apparently been free to choose the names of their children since 1993, but local prosecutors can report names they deem unsuitable to a family court. Another French court recently renamed a child called "Fraise" (strawberry) to "Fraisine," a popular 19th century name, citing potential teasing. Many international courts have assessed the suitability of baby names and ordered changes; in New Zealand, for example, "Number 16 Bus Shelter" passed muster but "Yeah Detroit" and a series of 38 consonants and 5 numbers ("Brfxxccxxmnpcccclllmmnprxvclmnckssqlbb11116") did not. *See The Washington Post* and *BBC*, January 26, 2015.

UK Group to Host Symposium Targeting Potential Impact of POPs on Obesity

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), an independent group charged with providing counsel to various UK government agencies, is holding a March 18, 2015, **symposium** in Birmingham about the possible role of exposure to persistent organic pollutants (POPs) on the development of obesity. The robust agenda will include presentations from UK and Italian experts. *See Food Standards Agency News Release*, January 28, 2015.

SCIENTIFIC/TECHNICAL ITEMS

CDC Study Targets Salt, Sugar in Infant and Toddler Foods

Researchers with the Centers for Disease Control and Prevention (CDC) have published a **study** claiming that many infant and toddler foods sold

in the United States contain too much sodium or sugar. Mary Cogswell, et al., "Sodium and Sugar in Complementary Infant and Toddler Foods Sold in the United States," *Pediatrics,* March 2015. Relying on a database of 1,074 infant and toddler foods and drinks that sourced nutrient information from a commercial database, manufacturer websites and major grocery stores, the study reported that "the majority of toddler cereal bars/breakfast pastries, fruit, and infant/toddler snacks, desserts, and juices contained ≥1 added sugar," that is, at least one added sugar on the ingredient list.

In addition, the study's authors noted that 41 of 79 infant mixed grains and fruits contained ≥1 added sugar, while 35 of these products derived more than 35 percent of their calories from sugar. They also concluded that (i) 72 percent of 72 toddler dinners were high in sodium content, containing more than 210 milligrams (mg) sodium per reference amount customarily consumed (RACC); (ii) toddler dinners contained an average of 2,295 mg sodium per 1,000 kilocalories (kcal); and (iii) savory infant/toddler snacks contained an average of 1,382 mg sodium per 1,000 kcal. By comparison, "the majority of the infant vegetables, dinners, fruits, and dry/instant cereals did not contain added sugars" and "all but 2 of the 657 infant vegetables, dinners, fruits, dry cereals, and ready-to-serve mixed grains and fruits were low sodium (≤140mg/RACC)."

"Parents can be assured that commercial foods for infants… sold in the United States in 2012 were generally acceptable in sodium and sugar content," states the study. "However, the majority of snacks, desserts, or juice drinks for infants or toddlers, and many commercial foods meant for toddlers aged ≥12 months were either high in sodium content or contained ≥1 added sugar."

Commenting on the results, the Center for Science in the Public Interest (CSPI) called the study "just one more nail in the coffin of future generations, as parents unsuspectingly feed their toddlers way-too-salty foods." But the Grocery Manufacturers Association (GMA) pointed out that the study did not consider any of the low-sodium formulations put on the market since 2012 and questioned whether the out-of-date findings would unnecessarily confuse parents "as they strive to develop suitable meal options that their children will enjoy." *See CSPI* and *GMA News Releases,* February 2, 2015.

High-Temperature Cooking Allegedly Linked to Alzheimer's Disease

A study has allegedly linked the advanced glycation end products (AGEs) formed when "food is cooked at high temperatures or aged for a long time" to increased Alzheimer's disease (AD) risk. Lorena Perrone and William B. Grant, "Observational and Ecological Studies of Dietary Advanced Glycation End Products in National Diets and Alzheimer's Disease Incidence and Prevalence," *Journal of Alzheimer's Disease,* February 2015. According to a February 3 IOS Press news release, AGEs not only "increase the risk of various chronic diseases through several mechanisms including increased inflammation and oxidative stress," but can bind to a receptor that "transports beta-amyloid

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proteins across the blood-brain barrier and contributes to the development of Alzheimer's disease."

Using a Mount Sinai School of Medicine study and dietary data from the United Nations Food and Agriculture Organization to estimate the AGE content of national diets, the study's authors evidently reported that "reduced dietary AGE significantly correlates with reduced AD incidence," while "estimates of dietary AGEs in the national diets corresponded well with AD prevalence data."

"In typical national diets, we found that meat made the highest contribution of AGEs, followed by vegetable oils, cheese, and fish," state the authors in the news release. "Foods such as cereals/grains, eggs, fruit, legumes, milk, nuts, starchy roots, and vegetables generally make low contributions to the total amount of AGEs in a diet, either because they are generally prepared at low temperatures or since they comprise smaller portions of diets."

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FOOD & BEVERAGE LITIGATION UPDATE

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.