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LEGISLATION, REGULATIONS AND STANDARDS

USDA Publishes 2013 Sunset Review Recommendations for Organic Program

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) has **published** a final rule addressing the recommendations submitted by the National Organic Standards Board (NOSB) as part of the 2013 sunset review of substances on USDA's National List of Allowed and Prohibited Substances (the National List), which governs the use of synthetic and nonsynthetic substances in organic crop and livestock production and handling. In addition to renewing for five years multiple exemptions (uses) and one prohibition on the National List in accordance with NOSB's recommendations, AMS has removed an exemption for the synthetic form of tartaric acid made from malic acid, thus prohibiting its use in organic handling.

Effective November 3, 2013, the final rule also includes the agency's response to comments on the renewals of two synthetic substances—EPA List 3 Inerts and cellulose—and one non-synthetic substance—carrageenan—that are currently permitted in organic crop production, handling and processing. In particular, AMS noted that "both commenters [sic] and the [Food and Drug Administration] have identified many deficiencies in the literature regarding the gastrointestinal toxicity of carrageenan, concluding that there is no information clearly demonstrating that there is evidence for a carcinogenic effect for food grade carrageenan use in foods or infant formula." See Federal Register, October 3, 2013.

FDA Extends Comment Period on Salmonella Risk from Tree Nuts

The Food and Drug Administration (FDA) has <u>extended</u> until December 16, 2013, the period for submission of comments, scientific data and other information related to its risk assessment of human salmonellosis associated with the consumption of tree nuts. Originally published in the July 18 *Federal Register*, the assessment seeks to quantify the public health risk associated with eating tree nuts potentially contaminated with *Salmonella* and evaluate the impact of interventions to prevent contamination with the bacterium or to reduce contamination levels.

Additional information about the risk assessment appears in Issue <u>491</u> of this *Update. See Federal Register,* October 4, 2013.



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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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

> Mark Anstoetter 816-474-6550 manstoetter@shb.com



or

Madeleine McDonough 816-474-6550 202-783-8400 mmcdonough@shb.com



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

French Safety Agency Warns of Energy Drink Risk

The French Agency for Food, Environmental and Occupational Health and Safety (ANSES) has <u>released</u> a report that warns of the risks associated with consumption of energy drinks, particularly for children, pregnant women and people with certain genetic predispositions, such as cardiovascular or psychiatric and neurological disorders, kidney failure or liver disease.

The agency also recommends that consumers stop drinking the beverages in combination with alcohol and during physical exercise, suggesting stricter laws on advertising and prohibiting the products from sporting events and festivals. Noting that caffeine has long been consumed throughout the world, ANSES reports that its "novel and increasingly popular presentation in the form of so-called energy drinks is changing consumption patterns," with approximately 30 percent of the French population consuming enough energy drinks "to push themselves into states of anxiety (around six espressos)."

French National Assembly Social Security Budget Rapporteur Gérard Bapt reportedly intends to propose a special tax on energy drinks in response to the "now proven associated risks to public health." See ANSES News Release, October 1, 2013; Tax-News.com, October 3, 2013.

LITIGATION

JPML Considers Request to Transfer Monsanto GM Wheat Suits

The U.S. Judicial Panel on Multidistrict Litigation (JPML) recently heard argument on the Center for Food Safety's motion to transfer to a multidistrict litigation (MDL) court pending lawsuits against Monsanto Co. involving the genetically modified (GM) wheat that appeared in an Oregon farmer's conventional wheat field and briefly disrupted exports to some of the nation's trading partners. *In re Monsanto Co. Genetically Engineered Wheat Litig.*, MDL No. 2473 (J.P.M.L., motion argued September 26, 2013). The center requested that suits filed in Idaho, Kansas, Oregon, and Washington be transferred to the Eastern District of Washington. Additional details about the Kansas litigation appear in Issue 486 of this *Update*.

Court Says Puréed Fruit Is "Real Fruit," Dismisses Consumer Fraud Claims

Calling it "ridiculous to say that consumers would expect snack food 'made with real fruit' to contain only 'actual strawberries or raspberries,' rather than these fruits in a form amenable to being squeezed inside a Newton," a federal court in California has dismissed without leave to amend consumer fraud claims against the company that makes Nabisco strawberry and raspberry Newton cookies. *Manchouck v. Mondeléz Int'l Inc.*, No. 13-2148 (U.S. Dist. Ct., N.D. Cal., decided September 26, 2013).



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The court determined that the plaintiff had Article III standing without alleging physical injury because this is not the sole measurement of injury-in-fact and the plaintiff alleged that she had paid a premium price for the products which she would not have purchased "at that price point absent the alleged misstatements." The court agreed with the defendant, however, that the plaintiff had failed to meet the plausibility pleading standard set forth in *Ashcroft v. lqbal*, 556 U.S. 662 (2009).

According to the court, "Here, the complaint alleges that a reasonable consumer would think that Newtons 'made with real fruit' exclude fruit purée. This strains credibility. First, the complaint does not dispute that the cookies contain real fruits in purée form. Second, even the most narrow definition of 'real fruit' does not exclude fruit that has been strained or blended into puréed form. Third, the packaging that said, 'made with real fruit,' also prominently displays a depiction of the cookies' puréed fruit filling. Fourth, the amended complaint admits that the list of ingredients on the packaging serves notice to consumers that the products contain, 'Raspberry Purée' and 'Strawberry Purée' respectively." The complaint also apparently failed to allege why the puréed forms of fruit are no longer "real fruit."

D.C. Court Dismisses Humane Society Pork Checkoff Suit

A federal court in the District of Columbia has dismissed, for lack of standing, a lawsuit filed by the Humane Society of the United States and several other plaintiffs against the U.S. Department of Agriculture (USDA), challenging the secretary's approval of the National Pork Board's purchase of the slogan "Pork, The Other White Meat" from the National Pork Producers Council (NPPC). *The Humane Soc'y of the U.S. v. Vilsack*, No. 12-1582 (U.S. Dist. Ct., D.D.C., decided September 25, 2013). Details about the lawsuit appear in Issue 455 of this *Update*.

According to the court, the individual pork farmer plaintiff lacked standing because he could not show that changes to the advertising funded by the pork checkoff program following the board's purchase and retirement of the slogan affected him financially. In fact, since the board began advertising with the slogan "Pork: Be Inspired," the net return on investment to pork producers rose from \$13.8 to \$17.4. While the farmer alleged that his return would have been even higher if the money had been spent on "other legitimate programs," the court found his argument "entirely conjectural and unsupported by facts." The farmer also claimed that the NPPC's lobbying, funded by the purchase, was contrary to his interests and harmed his operations. The court said that he failed to provide any facts to support an inference that NPPC's lobbying actually harmed his operations. The court also found that the individual plaintiff could show neither causation nor redressability.



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For similar reasons, the court concluded that the organizational plaintiffs could not establish standing either on their members' behalf or as organizations. As to the plaintiffs' organizational interest, the court said that their alleged harm—"having to devote significant resources to counter 'NPPC's checkoff-funded lobbying activities"—is not a cognizable injury because "lobbying is what these organizations do, so being prompted to do it can hardly qualify as an injury that confers constitutional standing." And "the fact that they have decided to redirect some of their resources from one legislative agenda to another is insufficient to give them standing."

Court Dismisses Misbranding Claims Against Welch Foods

A federal court in California has dismissed with limited leave to amend the second amended complaint filed on behalf of a putative nationwide class against Welch Foods, alleging that the company's juice, beverage, spread, and jelly labels and Website violate California labeling law by including "no sugar added," "all natural," "no artificial flavors," and "high in antioxidants" statements. *Park v. Welch Foods, Inc.*, No. 12-6449 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered September 26, 2013).

Agreeing that the complaint sounded in fraud and must comply with the heightened pleading standard of Federal Rule of Civil Procedure 9, the court noted that "Welch is after the who, what, where, when, and how surrounding the circumstances in which Plaintiffs were misled." The company apparently argued that "portions of the complaint are generously and blindly appropriated from similar complaints filed in this district," and that a 15-page limit would be appropriate. Still, "Welch wants to know specifically when and where Plaintiffs purchased the particular Welch food products at issue in this litigation. Welch also wants to know how Plaintiffs' purchase decisions were driven by the alleged misrepresentations on the packaging labels."

Observing that the 39-page complaint simply summarized food-labeling regulations, referred to agency guidance letters about products not at issue and appeared to "include claims from similar lawsuits filed in the district," the court found that the plaintiffs had "not supported their 'allegations with even a minimal degree of factual specificity." It also noted that the complaint does not clearly indicate the content of the labels on which the plaintiffs allegedly relied or the ads and Website statements they "saw and supposedly found misleading." Further, the plaintiffs "do not allege that they personally saw and/or relied on any misleading advertisements or website statements in particular."

The court dismissed the first six claims with leave to amend by October 30, 2013. It dismissed the plaintiffs' unjust enrichment/quasi-contract claim as "merely duplicative of statutory or tort claims."



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Court Allows ECJ and "All Natural" Claims to Proceed Against Blue Diamond

A federal court in California has denied the motion to dismiss filed in a putative nationwide class action alleging that Blue Diamond Growers misled consumers by labeling its almond milk products and snack foods as "all natural" and representing that they contain "evaporated cane juice," (ECJ) in violation of federal labeling requirements incorporated into state law. Werdebaugh v. Blue Diamond Growers, No. 12-2724 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered October 2, 2013). The court determined that the claims were not preempted by federal law or the primary jurisdiction doctrine, the plaintiff had standing to pursue claims regarding substantially similar products that he did not purchase, the claims were pleaded with sufficient particularity, and the defendant's conflict-of-laws challenge was premature.

Red Lobster Sued for Sexually Hostile Environment

As the fiscal year came to a close and on the eve of the federal government shutdown, the Equal Employment Opportunity Commission (EEOC) filed nearly two dozen employment discrimination lawsuits including one against GMRI, Inc. alleging discrimination based on sex on behalf of a class of women employees at a Salisbury, Maryland, Red Lobster Restaurant. *EEOC v. GMRI, Inc.*, No. 13-2860 (U.S. Dist. Ct., D. Md., filed September 30, 2013).

According to the complaint, the defendant's former culinary manager created a sexually hostile and offensive work environment for the two women who filed the complaint as well as "other similarly situated female employees" by engaging in frequent sexual touching, sexual comments, sexual advances, and vulgar sexual conduct. The conduct, which was allegedly "open and notorious and occurred on a frequent and routine basis," was purportedly condoned by a former general manager who "himself had a history of making sexually charged and vulgar comments about the female staff."

While EEOC litigation remains suspended during the shutdown, Red Lobster has reportedly stated that is has "strong defenses" and that "[t]he allegations relate to inappropriate conduct by a manager that occurred three years ago. We have a zero tolerance policy for any kind of harassment or discrimination. As soon as we were made aware of this situation in 2010, we investigated and terminated the manager responsible." See Corporate Counsel, October 3, 2013.

Preliminary Settlement of Diamond Shareholder Claims Approved

A federal court in California has preliminarily approved the settlement of shareholder claims that Diamond Foods, Inc. "deliberately understated the costs of walnuts and improperly accounted for payments made to walnut growers to increase apparent profits and maintain higher share prices" in anticipation of the anticipated purchase of Pringles with company stock. *In re*



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Diamond Foods, Inc. Securities Litig., No. 11-5386 (U.S. Dist. Ct., N.D. Cal., order entered September 26, 2013). Additional details about the litigation appear in issues 464 and 482 of this *Update*. Under the terms of the agreement, the defendants will pay to the class \$11 million and distribute 4.45 million shares of Diamond common stock—valued at \$85.1 million as of August 2013. According to the court, while the maximum aggregated damages totaled some \$430 million, the settlement is reasonable in light of "Diamond's weakened financial condition." It apparently has just \$7.2 million in cash and cash equivalents and carries \$579 million in long-term obligations. The final approval hearing will be held January 9, 2014.

Inconvenient Forum at Issue Again in Four Loko Death Suit

An Illinois appeals court has reversed a trial court determination that Illinois would not be an inconvenient forum for the defendants in a wrongful death lawsuit filed by the parents of a 15-year-old boy who allegedly drank two cans of the alcohol energy drink Four Loko and was killed on a Virginia highway after becoming disoriented. Rupp v. Phusion Projects, LLC, No. 1-12-2056 (III. App. Ct., order entered September 27, 2013) (not precedential). Additional information about the lawsuit appears in Issue 395 of this *Update*. According to the appeals court, while the trial court correctly weighed most of the private-interest factors presented, it should have considered the defendant's choice-of-law issue under the public-interest factor analysis. The appeals court also found that the trial court erred in stating that other defendants had not joined Phusion's forum non conveniens motion, because the record showed that they had done so. And finally, the court determined that the parties' motions to take judicial notice of related lawsuits subsequently filed in Illinois, Virginia and other jurisdictions were not before the trial court and must be considered on remand.

WTO Refers COOL Dispute to Compliance Panel, Delay Sought for New U.S. Rules

The World Trade Organization (WTO) has reportedly established a compliance panel at the request of Canada and Mexico in an ongoing dispute over the U.S. country-of-origin (COOL) meat labeling rules. Canada's International Trade Minister Ed Fast and Agriculture Minister Gerry Ritz applauded the WTO action, saying that the United States must "respect its international trade obligations and put an end to mandatory Country of Origin labeling."

Canada argues that recent changes to the COOL implementing regulations did not bring them into conformity with WTO obligations. Because the compliance panel consists of the original members who found that the U.S. law was unfair to foreign meat producers, the Canadian officials suggest that the process will be accelerated. If the challenge succeeds, "which may include



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an appeal to the WTO Appellate Body, Canada could seek authorization from the WTO to impose retaliatory tariffs on U.S. imports."

Meanwhile, meat and livestock organizations that have appealed a federal court's denial of their preliminary injunction seeking to block implementation of the amended COOL regulations have written to U.S. Department of Agriculture Tom Vilsack and Office of the U.S. Trade Representative Ambassador Michael Froman requesting that the rule not be enforced pending the outcome of the WTO proceedings. In their September 23, 2013, letter, they contend that the fate of the amended rules is uncertain and that a delay will "eliminate imposing the tens if not hundreds of millions of dollars in costs that [the Agricultural Marketing Service] calculated would be incurred by the supply chain to comply with a rule that may eventually be scrapped in a relatively short timeframe." More information about the lawsuit and WTO dispute settlement process appears in Issue 495 of this Update. See Law360, September 27, 2013; MarketWired.com, October 2, 2013.

OTHER DEVELOPMENTS

Corporate Europe Observatory Criticizes EFSA Ahead of **Transparency Conference**

Corporate Europe Observatory (CEO) recently joined a coalition of nongovernmental organizations in criticizing the European Food Safety Authority (EFSA) ahead of the agency's October 3, 2013, stakeholder meeting on transparency in risk assessment. Led by CEO and backed by groups such as Cancer Prevention and Education Society, Friends of the Earth Europe and GMWatch, the coalition argues in an October 1 open letter that EFSA's current system for approving food products for market is flawed insofar as the agency's decisionmaking process relies on confidential dossiers submitted by industry.

In particular, the signatories claim that under international and EU law, EFSA must disclose the contents of these dossiers and should also ensure that the studies used to support its market approvals adhere to the same high standards as those set by peer-reviewed journals. To this end, the coalition recommends that EFSA provide "complete, unrestricted and proactive online publication of applicants' files," which should contain data that is accessible and re-publishable as well as details about the protocol and research material used to gather the data, the laboratories that conducted the experiments, and funding sources. The letter also urges the agency to publish all available data, including raw data, in a "usable, editable format (e.g., spreadsheet) in order for the re-analysis work to be possible," and to publish and keep online "declarations of interest of EFSA's main experts and employees... for five years after their employment at EFSA has expired."



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"Having the applicant performing and reporting the tests on which its product will be assessed is casting doubt on the validity of the entire decision-making process: in such a context, and in the light of EFSA's institutional and financial limitations, full transparency and public scrutiny is the only real additional defence mechanism available to EFSA against potential capture by industry," states the letter. "This means providing access not only to the entire content of the applicant's dossier but also to the interests of the public decision-makers involved (EFSA experts and staff)." See CEO Press Release, October 2, 2013.

Food Expiration Dates Target of NRDC Report

The Natural Resources Defense Council (NRDC) and the Harvard Food Law and Policy Clinic have co-authored a September 2013 <u>report</u> claiming that the date label used on food products "is a key factor" in unnecessary food waste. Titled *The Dating Game: How Confusing Food Date Labels Lead to Food Waste in America*, the report focuses on the lack of federal standards for date labels such as "use by," "best before," "sell by," and "enjoy by," arguing that the variability in state and local rules sows confusion among consumers, undermines the system's goal of providing accurate indicators of freshness and harms both manufactures and retailers "by creating increased compliance burdens and food waste."

To combat these problems, the report recommends that stakeholders "standardize and clarify the food date labeling system across the United States" by establishing "a reliable, coherent, and uniform consumer-facing dating system" that clearly differentiates between "quality-based" and "safety-based" date labels. In particular, the report calls for (i) making "sell by dates invisible to consumers"; (ii) increasing "the use of safe handling instructions and smart labels"; (iii) including "freeze by dates and freezing information where applicable"; (iv) removing "quality-based dates on non-perishable, shelf-stable products"; and (v) ensuring that "date labels are clearly and predictably located on packages." In addition to urging the food industry to adopt these changes, the report calls on federal government to work with state agencies to reduce confusion around date labeling and consumer-facing organizations to educate consumers about the meaning of these labels.

MEDIA COVERAGE

Lappé Discusses "Food MythBusters" with Mother Jones

"The food industry is spending almost \$2 billion a year marketing directly to children and teens," opines food industry critic Anne Lappé in an October 2, 2013, interview with *Mother Jones* that focuses on her latest project, Food MythBusters. Discussing a range of topics from genetically modified organ-



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isms to food marketing and farm labor practices, Lappé not only argues that the food industry "has infiltrated all aspects of our children's lived experience, including their experience at school," but claims that legal restrictions on food marketing and advertising are necessary to protect children's health. She also criticizes the industry's move toward self-regulation, alleging that such initiatives have already failed.

"Diet-related illnesses are causing nearly as many deaths as tobacco-related illnesses, not to mention the impact on quality of life when you start to develop adult-onset diabetes as a child, or all these other diet-related illnesses," concludes Lappé, whose Food MythBusters project includes an online resource center featuring information from select food and farm organizations.

SCIENTIFIC/TECHNICAL ITEMS

Researchers Allegedly Identify Biological Pathway Linking Diabetes and Heart Disease

UC Davis Health System researchers have reportedly identified "a biological pathway that is activated when blood sugar levels are abnormally high and causes irregular heartbeats, a condition known as cardiac arrhythmia that is linked with heart failure and sudden cardiac death." Jeffrey Erickson, et al., "Diabetic hyperglycaemia activities CaMKII and arrhythmias by *O*-linked glycosylation," *Nature*, October 2013. According to a recent press release, the study's authors apparently found the biological link after conducting "detailed molecular experiments" using rat and human proteins and tissues, including "assessments of whole heart arrhythmias with optical mapping in isolated hearts and in live diabetic rats."

The results evidently showed "that the moderate to high blood glucose levels characteristic of diabetes caused a sugar molecule (O-linked N-acetylglucosamine, or O-GlcNAc) in heart muscle cells to fuse to a specific site on a protein known as calcium/calmodulin dependent protein kinase II, or CaMKII."This fusion with O-GlcNAc apparently led "to chronic overactivation of CaMKII and pathological changes in the finely tuned calcium signaling system it controls, triggering full-blown arrhythmias in just a few minutes."The authors also reported that inhibiting CaMKII or its union with O-GlcNAc effectively prevented the arrhythmias from occurring.

"The novel molecular understanding we have uncovered paves the way for new therapeutic strategies that protect the heart health of patients with diabetes," the senior author was quoted as saying. "Our discovery is likely to have ripple effects in many other fields. One key next step will be to deter-



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mine if the fusion of O-GlcNAc to CaMKII contributes to neuropathies that are also common among diabetics." See UC Davis Health System Press Release, September 29, 2013.

Study Claims Restaurant Menus Remain Unhealthy

A recent study asserts that the energy and sodium content of main entrées served in U.S. chain restaurants has remained unchanged over a one-year period, despite the enactment of federal regulations requiring menu labeling. Helen Wu & Roland Sturm, "Changes in the Energy and Sodium Content of Main Entrées in US Chain Restaurants from 2010 to 2011," *Journal of the Academy of Nutrition and Dietetics*, October 2013. Relying on data collected from chain restaurant Websites between spring 2010 and spring 2011, the study's authors noted that "mean energy and sodium did not change significantly overall, although mean sodium was 70 mg lower across all restaurants in added vs removed menu items at the 75th percentile." They also reported that even though fast-food chains reduced the mean energy in children's menu entrées by 40 kcal, the adult-sized dishes with reduced sodium levels "far exceeded recommended limits," while not all significant changes in energy or sodium content "were in the healthier direction."

"Restaurant menus did not get any healthier over time," said study author Helen Wu, a policy and research analyst at the Institute for Population Health Improvement at UC Davis Health System. "Across the restaurant industry, we see a pattern of one step forward, one step back. Restaurants make changes to their menus regularly, but they may make both healthy and unhealthy changes simultaneously. This study provides objective evidence that overall, we did not see a new wave of healthier entrées come in to replace less healthy ones." See UC Davis Health System Press Release, October 1, 2013.

OFFICE LOCATIONS

Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500

Kansas City, Missouri +1-816-474-6550

London, England +44-207-332-4500 Miami, Florida

+1-305-358-5171 Philadelphia, Pennsylvania +1-215-278-2555

San Francisco, California +1-415-544-1900 Tampa, Florida

+1-813-202-7100 **Washington, D.C.** +1-202-783-8400

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.



