

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

USDA Proposes Major Overhaul for School Meals

The U.S. Department of Agriculture (USDA) has issued a 78-page [proposed rule](#) revising school breakfast and lunch nutrition requirements as a way to combat childhood obesity. Noting that implementation would improve dietary habits and protect children's health, the rule is part of the Healthy, Hunger-Free Kids Act of 2010 recently signed into law.

Based on recommendations released in 2009 by the National Academies' Institute of Medicine, the revisions reportedly represent the first major overhaul to school meals in 15 years. Among other things, the proposal calls for meals served to approximately 32 million school children to (i) include more fruits, vegetables, whole grains, and fat-free and low-fat milk; (ii) limit sodium and saturated and *trans* fats; and (iii) help meet nutritional needs of children within their established calorie minimums and maximums.

"We understand that these improved meal standards may present challenges for some school districts, but the new law provides important new resources, technical assistance and flexibility to help schools raise the bar for our kids," Agriculture Secretary Tom Vilsack said in a statement. USDA requests comments by April 13, 2011. *See USDA News Release and Federal Register*, January 13, 2011.

Returned and Repackaged Hamburger Products Recalled from Prisons

After a Food Safety and Inspection Service (FSIS) investigation of complaints about discoloration and off-odors, a New Jersey-based meat processor has reportedly recalled more than 225,000 pounds of ground beef products distributed to penal institutions in California and Oregon. In a recall release, FSIS reported that its review "uncovered evidence to show that the establishment repackaged and recoded returned products and sent them out for further distribution to institutional customers." While no reports of illness were apparently associated with the recall, FSIS considers the products to be adulterated "because the establishment's food safety plan was inadequate to

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produce wholesome product." The meatpacker involved is One Great Burger. See *FSIS News Release*, January 10, 2011; *Meatingplace.com*, January 12, 2011.

NOP Issues Draft Organic Labeling Guidance

The U.S. Department of Agriculture's National Organic Program (NOP) has issued [draft guidance](#) "to address the labeling, composition of and use of percentage statements in 'made with organic (specified ingredients or food groups)'" Under NOP regulations, conventional non-organic ingredients produced without the use of genetically modified organisms, sewage sludge or ionizing radiations, as well as natural and synthetic substances exempted from the NOP's prohibited ingredients list, may comprise up to 30 percent of a product labeled "made with organic (specified ingredients or food group(s))."

Such labeling may also display the percentage of organic ingredients in the product, but must be accompanied by the appropriate "made with organic" statement. According to NOP, acceptable variations of percentage claim statements include: (i) "X% Organic," (ii) "X% Organic Ingredients," (iii) "Contains X% Organic Ingredients," and (iv) "Made with X% Organic Ingredients." Other percentage claims "may be acceptable as long as they are not misleading," notes NOP, which specifically prohibits "made with 100% organic (specified ingredients or foods groups)" labels because they may lead consumers into thinking "that the 'made with' product qualifies for the '100% organic' category."

NOP has issued draft guidance to clarify these regulations, addressing (i) "the use of nonorganic ingredients in 'made with organic (specified ingredients or food groups)' products," and (ii) "the use of statements about the percentage of organic ingredients within the 'made with organic (specified ingredients or food groups)' labeling category." The agency invites comments from producers, handlers, certifying agents, consumers, and other interested parties before March 14, 2011. See *Federal Register*, January 13, 2011.

EPA Proposal Would Ban Pesticide Used on Food, Packaging

The Environmental Protection Agency (EPA) has announced plans to implement a "phased-down withdrawal" of the pesticide sulfuryl fluoride. The fumigant apparently breaks down into fluoride and is used to control insects in stored grains, dried fruits, tree nuts, coffee and cocoa beans, and in food handling and processing facilities.

After reevaluating current science on fluoride, EPA concluded that "although sulfuryl fluoride residues in food contribute only a very small portion of total exposure to fluoride, when combined with other fluoride exposure pathways, including drinking water and toothpaste," its legal residue limits on food no longer satisfy the safety standard under the Federal Food, Drug, and Cosmetic

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Act. Proposing to phase out the pesticide over a three-year period, EPA will accept comments for 90 days after publication in the *Federal Register*. See *EPA Press Release*, January 10, 2011.

EU Threatens Regulation to Assuage Dioxin Fears

The European Commission (EC) has reportedly threatened to regulate the animal feed industry after dioxin-tainted eggs from Germany triggered a widespread investigation involving poultry and pork farms across the region. EC spokesperson Frederic Vincent apparently told reporters that a meeting with industry leaders produced “no concrete proposals” to prevent new contaminations, although participants have been given one month to suggest voluntary measures in lieu of legislation. “There will not be European compensation because it is not up to the European Union to fix the damage,” Vincent said.

Meanwhile, German MEP Peter Liese has called for “the dioxin crisis... to be resolved on a European level,” possibly through use of a monitoring system, as well as European Union (EU) compensation for farmers caught up in food scandals. “Although EU directives regulate in principle we need better controls throughout the EU. There is a lot of trade within the EU and imports are to a large extent already processed products,” Liese was quoted as saying. “That means that even labeling of eggs would in practice not be very helpful. Unilateral restrictions would disturb the common market and would not bring a lot of advancement for consumer protection.”

According to media sources, the latest round of testing has forced additional farm closures and livestock culls, including hundred of pigs in Lower Saxony. German officials have apparently traced the dioxin to an additive manufactured by Uetersen-based Harles & Jentzsch GmbH, which distributed its product to 25 feed producers and now faces allegations that it did not alert authorities to the contamination for months. The event has since raised questions about allowing companies to handle recycled fats destined for both feed and industrial markets, as was the case in the German incident. See *AFP*, *Star-Tribune* and *Time*, January 10, 2011; *The Parliament*, January 12, 2011.

Harles & Jentzsch “is a prime example of what happens when producers are held to lax standards,” opines a January 10, 2011, *Spiegel* editorial on “the criminal machinations” of feed suppliers. “[Harles & Jentzsch] inspected its fatty acids three times last year. In each of these self-inspections, dioxins levels were found to be substantial[sic] higher than the allowable maximum of 0.75 nanograms per kilo... But in none of these cases did the company inform the authorities, nor did it ever notify customers or recall its products.”

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UK Nanotechnologies and Food Discussion Group Holds Initial Meeting

The U.K. Food Standards Agency's (FSA) Nanotechnologies and Food Discussion Group has held its first meeting to consider advancing recommendations from a House of Lords Committee on Science and Technology 2010 report. Fifteen stakeholders from consumer organizations, academia, industry, and government departments met on January 13, 2011, to "exchange information between different sectors within the nanotechnologies and food groups," according to FSA.

Established to address concerns that the U.K.'s food and packaging sectors were too secretive about nanotechnology, the group reportedly plans to meet three or four times annually with a review after 18 months. Issues to be discussed include (i) European Union regulations and definitions, (ii) guidance for assessing nanomaterials, (iii) intelligence gathering on nanotechnology research conducted by the food industry, and (iv) a proposal to create a U.K. register of "nanofoods" on the market. See *FSA Press Release*, January 12, 2011; *FoodProductionDaily.com*, January 13, 2011.

California Agency Proposes NSRL for Chemical Common in Foods After Cooking

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has [proposed](#) a no significant risk level (NSRL) of 16 micrograms per day for 4-methylimidazole (4-MEI), a chemical commonly present in foods such as wine, soy sauce and Worcestershire sauce after they have been cooked. The food industry was apparently unable to prevent OEHHA from listing the ubiquitous chemical as a carcinogen under Proposition 65 (Prop. 65) and may now be considering challenging the NSRL. The proposed threshold will reportedly require Prop. 65 warnings on thousands of products. The chemical is also apparently used in the production of some pharmaceuticals. OEHHA requests comments by February 21, 2011. See *Inside Cal/EPA*, January 13, 2011.

LITIGATION

U.S. Supreme Court Declines Review of Doffing-and-Donning Ruling

The U.S. Supreme Court has denied the *certiorari* petition filed by Kraft Foods, seeking review of a [Seventh Circuit ruling](#) that requires the company to pay for the time it takes workers to change into and out of safety gear and work clothes, despite a collective bargaining agreement to the contrary. *Kraft Foods Global, Inc. v. Spoerle*, No. 10-580 (U.S., cert. denied January 10, 2011).

According to the Seventh Circuit, "Management and labor acting jointly have no more power to override state substantive law than they have when acting individually." The U.S. Supreme Court's denial carries no precedential weight; thus, the ruling, based on Wisconsin law, is limited to the Seventh Circuit.

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Kraft will apparently begin paying 1,300 current and former employees about \$4 million in back pay. A company spokesperson reportedly said, "With this decision [the doffing-and-donning] benefit is restored to employees. We are happy to put this behind us so we can work together to continue to focus on making high-quality, delicious products for our consumers." See *Meatingplace.com*, January 11, 2011.

Court Dismisses Class Action over Salt in Denny's Menu Items

A New Jersey appellate court has dismissed the second amended complaint in a putative class action filed by a man who claims that Denny's meals contain excessive undisclosed levels of sodium in violation of the state's Consumer Fraud Act. [*DeBenedetto v. Denny's, Inc., No. A-4135-09T1 \(N.J. Super. Ct. App. Div., decided January 11, 2011\)*](#). The plaintiff was represented by the Center for Science in the Public Interest. Additional information about the litigation appears in [Issue 312](#) of this *Update*.

The court agreed with the trial judge that the plaintiff's complaint was, in essence, a product liability claim for failure to warn for which the state's product liability law provided "a sole and exclusive remedy." In the absence of proof of injury, the courts determined that the plaintiff failed to state a claim on which relief can be granted. The appellate court disagreed with the plaintiff that recent state supreme court rulings on affirmative acts of misrepresentation and the economic loss rule could be applied to his claims. The court emphasized that a plaintiff alleging product defect or danger "must also allege 'harm.'" In this case, "neither the plaintiff nor the putative class he claimed to represent asserted any physical injury or harm as the result of defendant's failure to disclose the sodium content."

In a footnote, the court observed that legislation effective January 17, 2011, will require restaurants to disclose the calorie content of their menu items, but it does not require sodium content disclosure. According to the court, "An earlier version of the legislation, which the Legislature chose not to enact, would have required restaurants to also divulge the sodium content." The court further noted, while the law is not dispositive on the issues raised in the appeal, "the enactment of that statute sends a strong signal that the public policy of this State does not require a restaurant to disclose the sodium content of the food it sells."

This is not the first time that a court has dismissed excessive salt-related litigation against Denny's. In April 2010, a federal district court in Illinois dismissed alleged deceptive omissions claims under that state's consumer fraud law. Further details about the case can be found in [Issue 345](#) of this *Update*.

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Bayer CropScience Settles Mississippi Rice Farmer Claims

Germany-based Bayer CropScience AG has reportedly agreed to pay four Mississippi rice farmers \$873,000, or about \$300 per acre, for losses they allegedly incurred due to the contamination of their crops with Bayer's genetically modified strain. *In re: Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., settlement announced January 12, 2011). These cases were apparently set for trial January 18, 2011. They are part of a larger multidistrict litigation involving thousands of claims that followed the 2006 contamination which led the European Union to close its markets to conventional rice from U.S. farmers. The company has recently lost six cases with related claims tried before federal and state juries; most are on appeal. See *Product Liability Law 360*, January 12, 2011.

Insurance Coverage Claims Settled in Pistachio Recall Cases

Setton International Foods, which recalled more than 15 million pounds of pistachios in 2009 when *Salmonella* was detected in a delivery to one of its customers, has reportedly entered a settlement agreement with its insurers in a dispute over coverage for third-party claims. While the terms of the settlement have not been disclosed, a federal court in California has apparently dismissed the claims Setton filed against five insurance companies. According to a news source, Setton claimed that its insurers failed to provide assistance in defending or negotiating the third-party claims, and this purportedly led to the company's exposure to increased liability. See *Product Liability Law 360*, January 7, 2011.

Amended Complaint Says Gerber Failed to Warn About Lead in Apple Juice

According to a press report, an amended putative class complaint has been filed in a Florida federal court against two companies that make and sell apple juice for children's consumption, alleging that by failing to warn about the presence of lead in the juice the companies have violated state deceptive and unfair trade practices law. *Poulis v. Gerber Prods. Co.*, No. 10-81475 (U.S. Dist. Ct., S.D. Fla., amended complaint filed January 11, 2011).

The complaint was originally filed in state court soon after a California nonprofit organization notified the companies in June 2010 that their products contained lead in excess of levels established as safe under that state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). It was removed to federal court in November. The plaintiffs have not apparently alleged personal injury from the exposure, but claim they would not have purchased the companies' products if they had known about the lead content. They are seeking damages and a corrective advertising campaign. See *Product Liability Law 360*, January 11, 2011.

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Retail Food Interests Allege Price Fixing in Egg Market

A coalition of food wholesalers and retailers has filed an antitrust lawsuit in a Kansas state court against egg producers and industry trade groups alleging that, by reducing the number of hens, increasing egg exports and decreasing hen lifecycles, the defendants conspired to manipulate egg prices, which have more than doubled in recent years. [*Associated Wholesale Grocers, Inc. v. United Egg Producers, No. 10-2181 \(Kan. Dist. Ct., 29th Jud. Dist., Wyandotte County, filed December 23, 2010\)*](#). Similar class-action lawsuits nationwide were consolidated in multidistrict litigation (MDL) proceedings in a Pennsylvania federal court; the Kansas plaintiffs apparently opted out of class to file their own claims.

The petition, alleging violations of the Kansas Restraint of Trade Act, discusses the U.S. Department of Justice investigation into industry practices and relies on some documents produced during the MDL proceedings. Several settlements have apparently been reached in the MDL, and one of the defendants apparently agreed to produce evidence of the purported conspiracy. The plaintiffs seek a declaration that the defendants violated Kansas law, treble damages, interest, attorney's fees, and costs. *See The Kansas City Star*, January 12, 2011.

California's Approval of Pesticide Ingredient Challenged

A coalition of pesticide watchdogs and farm workers has filed a petition in a California state court seeking review of a Department of Pesticide Registration (DPR) decision to allow the use of pesticides containing methyl iodide despite evidence that the chemical is highly toxic. [*Pesticide Action Network N. Am. v. Cal. Dep't of Pesticide Regulation, No. RG10553804 \(Cal. Super. Ct., Alameda County, filed December 30, 2010\)*](#).

The chemical is allegedly used in fumigants intended to sterilize soil before planting crops such as strawberries, tomatoes, peppers, fruit and nut trees, grape vines, and ornamentals. The petitioners claim that breathing the chemical causes nausea, slurred speech and vomiting, permanent damage to the lungs, liver, kidneys and central nervous system, as well as fetal miscarriage. They also claim that direct contact with skin causes burns and that the chemical is listed as a known carcinogen under Proposition 65. The petition contends that exposure occurs through the air, soil and groundwater.

According to the petitioners, the risk assessment that DPR conducted when considering whether to register pesticides containing methyl iodide relied on numerous assumptions which OEHHA, the agency with Proposition 65 oversight, criticized on a number of grounds. The petitioners also allege that a DPR scientific review committee disputed many of the agency's assumptions and questioned the safe exposure level the agency established. Still, DPR decided to register methyl iodide for use in California, establishing "a regula-

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tory target level of 32 parts per billion (ppb) averaged over a 24-hour period for bystanders, and 96 ppb averaged over an 8-hour period for workers.” According to the petitioners, these target levels “are more than 100 times greater than many of the reference concentrations established in the final risk assessment, including the reference concentrations for fetal death.”

Alleging violations of various state laws, the petitioners seek a declaration that DPR’s decision to register methyl iodide and a related emergency regulation designating the pesticide as a restricted material were unlawful, a stay of the registration decision, a temporary restraining order, and permanent injunctive relief.

OTHER DEVELOPMENTS

American Heart Association Calls for Intensified Efforts to Reduce Sodium

The American Heart Association (AHA) is urging the food industry, health professionals, government, and the public to “intensify efforts to reduce the amount of sodium (salt) Americans consume.” Published as a presidential advisory in an upcoming issue of its journal *Circulation*, AHA says its science-based recommendations advocate no more than 1,500 mg of sodium daily for the general public. The group claims that current sodium intake is more than two times higher, with 77 percent coming from packaged, processed and restaurant foods.

“Even a modest decline in intake—say 400 mg per day—would produce benefits that are substantial and warrant implementation,” according to the advisory, which warns that increased sodium consumption can lead to high blood pressure and heart, kidney and blood vessel problems. With its 2020 impact goal aimed at reducing deaths from cardiovascular disease and stroke by 20 percent, the advisory stressed that “the potential health benefits of sodium reduction are enormous and extend to all Americans.” See *AHA Press Release*, January 13, 2011.

AFBF Asks Industry to Handle GM Crop Patent Expirations

The American Farm Bureau Federation (AFBF) has reportedly voted to amend its policy on the expiration of genetically modified (GM) crop patents, calling on industry to develop “a protocol for biotech crops before coming off patent.” With patents set to expire for more than 24 GM varieties in coming years, the 6-million member farmers’ coalition has evidently asked industry to craft a plan aimed at avoiding shortages or trade disruptions. AFBF delegates at an Atlanta, Georgia, meeting apparently discussed grower and seed group concerns about whether generic seed versions will be available and accepted by other nations. “There just needs to be a way to deal with it,” said AFBF Director of International Policy Rosemarie Watkins. See *Reuters*, January 13, 2011.

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Rudd Center Announces Spring 2011 Seminar Series

Yale University's Rudd Center for Food Policy and Obesity has announced its [Spring 2011 Seminar Series](#) featuring the interdisciplinary work of public policy and health advocates, as well as legal and industry insights. Speakers for the series include (i) Campaign for Tobacco-Free Kids President Matthew Myers (*Advocacy Lessons from the Battle to Reduce Tobacco*); (ii) Cornell Food and Brand Lab Director Brian Wansink (*Mindless Eating Solutions*); (iii) San Francisco Supervisor Eric Mar (*Creating Access to Healthier Meal Options*); (iv) Legacy CEO Cheryl Heaton (*Lessons Learned from the Tobacco Wars*); (v) Johns Hopkins Bloomberg School of Public Health Professor Stephen Teret (*Innovative Legal Strategies for Food Policy*); and (vi) National Restaurant Association CEO Dawn Sweeney (*Today's Restaurant Industry: Empowering Consumers with Healthy Choices and Nutrition Information*). Hosted at the Rudd Center in New Haven, Connecticut, these seminars are open to the public and run from January 19 through April 20.

MEDIA COVERAGE**Jessica Leeder, "Honey laundering: The sour side of nature's golden sweetener," *The Globe and Mail*, January 5, 2011**

"As crime sagas go, a scheme rigged by a sophisticated cartel of global traders has all the right blockbuster elements: clandestine movements of illegal substances through a network of co-operatives in Asia, a German conglomerate, jet-setting executives, doctored laboratory reports, high-profile takedowns and fearful turncoats," opens *Globe and Mail* food reporter Jessica Leeder in this exposé tracing the honey market from Chinese beekeepers, who are allegedly "notorious" for using banned antibiotics and diluting their products, to North America, where they are "baked into everything from breakfast cereals to cookies and mixed into sauces and cough drops."

Leeder claims that imported honey sold in North America "is more likely to be stamped as Indonesian, Malaysian or Taiwanese, due to a growing multimillion dollar laundering system designed to keep the endless supply of cheap and often contaminated Chinese honey moving into the U.S., where tariffs have been implemented to staunch the flow and protect its own struggling industry." She follows the route of Chinese honey through one German conglomerate, Alfred L. Wolff GmbH (ALW), accused in U.S. courts of "networking with Chinese honey producers and brokers desperate to unload cheap products." According to Leeder's research, "In exchange for contracts with ALW, honey brokers agreed to move Chinese-origin honey to Russia, India, Indonesia, Malaysia, Mongolia, the Philippines, South Korea, Taiwan and Thailand."

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Leeder notes, however, that a recent sting operation targeting ALW has done little to curb the number of “suspect” imports from countries that do not actually produce honey. “It’s kind of like they’re running a car-stealing ring,” one domestic beekeeper was quoted as saying. “You catch the guy stealing the car and put him out of business. But the guy that’s laundering, the chop shop or the packer, he just finds another supplier. I think it’s going to keep getting worse until we catch a couple of big ones, give them a little jail time.”

Bryant Stamford, “Government Should Step In to Help Kids,” *Courier-Journal.com*, January 13, 2011

“I don’t want any more government interference than the next guy, but I believe that the precedent has already been set for successful government intervention on behalf of improving our health,” writes Hanover College Kinesiology and Integrative Physiology Professor Bryant Stamford in the first of a two-part article comparing obesity prevention tactics to federal curbs on tobacco advertising. Acknowledging the public outcry against fast-food incentive bans, Stamford suggests that the government would not set “a dangerous precedent” insofar as it has already made a concerted effort to stymie youth tobacco use with product warnings and advertisement restrictions. Without these measures, he claims, “the cigarette industry would continue to run roughshod over the American public with the specific purpose of capturing us when we are young, addicting us and ensuring that the majority of the addicted will be customers for life.”

For Stamford, the parallels between the tobacco and fast food industries are “unmistakable,” with both allegedly seeking to “attract children and take firm hold of them.” He argues that government thus has the responsibility to protect young diners who are not able “to make the judgment that foods loaded with fat and sugar are bad for them, especially if they taste good.”

“The bottom line is maybe the government shouldn’t legislate what we eat as adults, even if it’s obvious that it is destroying our health,” concludes Stamford. “However, I believe we need to do whatever it takes to protect our children and influence them in the right way.”

SCIENTIFIC/TECHNICAL ITEMS

New Study Questions HDL Cholesterol’s Role

A recent study has reportedly questioned the role of HDL cholesterol in lowering heart disease risk, suggesting instead that one specific protein or compound in so-called “good” cholesterol might be better than others at removing bad cholesterol. Amit Khera, et al., “Cholesterol Efflux Capacity, High-Density Lipoprotein Function, and Atherosclerosis,” *New England Journal of Medicine*, January 13, 2011. According to the study abstract, researchers

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measured cholesterol efflux capacity—or how well HDL extracted cholesterol from cells—in “203 healthy volunteers who underwent assessment of carotid artery intima-media thickness, 442 patients with angiographically confirmed coronary artery disease, and 351 patients without such angiographically confirmed disease.”

The results evidently showed that overall HDL levels were “a less effective” predictor of heart disease than HDL’s ability to remove cholesterol. As one study author noted, these findings could help researchers identify “a particular protein that’s a major determinant” of cholesterol efflux capacity, thus allowing them to test for poor HDL functioning and increased heart disease risk. *See MyHealthNewsDaily*, January 13, 2011.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

