

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Department of Health and Human Services (HHS)

[1] HHS/FDA Food and Drug Safety Office Opens in Costa Rica

HHS Secretary Mike Leavitt and Food and Drug Administration Commissioner Andrew von Eschenbach traveled to Costa Rica this week to open an HHS/FDA office that will serve Latin America in the hope of improving collaboration on food and product safety issues. Plans for the new office were apparently launched in June 2008, when health ministers from Central America and Panama gathered in El Salvador to develop a framework for ensuring the trade of quality goods among the countries. Similar HHS/FDA offices are already operating in Brussels, Beijing, Shanghai, and Guangzhou, and other offices will open in two cities in India and a location in the Middle East. The stated goal of the HHS/FDA “Beyond Our Borders Initiative is to foster collaboration with regulatory authorities around the world, as well as to forge partnerships with industry on the safety of food, animal feed, drugs and medical devices.” See *HHS Press Release*, January 7, 2009.

Food & Drug Administration (FDA)

[2] FDA Issues Final Rule on Labeling Cochineal Extracts

FDA this week [issued](#) a final rule requiring food and cosmetic manufacturers to declare the presence of cochineal extract and carmine in their products. Derived from dried insect bodies, the two coloring agents were previously labeled under “artificial colors” or “color added” on ingredient lists. “This final rule responds to reports of severe allergic reactions, including anaphylaxis to cochineal extract-containing food and carmine-containing food and cosmetics and will allow consumers who are allergic to these color additives to identify and thus avoid products that contain these color additives,” according to FDA, which requires full compliance with the rule by January 5, 2011. See *FoodNavigator-USA.com*, January 6, 2009.

Meanwhile, the Center for Science in the Public Interest (CSPI) has criticized the final rule for failing to indicate the extracts’ insect origins. The consumer advocacy group first petitioned FDA in 1998 for more stringent labeling of cochineal and carmine, citing their widespread use in “dozens of reddish-colored foods and beverages, including fruit drinks, ice creams, yogurts, and candies.” “[T]he FDA should have required labels to disclose that carmine and cochineal are extracted from insects,



which many consumers – including vegetarians, Jews and Muslims – would be interested to know,” opined CSPI in a recent press release. See *The New York Times’ Well Blog* and *CSPI Press Release*, January 5, 2009.

[3] FDA Reports More Cases of Melamine in U.S. Infant Formula

FDA has reportedly detected the industrial chemical melamine and its byproduct cyanuric acid in additional cans of U.S.-manufactured infant formula, but stressed that the levels are below the safety threshold set for young children and infants. Four of the 89 infant formula products tested by FDA contained trace amounts of melamine or cyanuric acid, which are used during the manufacturing process as disinfectants and in some food packaging. FDA and other food safety experts have apparently stated that this trace contamination most likely occurred during processing and not as the result of intentional adulteration. See *Food & Water Watch Blog*, January 5, 2009; *The Associated Press*, January 7, 2009.

Meanwhile, Chinese courts started criminal trials for six cattle farmers and milk collectors accused of making melamine protein powder and adding it to raw milk sold to Chinese dairies, including the government-owned Shijiazhuang Sanlu Group Co. Sanlu recently declared bankruptcy as a result of the nationwide scandal arising from the contamination of infant formula, which allegedly killed six children and sickened more than 300,000. Former Sanlu executive Tian Wenhua has since pleaded guilty to selling fake and substandard milk powder, according to the state-run media. See *China Daily*, December 25, 2008; *The Jurist*, December 26 and 27, 2008; *The New York Times*, January 1, 2009.

In a related development, the American Society of Pediatric Nephrology (ASPN) has advised U.S. parents who adopted Chinese-born infants between 2007 and 2008 to monitor their children for signs of kidney ailments. At least one adoptive parent has apparently reported a diagnosis of kidney stones in her infant daughter born in an area of China implicated in the tainted milk investigation. “[P]arents of adopted children from China who are aware, or suspect a problem stemming from potential melamine contamination might be well advised to consult a lawyer conversant with the issue,” advised one article appearing January 6, 2009, on the *LawyersandSettlements.com* Web site.

U.S. Department of Agriculture (USDA)

[4] Mexico Resumes U.S. Meat Imports

In late December 2008, Mexico banned imports of meat from 30 U.S. processing facilities, telling the USDA that sanitary issues were to blame, although some, including Senator Charles Grassley (R-Iowa), suggested that the move was in retaliation for the new country-of-origin labeling (COOL) rules that took effect September 30. Mexican officials denied any connection and reportedly lifted the embargo for 26 of the plants as of December 30. According to a news source, Mexico is the leading buyer of U.S. meat, and the suspension led to a sharp decline in cattle and hog futures at the Chicago Mercantile Exchange. U.S. and Mexican officials were reportedly scheduled to meet January 5, 2009, to discuss meat import issues.

Meanwhile, Mexico has reportedly joined Canada before the World Trade Organization seeking consultations with the United States over the COOL regulations. The two countries are apparently most



concerned about the impact on meat and livestock, which must be born, raised and slaughtered in the United States to be labeled as U.S. products. According to *The Wall Street Journal*, Mexico's Economy Ministry "considers that the measure generates discrimination against Mexican products, since the U.S. consumer will prefer products labeled as originating in the U.S." Mexican cattle exports to the United States in 2008 reportedly fell by more than half their previous levels. See *The Wall Street Journal*, December 18, 2008; *Reuters*, December 26, 2008; *Associated Press*, December 27, 2008; *CQ Today* and *Pork*, December 31, 2008.

[5] **USDA Announces Second Dietary Guidelines Advisory Committee Meeting**

USDA and the Department of Health and Human Services have [announced](#) the second meeting of the Dietary Guidelines Advisory Committee to discuss its recommendations for updating the 2005 Dietary Guidelines for Americans. Slated for January 29-30, 2009, the meeting will "include presentations on the descriptive statistics on usual nutrient and food-ground intakes in the U.S. population and MyPyramid research updates." USDA is also soliciting oral testimony and written comments from the public, the latter of which must be received by January 23 to ensure transmission to the committee before the meeting.

[6] **FSIS Seeks Members for National Advisory Committee on Meat and Poultry Inspection**

USDA's Food Safety and Inspection Service (FSIS) has published a [notice](#) soliciting nominations for membership on a national advisory committee that addresses meat and poultry inspection issues. Names and curriculum vitae must be postmarked no later than January 23, 2009. FSIS is seeking a diverse

membership drawn from industry, academia, state and local government officials, public health organizations, and consumers and consumer organizations. The committee "provides advice and recommendations to the Secretary on meat and poultry inspection programs." See *Federal Register*, December 24, 2008.

International Organization for Standardization (ISO)

[7] **ISO Publishes Technical Report on Safe Handling of Nanotechnology in the Workplace**

An ISO technical committee focusing on nanotechnology issues has developed a technical report (ISO/TR 12885:2008) that provides "advice for companies, researchers, workers and other people to prevent adverse health and safety consequences during the production, handling, use and disposal of manufactured nanomaterials." Titled *Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, the report "is expected to be widely adopted as a foundation for national nanotechnology occupational safety and health programs around the world," according to the project leader, who also serves as special assistant to the director of the National Institute for Occupational Safety and Health.

ISO is an international standard-setting organization that brings together experts from around the world to establish technical standards that are often adopted by the governments of member states; each national delegation develops its positions in consultation with all potentially affected stakeholders. The group that developed this report is ISO/TC 229,



Nanotechnologies, Working Group 3, Health, Safety and the Environment, which is led by the United States under the guidance of an Intel Corp. representative. Nanomaterials are used in a host of consumer products, including food packaging materials. See *ISO Press Release*, January 5, 2009; *ANSI Press Release*, January 7, 2009.

State and Local Governments

[8] Cal/EPA Air Resources Board Solicits Research Concepts

The Air Resources Board (ARB) of California's Environmental Protection Agency has published a [request](#) for research concepts for its 2009-2010 annual research plan. Among the general areas of research that ARB would like to fund are issues related to agriculture and to health and exposure. The deadline for concept submissions is January 20, 2009. Due to anticipated budget shortfalls, the agency has indicated that co-funded proposals are more likely to be approved and funded.

ARB is interested in funding research relating to confined animal facility operations emissions, pesticide emission assessments, air emissions in agricultural ecosystems involving "nitrogen fate from fertilizer application," and "[c]omparative assessment of emissions from various agricultural practices, including conservation management, conservation tillage, and use of equipment to reduce particulate entrainment emissions or VOC emissions." Under the "health and exposure" rubric, ARB is seeking concept submissions relating to the "[i]mpact of nanoparticles in products and materials on personal and indoor exposures, including exposure both to nanoparticles and to their toxic components (e.g., metals)."

[9] Food Processors Urge California to Delay New Prop. 65 Rules on Exposure to Beneficial Nutrients in Food

California's Office of Environmental Health Hazard Assessment (OEHHA) is considering adopting [rules](#) under Proposition 65 (Prop. 65) that are intended to prevent overexposure to beneficial nutrients in food. The agency's "Initial Statement of Reasons" for the proposed rules, still in draft, note that "[e]xcessive exposures to some [vitamins and minerals necessary to promote human health] have the potential to cause cancer or adverse reproductive effects." OEHHA plans to establish the level of a listed chemical that does not constitute an exposure within the meaning of Prop. 65 and thus would not require warnings. Previous drafts indicated that the agency would rely on "Recommended Dietary Allowance" levels, but the most recent version indicates that levels for individual chemicals will be made on the basis of a chemical-by-chemical evaluation. OEHHA has also apparently indicated its intention to address human nutrients and plant nutrients separately.

According to the California League of Food Processors, which has expressed concerns about the draft rules in a [comment letter](#), OEHHA should delay its adoption of the rules until it can show that the plan is "practical, enforceable, based on sound science, and whether it may lead to more, rather than less, expensive and frivolous litigation." The group cites boron as an example of a chemical that is ubiquitous in fruit and vegetable horticulture. "Once the plant material is harvested, it is virtually impossible to determine whether any boron that might be detected in a can of tomatoes or bag of frozen spinach came from the soil, fertilizer, irrigation water, or all of the above," the processors note, adding that it would be difficult to prove if the



chemical is naturally occurring, and thus exempt from Prop. 65 warning requirements, or would require warnings.

OEHHA will accept additional public comments on the proposal until January 12, 2009. Prop. 65 is the voter-approved California law that requires warnings on products containing chemicals known to the state to cause cancer or present reproductive health risks. See *Inside Cal/EPA*, December 26, 2008.

Litigation

[10] Ninth Circuit Turns Down Gerber Request for Rehearing in Fruit Juice Snacks® Case

The Ninth Circuit Court of Appeals has denied the request by Gerber Products Co. to rehear the court's April 2008 decision overturning the dismissal of putative class claims that the company's Fruit Juice Snacks® packaging misled consumers. *Williams v. Gerber Prods. Co.*, No. 06-55921 (9th Cir., amended opinion filed December 22, 2008). A detailed summary of the court's April ruling appears in issue 258 of this Update.

In its amended opinion, the court eliminated one sentence and reorganized two other sentences, but did not otherwise change its ruling that a detailed ingredients list in small type cannot shield a food manufacturer from liability for claims that its packaging misrepresents the quality of the product. "Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging."

The product at issue, intended for toddlers, is sold in a package with images of oranges, cherries and strawberries, although the lead ingredients are corn syrup and sugar. The court observed that

calling such a product "nutritious" alone would be little more than non-actionable puffery, but noted that the packaging had a "number of features" that "could likely deceive a reasonable consumer." A spokesperson for the Center for Science in the Public Interest (CSPI) hailed the ruling, stating, "The Court's decision is a warning to all companies that try to make junk food look healthy by depicting nutritious fruits, vegetables, and whole grains on labels of sugary, high-calorie snacks." CSPI will apparently serve as lead counsel when the proceedings resume. See *CSPI Press Release*, January 2, 2009.

[11] Industry Groups Challenge California Ban on Food from Downer Livestock

According to news sources, litigation has been filed in California challenging a new law that prohibits the sale or distribution of food from non-ambulatory livestock. One of the suits, filed in late December 2008 by the National Meat Association, claims that the state's hog industry should be exempt. An association spokesperson reportedly indicated that "hog fatigue" causes hogs to lie down occasionally, but that nothing is wrong with these animals.

The American Meat Institute (AMI) filed a motion to intervene, arguing that the law as a whole is preempted by the Federal Meat Inspection Act. An AMI press release notes, "on some occasions all species can become injured even until the last minutes before processing, but an injury like a broken ankle does not automatically make livestock unfit for consumption."

The California law (A.B. 2098), effective January 1, 2009, amended the state penal code by proscribing any slaughterhouse use of non-ambulatory animals. The bill's sponsor called the



industry groups challenging the law “extreme and irresponsible,” saying, “They believe they have the right to process diseased and disabled animals and they feel the state of California does not have the right to protect consumers.” A hearing on the matter will apparently be held in a federal court in Fresno some time in January. *See American Meat Institute Press Release*, December 24, 2008; *Press-Enterprise*, January 7, 2009.

[12] FDA Wins Injunction Against Dairies Deviating from Drug Laws

The Food and Drug Administration (FDA) has apparently prevailed in proceedings seeking injunctive relief against two New Mexico dairies that “were not keeping adequate medication records to prevent unsafe drug residues in cattle offered for slaughter” and “were using medications for unapproved indications not specified on the drug label” without a valid veterinarian-client-patient relationship. The companies, Do-Rene and Clover Knolls Dairies, were warned about these violations in 2005 and 2008 following inspections and tissue sampling. Apparently, some of the dairies’ cows tested positive for illegal levels of a number of drugs, including one “expressly forbidden for use in lactating cows.” According to FDA, “These residues may cause allergic reactions in extremely sensitive individuals, and they may contribute to forming antibiotic-resistance in bacteria.” Future violations may result in civil or criminal penalties. *See FDA Press Release*, January 2, 2009.

[13] Parties to *Trans* Fat Class Action Against Wendy’s Agree to Settle

A California woman who claimed that Wendy’s International, Inc. violated state consumer protection laws by misrepresenting the *trans* fat content of

its French fries and fried chicken products has entered a settlement agreement with the fast-food company. *Yoo v. Wendy’s Int’l, Inc.*, No. 07-4515 (U.S. Dist. Ct., C.D. Cal., settlement filed December 2008). For purposes of the settlement, the parties agreed to the certification of a nationwide class of those who purchased Wendy’s fries and chicken for the past two years. Without conceding any liability, Wendy’s agreed to (i) eliminate *trans* fat from its frying process, (ii) submit to independent testing, (iii) donate \$1.8 million to cancer, diabetes and heart associations, and (iv) not oppose a fee award of up to \$1.09 million to class counsel in the *Yoo* action. Attorneys representing class claimants in similar litigation filed in New York and Florida will share the fee distribution. Wendy’s also agreed to attribute the \$2.2 million value of the “cost to it and its suppliers to eliminate *trans* fat from the frying process” to the settlement class.

Media Coverage

[14] Seattle Newspaper Exposes Widespread “Honey Laundering”

“A far cry from the innocent image of Winnie the Pooh with a paw stuck in the honey pot, the international honey trade has become increasingly rife with crime and intrigue,” claims a recent *Seattle Post-Intelligencer* (*Seattle P-I*) investigative report on the widespread practice of “honey laundering,” the illegal practice of transshipping products through other countries to avoid U.S. import fees, protective tariffs or taxes. In addition, the global market is “plagued by foreign hucksters and shady importers who rip off conscientious U.S. packers with honey diluted with sugar water or corn syrup – or worse, tainted with pesticides or antibiotics.”



Seattle P-I allegedly found that (i) “tens of thousands of pounds of honey entering the U.S. each year come from countries that raise few bees and have no record of producing honey for export”; (ii) “only a small fraction [of honey] is inspected, and seizures and arrests remain rare”; and (iii) “[t]he feds haven’t adopted a legal definition of honey, making it difficult for enforcement agents to keep bad honey off the shelves.” The article also highlighted a series of import alerts issued for Chinese honey that contained the highly toxic antibiotic chloramphenicol as well as iprofloxacin and Enrofloxacin, which are prohibited by FDA in food products. Chinese beekeepers first started using the antibiotics in 1997 after bacteria infected hundreds of thousands of their hives, notwithstanding the Ministry of Agriculture’s 2005 ban on chloramphenicol in food production. See *Seattle Post-Intelligencer*, December 29 and 30, 2008.

[15] Marlana Spieler, “Saving a Squirrel by Eating One,” *The New York Times*, January 7, 2009

“While some have difficulty with the cuteness versus deliciousness ratio – that adorable little face, those itty-bitty claws – many feel that eating a squirrel is a way to do something good for the environment while enjoying a unique gastronomic experience,” writes *New York Times* journalist Marlana Spieler in this article chronicling Britain’s efforts to save its indigenous red squirrel population from an influx of North American gray squirrels. “The grays take over the reds’ habitat, eat voraciously and harbor a virus named squirrel parapox (harmless to humans) that does not harm grays but can devastate reds,” according to Spieler, who credits the “Save Our Squirrels” campaign with creating a market for culled squirrel meat among TV

chefs, cookbooks, farmers’ markets, and restaurants. Hunters, gamekeepers and the U.K. Forestry Commission apparently supply the delicacy, which has been promoted as a low-fat alternative to other game animals. “Part of the interest is curiosity and novelty. It’s a great conversation starter for dinner parties,” one squirrel purveyor was quoted as saying.

Scientific/Technical Items

[16] Researchers Link Food Additive in Processed Foods to Growth of Lung Tumors

According to animal studies conducted by Korean-based researchers, a common food additive used in processed meats and chicken, when fed to mice at levels roughly equivalent to human intake, increases lung tumor progression and growth. Hua Jin, et al., “High Dietary Inorganic Phosphate Increases Lung Tumorigenesis and Alters Akt Signaling,” *American Journal of Respiratory & Critical Care Medicine* (2009). While phosphate is apparently an essential nutrient, its increasing use in foods ranging from processed meats to cheeses, beverages and bakery goods has more than doubled human intake since the 1990s to some 1,000 mg daily. The scientists concluded that “careful regulation of dietary Pi may be critical for lung cancer prevention as well as treatment.” See *Foodnavigator-usa.com*, January 6, 2009.



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