

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

APHIS Partially Deregulates GE Sugar Beet Root Crop Production

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has [announced](#) its decision to partially deregulate the Roundup Ready® sugar beets developed by the Monsanto Co. These genetically engineered (GE) sugar beets resist the company's Roundup Ready® herbicide. A court previously determined that APHIS violated the National Environmental Policy Act by deregulating the sugar beets without conducting an environmental impact statement (EIS). APHIS's interim action was taken on the basis of its finding of no significant impact on human health or the environment by the GE sugar beet root crops and will remain in effect until its EIS is completed in 2012.

The agency's action means that farmers can continue planting GE sugar beets under mandatory conditions that will restrict their movement and environmental release. According to APHIS, these conditions will ensure "that the implementation of this interim regulatory action will not result in any environmental impacts which may significantly affect the quality of the human environment." APHIS refused to partially or fully deregulate GE sugar beet seed production, thus it remains subject to the agency's regulations governing the introduction of certain GE organisms. *See Federal Register*, February 8, 2011.

FSIS Considers Animal Rights Groups' Petitions on Downer Livestock

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has requested comments on two [petitions for rulemaking](#) submitted by animal rights groups seeking reformed regulations concerning "the disposition of non-ambulatory disabled" livestock at slaughter. FSIS also plans to clarify its requirements for "condemned non-ambulatory disabled cattle at official slaughter establishments."

The Humane Society of the United States (HSUS) apparently asked FSIS to "repeal a provision in its ante-mortem inspection regulations that permits

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veal calves that are unable to rise from a recumbent position and walk because they are tired or cold to be set apart and held for treatment." Current provisions allow those calves, if found free of disease, "to proceed to slaughter if they are able to rise and walk after being warmed or rested" and ultimately processed for human food. HSUS has petitioned the agency to amend the regulations "to require that non-ambulatory disabled veal calves be condemned and promptly and humanely euthanized." The petition asserts that the "set-aside" provision "encourages conduct such as dragging, kicking, excessive shocking, and other means of forced movement" in connection with slaughter.

Farm Sanctuary, a farm-animal protection organization, has petitioned FSIS to amend the federal meat inspection regulations "to prohibit the slaughter of non-ambulatory disabled pigs, sheep, goats, and other amenable livestock" for human food. Asserting that the practice encourages inhumane treatment, the petition also notes that prohibiting such slaughter "will encourage livestock producers and transporters to improve their handling practices" and that "such action is needed to prevent diseased animals from entering the human food supply." FSIS has requested comments by April 8, 2011. See *Federal Register*, February 7, 2011.

Single-Method Test that Detects Nine Sweeteners Adopted as European Standard

The European Committee for Standardization has approved a single-test method that can detect nine different sweeteners and their dosages in drinks, and canned and bottled fruits. Developed by the European Commission's Joint Research Center's (JRC's) Institute for Reference Materials and Measurements, the method sets national standards for European Union (EU) member states, Croatia, Iceland, Norway, and Switzerland to evaluate sweetener levels in imported foodstuffs and those produced within the EU.

Using a high-performance "liquid chromatographic with evaporative light scattering detection," the method can simultaneously test for six EU authorized sweeteners: acesulfame-K (ACS-K), aspartame (ASP), cyclamic acid (CYC), saccharin (SAC), sucralose (SUC), and neohesperidine dihydrochalcone (NHDC). It can also test for three non-authorized sweeteners: neotame (NEO), alitame (ALI) and dulcin (DUL).

According to JRC, the method "can provide several pieces of information which are needed to correctly label the food. It can provide whether or not the non-authorized or the authorized sweeteners have been used. It can also show whether the concentration of the authorized six sweeteners is below the given maximum dosage as described in current EU legislation." See *JRC Press Release*, February 7, 2011.

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Germany Approves Feed Safety Measures

The German Cabinet has reportedly approved an action plan proposed by Food, Agriculture and Consumer Protection Minister Ilse Aigner that incorporates “tighter rules for dioxin checks into the Food and Feed Code (LFGB)” and proposes several statutory changes to feed production regulations. A response to dioxin-tainted animal feed that temporarily disrupted the European Union’s (EU’s) egg, poultry and pork supply, this early warning system will “enable the supervisory authorities in Germany to respond in a quicker and more targeted manner,” said Aigner, who has vowed “to promote these rules at EU-level.”

The new rules require German food and feed manufacturers “to report all test results on dioxins and similar problem substances to the competent authorities,” who will verify the information and act “immediately” if necessary, and directs private laboratories to “automatically report alarming measurement results of undesired substances that are hazardous to health in foods and animal feed.” According to the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV), regulators have, “for many years, been collecting data on the levels of dioxins and dioxin-like compounds in foods and animal feed,” but now this information and industry’s internal controls are “to be brought together in a joint data pool at the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) in Berlin.” The office will evaluate this data each quarter in an effort to “instigate counter-measures more quickly.”

In addition, BMELV has announced plans to revise the statutory orders governing the approval of feed businesses and the separation of feed fats and industrial fats during production. The ministry has also committed to creating “binding positive list of feed materials... at EU level,” as well as amending the Consumer Information Act “to make it mandatory for the competent authorities to publish without delay the results they have from official food controls and inspection on all infringements that have occurred due to maximum limits being exceeded.” Cabinet ministers are still debating, however, whether “an infringement of the Food and Feed Code should be classified as either a criminal or a regulatory offence or whether the current range of penalties is still appropriate.” See *BMELV Press Release*, February 2, 2011.

Massachusetts Health Regulators Move to Limit Junk Food in Public Schools

Massachusetts public health regulators have reportedly approved proposed rules that would prohibit public schools from selling sweetened soft drinks, salty and calorie-laden packaged snacks, and white bread sandwiches as a way to combat childhood obesity. Effective in the 2012-13 school year, the proposed regulations need the approval of the state’s Public Health Council, which is expected to consider the issue in spring 2011.

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According to a news source, the proposed regulations would apply to a la carte lines, snack shops and vending machines, but not main cafeteria lines. "You don't want to be feeding kids a bunch of sugar or low-nutrient foods and expect them to be well-prepared to learn," said Jill Carter, executive director of the Health and Wellness Department in Boston's public schools. *See The Boston Globe*, February 10, 2011.

States Rights Moves into the Food Safety Arena

Utah State Representative Bill Wright (R-Holden) has reportedly introduced legislation (H.B. 365) that would exempt from federal regulation all foods grown and consumed within the state's borders. He was quoted as saying, "Within the state, it's state's rights. We already have regulations over those items. We function well now. We don't think they have a right or authority to regulate those items that are not in interstate commerce, as long as they're grown within the state, packaged in the state and remain in the state."

A Center for Science in the Public Interest (CSPI) spokesperson apparently responded by claiming that the politician was "playing to people's fears and misrepresenting the facts and doing it for political purposes." According to CSPI, Utah merited a "D" grade for its ability to detect contaminated food outbreaks. Some produce and livestock farmers echoed Wright's concerns, contending that regulations and inspections add costs to their operations. An organic farmer reportedly said, "We don't have to be certified organic and if we weren't, we'd never hear from [federal inspectors]. The amount of regulation they do isn't too much. They aren't too severe." *See The Salt Lake Tribune*, February 5, 2011.

LITIGATION

Judicial Panel Denies Request to Centralize Contaminated Baby Formula Lawsuits

The Judicial Panel on Multidistrict Litigation has denied a plaintiff's motion to centralize several lawsuits involving recalled infant formula, purportedly contaminated with insects, before a multidistrict litigation (MDL) court for pretrial proceedings. *In re: Abbott Labs., Inc., Similac Prods. Liab. Litig.*, MDL No. 2211 (J.P.M.L., decided February 4, 2011).

The panel noted that while it had centralized food-product contamination lawsuits in the past, it would not be appropriate to do so here because individual issues predominated over common ones. According to the panel, "discovery and motion practice may be expected to concern (1) the particular product each plaintiff purchased, (2) any injuries that consumption of the product caused, (3) whether the product contained beetles or beetle larvae,

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and/or (4) what advertising or other representations were made to each particular plaintiff (and, relatedly, whether the plaintiff relied upon those representations)."

Still, the panel encouraged the parties to pursue a voluntary coordination strategy, "to minimize the potential for duplicative discovery and/or inconsistent pretrial rulings." The cases that will be litigated separately are: *Tosh-Surryhne v. Abbott Labs., Inc.*, No. 10-02603 (E.D. Cal.); *Gray v. Abbott Labs., Inc.*, No. 10-06377 (N.D. Ill.); *Brown v. Abbott Labs, Inc.*, No. 10-06674 (N.D. Ill.); *Brander v. Abbott Labs., Inc.*, No. 10-03242 (E.D. La.); and *Leonard v. Abbott Labs., Inc.*, No. 10-04676.

India Supreme Court Requests Removal of Industry Reps from Safety Enforcement Panels

Ruling on a request by a non-governmental organization (NGO), two supreme court justices in India have reportedly asked the government to remove food and soft drink company representatives from food-safety standards and enforcement panels. According to the justices, the industry representation clearly breaches the mandate of the Food Safety and Standards Act, 2006. Under the law, government panel members must be independent scientific experts who may consult with the food industry and consumers before adopting standards regulating the manufacture, storage, distribution, sale, and import of food products.

The NGO had reportedly sought a scientific investigation into the contents of soft drink beverages, claiming that their consumption is a major cause of adolescent obesity. An industry spokesperson apparently responded by calling obesity a rich man's problem in a country where more than a third of the population lives below the poverty line. He cited the Indian Council for Medical Research, which stated, "[A]vailable literature does not clearly establish a direct cause and harmful effect relationship between consumption of carbonated beverages and its effects on human health." See *The Times of India*, February 9, 2011.

Recalled Ground Red Pepper Sparks Litigation Between Spice Companies

Adams Extract & Spice has sued Van de Vries Spice Corp. in a New Jersey federal court alleging damages in excess of \$75,000 due to a 2009 spice recall involving ground red pepper allegedly contaminated with *Salmonella*. *Adams Extract & Spice, LLC v. Van de Vries Spice Corp.*, No. 11-00720 (U.S. Dist. Ct., D.N.J., filed February 8, 2011). Apparently, Van de Vries sold 11,000 pounds of the spice to Adams Extract which then incorporated it into various products sold under its brand name. After learning about the contamination risk, Adams Extract issued a product recall that allegedly "resulted in significant damages to Adams Extract."

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Alleging negligence by failure to comply with Food and Drug Administration standards, breach of contract, breach of warranty, and strict product liability, Adams Extract seeks compensatory damages, interest, costs, and delay damages.

Welch's Agrees to Settle Pomegranate Juice False-Advertising Claims

The parties litigating whether Welch Foods, Inc. falsely labeled its "100% Juice White Grape Pomegranate flavored 3 juice blend" beverage have filed a stipulation of settlement in a California federal court. *Burcham v. Welch Foods, Inc.*, Nos. 09-05946 and 10-01427 (U.S. Dist. Ct., C.D. Cal., filed February 7, 2011). Under the agreement, a nationwide class of consumers would release their claims in return for refunds and coupons for replacement products, depending on whether they can prove that they purchased the product. The company would place coupons for free juice products in Sunday newspapers throughout the United States at a total value of \$30 million.

While Welch's continues to maintain that the labeling claims are preempted by federal law and that the company has complied in all respects with federal law, it also claims that it lost money selling the white grape pomegranate juice. Acknowledging the difficulties in locating class members, Welch's has also agreed to make product donations of not less than \$350,000 to charitable organizations of its choosing. According to the stipulation, class counsel agreed to seek a fee and expense award of less than \$1.25 million, and Welch's reserved the right to challenge that application to the extent that it exceeds \$450,000. The lead plaintiff will be awarded \$2,500 if the settlement is approved.

"Red Bull" Defense Joins "Twinkie" Defense in Crime Annals

According to a news source, a prosecutor in Florida appears willing to accept an insanity defense in the case of a man who murdered his father while depressed, sleep-deprived and under the purported influence of an energy drink. A psychiatrist reportedly testified during a bond reduction hearing that defendant Stephen Coffeen, who allegedly smothered his father in 2009, suffered a "psychotic break" that was "accelerated by his use of Red Bull." The defendant's brother, Thomas Coffeen, is apparently skeptical about the defense, writing to the court, "since when is being tired, and high on an energy drink, an excuse for cold blooded murder, anyway?" The court has denied bond and set another hearing in the case for February 17, 2011. See *St. Petersburg Times*, February 7, 2011.

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OTHER DEVELOPMENTS

USDA Economist Says Questions Remain About Use of Nanotech in Foods

A U.S. Department of Agriculture (USDA) economist, writing in the *Journal of Consumer Affairs*, has reportedly cited the lack of a suitable definition for nanotechnology as an obstacle to the potential labeling of foods and packaging incorporating nanoparticles or materials. According to Jean Buzby, while the National Nanotechnology Initiative defines nanotechnology in terms of size, i.e., “dimensions between approximately 1 and 100nm,” this range “is an arbitrary measure and was not set on any real meaning or relationship between particle size and toxicological effects or kinetics, such as chemical reaction rates.” Buzby apparently opines that the technology’s potential benefits need to be communicated to the public and calls for increased funding for safety research.

In a related development, the Carolina Academic Press is reportedly poised to release a law school treatise on nanotechnology titled *Nanotechnology Law and Policy Cases and Materials*. Authored by Texas Tech University School of Law Professor Victoria Sutton, the book focuses on “the scope of nanotechnology as a science and as a commercialized application of science, and the legal, regulatory and policy aspects of this emerging technology.” The [table of contents](#) indicates that the book will cover international, federal, state, and local regulation, constitutional and intellectual property issues, as well as the few cases to date involving nanotechnology. See *FoodNavigator-USA.com*, February 9, 2011.

AICR/WCRF Release Preventable Cancer Estimates

The American Institute for Cancer Research (AICR) and World Cancer Research Fund (WCRF) recently released an updated [expert policy report](#) estimating that 340,000 cancer cases in the United States could be prevented each year through “eating a varied and healthy diet, undertaking regular physical activity, being at a healthy weight and limiting alcohol intake.” According to a February 3, 2011, joint press release, positive changes in these lifestyle factors could achieve “significant reductions in particularly common cancers..., including breast (38 percent of cases), stomach (47 percent of cases) and colon (45 percent of cases).”

Reflecting the most recent global incidence data from GLOBOSCAN 2008, these revised estimates evidently square with the World Health Organization’s 2010 *Global Recommendations on Physical Activity for Health*, which concluded that “regular physical activity can prevent many diseases such as breast and colon cancers, cardiovascular diseases, and diabetes.” In addition, AICR and WCRF have noted that “other choices we make personally or collectively can reduce the risk of cancer including not using tobacco, avoiding excessive sun

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exposure, and protecting against cancer-causing infections.” The two groups have thus urged Americans to sign the World Cancer Declaration to help reduce global tobacco consumption, obesity and alcohol intake by 2020, and to motivate global leaders “to set realistic and achievable directives” for cancer prevention at the September 2011 U.N. Summit for Non-Communicable Diseases.

MEDIA COVERAGE

Mark Bittman, “Is ‘Eat Real Food’ Unthinkable?,” *The New York Times*, February 8, 2011

New York Times food columnist Mark Bittman tackles the U.S. Department of Agriculture’s (USDA’s) latest dietary guidelines in this opinion piece claiming that “the agency’s nutrition experts are at odds with its other mission: to promote our bounty in whatever form its processors make it.” According to Bittman, the guidelines are clearest when promoting “good” foods like fresh produce, but become “vague” when describing what not to eat, often resorting to scientific language and acronyms like SOFAS—Solid Fats and Added Sugars—“to avoid offending meat and sugar lobbies.”

“The [USDA] can succeed at its conflicting goals only by convincing us that eating manufactured food lower in SOFAS is ‘healthy,’ thus implicitly endorsing hyper-engineered junk food with added fiber, reduced and solid fats and so on, ‘food’ that is often unimaginably far from its origins,” opines Bittman. “The advice people need is to cook and eat more real food, at the expense of the junk served in most restaurants and take-out places.”

SCIENTIFIC/TECHNICAL ITEMS

Research Points to Contaminated Wrapper as Source of PBDEs in Butter

Based on a small sample of butter purchased in Texas grocery stores, researchers have concluded that high levels of polybrominated diphenyl ethers (PBDEs) found in one sample “were likely transferred from contaminated wrapping paper to butter.” Arnold Schecter, et al., “Contamination of U.S. Butter with Polybrominated Diphenyl Ethers from Wrapping Paper,” *Environmental Health Perspectives*, 2011. While they were unable to pinpoint the contamination’s source, the study’s authors suggest that their research can “serve to alert the public, scientists, food processors, and regulatory agencies that relatively high levels of food contamination with emerging POPs [persistent organic pollutants] sometimes occurs.” They call for additional research and spot checks by regulatory agencies “to determine when and where screening for POPs contamination of food is most appropriate and would also help reduce incidence of contaminated food sold to the public.”

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Meanwhile, in commentary on recent scientific literature involving food contact materials, an assistant University of Rochester obstetrics and gynecology research professor suggests that insufficient attention is being paid to “a broad swath of chemicals found in canned, packaged and other processed food.” Emily Barrett calls the plastics used to package foods “a forgotten component of food safety.” She cites research that has found endocrine disruptors, such as bisphenol A and phthalates, as well as carcinogens, such as benzophenone, in food packaging, noting that they are not routinely tested or regulated in food. See *Environmental Health News*, February 7, 2011.

Research Probes Association Between Diet Soda and Stroke Risk

A study presented at the American Stroke Association’s International Stroke Conference 2011 has reportedly linked daily diet soda consumption “to a higher risk of stroke, heart attack and vascular-related deaths.” Led by University of Miami scientist Hannah Gardener, researchers analyzed soft drink consumption for 2,564 people enrolled in the Northern Manhattan Study (NOMAS), grouping participants into seven categories ranging from those who drank less than one soda of any kind per month, to those who reported daily regular or diet soda consumption. The study results evidently showed that, after an average follow-up of 9.3 years, participants who drank one diet soda every day “had a 61 percent higher risk of vascular events than those who reported no soda drinking.”

“This study suggests that diet soda is not an optimal substitute to sugar-sweetened beverages, and may be associated with a greater risk of stroke,” Gardener was quoted as saying. She added, however, that “diet soda drinkers need to stay tuned” for further studies before changing their behaviors. See *Stroke Conference 2011 News Release, MSNBC.com* and *ABC News*, February 9, 2011.

Obesity Study Questions Timing of Solid Food Introduction

A recent study has claimed that, “among formula-fed infants or infants weaned before the age of 4 months, introduction of solid foods before the age of 4 months was associated with increased odds of obesity at age 3 years.” Susanna Huh, et al., “Timing of Solid Food Introduction and Risk of Obesity in Preschool-Aged Children,” *Pediatrics*, February 2011. Harvard researchers apparently followed 847 children enrolled in a pre-birth cohort study known as Project Vida, using “separate logistic regression models for infants who were breastfed for at least 4 months (‘breastfed’) and infants who were never breastfed or stopped breastfeeding before the age of four months (‘formula-fed’), adjusting for child and maternal characteristics.” The study findings apparently indicated that, among the formula-fed infants only, “introduction of solid foods before 4 months was associated with a six-fold increase in odds of obesity at age 3 years.”

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"One possible reason why we saw an association among formula-fed but not breastfed infants is that formula-fed infants may increase their energy intake when solids are introduced. Breastfeeding may promote self-regulation of an infant's energy intake, and the mother may learn to recognize her infant's hunger and satiety cues," speculated the study authors, who noted that their results supported the American Academy of Pediatrics' recommendations to introduce solids between 4 and 6 months of age. *See The Wall Street Journal*, February 7, 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.

