

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

Legislation Grapples with Bioengineered Animals

U.S. Representative Rosa DeLauro (D-Conn.) has introduced a bill ([H.R. 6325](#)) that would require labeling for food that contains genetically engineered (GE) animal products. The Consumer Right to Know Food Labeling Act of 2010 would amend the Food, Drug, and Cosmetic Act and Meat Inspection Act to compel the disclosure of product ingredients derived from cloned animals or their progeny. It would also mandate labeling for food products that contain GE salmon. In addition to providing for civil penalties and citizen suits in the event of misbranded food, the bill would direct the U.S. Department of Agriculture and Food and Drug Administration (FDA) to develop and implement a recordkeeping audit trail applicable to “any person that prepares, stores, handles, or distributes a cloned product for retail sale.”

“A recent Food & Water Watch survey revealed that 78 percent of Americans do not want genetically-engineered salmon to be approved and made available in stores and restaurants,” DeLauro said in a recent press release. “Because the FDA is treating these genetically-modified salmon not as a food issue but as an animal drug issue, current regulations would leave the consumers unable to discern between these new modified salmon and traditional salmon. If FDA approves the genetically-modified salmon the American public deserves to know about the truth about their food, and this legislation will ensure that they are provided with this critical information.” See *DeLauro Press Release*, September 29, 2010.

Meanwhile, U.S. Representative Don Young (R-Alaska) has introduced legislation ([H.R. 6265](#)) to prevent FDA from approving GE fish altogether. The bill would revise the federal Food, Drug and Cosmetic Act to deem any GE fish unsafe, “notwithstanding any other provision of this section.”

“There are serious health and environmental impacts that a genetically-modified fish could create,” Young was quoted as saying. “The FDA is treating this hearing process as an animal drug issue, which means it will not adequately address how this product will affect humans when consumed or how it might affect wild fish stocks if accidentally exposed.” See *Alaska Business Monthly*, September 30, 2010.

In a related development, Food & Water Watch has stepped up its campaign to block FDA approval for the first GE fish variety, a product known as AquAdvantage® salmon that contains both Chinook and ocean pout genes to promote faster

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maturation. The consumer watchdog has asked for donations to fund its efforts to (i) "gather 50,000 comments to the FDA by November 22nd, opposing the approval of GE salmon, and requiring the labeling of this salmon as genetically engineered, if it's approved"; (ii) "send organizers to key congressional districts to build support for legislation that will ban GE salmon"; and (iii) "distribute hundreds of action toolkits to folks like you who can gather actions in their local community." The organization has called the crusade one of its most important "because once frankenfish are introduced, they cannot be taken back."

FDA Calls Fruit Product Misbranded, Ingredients and Missing Calorie Disclaimer at Issue

The Food and Drug Administration (FDA) has issued a [warning letter](#) to Chiquita Brands International, Inc. indicating that the company is violating the Federal Food, Drug, and Cosmetic Act by misbranding several of its pineapple products. According to FDA, because Pineapple Bites with Coconut® is made with a coconut flavored spray, the product's statement of identity and ingredient statement are false and misleading and should instead be identified as containing "coconut flavor."

The labeling also apparently states that the product contains antioxidants but does not include the names of the nutrients that are the subject of the claim. FDA further contends that the products include the claim "Plus Phytonutrients." Because no recommended daily intake or daily recommended value has been established for phytonutrients, such nutrient content claims are not authorized, according to the agency. The products also apparently include the statement "Only 40 calories," which FDA says implies that the products are "low calorie" foods. Low-calorie foods are those that do not contain more than 40 calories per reference amount customarily consumed (RACC), in this case, 2 tablespoons for fruit products. According to FDA, the pineapple products contain 40 calories for each piece, or about 70 calories per RACC, which would require a disclaimer: "Only 40 calories per serving, not a low calorie food."

FDA contends that the products are also misbranded because they contain ascorbic acid and citric acid but fail to declare these preservatives with a description of their functions. The agency refers to an earlier problem the company had with *Salmonella* contamination in its romaine lettuce product and faults the company for its response to the agency's good manufacturing practices violations citation. FDA calls for the company to respond within 15 days regarding steps taken to correct the noted violations.

CDC Announces Grants for Sodium-Reduction Strategies

The U.S. Centers for Disease Control and Prevention (CDC) recently announced five grants geared toward researching, developing and implementing sodium-reduction strategies. Totaling \$1.9 million, the grants "will support policy strategies to create healthier food environments and help reduce sodium intake for a three-year funding period," stated CDC, which identified the grantees as California (working with Shasta County); Kansas (working with Shawnee County); Los Angeles County; New York City; and New York state (working with Broome and Schenectady counties).

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The agency specifically cited studies indicating “that on average U.S. adults consume more than 3,400 milligrams of sodium per day,” with an estimated 77 percent of this intake coming from “processed and restaurant foods.” According to CDC, each funded project will implement “at least one major sodium reduction policy as well as evaluation activities” that build on existing community policies “to improve nutrition and lower blood pressure.” Such activities could include “working with restaurants and food service suppliers, grocery stores, schools, hospitals and government facilities to develop low sodium food policies, and media campaigns to help raise awareness of the dangers of too much sodium in the diet.” See *CDC Press Release*, October 1, 2010.

Nitrosamines Targeted Under Potential EPA Regulatory Paradigm

The Environmental Protection Agency (EPA) is reportedly considering addressing toxins in drinking water by regulating them in groups, rather than continuing to address them contaminant-by-contaminant, and has identified nitrosamines as one of the first groups that could be subject to the new paradigm. Other groups under consideration are pesticides, volatile organic compounds and chlorinated disinfection byproducts.

EPA Administrator Lisa Jackson apparently proposed taking this approach earlier in the year, and the agency conducted a number of workshops over the summer to gauge stakeholder support. *InsideEPA.com* obtained a draft discussion paper from a September 2010 meeting; it details a number of ways toxins can be grouped, including (i) similar effects on human health and the environment, (ii) similar water treatment options, and (iii) occurrence similarities, i.e., likely to occur with other chemicals in the group.

Drinking water industry officials have apparently expressed concerns with EPA’s proposal to address nitrosamines in the near future, noting that treating water for these substances is “difficult and challenging and expensive” and unlikely to reduce total exposures in any significant way given that “there is a lot more [of the compound] in beer and hot dogs” than in drinking water. Nitrosamines are used in rubber, pesticide and cosmetic manufacturing; people are also exposed to them in many protein-rich foods. EPA has reportedly claimed that the benefits of a grouping approach include better accounting for the risks of multiple contaminants, expediting regulation of emerging contaminants and giving water utilities the opportunity to make better long-term investment plans. See *InsideEPA.com*, October 12, 2010.

FOP Nutrition Rating Systems Addressed in New IOM Report

The Institute of Medicine (IOM) has [released](#) the first phase of its report on front-of-package (FOP) rating systems and symbols for food products and recommends that the nutrients of greatest concern to consumers—calories, saturated fats, *trans* fat, and sodium—as well as serving size, should be highlighted, with calorie-count and serving-size information displayed prominently. According to IOM, “The inclusion of total calories is one way to emphasize the importance of calories in the diet and may help consumers identify lower calorie foods and track the number of calories

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consumed, . . . [while] serving size information may help consumers better visualize realistic serving sizes and put that portion into context with the other foods and beverages they are consuming.”

Sponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration (FDA), the report, titled “Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase 1 Report,” examines and compares 20 different FOP nutrition rating systems. Among the FOP systems reviewed were programs developed by food companies such as General Mills, PepsiCo and Kellogg; the governments of Australia, Great Britain, and Sweden; and the American Heart Association. Phase 2, expected to conclude in 2011, will assess consumers’ use and understanding of FOP symbols and determine which rating systems best promote public health.

The principles guiding the report’s approach included the following: (i) “A well-balanced, high-quality diet consistent with the *Dietary Guidelines for Americans* is essential for the health of Americans, and front-of-package labeling is one tool among many geared toward helping Americans make healthful choices”; (ii) “Front-of-package systems will focus on nutrients or food components that are most strongly associated with diet-related health risks affecting the greatest number of Americans”; (iii) “The information highlighted in front-of-package systems will be consistent with the Nutrition Facts panel”; and (iv) “Front-of-package systems will apply to as many foods as possible.”

According to the report, the authors’ deliberations were also informed by these findings: (i) “Obesity, cardiovascular disease, type 2 diabetes, and certain types of cancers are the health risks affecting the greatest number of Americans that are also most strongly associated with diet”; and (ii) “Americans consume too many calories, saturated fats, *trans* fat, and added sugars; too much sodium; and too little Vitamin D, calcium, potassium, and fiber.”

The Center for Science in the Public Interest (CSPI) criticized the report for not advocating disclosures about the amount of added sugars. CSPI Executive Director Michael Jacobson was quoted as saying, “Unfortunately, without disclosing the amount of added sugars, a soft drink with that labeling would look pretty good because it has no fat and virtually no sodium.” Jacobson also maintained that FDA should just ban *trans* fat altogether instead of highlighting it on FOP labels. He appeared to endorse a red-yellow-green color coding system, but noted that industry was unlikely to support such symbols. “Companies don’t want their less healthful products clearly labeled as such, but that’s the kind of system that would most benefit consumers,” he said.

Meanwhile, food nutrition professor Marion Nestle responded to the report by commenting that the IOM “did a terrific analysis of current FOP schemes,” noting how confusing they can be to consumers because different programs result in different ratings for similar products. She opined that *trans* fat information seems unnecessary since it has been removed from most packaged food, but thought IOM erred by rejecting the idea that information about added sugars would be useful. According to the report, the addition of sugars to food products is best reflected in a rating system that highlights calories per serving. See *CSPI Press Release, News from the National Academies*, and *Food Politics*, October 13, 2010.

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ASTM Forms Subcommittee to Address Consumer Goods Containing Nanoparticles

ASTM International, formerly known as the American Society for Testing and Materials, has [announced](#) the formation of a subcommittee to develop standards for nanoparticle-enabled consumer products, such as goods that contain nanoscale silver. The new "Subcommittee on Nano-Enabled Consumer Products" (E56.06) will be part of "Committee 56 on Nanotechnology," established in 2005 to develop standard terms, toxicity test methods, workplace handling guidance, and other voluntary standards for organizations working with nanoengineered materials.

ASTM seeks subcommittee members with expertise in analytical chemistry, measurement methods, textiles, consumer product safety, exposure assessment, and environmental chemistry. They will "develop standards for determining the presence of engineered nanomaterials in consumer products and understanding the potential for exposure from the use of these consumer products." Planned projects include standards for measuring and evaluating the form of silver in textiles and liquids and standards for assessing nanosilver exposure potential from use of textile and liquid consumer products. *See ASTM Press Release*, September 2010, and *BNA Daily Environment Report*, October 8, 2010.

Canada Adds BPA to Toxic Chemical List

Environment Canada has published a [final order](#) adding bisphenol A (BPA) to Schedule 1 of the Canadian Environmental Protection Act 1999 (CEPA 1999), a move that will make it easier for agencies to regulate the substance. "The Government of Canada has a strong record of taking action on Bisphenol A to protect the environment and health of Canadians," stated Environment Minister Jim Prentice in an October 13, 2010, press release. "We are continuing our leadership on this issue and Canadians can rest assured that we are working hard to monitor and manage Bisphenol A."

Claiming that BPA exposure "can result from dietary intake, environmental media, use of consumer products, and other sources," the final order adopts "a precautionary approach" based on animal and human studies that allegedly showed the potential for neurobehavioral and developmental effects in newborns and infants. The order also notes environmental concerns, citing evidence "that exposure to bisphenol A, particularly at sensitive life cycle stages, may lead to permanent alterations in hormonal, developmental or reproductive capacity for aquatic organisms."

According to Environment Canada's director general of science and risk assessment, the new designation for BPA signals the government's readiness to act. George Enei apparently told media outlets that the first steps would likely involve regulating factories that release BPA into the air and water. Rick Smith, executive director of Canadian advocacy organization Environmental Defence, reportedly concurred, "This toxic designation is a very strong regulatory power that gives them firm legal footing on any number of things."

Meanwhile, the American Chemistry Council (ACC) has refuted the science behind the final order, which came on the heels of the European Food Safety Authority's decision not to readjust its BPA assessment in light of recent findings. "Environment

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Canada's announcement is contrary to the weight of worldwide scientific evidence, unwarranted and will unnecessarily confuse and alarm the public," ACC Executive Director Steven Hentges was quoted as saying. See *The New York Times*, October 13, 2010.

Japan Weighs Voluntary Disclosure of *Trans* Fat Content

The Japanese Consumer Affairs Agency has reportedly unveiled draft guidelines that would ask food manufacturers to voluntarily disclose the *trans* fat content of their products. Intending to finalize the guidelines by the end of 2010, the agency has called for labeling that indicates the amount of *trans* fat per 100 grams or per meal. The guidelines not only reflect the mandatory measures taken by other countries, but apparently aim to reduce the incidence of cardiovascular disease. According to *The Japan Times*, "The agency is also considering legislation to make these kinds of food labeling mandatory." See *The Japan Times*, October 9, 2010.

LITIGATION**Supply Chain Litigation Follows Soy Grit *Salmonella* Contamination and Recall**

A company that makes name- and store-brand food products, including cereals, granola products, pastas, and bakery goods, has sued the supplier of soybean food ingredients allegedly contaminated with *Salmonella*, seeking in excess of \$7 million in damages. *Ralcorp Holdings, Inc. v. Thumb Oilseed Producers' Coop.*, No. 10-1898 (U.S. Dist. Ct., E.D. Mo., filed October 8, 2010). According to the complaint, the companies contracted for the purchase of the defendant's soy grits under an agreement that guaranteed they would be suitable for human consumption and that the defendant would indemnify and pay damages to the plaintiff for any warranty breaches.

Plaintiff Ralcorp Holdings alleges that it incorporated most of the soy grits into its products, specifically granola bars and trail mixes, for sale to a number of retail companies with which Ralcorp had also contracted. Before delivering the final products, Ralcorp claims that it discovered the soy grit ingredient "was, and had been at the time of delivery, contaminated with salmonella." Ralcorp then notified the retailers, the defendant and the Food and Drug Administration (FDA), which confirmed the contamination. Ralcorp has attached to its complaint FDA's "inspectional observations" following inspection of the defendant's facilities, finding unsafe manufacturing practices and unsanitary conditions, as well as the agency's June 24, 2010, warning letter to the defendant.

Claiming actual damages of about \$1 million and lost future profits due to loss of existing customers in excess of \$6 million, Ralcorp alleges breach of contract and express warranties, negligence and negligent misrepresentation, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose. According to a news source, the contamination affected a Trader Joe's outlet in California, which was forced to recall the Chocolate Chip Chewy Coated Granola Bars that a Ralcorp subsidiary had manufactured under the Trader Joe's brand. The plaintiff reportedly had revenue of \$3.9 billion in 2009. See *St. Louis Business Journal*, October 12, 2010.

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POM Wonderful Sued in Florida for Making Health Claims

A putative class action has been filed in a federal court in Florida against POM Wonderful, LLC and its holding company, alleging that the defendants deceived consumers in the state by making health-benefit claims for POM's pomegranate juices, pills, extracts, and concentrated liquids. *Cortez v. POM Wonderful, LLC*, No. 10-23680 (U.S. Dist. Ct., S.D. Fla., Miami Div., filed October 13, 2010).

Alleging damages in excess of \$5 million, the named plaintiff cites the Food and Drug Administration's warning letter to the company and the Federal Trade Commission's recently filed administrative complaint to support claims that the company's representation about its products are "false and misleading." Among the product claims alleged to be false are that it will prevent, mitigate and/or treat atherosclerosis, blood flow/pressure, prostate cancer, erectile dysfunction, cardiovascular disease, LDL cholesterol, and other age-related medical conditions.

Seeking to certify a statewide class of consumers who bought the products from September 29, 2006, to the present, the plaintiff alleges violations of Florida's Deceptive and Unfair Trade Practices Act and unjust enrichment. He seeks compensatory damages, costs and attorney's fees.

Data Underlying Atrazine Research Sought Under FOIA Lawsuit

The U.S. Department of Health and Human Services (HHS) and the National Institute of Environmental Health Sciences (NIEHS) have been sued in federal court under the Freedom of Information Act (FOIA) for their alleged failure to produce data and research relating to the herbicide atrazine. *Beveridge & Diamond, P.C. v. HHS*, No. 10-1713 (U.S. Dist. Ct., D.D.C., filed October 7, 2010). According to the complaint, the Environmental Protection Agency (EPA) is conducting a comprehensive atrazine review that includes the research of a NIEHS research scientist who worked for EPA in the past. The plaintiff allegedly sought the researcher's data from EPA, but was told she had taken all of her material to NIEHS.

NIEHS has allegedly failed to respond to the plaintiff's request for data, information and reports related to Dr. Suzanne Fenton's research on atrazine. The plaintiff alleges, "It is critical that NIEHS promptly provide the requested information to allow for meaningful and appropriate public review and analysis of this information." The FOIA request was for everything on atrazine in Fenton's files going back to January 2000 as well as correspondence with others about it. The plaintiff seeks a declaration that the agencies' failure to disclose the requested records is unlawful, an order requiring the agencies to disclose the records and attorney's fees.

In August 2010, NIEHS announced that Fenton's research "shows that male rats prenatally exposed to low doses of atrazine, a widely used herbicide, are more likely to develop prostate inflammation and to go through puberty later than non-exposed animals. The research adds to a growing body of literature on atrazine, an herbicide predominantly used to control weeds and grasses in crops such as corn and sugar cane. Atrazine and its byproducts are known to be relatively persistent in the environment, potentially finding their way into water supplies." See *NIH News*, August 24, 2010.

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Federal Court Grants Preliminary Approval to Settlement in Frosted Mini-Wheats® Case

A federal court in California has approved a motion for preliminary approval of a class action settlement in litigation involving allegedly fraudulent claims that Kellogg Co.'s Frosted Mini-Wheats® cereal "was clinically shown to improve children's attentiveness by nearly 20%." *Dennis v. Kellogg Co.*, No. 09-1786 (U.S. Dist. Ct., S.D. Cal., decided October 14, 2010). The settlement class consists of everyone in the United States who bought the product between January 2008 and October 2009. The company has agreed to create a \$2.75 million fund "to provide cash payments to class members who submit valid Claim Forms. Class members may recover the full purchase price of the cereal they purchased (\$5 per box), up to three boxes." Any funds remaining will be "distributed to appropriate charities pursuant to the *cy pres* doctrine."

The company will also distribute specified food items valued at \$5.5 million to charities feeding the indigent and will pay the costs of class notice, claims administration and attorney's fees and expenses up to \$2 million. According to the court, the proposed settlement appears to be fair and, "because identification of class members in this case is difficult or impossible, the requirement that Defendant make a substantial charitable donation is appropriate." The reasonableness of class counsel's fees will be determined at the final settlement hearing, scheduled for February 14, 2011. The court's order includes approval of the method of class notice and a mechanism for class members and others to object to the proposed settlement.

Batali and Bastianich Targeted in New Restaurant Worker Lawsuit

Twenty-seven waiters, busboys and others at New York City's Del Posto restaurant have reportedly filed a lawsuit against owner Mario Batali and partners Joseph and Lidia Bastianich, claiming that they were not paid a legal wage. The plaintiffs allege that the restaurant's managers pooled workers' tips in violation of state labor laws and wrongfully withheld a portion of the gratuities on wine and cheese sales. The tip pool was allegedly divided on the basis of a point system, and the plaintiffs also reportedly contend that staff working banquets did not get their proper share of the service charge billed to customers, instead receiving a flat fee. The suit, which is at least the third involving a Batali-owned facility, seeks back pay, unspecified damages and attorney's fees. See *msnbc.com*, October 12, 2010.

OTHER DEVELOPMENTS

FAO Announces Eradication of Cattle Plague Virus

The U.N. Food and Agriculture Organization (FAO) has [announced](#) the pending eradication of a fatal cattle virus known as rinderpest, hailing the achievement as "the first time in history that humankind has succeeded in wiping out an animal disease in the wild, and only the second time, after smallpox in 1980, that a disease has been eliminated thanks to human efforts." According to FAO, the global disease "does not affect humans directly, but its ability to cause swift, massive losses of

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cattle and other hoofed animals has led to devastating effects on agriculture for millennia, leaving famine and economic devastation in its wake.”

Reporting that the last known rinderpest outbreak occurred in 2001 in Kenya, FAO attributed its success to the Global Rinderpest Eradication Program (GREP) launched in 1994. GREP led partnerships with international and domestic agencies that aimed to characterize the disease, promote vaccination and coordinate eradication campaigns. With the World Organization for Animal Health (OIE), FAO plans to declare the virus officially eradicated by mid-2011. After that time, FAO will implement a strategy to monitor the rinderpest situation with activities that include historical accounts, contingency plans and biological materials surveys.

“We are confident that the World Assembly of Delegates of the OIE will officially recognize all remaining countries as free from the disease in May 2011 and thus close on that day OIE Pathway activities for rinderpest eradication,” stated OIE Director General Bernard Vallat in an October 14, 2010, FAO press release. “The OIE program was launched back in 1989 and has been extremely reliable in assessing the presence or absence of the virus in all countries worldwide. It should serve future ventures in eradicating other animal diseases.”

SCIENTIFIC/TECHNICAL ITEMS

Gene Sites Linked to Obesity, Fat Distribution

An international research consortium has released a [study](#) that identifies 18 new gene sites linked to overall obesity and a related [report](#) that pinpoints 13 new gene sites connected to fat distribution. Published in the October 2010 online edition of *Nature Genetics*, the studies relied on data from approximately 250,000 participants to gain an understanding of why some people are susceptible to obesity.

Researchers reportedly concluded that people with more than 38 genetic variants linked to increased body mass index were 15 to 20 pounds heavier than those who carried fewer than 22 of the variants. In the fat-distribution study, researchers found women were more inclined to have genetic variants that predicted fat development in the hips and thighs rather than the abdomen.

Participating researchers told a news source that discovering which genes play a role in obesity could lead to underlying biological processes that could eventually help treat the condition. “If we could understand a lot more about why people are resistant to our environment and stay lean despite all the pressures there are to gain weight, we’d have a better shot at getting better therapies than we have now,” Boston researcher Joel Hirschhorn said. See *The Wall Street Journal*, October 11, 2010.

Scientists Develop Food-Grade Nanoemulsion

Researchers with the University of Massachusetts Food Science Department have reportedly developed a technique to create transparent, food-grade nanoemulsions using high-pressure homogenization methods. Cheng Qiana and David Julian McClements, “Formation of Nanoemulsions Stabilized by Model Food-Grade

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Emulsifiers using High Pressure Homogenization: Factors Affecting Particle Size," *Food Hydrocolloids*, October 2010.

According to the study, "Nanoemulsions are finding increasing utilization in the food and beverage industries for certain applications because of their unique physicochemical and functional properties: high encapsulation efficiency; low turbidity; high bioavailability; high physical stability." Because the nanoparticles can be made transparent, the new technology could act as a delivery system "for non-polar functional components, such as lipophilic bioactive lipids, drugs, flavors, antioxidants, and antimicrobial agents."

In a related development, a European non-profit media agency specializing in science and technology news has issued a summary that characterizes how NGOs have responded to nanotechnology. Citing Greenpeace Research Laboratories, Friends of the Earth, and European Environmental Bureau, *Youris.com* claims that NGOs have widely criticized the rapid development of nanomaterials as well as the regulatory framework meant to address concerns over potential toxicity. "Precaution is a word that unites most if not all non-profit organizations concerned with nanotechnology," concludes *Youris.com*. "They are blowing the whistle on manufacturers, pointing out that potentially unsafe products should not be on the market. The European Parliament as well as governments in many countries are listening and developing ways to assess possible nanomaterial hazards. This development will most likely continue until sufficient research results are available to thoroughly describe potential risks. When the results are published, these organizations can rewrite their policies." See *Youris.com*, October 5, 2010.

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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.

