

**FOOD & BEVERAGE
LITIGATION UPDATE**



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LEGISLATION, REGULATIONS AND STANDARDS

FDA Decides Not to Decide on Safety of GM Salmon

A Food and Drug Administration (FDA) advisory panel has reportedly declined to take action or make any recommendations about the safety of genetically modified (GM) salmon at the conclusion of [hearings](#) that drew considerable media and public attention. A Massachusetts-based company has been trying to bring its AquAventure® salmon to the market for more than 10 years. If it succeeds, the fish, which reportedly grow to full size in half the time as conventional salmon, will be the first GM animal sold for human consumption. According to a news source, FDA’s Veterinary Medicine Advisory Committee indicated that it lacked sufficient safety data to make a determination and suggested that the government undertake a more rigorous analysis of potential health effects and environmental impact.

Agency documents made available before the hearing reportedly indicated that FDA was prepared to conclude that no biologically relevant differences between GM salmon and conventional salmon existed and that its consumption posed a reasonable certainty of no harm. Environmentalists and consumer activists have expressed concerns about the safety of GM foods and complained that FDA gave too little time for the public to comment on the technical information it released in advance of the hearings and that some of those sitting on the advisory committee either have no expertise in the matter or represent industry interests.

Consumers Union apparently contends that GM salmon could pose an allergic reaction in sensitive individuals and that “FDA should be requiring studies with data from many more engineered fish, not the tiny sample of six fish on which it currently bases its conclusions.” Others are reportedly concerned about hazards the GM fish might pose to wild populations.

Another issue facing the agency is whether to require a product label identifying it as genetically modified, and the second day of hearings was devoted to this matter. Consumer groups reportedly urged FDA to require GM labeling, while industry interests said that current rules preventing such labeling should apply. According to news sources, a decision on either issue is apparently months away. FDA must publish an environmental assessment for public comment and then will determine whether it will file a “finding of no significant impact” or an “environmental impact statement,” then rely on its findings to decide whether to allow the sale of the

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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salmon. Thereafter, it could apparently take two years before the first GM fish appear in the marketplace. See *Grist.org*, September 20, 2010; *The Wall Street Journal*, September 20 and 22, 2010; *Food Politics*, *The New York Times*, *Slate*, *msnbc.com*, *Knight Science Journalism Tracker*, *Greenwire*, September 21, 2010.

Senator Schumer Calls for Crackdown on Falsely Labeled "Organic" Products from China

Concerned about certified-organic agricultural interests in his state and consumer confidence in the "organics" label, Senator Charles Schumer (D-N.Y.) has called on Agriculture Secretary Tom Vilsack to "ensure that foreign imports, especially from China, meet the same high standards as domestically produced organic products." In his September 20, 2010, [letter](#), Schumer refers to media accounts questioning the validity of organic claims for Chinese agricultural exports and a U.S. Department of Agriculture (USDA) audit that revealed "potential problems with oversight of Chinese-produced organic products."

Schumer urges the agency "to review its system of oversight for foreign certifiers, especially those operating in China," to ensure that current practices comply with U.S. standards. Schumer states, "[G]iven China's extremely poor track record on ensuring the safety and quality of its products, it is imperative that USDA thoroughly scrutinize its program to certify Chinese organic products to determine if it is managed and funded appropriately." He also contends that without a mechanism to distinguish between organic and non-organic imports via customs statistics presents "a huge gap in the system" hindering USDA oversight.

Egg Facility Owner Apologizes to House Lawmakers for *Salmonella* Outbreak

Austin DeCoster, who owns the Iowa egg production facility at the center of a *Salmonella* outbreak that has sickened hundreds, reportedly testified during a U.S. House Energy and Commerce subcommittee [hearing](#) that his company "was horrified to learn that our eggs may have made people sick." DeCoster was also quoted as saying, "We apologize to everyone who may have been sickened by eating our eggs."

With evidence apparently mounting that DeCoster operations have been flouting worker, environmental and food safety regulations for years, it is reportedly becoming clearer to legislators that food safety "is a public health imperative" that should be addressed at the federal level. DeCoster egg farms on the East Coast were reportedly responsible in the 1980s for *Salmonella* outbreaks that killed a number of people and sickened hundreds more, leading several states to ban the sale of his eggs. During the hearing, Democratic Representative Edward Markey (Mass.) called for Republican Senators to support the food-safety legislation stalled before that body, saying "They must release this bill so that we can protect millions of families." Representative Henry Waxman (D-Calif.) was quoted as saying, "DeCoster farms have had warning after warning. Yet they continue to raise chickens in slovenly conditions and to make millions of dollars by selling contaminated eggs."

DeCoster's son Peter, who is Wright County Egg's chief operating officer, reportedly testified that the company did not test its eggs for *Salmonella* despite tests showing

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the barns were contaminated, because “our perception was that egg test results always would be negative.” Since the outbreak, the company has had more than 70,000 eggs tested, and the contamination was apparently confirmed. Peter DeCoster has reportedly indicated that the company will vaccinate all of its flocks. He also said during the hearing that Food and Drug Administration inspectors did not apparently find any problems at the company’s feed plant in May 2010. The feed has reportedly been cited as a potential source of the contamination.

The other company involved in the outbreak is reportedly terminating its marketing relationship and other ties to Wright Egg. According to a news source, Hillandale Farms President Orland Bethel invoked his Fifth Amendment right against self-incrimination and did not answer questions during the hearing. See *The New York Times*, September 21-23, 2010; *Product Liability Law 360*, September 22, 2010; and *The Wall Street Journal*, September 23, 2010.

U.S. Senate Confirms Key Food Safety Official

The U.S. Senate recently confirmed Elisabeth Hagen as the U.S. Department of Agriculture’s (USDA’s) under secretary for food safety. President Barack Obama (D) used a “recess appointment” in August 2010 to install Hagen as USDA’s top food-safety official after the Senate had not yet confirmed her appointment since her nomination nearly a year earlier.

USDA Secretary Tom Vilsack was quoted as saying that Hagen’s background as USDA’s chief medical officer and senior executive within its Food Safety and Inspection Service will serve her well because “there is no higher priority at USDA than ensuring that Americans have access to a safe and healthy food supply.” See *USDA Press Release*, September 16, 2010.

Nanomaterials to Take Prominent Role in Upcoming NOSB Meeting; Organic Hops Group Questions Petitioning Process

The U.S. Department of Agriculture’s National Organic Standards Board (NOSB) has [announced](#) an October 25-28, 2010, public meeting in Madison, Wisconsin, to review proposed recommendations for the National List of Allowed and Prohibited Substances, which governs the use of synthetic and non-synthetic materials in organic production and handling. NOSB will accept written comments and requests for oral presentations until October 12, 2010.

The [agenda](#) covers petitioned material and sunset review recommendations for a number of substances, as well as proposed guidance on nanotechnology, “Made With” organic claims and changes to the NOSB policy and procedure manual. In particular, the meeting will address the NOSB Materials Committee’s recommendations for prohibiting engineered nanomaterials in organic production, processing and packaging. According to the committee, concerns about nanotechnology include “the ability of the regulatory agency, the National Organic Program (NOP), to fully control two of the major sources of contamination in final organic food products: food contact surfaces and primary packaging.” The committee has thus asked NOP to (i) accept its definition of engineered nanomaterials; (ii) “disallow the engineered nanomaterials form of substances

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currently on the [National List]"; (iii) accept engineered nanomaterials as synthetic substances; (iv) acknowledge that engineered nanomaterials "may have unique properties that distinguish them from all listings of these substances in a bulk form"; (v) "determine whether enforcement of restrictions in primary packaging and food contact surfaces is possible, practical, and legal"; and (vi) schedule a symposium to further discuss these issues. *See Federal Register*, September 20, 2010.

Meanwhile, the American Organic Hop Grower Association (AOHGA) has already issued a [statement](#) decrying NOSB's denial of its petition to remove hops from the National List, which currently permits the use of non-organic hops in organic beer. According to AOHGA, NOSB's recommendation concluded that organic hops were not available "in the form, quantity, or quality to currently justify removal from [the List]. To do so would negatively impact the organic brewing industry."

AOHGA has since disputed this finding and urged its supporters to submit comments to NOSB in advance of the public meetings, "where the final decision will likely be made." The association has specifically faulted NOSB for holding hops "to a higher standard than virtually any other agricultural product," including other beer ingredients like barley, by allegedly insisting that all 150 varieties become available in organic form before removal from the list. AOHGA has thus questioned the transparency of the petitioning process, claiming "the possibility that there were private comments made" in addition to the three on public record: "two in favor of changing the rules, and one by a brewer who has since been working with growers to ensure his supply of organic hops." *See AOHGA Press Release*, September 2010.

EPA Issues Rule on Multi-Walled and Single-Walled Carbon Nanotubes

The Environmental Protection Agency (EPA), concerned about potential hazards to human health and the environment, has issued a final [rule](#) that will require anyone intending "to manufacture, import, or process either [multi-walled or single-walled carbon nanotubes] for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity."

Effective October 18, 2010, the rule applies to chemicals identified generically (for confidentiality reasons) as PMN P-08-177 and PMN P-08-328. The notice requirement will give EPA the opportunity to evaluate any proposed new use and regulate prospective manufacturers, importers or processors before the use occurs. Among other matters, those working with the substances will be required to use protective equipment, such as full-face respirators, gloves and protective clothing.

According to a news source, this is EPA's first rule for significant new uses of carbon nanotubes, which are apparently used in advanced composites, fuel cells and electronics. Due to their strength and other properties, they are reportedly the most widely used nanoscale products and are considered to have a broad array of potential commercial applications. Researchers have apparently found that some carbon nanotubes have effects similar to asbestos when injected into the lungs of lab mice. The rule also prohibits the chemicals' release into water. *See Federal Register*, September 17, 2010; *Inside EPA*, September 20, 2010.

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EFSA Reaffirms Safety of Food Derived from Cloned Pigs, Cattle

The European Food Safety Authority (EFSA) has published a scientific [statement](#) reaffirming its 2009 conclusion that “in relation to food safety, there is no indication that differences exist for meat and milk of clones and their progeny compared with those from conventionally bred animals.” The food safety watchdog’s assessment, however, pertains only to pigs and cattle because “there is still limited information available on cloning” of other species.

The European Commission in May 2010 asked EFSA for an update on scientific developments regarding the safety of cloning farmed animals for food production. In response, EFSA’s Scientific Committee reviewed approximately 100 recent studies and other data from European research centers to determine that no new scientific information has surfaced to change its conclusions about cloned pigs and cattle. According to the statement, EFSA also reconfirmed its previous conclusion that “mortality rates and the number of animals born with developmental abnormalities are higher in animal clones than in conventionally bred animals” due primarily to “epigenetic dysregulation,” a reprogramming of the donor cell. See *EFSA Press Release*, September 17, 2010.

Boston Considers Action on Sugary Drink Sales in City-Owned Buildings

Boston city officials are reportedly considering a move to prohibit or restrict sugar-sweetened beverages sold on city-owned property as a way of combatting obesity. The city, which has already prohibited smoking in restaurants and bars and *trans* fat in fast food restaurants and bakeries, recently convened health, education and housing leaders to develop a policy to reduce sugary beverage consumption. While such a policy has yet to be officially drafted, Barbara Ferrer, executive director of the Boston Public Health Commission, told a news source that such a move seemed inevitable based on the city’s earlier promise to fight obesity by decreasing sweetened soda consumption through “counter-advertising and policy change.”

Ferrer was quoted as saying that she expects public resistance to the potential ban because people view soft drinks differently from tobacco. “I think we’re going to run into a big issue of people saying, ‘Why would you take away our sodas, why are you interfering with what we’re eating and drinking?’ Unlike tobacco that is always harmful and if a person is smoking in the workplace it harms other people, I think people will look at sugar-sweetened beverages differently,” she said. See *The Boston Globe*, September 20, 2010.

LITIGATION

Snapple Seeks to Dismiss Remaining Individual Claims in HFCS Litigation

Snapple Beverage Corp. has requested that a federal district court dismiss the individual claims remaining in litigation alleging that the company misled consumers by labeling beverages containing high-fructose corn syrup (HFCS) as “all natural.” *Weiner v. Snapple Beverage Corp.*, No. 07 Civ. 8742 (U.S. Dist. Ct.,

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S.D.N.Y., motion filed September 17, 2010). In August 2010, the court issued an order denying plaintiffs' request to certify a statewide class of claimants. Additional information about that order appears in [Issue 363](#) of this *Update*.

According to the defendant's memorandum of law supporting its motion, while the plaintiffs "seek recovery of an alleged 'price premium'" that they paid for the products, they (i) do not know how much they actually paid for Snapple, (ii) made no effort to determine how comparable products were priced when they purchased Snapple beverages, (iii) lack any receipt to document a Snapple purchase, (iv) "cannot recall with any certainty the price they paid for even one of their Snapple purchases," and (v) admitted that Snapple product prices varied depending on where they made the purchase and the availability of discounts.

Without such evidence, Snapple contends that plaintiffs cannot prove causation. In fact, "each [plaintiff] bought Snapple for a host of reasons unrelated to the labeling," including taste and hydration. Snapple argues, "Neither Weiner nor McCausland identified all natural labeling as his primary motivation for buying Snapple." Their reasons for making any particular beverage purchase on any day depended on mood, health, the type of container in which available beverages were sold, and taste. Snapple also argues that the plaintiffs' requests for injunctive relief are moot, because the company is no longer selling any product containing HFCS and labeled "All Natural."

Defense Counsel Asserts Caffeine Overdose Led to False Murder Confession

A Kentucky man accused of murdering his wife reportedly notified the court that he would defend himself by claiming that a high caffeine intake, from soft drinks, energy drinks and diet pills, made him temporarily insane and unable to form the requisite criminal intent to kill his wife. During opening statements, however, his attorney apparently stated that Woody Will Smith did not murder his wife, but provided a false confession to police because of high stress from large amounts of caffeine and a lack of sleep.

According to news sources, the caffeine defense has been used before and was successful in the case of an Idaho man who allegedly injured two pedestrians with a car. A judge reportedly concluded that this man could not form the mental intent to commit the crime after consuming two large cups of coffee following a restless night and weeks of hard work. Experts have indicated that too much caffeine can have negative effects on the body, and the *Diagnostic & Statistical Manual of Mental Disorders* classifies "caffeine intoxication" as one of four valid caffeine-induced mental disorders.

Still, prosecutors reportedly intend to portray Smith as an angry man who attacked his wife during a fight and that witnesses who saw him after the killing did not see any sign of insanity or temporary psychosis. Prosecutors have also indicated that there is no evidence he had taken diet drugs or consumed energy drinks before his wife died. Smith allegedly tested negative for amphetamine-type substances shortly after the murder. See *Yahoo! News* and *The Associated Press*, September 20, 2010; *MSNBC.com* and *Time*, September 21, 2010.

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Russian Seed Bank May Be Spared

After a Russian court approved the transfer to a housing development foundation of land outside St. Petersburg where more than 6,000 varieties of fruits and berries are grown, scientists fearing the loss of a major seed bank were reportedly heartened to learn that President Dmitry Medvedev has taken an interest in the matter and ordered a review of the decision. An earlier report about the court ruling appears in [Issue 360](#) of this *Update*. The foundation has also reportedly postponed a planned auction of part of the land and will have an independent expert audit conducted to assess the uniqueness of the plants growing there and how much acreage is involved. Interested parties are apparently seeking a compromise; the auction may be delayed for five to seven years to allow the plant collection to be relocated. See *Science*, August 20, 2010; *Sciencemag.org* and *Global Crop Diversity Trust*, September 10, 2010.

OTHER DEVELOPMENTS

IOM Launches New Obesity Prevention Activity

The Institute of Medicine's (IOM's) Food and Nutrition Board recently launched a new activity titled "[Accelerating Progress in Obesity Prevention](#)," which aims to review IOM's obesity-prevention strategies and make further recommendations. Sponsored by the Robert Wood Johnson Foundation, an ad hoc committee of academic, industry and scientific experts will undertake a 21-month study intended for regulators, policy makers, foundations, and community-based organizations, and other health professionals.

During this process, the committee will (i) consider the progress of previous IOM recommendations, using "available reports, articles, analyses, surveys, legislation and regulations, 'report cards,' and other relevant literature"; (ii) "develop guiding principles for choosing a set of recommendations"; (iii) "identify a set of recommendations that the committee determines to be fundamental for substantial progress in obesity prevention over the next decade"; and (iv) "recommend potential indicators that can act as markers of progress and that can be readily evaluated through the use of current data bases and/or relatively simple measures or surveys." The committee has also announced a September 30, 2010, open session meeting that includes a sponsorship briefing.

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Previous Report Underestimate Human BPA Exposure

A recent study has reportedly claimed that human exposure to bisphenol A (BPA) greatly exceeds the daily threshold set by the U.S. Environmental Protection Agency, which specifies the upper limit of BPA intake at 50 micrograms per kilogram of body weight. Julia Taylor, et al., "Similarity of Bisphenol A Pharmacokinetics in Rhesus Monkey and Mice: Relevance for

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Human Exposure," *Environmental Health Perspectives*, September 2010. According to media sources, the study pegged human BPA exposure at more than eight times this threshold and speculated that exposure occurs "via multiple routes."

The study also allegedly suggested that mice, monkeys and humans all process and excrete BPA at similar rates. The lead author reported that blood samples taken from both mice and rhesus monkeys contained "biologically active" amounts of BPA, raising questions about whether the liver effectively expels the substance or allows it to enter the bloodstream, where it could conceivably mimic estrogen and other hormones. "These data should make us reconsider some previously held hypotheses about BPA, such as how quickly it is cleared from the body and the differences in metabolism between species," stated Linda Birnbaum, director of the National Institute of Environmental Health Sciences, in response to the findings. "The paper emphasizes the need to better understand all the potential sources of human exposure."

Meanwhile, another researcher who contributed to the study has received a \$100,000 prize for his work on BPA. The Heinz Awards recognized University of Missouri-Columbia Professor Frederick vom Saal for his investigations into the chemical's purported link to abnormal cell development. "The new results clearly demonstrate that rodent data on the health effects of BPA are relevant to predictions regarding the health effects of human exposure to BPA," vom Saal was quoted as saying. "Further evidence of human harm should not be required for regulatory action to reduce human exposure to BPA." See *University of Missouri-Columbia Press Release*, September 20, 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.

