

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Environmental Protection Agency (EPA)

[1] Comment Sought on Petition for Nanoscale Silver Rulemaking

EPA has published a [notice](#) seeking public comment on a petition filed by a number of environmental and consumer interest groups calling on the agency to classify nano-silver as a pesticide, require “formal pesticide registration of all products containing nanoscale silver, analyze the potential human health and environmental risks of nanoscale silver, [and] take regulatory actions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) against existing products that contain nanoscale silver.” Comments must be submitted by January 20, 2008.

According to the notice, potentially affected parties are those businesses “engaged in the manufacturing of pesticides and other agricultural chemicals.” The petitioners, including the International Center for Technology Assessment, Friends of the Earth, Food & Water Watch, and the Consumers Union, apparently note that “scientists have identified that nanoscale materials can have fundamentally different properties from the non-nanoscale or bulk forms of the same compounds, and that these unique properties may pose new envi-

ronmental and human health risks.” The petitioners also apparently contend that “the Agency has not provided adequate regulatory oversight for this emerging technology” and request the action because of “the rapid commercialization of nanotechnology.” See *Federal Register*, November 19, 2008.

Food & Drug Administration (FDA)

[2] FDA Opens First Offices in China to Boost Import Safety; Chinese Regulators Plan to Overhaul Dairy Industry

FDA has reportedly opened the first of several overseas offices in Beijing, China, where eight U.S. officials described as “inspectors and senior technical experts in foods, medicines and medical devices” will work with Chinese regulators to improve export safety. FDA plans to launch two additional branches in Shanghai and Guangzhou, as well as expand its presence in India and Latin America. The agency will also train and certify third-party inspectors to ensure the safety of products bound for the U.S. market.

FDA has lately come under fire for failing to “[keep] pace with the growing number of food firms,” according to the U.S. Government Accountability Office, which said federal regulators have “little assurance that companies comply with food-labeling laws and regulations.” Furthermore, China’s reputation has suffered both domestically and abroad as reports of melamine-tainted infant



formula and agricultural products continue to surface. “We’re opening up a new era, not just new offices,” stated Health and Human Services Secretary Michael Leavitt, announcing “a permanent FDA presence in China.” See *The New York Times*, November 19, 2008.

In a related development, Chinese authorities have reportedly announced they will rework the entire dairy industry by October 2011. The new plan will apparently include product tracking from source to sale, imposition of production standards and closure of businesses failing to comply, and the adoption of tools at the local level to examine dairy products for safety. The initiative follows a melamine contamination scandal that is known to have killed four infants and sickened tens of thousands of children who developed kidney stones after consuming tainted milk products and baby formula. The chemical was also found in a range of products, including beverages and candy, exported to 13 countries in Asia and Europe, as well as Australia and the United States. See *Product Liability Law* 360, November 20, 2008.

U.S. Department of Agriculture (USDA)

[3] Organic Standards Board OKs Feeding Wild Fish to “Organic” Farmed Fish

Food activist Marion Nestle reports in her “What to Eat” blog that the USDA’s National Organic Standards Board has approved a rule to allow “farmed carnivorous fish to eat meal and oil derived from sustainably wild-caught fish.” The board’s decision means that wild fish cannot be classified as organic, but farm-raised fish can be considered organic even if they eat fish meal made with wild fish. Citing *Food Chemical News*, Nestle notes that

the board also approved the use of open net pens in organic aquaculture with restrictions to prevent farmed fish from escaping and the recycling of nutrients. “Net pens would only be allowed in specified areas to avoid lice contamination.”

Consumers Union reportedly criticized the proposal at a press conference held before the board meeting at which the vote was taken, focusing on the use of “net cages,” which purportedly allow waste and disease from fish farms to enter the ecosystem, and allowing wild fish, which can carry toxins like PCBs, to be used in feed for “organic” fish. Supporters of the rule reportedly argue that it is a “very rigorous standard that will be very difficult for [fish] farmers to meet,” and that toxins can be filtered out during the production of fish meal. See *Chicago Tribune*, November 15, 2008; *whattoeat-book.com*, November 20, 2008.

State and Local Governments

[4] OEHHA Announces Public Workshop and Comment Deadline on Regulation to Give Food Retailers Prop. 65 Warnings Guidance

California EPA’s Office of Environmental Health Hazard Assessment (OEHHA) has [scheduled](#) a public workshop on December 3, 2008, to discuss how food retailers can provide warnings about foods containing chemicals that are listed under Proposition 65 as chemicals known to the state to cause cancer or reproductive hazards. The agency formed a workgroup to address the matter and has drafted “operating principles” based on its input. Among the concepts the agency is considering are a central “clearinghouse” of warning messages created by food manufacturers, point-of-sale pamphlets, cash-register-receipt warnings, on-product warning



labels, or shelf signs. Public comments can be submitted during the workshop or in writing until January 16, 2009.

Litigation

[5] MDL Court Approves \$24 Million Contaminated Pet Food Settlement

A multidistrict litigation (MDL) court in New Jersey has entered an order approving the settlement of claims that pet food contaminated with melamine and cyanuric acid sickened and killed thousands of cats and dogs in the United States. *In re Pet Food Prods. Liab. Litig.*, MDL No. 1950 (U.S. Dist. Ct., D. N.J., filed November 18, 2008). In its 65-page opinion, the court certified the class for settlement purposes and approved an award of \$24 million to the plaintiffs and nearly \$6.4 million in attorney's fees. The court also denied a motion to intervene, overruled several objections and granted a motion to strike a separate motion for attorney's fees.

Pet owners will be eligible for documented economic damages, such as veterinary bills, cremation, burial services, costs of new pets, and healthy pet screenings. Claims without documentation will be paid up to a maximum of \$900 for each claimant. If the claims exceed the available funds, the payments "will be subject to a pro rata reduction." Of the \$24 million, \$250,000 is set aside for reimbursement of product purchases, and \$400,000 is available for health screenings. Any undistributed funds will be used as a charitable contribution "to animal welfare-related organizations both in the United States and Canada." The defendants that manufactured the recalled pet foods, without conceding liability, "agreed to continue to administer their internal quality assurance programs to

regularly test shipments of raw wheat gluten and rice protein concentrate imported from China for the presence of melamine and cyanuric acid until May 30, 2009."

The intervenors are involved in pending false-advertising litigation involving pet food not contaminated or recalled, but just labeled "Made in the United States." The court found that their claims were not released by the settlement. Objectors involved in litigation alleging that marketing pet food as healthy, premium or human grade was false and misleading because such pet food products allegedly contained "nonedible garbage, by-products and waste that is unfit for human consumption," were also denied relief because the court was satisfied that the MDL release did not encompass all of their claims. Other objectors sought criminal and punitive sanctions, testing of pet food in perpetuity, stronger enforcement of safety regulations, emotional damages, and future damages. The court noted its inability to provide some of this relief or its unavailability as a matter of law.

The court determined that the settlement was fair, reasonable and adequate and that attorney's fees equal to 25 percent of the settlement fund, plus reimbursement of expenses of nearly \$400,000, were reasonable. The court decided that one law firm's motion for attorney's fees was premature because co-lead counsel were responsible for allocating fees, and the firm had not submitted documentation in support of its claim. "Thus, their objection that they anticipate not being fairly compensated is premature." The settlement applies to the more than 100 class actions filed in federal court and transferred to the MDL court; as of the end of September 2008 some 9,300 class members from the United States and Canada had submitted claims, with 115 opting out and 28 objecting.



[6] Settlement Reached in Splenda® Marketing Dispute

According to a news source, the lawsuit instituted by the Sugar Association to challenge the marketing of the artificial sweetener Splenda® as “made from sugar so it tastes like sugar” has been resolved through a confidential settlement agreement. The trade organization alleged that McNeil Nutritionals’ product promotion deliberately misinformed consumers who would be led to believe that Splenda® contained sugar. A Sugar Association spokesperson reportedly said, “The sugar industry is very satisfied with the settlement and with what they believe will be the outcome of the settlement in terms of marketing of the product.” According to a McNeil spokesperson, the tag line is still in use. See *Foodnavigator-usa.com*, November 18, 2008.

[7] *E. Coli* Class Action Against Nebraska Beef Removed to Federal Court

Strict liability and breach of warranty claims filed in an Ohio state court in July 2008 after an *E. coli* outbreak linked to ground beef sold by Nebraska Beef sickened at least 19 in that state have been removed to federal court. *Schlagel v. Nebraska Beef, Ltd.*, No. 08-01091 (U.S. Dist. Ct., S.D. Ohio, removed November 17, 2008). The named plaintiff of this putative class action is a 4-year-old girl, who allegedly “suffered serious physical and emotional injuries.” The proposed class would include “All Ohio claimants who have suffered personal injury caused by Nebraska Beef’s contaminated *E. Coli* 0157:H7 meat.” The contamination led to the recall of more than 5 million pounds of meat. The company has reportedly denied the allegations and challenges the suitability of the case for class treatment. See *Product Liability Law 360*, November 18, 2008.

Other Developments

[8] Pew Produce Safety Project Criticizes Government *Salmonella* Response

The Produce Safety Project of the Pew Charitable Trusts has issued a [report](#) following its review of the government response to this summer’s *Salmonella* Saintpaul outbreak that affected thousands of consumers in many states and was never definitively linked to a source, although tomatoes and jalapeno peppers were alternately blamed.

Citing specific examples of confusing, uncoordinated and poorly planned communiqués from multiple government agencies, the report calls for more post-mortem study of the government’s response to clarify its shortcomings and inform future efforts.

Noting that federal agencies pointed to tomatoes as the cause of the outbreak, but that no contaminated tomato was ever found, the Pew report suggests that the error not only failed to adequately protect consumers but also cost the agricultural industry millions in losses and could have long-term impacts as consumers lose confidence in the safety of “fresh produce in general and fresh tomatoes in particular.” The report concludes, “A lack of FDA-mandated preventive safety standards for domestic and imported fresh produce has long been recognized as a major issue. Instead of using this most recent outbreak to move forward, FDA officials continue to say that they must wait for Congress to give them explicit authority to act. The outbreak response was marked by a lack of organization, capacity and coordination that calls into question the public-health effectiveness of the response. Finally, messages to the public were often mixed, if not contradictory.”



Among the specific mixed messages cited in the report is an outbreak map that was posted on the Centers for Disease Control and Prevention Web site and changed three times over a three-day period, offering “three different visual ways of understanding and interpreting the outbreak.” The report notes, “While it was commendable that CDC sought during the course of the outbreak to find better and more complete ways to communicate graphically, it is troubling that this determination was not made beforehand; it might have minimized the confusion and frustration experienced by state officials, the produce industry and consumers. The report also includes a timeline of events, and a copy of the questionnaire used with those affected by the outbreak to help public-health officials identify potential sources.

[9] Milwaukee *Journal Sentinel* Continues Bisphenol A Exposés

In a continuing series on the purported health effects of bisphenol A (BPA), a chemical widely used in plastic food storage containers and metal food cans, the Milwaukee *Journal Sentinel* has reported that all of the 10 “microwave safe” containers tested at the newspaper’s request leached BPA when heated in a microwave or conventional oven. While food companies advise worried parents to avoid microwaving food in plastic containers with the recycling number 7 stamped on the bottom, researchers apparently found that even those stamped with 2 and 5 leached the chemical. The highest bisphenol A levels reportedly leached from a can of liquid infant formula and a plastic food-storage container.

Food company officials apparently responded to the findings by claiming that the low levels leached are insignificant. According to the *Journal Sentinel*,

several peer-reviewed studies show harm to animals at levels similar to those detected in the newspaper’s tests, which were conducted to determine BPA prevalence in a typical infant’s diet. “In what is believed to be the first analysis of its kind by a newspaper, the *Journal Sentinel* found that an average 1-month-old girl is exposed to the same amount of BPA that caused mammary gland changes in mice. Those same changes in humans can lead to breast cancer.”

The tests involved new containers; the foods in them were replaced with a mixture of water and alcohol, a typical testing protocol. Bisphenol A experts reportedly said that such tests likely underestimated the amounts of BPA that would leach from reusable products and did not account for variables of fats and acids in foods that are more likely to encourage leaching. See *Journal Sentinel*, November 15, 2008.

In a related development, several bisphenol A studies were presented during the annual meeting of the American Society for Reproductive Medicine. One reportedly showed that the chemical can interfere with the development of uterine cells, which could prevent the embryo from attaching to the uterus; another showed a small trend among women with measurable BPA, who sought to undergo *in vitro* fertilization, not to become pregnant. See *Foodnavigator-usa.com*, November 14, 2008.

[10] UK Soil Association Calls for Action on Antibiotic-Resistant *E. Coli*

The UK Soil Association has reportedly urged veterinarians to limit their penicillin use after health officials found that cows from one unidentified English farm are carriers of extended-spectrum beta-lactamase (ESBL) *E. coli*, a rare



antibiotic-resistant strain of the disease. Although the organic watchdog noted that the government has asked the farmer and his family to follow strict hygiene procedures, regulators have not placed any restrictions on the movement or sale of the infected herd. “The government often calls on doctors to prescribe antibiotics less often. But similar advice needs to be given to veterinary surgeons and farms,” stated a policy advisor for the Soil Association, which, as of 2009, will also no longer certify organic farms that treat their livestock with a class of antibiotics known as cephalosporins. *See FoodProductionDaily.com*, November 19, 2008.

Media Coverage

[11] James E. McWilliams, “Our Home-Grown Melamine Problem,” *The New York Times*, November 17, 2008

This op-ed article examines the widespread presence of melamine in U.S. agriculture, claiming that despite China’s highly publicized problems with the industrial plasticizer, “what the American consumers and government agencies have studiously failed to scrutinize is how much melamine has pervaded our own food system.” James McWilliams, a history professor at Texas State University at San Marcos, argues that the recent spate of melamine-related incidents “points to the much larger relationship between industrial waste and American food production.” He notes that melamine is routinely added to domestic fertilizers “because it helps control the rate at which nitrogen seeps into the soil,” where it then accumulates as salt crystals that mix with other nutrients essential to crops. In addition, McWilliams warns that the “Byzantine reality” of global food networks makes it nearly impossible to ensure that all imported products are safe.

McWilliams recommends that even as it scrutinizes China’s promise to clean up its food supply, “the United States should seize upon the melamine scandal as an opportunity to pass federal fertilizer standards backed by consistent testing of this compound, which could very well be hidden in plain sight.” “Regulations might be lax when it comes to animal feed and fertilizer in China,” he opines, “but take a closer look at similar regulations in the United States and it becomes clear that they’re vague enough to allow industries to ‘recycle’ much of their waste into fertilizer and other products that form the basis of our domestic food supply.”

Scientific/Technical Items

[12] Researchers Link Obesity Rates to Time Spent Watching Fast-Food Ads

Economists with the National Bureau of Economic Research have published a study that examines data compiled between 1979 and 1997 to “estimate the effects of TV fast-food restaurant advertising on children and adolescents with respect to being overweight.” Shin-Yi Chou, *et al.*, “Fast-Food Restaurant Advertising on Television and Its Influence on Childhood Obesity.” *The Journal of Law and Economics*, November 2008. They conclude that a ban on these advertisements “would reduce the number of overweight children ages 3-11 in a fixed population by 18 percent and would reduce the number of overweight adolescents ages 12-18 by 14 percent.”

The researchers used a statistical model to analyze data on some 13, 000 children to link obesity rates to the amount of time children spent watching fast-food advertising on television. In



recent years, a number of fast-food chains and food manufacturers have joined the Council of Better Business Bureaus' Children's Food and Beverage Advertising Initiative, pledging to use one-half of their youth advertising dollars to promote healthier dietary choices or more active lifestyles. It is unknown whether these efforts would change the correlations observed. *See Advertising Age*, November 19, 2008; *injuryboard.com*, November 20, 2008.

[13] Study Allegedly Links Maternal High-Fat Diet to Increased Risk of Obesity in Offspring

A recent study explores the claim that rats fed a high-fat diet (HFD) during pregnancy produce offspring predisposed to overeating and obesity. Guo-Qing Chang, et al., "Maternal High-Fat Diet and Fetal Programming: Increased Proliferation of Hypothalamic Peptide-Producing Neurons That Increase Risk for Overeating and Obesity," *Journal of Neuroscience*, November 2008. The Rockefeller University researchers examined the possibility that an HFD "alters the development" *in utero* of "hypothalamic peptides involved in controlling food intake and body weight." Compared with the progeny of mothers fed a balanced diet, fetuses exposed to an HFD showed alterations in their hypothalamic peptide-producing neurons that could lead to the "long-term behavioral and physiological changes observed in offspring after weaning, including an increase in food intake, preference for fat, hyperlipidemia, and higher body weight."

While some scientists warned that the animal study involved an unnatural diet, others thought the evidence lent credence to the belief that maternal diets have long-lasting genetic effects. "The message is clear," stated the medical director of the non-

profit Weight Concern. "We are not just 'what we eat'; we are also to some extent 'what our mothers eat.'" *See BBC News*, November 17, 2008.

[14] Greenpeace Urges Ban in Light of Study Allegedly Linking GM Crops to Lower Fertility in Mice

A study commissioned by the Austrian Ministries for Agriculture and Health has reportedly linked genetically modified crops to lower fertility rates in mice, prompting Greenpeace International to reiterate its call for a global ban. Led by University of Vienna Professor of Veterinary Medicine Jurgen Zentek, researchers concluded that compared to mice on a normal feed mix, those fed a diet of 33 percent GM corn produced third and fourth litters with fewer offspring of lower birth weights. The team described the results as "statistically significant," adding that more females in the GM-diet group "remained without litters than in the control group." In response to the finding, one Greenpeace scientist told the *Daily Mail* that GM food "appears to be acting as a birth-control agent, potentially leading to infertility. If this is not reason enough to close down the whole biotech industry once and for all, I am not sure what kind of disaster we are waiting for," he opined. *See The Daily Mail*, November 12, 2008.

[15] Scientist Warns CDC About Up-tick of *C. Difficile* in Foods

A University of Arizona scientist has reportedly warned the U.S. Centers for Disease Control and Prevention (CDC) that more than 40 percent of prepackaged meats sampled in 2006 tested positive for *Clostridium difficile*, an intestinal bug usually associated with hospitals and nursing homes. In addition, Professor of Veterinary Science J. Glenn



Songer apparently found that 30 percent of the contaminated meats carried a highly toxic strain of *C. difficile* that is also resistant to drug treatments. He warned that not only is this disease difficult to trace to its source, but it survives most forms of sterilization, including cooking. “These data suggest that domestic animals, by way of retail meats, may be a source for *C. difficile* for human infection,” Songer told *MSNBC.com*, which reported on the emergence of the super bug in supermarket products like ground beef, turkey and ready-to-eat summer sausage.

Yet, “There are no documented cases of people getting *Clostridium difficile* from eating foods that contain *C. difficile*,” according to L. Clifford McDonald, chief of prevention and response for a CDC division. Other scientists also noted that *C. difficile* might be prevalent in other environments, urging further research. “The connection between the animal, food and the disease has not been made,” said *C. difficile* expert Dale Gerding of the Stritch School of Medicine at Loyola University in Chicago. “But that doesn’t mean it’s not there.” See *MSNBC.com*, November 18, 2008.



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