Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

*Government Accountability Office (GAO)

[1] GAO Audit Examines Successes of Consolidated Food Safety Systems

A recent GAO **report** ordered by Senator Dick Durbin (D-Ill.) and Representative Rosa DeLauro (D-Conn.) has examined food safety systems in six other countries and the European Union, concluding that "the selected countries have a comprehensive, risk-based approach to ensuring the safety of imported food."

GAO looked at the laws, directives and other guidance materials supplied by reorganized or consolidated food safety systems in Canada, Germany, Ireland, Japan, the Netherlands and the United Kingdom, as well as the European Union, to identify key program elements. The audit specifically noted that these food safety systems incorporated: (i) farm-to-table oversight; (ii) producer responsibility; (iii) separate risk assessment and risk management; (iv) risk-based inspection systems; (v) equivalent safety standards for imported foods; (vi) traceback procedures; (vii) cooperation between government veterinarians and public health officials; and (viii) mandatory recall authority.

"I hope today's report serves as a wake-up call for the administration and others in Congress," Durbin was quoted as saying. "We need a thoughtful overhaul and reorganization of America's food safety system." *See The Chicago Tribune*, July 16, 2008.

U.S. Department of Agriculture (USDA)

[2] USDA to Publicize List of Retailers Receiving Recalled Meat and Poultry

USDA has announced its intention to publicize a list of stores "receiving meat and poultry products involved in Class I recalls – those of the most serious concern to the public health." Beginning next month, the Food Safety and Inspection Service (FSIS) Web site will name implicated establishments within three to 10 business days of a recall to help consumers identify products posing "a reasonable probability of serious health consequences or death for those with weakened immune systems." The list will include supermarkets and grocery stores, convenience stores, meat markets, wholesale clubs, and supercenters. FSIS will also share the list with state and local officials to better enforce safety measures.

"The identity of retail stores with recalled meat and poultry from their suppliers has always been a missing piece of information for the public during a recall," USDA Secretary Ed Schafer stated in a July 11, 2008, press release. "People want to know if they need to be on the lookout for recalled meat and poultry from their local store and by providing

lists of retail outlets during recalls, [FSIS] will improve public health protection by better informing consumers."

Backed by Senators Richard Durbin (D-Ill.), Tom Harkin (D-Iowa). Bob Casey (D-Penn.), and Sherrod Brown (D-Ohio), the rule change drew their praise but also prompted criticism for failing to include all recall classifications. In addition, the consumer interest group Food and Water Watch noted that the new system would not extend to Class II recalls like the one issued by Westland/Hallmark Meat Co., which in 2008 pulled 143 million pounds of ground beef off the market for alleged humane-handling violations. "I am somewhat disappointed that the proposed rule is limited to only recalls of tainted food that could cause serious injury or result in death and hope the USDA will broaden the rule to include other classes of recalled product as well," Durbin said.

The Grocery Manufacturers Association, however, has warned that excessive or out-of-date disclosures could mislead buyers. "The most important information for consumers to have in a USDA recall is the brand name, container size and manufacturer coding information marked on meat and poultry products," a GMA spokesperson was quoted as saying. *See Product Liability Law 360°, Food and Water Watch Press Release* and *The Los Angeles Times*, July 11, 2008; *Federal Register*, July 17, 2008.

[3] AMS Proposes Extending Use of Methionine in Organic Poultry

USDA's Agricultural Marketing Service (AMS) has **proposed** extending by two years a provision that allows the use of the synthetic feed additive methionine and its analogues in organic poultry production. Classified as an essential amino acid, methionine is a colorless or white water-soluble crystalline powder regulated as an animal feed nutritional supplement. The National Organic Standards Board (NOSB) has apparently received several petitions requesting an extension until October 1, 2010, for methionine use, in part because the amino acid is critical to healthy poultry development. "The NOSB has determined that while wholly natural substitute products exist, they are not presently available in sufficient supplies to meet poultry producers needs," AMS states in a July 14, 2008, *Federal Register* notice. "Loss of the use of methionine, at this time, would disrupt the well-established organic poultry market and cause substantial economic harm to organic poultry operations."

In a related **development**, AMS is also seeking comments on 12 substances slated for sunset review on the National List of Allowed and Prohibited Substances, which governs the use of synthetic or artificial substances in organic production and handling. NOSB has recommended renewing 11 exemptions and one prohibition on the list and correcting the tartaric acid listings "by adding annotations originally recommended to the Secretary on November 1, 1995." The board has proposed allowing the continued use of the following six synthetic substances in organic crop production: (i) copper sulfate as an algicide; (ii) ozone gas for use as an irrigation system cleaner only; (iii) peracetic acid for use in disinfecting equipment, seed and asexually propagated planting material and to control fire blight bacteria; (iv) copper sulfate as a tadpole shrimp control in aquatic rice; (v) synthetic inert ingredients used in passive pheromone dispensers; and (vi) cellulose for use in regenerative casings, as an anti-caking agent and a filtering aid.

In addition, NOSB has recommended continuing approval for the following non-agricultural, non-synthetic substances in products labeled "organic":

(i) agar-agar; (ii) animal enzymes, including rennet, catalase, animal lipase, pancreatin, pepsin, and trypsin; (iii) calcium sulfate; (iv) carrageenan; and (v) glucono delta-lactone. The board would prohibit the further use of calcium chloride in organic crop production except as "foliar spray to treat a physiological disorder associated with calcium uptake."

Environmental Protection Agency (EPA)

[4] EPA Acrylamide Study Draws Questions from Advisors, Industry

EPA's Science Advisory Board (SAB) has apparently raised questions about the agency's draft Integrated Risk Information System (IRIS) assessment for acrylamide, a chemical byproduct of the cooking process. Concluding that acrylamide is a "likely" human carcinogen, the draft set a new oral reference dose (RfD) of 0.003 milligrams per kilogram of bodyweight per day (mg/kg-day) and a first-ever inhalation reference concentration (RfC). EPA based its findings on two animal studies tracking chronic acrylamide exposure through drinking water: a 1986 study that identified degenerative lesions in the peripheral nerves of male rats and a 1995 study focused on carcinogenic properties.

Although the SAB panel called the agency's cancer determination "scientifically supportable," it nevertheless criticized EPA for using only one study to reinforce its conclusion. The board reportedly urged EPA to discuss "the strengths and limitations of both studies" in greater depth, taking specific issue with a description of the 1995 study as "superior" and "larger and better designed" than comparable research. Some panelists also advised EPA to delay finalizing the IRIS draft until the Food and Drug Administration publishes the results of its own acrylamide research. "The main concerns with these studies are that they were primarily designed as cancer bioassays and therefore did not induce the most sensitive measures of neurotoxicity," the SAB report stated. "Nevertheless, the panel agreed that the selected studies did have some important strengths, including reasonable statistical power due to the relatively large number of animals."

The Grocery Manufacturers Association (GMA) previously expressed similar concerns about the 1995 study. The association's consultant, the Sapphire Group, concluded in comments submitted to EPA on April 2, 2008, that the IRIS assessment "lacks considerations of key data and important evaluative approaches, resulting in our conclusion that the draft's resulting cancer potency and risk estimates per unit of dose are unjustifiably high, and lack the necessary validity to estimate cancer risk to humans ingesting acrylamide." *See EPA Science Advisory Board Draft Report*, June 30, 2008; *Inside EPA*, July 11, 2008.

European Food Safety Authority (EFSA)

[5] EFSA Opinion Highlights Aluminum Levels in Infant Formula

EFSA recently published an **opinion** concluding that a significant part of the European population may routinely exceed safety thresholds for dietary aluminum intake. The opinion established a tolerable weekly intake (TWI) of 1 milligram of aluminum per kilogram of bodyweight (mg/kg bw), but EFSA warned that some consumers get double this amount from their diets. "Aluminum in foods originates from its natural occurrence, from the use of food additives containing aluminum and from the presence of aluminum in food contact materials

such as pots, pans and foil," according to EFSA. The agency listed cereals and cereal products; vegetables; beverages like tea and cocoa; and some infant formulas as the main contributors to dietary aluminum intake.

The European Commission requested that EFSA's Panel on Food Additives, Flavorings, Processing Aids and Food Contact Materials (AFC) develop an opinion after the Joint FAO/WHO Expert Committee on Food Additives (JECFA) arrived at similar conclusions in 2006. While EFSA did not provide specific data on the role of additives, the panel found that some milk-based or soy-based formulas exposed infants to aluminum levels averaging 0.9 mg/kg bw per week and 1.1 mg/kg bw , respectively. The opinion also noted that aluminum levels in some brands were four times higher than average concentrations. "This review is timely because it has highlighted the need for better data on the sources and extent of use of aluminum in food, so that exposure can be reduced for those who may be exceeding the TWI," stated AFC Chair Sue Barlow. *See Food Standards Agency Press Release*, July 15, 2008; *Food Production Daily.com*, July 16, 2008.

United Kingdom (UK)

[6] Cabinet Office Issues Strategic Unit Report on Food Policies

The UK Cabinet Office recently published a Strategy Unit **report** that addresses policy issues related to food production and consumption, health and the environment. The report identifies challenges arising from (i) a recent increase in global commodity prices; (ii) the failure of UK diets to meet nutritional guidelines; (iii) the need for improved safety protocols; and (iv) the environmental impact of food production and consumption. "The Government's vision for the food system is one that is more sustainable – economically, socially and environmentally," states the report. "The future strategic policy objectives for food should be to secure: fair prices, choice, access to food policy and food security through open and competitive markets; continuous improvement in the safety of food; a further transition to healthier diets; and a more environmentally sustainable food chain."

The Cabinet Office specifically recommends that the UK "take a leadership role in looking at how the world can meet the twin challenges of climate change and global food security," noting that a forthcoming project from the chief scientific adviser will explore "how the food system and its associated policies will need to mitigate and adapt to climate change." The report also announces a partnership between the Department for Environment, Food and Rural Affairs (Defra), Food Standards Agency (FSA) and Department of Health (DH) to "develop and engage public and food businesses in a new shared vision to guide food strategy." In addition, Defa will join with other European companies to set climate change priorities and investigate agricultural solutions.

The report further argues that "70,000 premature deaths could be prevented each year" if UK diets matched nutritional guidelines. To meet this goal, DH will launch a new Healthier Food Mark for public food, according to the Cabinet Office. The 10-month strategic project also urges FSA to provide access to "integrated government information on a healthy, environmentally sustainable diet" and to work with the food industry to improve information and "healthier choice options when eating out." *See Cabinet Office Press Release* and *Executive Summary*, July 7, 2008.

Canada

[7] Canada Questions Need to Regulate Nanotechnology in Consumer Products

An expert **report** commissioned by Health Canada and other government agencies has reportedly warned regulators that nanomaterials could pose a unique safety risk to humans. Titled *Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale*, the report by the Council of Canadian Academies encourages regulators to increase oversight for this field of emerging technology. The council concluded that "there are inadequate data to inform quantitative risk assessments on current and emerging nanomaterials," but added that small particles could "usurp traditional biological protective mechanisms" leading to "enhanced toxicological effects." The assessment also recommends that regulators close loopholes in existing laws to prevent manufacturers from submitting nanomaterials as different configurations of pre-approved chemicals. "Current regulatory triggers are not sufficient to identify all nanomaterials entering the market that may require regulatory oversight," stated the council, which pointed to polychlorinated biphenyls and the herbicide Agent Orange as examples of widely used chemicals later deemed harmful by authorities. *See Globe and Mail*, July 10, 2008.

In a related development, the Woodrow Wilson Center's Project on Emerging Nanotechnologies (PEN) and the Grocery Manufacturers Association (GMA) has published a July 2008 report titled ***Assuring the Safety of Nanomaterials in Food Packaging: The Regulatory Process and Key Issues***. The report focuses on the key legal, technical and environmental issues faced by manufacturers seeking to incorporate nanotechnology into food contact materials.

In particular, the report addresses: (i) marketing nanoscale versions of previously approved products; (ii) FDA guidance regarding independent GRAS [generally recognized as safe] determinations; (iii) the ability of the FDA petition process to ensure safety and foster public understanding of novel products; and (iv) how to define the scope of nano-specific FDA guidelines in the future. PEN also emphasizes the need to assess the unique chemical and toxicological properties of nanoscale materials that may require the development of new exposure triggers, data requirements and testing protocols. "For the foreseeable future, however, early consultation with FDA is advisable for parties seeking to develop and market [engineered nanoscale materials] food contact substances," the report concludes.

[8] "Made in Canada" Label Approved for Food Products

The Canadian government this week approved new rules restricting the use of "Made in Canada" labels on food products. Current regulations allow products to display a "Made in Canada" label if at least 51 percent of its production costs are incurred within the country. As of January 1, 2009, foods marketed as a "Product of Canada" must demonstrate that all of its major ingredients and labor are domestic. In addition, some products manufactured in Canada from imported ingredients can qualify to carry a modified label. "The basis of this policy is making sure that consumers don't get information from products that is false," stated a spokesperson for the Canadian Food Inspection Agency, which instituted the changes as part of the Food and Consumer Safety Action Plan announced in December 2007. *See The Toronto Star*, July 16, 2008.

State and Local Governments

[9] California Legislature Passes *Trans* Fat Ban

The California Legislature has narrowly passed a bill (A.B. 97) that would require the state's restaurants, hospitals and other food-preparation facilities to eliminate all *trans* fats from their menus.

If signed into law by Governor Arnold Schwarzenegger (R), the measure would prohibit *trans* fat in oils, shortening and margarines by January 1, 2010, and in all ingredients by January 1, 2011, imposing fines of up to $1,000 for violations. The legislation also permits local governments to create ordinances like those in San Francisco, which awards "*trans* fat-free" decals to restaurants passing a voluntary $250 inspection. The law would not apply to pre-packaged foods regulated by the Food and Drug Administration or school cafeterias subject to a separate *trans* fat ban taking effect next year.

Meanwhile, the Golden Gate Restaurant Association has described the measure as unnecessary given California's plethora of healthy dining options, emphasizing the need for national regulations applicable to packaged goods. The California Conference of Directors for Environmental Health also noted that the bill does not address funding sources. "The thing in enforcement is that it's difficult to verify the absence of *trans* fat in hundreds of thousands of different products," Executive Director Justin Malan was quoted as saying. He reportedly argued that a lack of proper funding will result in "cursory" inspections. *See The San Francisco Chronicle* and *The Sacramento Bee*, July 15, 2008.

Media Coverage

[10] Roni Caryn Rabin, "New Yorkers Try to Swallow Calorie Sticker Shock," *MSNBC.com*, July 16, 2008

"Many New Yorkers are finding that even the foods they thought were lower calorie really aren't," writes Roni Caryn Rabin in this *MSNBC* article describing consumers' reactions to the new New York City menu labeling laws. Rabin interviewed several residents suffering "the throes of stick shock" as they navigated restaurant menus displaying calorie counts alongside popular items, such as T.G.I. Friday's "pecan-crusted chicken salad, served with mandarin oranges, dried cranberries and celery" listed at 1,360 calories. "That surprised me the most because they market it as a healthy option," one diner told Rabin. "It's like false advertising. You think it's better than the burger and fries. It's misleading."

Meanwhile, New York City health officials have estimated that the new rules could "reduce the number of obese New Yorkers by 150,000 over the next five years and prevent 30,000 cases of diabetes," according to Rabin. She nevertheless notes that while some diners changed their orders, others vowed not to alter their eating habits or simply sought out menus without the added nutritional information. The city's labeling law applies only to restaurants with 15 or more outlets nationwide and can fine non-compliant establishments up to $2,000 depending on the violation. "We're still in court, but the ruling is in effect," a health department spokesperson was quoted as saying.

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