

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] House Subcommittee Hears Testimony on Amended Executive Order

A subcommittee of the House Committee on Science and Technology recently held hearings to address concerns over an executive order (E.O. 13422) issued by President George Bush (R) in January 2007 that made changes to E.O. 12866, governing administrative oversight of federal regulatory agencies. Essentially, the changes require regulatory agencies to “identify in writing the specific market failure” justifying a new regulation, to subject their guidance documents to review procedures, and to appoint a “regulatory policy officer,” who is a presidential appointee, to approve each regulatory undertaking. Additional information about the amendment appears in issue 199 of this Report.

The first hearing was held in February; the Subcommittee on Investigations and Oversight conducted its second [hearing](#) on April 26. Testifying were administrative law experts and former government officials who could answer (i) how the amendment was developed and what its consequences are, (ii) what the shift to a “market failure” standard for justifying proposed regulation means,

and (iii) what consequences can be expected from a change to the status and authority of regulatory policy officers.

Critics of the Bush amendment contend that it concentrates too much power in the executive and usurps congressional authority, while leading to delays in rulemaking. Supporters contend that it will provide greater transparency and limit unnecessary regulation.

Testifying in support of the amendment was a former acting administrator of the Office of Information and Regulatory Affairs (OIRA), which reviews all regulatory proposals. Arguing that the amendment made no substantive changes to the way the White House oversees federal agencies, Steven Aitken identified nutritional labeling requirements for packaged foods as a classic example of what constitutes regulation necessitated by a lack-of-information “market failure.” More specifically, Aitken pointed to the Food and Drug Administration’s (FDA’s) regulation concerning *trans* fat labeling to assuage any fears that the amendment would prevent agencies from issuing regulations to protect public health and safety.

Other supporters, from the AEI-Brookings Joint Center for Regulatory Studies, praised the amendment’s requirement that guidance materials be subjected to White House oversight, noting that FDA has more than 1,500 guidance documents currently in use. They did acknowledge that, at least in some instances, “applying some of the same standards to federal guidance as now apply to regulation will



allow big business to exert more control over the process, either by delaying the issuance of guidance or changing the guidance to meet its needs.”

A law professor from the University of Connecticut also used a food-related regulation in his presentation to undercut another witness’s characterization of regulations with zero benefits. Professor Richard Parker mentioned an FDA rule that regulates the safe handling of seafood in commercial processing plants. While some contend that it confers no benefits, Parker argued that avoiding acute poisoning is, indeed, a benefit, which may not be quantifiable but is important nonetheless. Parker focused his testimony on unsupportable claims by regulatory opponents about the costs of regulation and expressed his concern that “OIRA insists on viewing regulatory policy through the prism of numbers.”

Those witnesses opposing the Bush amendment recommended that Congress (i) refuse to pay the salaries of regulatory policy officers who will now develop the agencies’ rulemaking agendas, (ii) allow the public to contact such officers directly and to learn the proposed regulatory activities that these officers have decided the agency will not pursue, or (iii) require agencies to submit an annual report to Congress on activities that have been delayed, withdrawn or rejected by the regulatory policy officers.

Food and Drug Administration (FDA)

[2] FDA Creates New Food Safety Position

FDA Commissioner Andrew von Eschenbach, M.D., this week named David Acheson, M.D., the assistant commissioner of food protection, a new position responsible for “strategic and substantive food safety and food defense matters,” according to

an agency [press release](#). Acheson currently serves as director of the Office of Food Defense, Communication and Emergency Response at FDA’s Center for Food Safety and Applied Nutrition, where he manages foodborne illness investigations and risk assessment programs. In addition to working with FDA product centers and the Office of Regulatory Affairs, his duties will include “the development of an agency-wide, visionary strategy” to identify failings in the global food supply and prioritize safety challenges. Acheson will also report to the Department of Health and Human Services and other government agencies involved in FDA food defense initiatives.

The announcement coincided with a House Committee on Oversight and Government Reform hearing on FDA’s effectiveness. “By the end of these hearings, we will have a better idea of the impact of budget cuts and cronyism on the current problems,” Committee Chair Henry Waxman (D-Calif.) said in opening the proceedings, which included testimony from Eschenbach and former FDA commissioners Donald Kennedy, Frank Young and David Kessler. The hearing focused on the agency’s (i) resources and funding; (ii) scientific integrity; (iii) enforcement activities; and (iv) legal authority and governing provisions. “We are seeing a confluence of factors – chronic under-funding, a lack of enforcement authority, severely outdated scientific and regulatory frameworks – that are creating a lack of confidence in the agency,” Kessler testified, adding that the globalization of the food market poses significant challenges for the future.

[3] Melamine-Tainted Animal Feed Unlikely to Harm Human Health, Say FDA and USDA

FDA and agriculture department officials this week said that melamine-tainted pet food salvaged



as livestock feed poses little risk to human health. The agencies estimate that 6,000 hogs in eight states were exposed to melamine, in addition to broiler chickens on at least 38 Indiana poultry farms. Although the chickens have already entered the food supply, USDA will euthanize the swine as a precaution and compensate pork producers for economic damages. "At this time, we have no evidence of harm to humans associated with the processed pork product, and therefore no recall of meat products processed from these animals is being issued," stated a joint FDA/USDA [press release](#), which noted that even if minimal amounts of the chemical passed into the meat, "pork is only a small part of the average American diet." See *FDA/USDA Press Releases*, April 26 and 28, 2007; *The Washington Post*, April 27 and May 2, 2007; *Reuters*, May 1, 2007; *The New York Times*, May 1 and 2, 2007.

FDA first identified melamine and a related compound, cyanuric acid, in rice protein and wheat gluten imported from China, which reportedly tolerated manufacturers that used the plasticizer to boost protein counts. "Many companies buy melamine scrap to make animal feed, such as fish feed," one manager of a Chinese chemical company told *The New York Times*. "No law or regulation says 'don't do it,' so everyone's doing it," he said, although the country last week prohibited the practice. Past U.S. inquiries into China-based food producers apparently unearthed similar violations, including soy sauce made from human hair and eels raised on contraceptives. "This was standard stuff after World War II, when animal feed was adulterated with urea," Marion Nestle, Ph.D., was quoted as saying. "This is simple greed. It's like they're adding water to the wheat gluten." See *The New York Times*, April 30 and May 3, 2007.

Meanwhile, FDA has banned several food additives from China while it investigates two exporters implicated in the controversy, but sourcing the contamination has proved difficult because many agricultural commodities are traded online. "Records relating to the importation of these products indicate that these two firms had manufactured the ingredients in question," a recent FDA [alert](#) explained. "There is strong evidence, however, that these firms are not the actual manufacturers." Xuzhou Anying Biologic Technology Development Co., for example, reportedly shipped more than 700 tons of mislabeled wheat gluten through textile manufacturer Suzhou Textiles Silk Light and Industrial Products, thereby circumventing government food regulators. Chinese officials have also maintained that Xuzhou did not manufacture the wheat gluten itself but received it from at least 25 different suppliers, any of which could have used melamine to meet U.S. protein thresholds. The company, however, had previously posted Internet advertisements seeking melamine scrap. See *The Washington Post*, May 1, 2007; *The New York Times*, May 3 and 4, 2007.

Las Vegas-based ChemNutra Inc., which received the tainted shipments from Suzhou Textiles, told the press that records showed Xuzhou as the manufacturer of "food-grade" wheat gluten and that its representatives had visited the supplier. Blamed in a number of pet deaths, the contamination has reportedly shaken U.S. consumers and prompted advocacy groups to criticize the FDA for failing to protect the food supply. The agency employs 1,750 inspectors for all ports and domestic food-production plants, according to *Times* reporter Alexei Barrionuevo, in comparison to 9,000 USDA inspectors designated for only 20 percent of the food supply. "They have fewer people inspecting product



at the ports than ever before,” said a Center for Science in the Public Interest spokesperson. “Until China gets programs in place to verify the safety of their products, they need to be inspected by U.S. inspectors. This open-door policy on food ingredients is an open invitation for an attack on the food supply, either intentional or unintentional.” See *The New York Times*, May 1, 2007; *The Washington Post*, May 2, 2007.

[4] **Chocolate Purists Fight Petition to Allow Ingredient Substitution**

Chocolate lovers have reportedly united against an industry-backed petition that proposes allowing chocolate manufacturers to substitute vegetable fats for cacao fat, an ingredient some purists say is critical to chocolate’s identity. FDA has received more than 225 comments on the petition, which critics have condemned as a cost-cutting measure that strips chocolate of any natural health benefits derived from the flavonoids in cocoa butter. Meanwhile, the Chocolate Manufacturers Association has neither accepted nor rejected the proposal. “We want to emphasize that by co-signing the food industry petition, CMA has not endorsed any particular changes to the standards of identity for chocolate products,” stated the group. See *The Washington Post* and *ABC News*, April 27, 2007.

Department of Health and Human Services

[5] **Bisphenol A Expert Panel Postponed**

The National Toxicology Program this week [announced](#) that the bisphenol A expert panel scheduled for May 21-23, 2007, has been postponed until further notice. During this time, NTP will audit the bisphenol A report prepared by Sciences

International Inc., an independent contractor hired to review more than 500 scientific studies on the chemical’s alleged link to cancer and reproductive disease in animals. NTP earlier this month fired Sciences International over a potential conflict of interest, citing evidence that the Virginia-based company counted bisphenol A manufacturers Dow Chemical and BASF among its corporate clients. NTP has also extended the deadline for written comments on the draft report until June 20, 2007. See *The Washington Post*, April 17, 2007.

Institute of Medicine (IOM)

[6] **IOM Issues Standards for Competitive Foods in Schools**

The National Academies’ Institute of Medicine recently issued a report, titled *Nutrition Standards for Food in Schools: Leading the Way toward Healthier Youth*, that recommends guidelines for “competitive” a la carte foods sold in school vending machines, stores, and cafeterias. The standards, which outline a two-tier system for all products not included in federally reimbursable school meals, would require that packaged servings of snacks, foods and beverages (i) obtain no more than 35 percent of total calories from fat; (ii) obtain less than 10 percent of total calories from saturated fats; and (iii) are *trans* fat-free. In addition, these items should provide no more than 35 percent of calories from total sugars per portion, with the exceptions of whole fruits and vegetables, juices without added sugars, and non- or low-fat dairy products. Snacks should also contain fewer than 200 calories and 200 mg. of sodium per packaged portion, according to IOM. Available to all age groups throughout the day, “Tier 1” items would fall within these guidelines and provide at least one serving of fruits, vegetables,



whole grains or low-fat dairy. Restricted to after-school hours in high schools, “Tier 2” products, such as low-salt baked potato chips, are those that conform to the guidelines but do not necessary fulfill nutritional requirements. IOM also advises prohibiting caffeinated drinks and restricting diet beverages that contain sugar substitutes. *See IOM Press Release and Report Brief*, April 25, 2007.

Commissioned by Congress, the IOM report has been endorsed by some legislators, health groups and consumer watchdogs as the latest answer to childhood obesity. “For the first time, we have a gold-standard recommendation,” said Senator Thomas Harkin (D-Iowa), who earlier this year introduced a bill (S. 771) to close a “junk-food loophole” in federal school nutrition laws. The Center for Science in the Public Interest also hailed the IOM rules as “far superior to the current national school food standards,” although the Grocery Manufacturers Association and American Beverage Association argued that the IOM report overlooks recent industry-led initiatives. “Today’s IOM report shines an important spotlight on the issue of obesity, but ignores the tremendous progress that has been made in recent years in improving the school food environment,” stated a GMA press release. *See GMA Press Release and CSPI Press Release*, April 25, 2007; *Associated Press*, April 25 and 30, 2007; *The Wall Street Journal* and *The Washington Post*, April 26, 2007.

Litigation

[7] Ninth Circuit Upholds Current “Dolphin-Safe” Tuna Standards

The Ninth Circuit Court of Appeals has vacated a finding by the Secretary of Commerce that catching yellowfin tuna by encircling dolphins with purse-

seine nets does not have a significant adverse impact on dolphin stocks, ruling that the finding was arbitrary and capricious because the agency “still has not complied with Congressional mandates for scientific studies.” [*Earth Island Inst. v. Hogarth*, No. 04-17018 \(9th Cir., decided April 27, 2007\)](#). Thus, the court found that the agency lacks Congressional authority to change the qualifications for labeling tuna as dolphin safe.

The issue arose in a dispute that began in 1999, when the commerce secretary made an initial finding, “despite inconclusive evidence,” that the U.S. tuna fishery “was not having an adverse impact on the dolphin population.” Environmental groups successfully challenged that finding, and the agency conducted additional studies, reaching the same conclusion in 2002. A U.S. district court vacated the secretary’s finding again and declared that dolphin-safe labeling may not be used for tuna caught with purse-seine nets.

Agreeing with the district court that the secretary’s finding “was not rationally connected to the best available scientific evidence,” the Ninth Circuit further agreed that “the Final Finding was, to at least some degree, influenced by political, rather than scientific, concerns.” The appeals court further agreed to take the “rare” step of vacating the secretary’s decision without remanding for further administrative proceedings, but modified the district court’s disposition by lifting its order directing the secretary to undertake enforcement measures. Instead, the court instructed the district court to limit its mandate to one directing the secretary to vacate the agency’s final finding of no significant adverse impact. “This means as a practical matter that pursuant to the current statute, there will be no change in tuna labeling standards absent new Congressional directive.”



In a related development, *National Geographic* reports that glow sticks, which are used in commercial longline fishing operations, are also attracting and leading to the deaths of tens of thousands of sea turtles. Researchers have reportedly found that the turtles are attracted to yellow, blue and green chemical glow sticks, in addition to orange LEDs. They are conducting tests to see if shading the lights or using pulsing lights may be less attractive to the turtles. See *NationalGeographic.com*, April 27, 2007.

[8] Pet Food Maker Sues Supplier of Contaminated Wheat Gluten

Menu Foods Midwest Corp. has filed a petition in a Kansas state court against ChemNutra, Inc., seeking damages for the cost of investigating the cause of pet deaths allegedly due to contaminated pet food and the costs of recalling, storing and disposing of the contaminated food. *Menu Foods Midwest Corp. v. ChemNutra, Inc.*, No. 07-CV-69 (Lyon County District Court, Kansas, filed April 23, 2007). The pet-food maker also seeks indemnification for all costs associated with the recall and litigation pending against it. Menu Foods is currently defending numerous putative class-action lawsuits pending throughout the United States and Canada. According to the petition, "Instead of delivering high quality wheat gluten, ChemNutra shipped an [sic] contaminated product that contained melamine, a substance not approved by the Food and Drug Administration for pet food." The petition includes counts for breach of contract, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, declaratory judgment: indemnification, and contribution.

ChemNutra has posted a letter to pet owners and pet food businesses on its [Web site](#) claiming that it, too, has been "victimized." The letter further states, "We are appalled and distressed that Menu Foods took so long to recall its products, although it clearly suspected there was a problem for weeks prior to the first recall. And it wasn't until eight days before they issued their first recall that Menu Foods told us that wheat gluten was one of many ingredients it was investigating." Company CEO Steve Miller contends that the firm "will never again do business with the supplier of the suspect wheat gluten," which "had been recommended to us by a long-time reliable source in China, and presented what appeared to be legitimate proof that its product was safe."

Meanwhile, the general manager of one of the Chinese companies under investigation for selling contaminated wheat gluten to pet food suppliers in this country has reportedly been detained by local authorities. Police have not indicated on what charges Mao Lijun is being held. Mao has apparently denied knowing how melamine contaminated pet food ingredients sold under his company's label and insisted his company only sells its products in the domestic market. See *The New York Times*, May 4, 2007.

[9] Federal Court Dismisses *Trans* Fat Case Against Yum! Brands

A federal district judge has dismissed a physician's claims that KFC misled the public by failing to disclose the presence of *trans* fats in its foods. [Hoyte v. Yum! Brands, Inc., No. 06-1127 \(U.S. District Court, District of Columbia, decided May 2, 2007\)](#). The court determined that plaintiff's breach of implied warranty of merchantability claim failed because he had not alleged any injury. So



ruling, the court declined to find “as a matter of law, that the consumption of fat – including *trans* fat – is indeed within the reasonable expectations of the consumers of fried chicken and French fries prepared in fast food kitchens.” The court also found that the plaintiff lacked standing to bring a claim for breach of the D.C. Consumer Protection Act, again for his failure to “present an actual or threatened injury-in-fact.” Finally, the court dismissed the plaintiff’s negligent misrepresentation claim because KFC’s assertion that its restaurants serve the “best food,” “is a non-measurable, ‘bald statement of superiority’ that is non-actionable puffery.”

Other Developments

[10] Advocacy Group Launches Effort to Fire Shrek from Obesity Campaign

The Campaign for a Commercial-Free Childhood (CCFC) is [calling](#) on consumers to ask Health and Human Services (HHS) Secretary Michael Leavitt to stop using the animated-movie ogre Shrek in its anti-obesity campaign. Shrek is apparently appearing in public service announcements to promote a healthy lifestyle by urging children to exercise. According to the advocacy group, the upcoming movie “Shrek the Third” is currently being marketed by “sixteen separate food promotions” for candy, sugary cereal, soft drinks, and cookies. “Surely Health and Human Services can find a better spokesperson for healthy living than a character who is a walking advertisement” for high-calorie foods, CCFC Executive Director Susan Linn said in a recent letter to HHS. An agency spokesperson apparently responded by saying the rotund character is very well-known “in the target population of this campaign. We have always

promoted a balanced, healthy diet, which does not necessarily exclude the occasional treat.” See *The Los Angeles Times*, April 25, 2007; *The New York Times*, April 28, 2007.

Media Coverage

[11] Regulatory Foot-Dragging Charged in Occupational Exposure to Diacetyl

The New York Times recently profiled problems that workers in microwave popcorn plants have had when exposed to diacetyl, a food-flavoring agent, purportedly linked to a life-threatening lung disease. According to the article, the Occupational Safety and Health Administration (OSHA) reacted tepidly to the issue when it emerged in Missouri seven years ago and only in April 2007 informed Congress that it would prepare a safety bulletin and planned to inspect a few dozen of the thousands of food plants using the additive. Agency critics called this initiative disappointing, claiming that diacetyl is widely used in food factories.

The nation’s workplace safety agency has apparently “issued the fewest significant standards in its history” and has “imposed only one major safety rule” since George W. Bush became president. Assistant Secretary of Labor for OSHA Edwin Foulke, a self-proclaimed “true Ronald Reagan Republican” who “firmly believes in limited government,” reportedly contends that “the science is murky” on whether diacetyl causes injury. But scientists and physicians with the National Institute for Occupational Safety and Health disagree, claiming strong evidence links the additive to bronchiolitis obliterans.

Administration officials currently favor voluntary agreements with U.S. businesses, but only 61 food



plants participate in OSHA's "voluntary compliance" programs. According to AFL-CIO Occupational Safety and Health Director Peg Seminario, "OSHA has been focusing on the best companies in their voluntary protection program while doing nothing in the area of standard setting. They've simply gotten out of the standard-setting business in favor of industry partnerships that have no teeth." Apparently, three of the biggest industries regulated by the agency, transportation, agribusiness and construction, "have given more than \$630 million in political campaign contributions since 2000, with nearly three-quarters of that money going to Republicans."

With Congress in Democratic hands, new oversight hearings are being held, including one on April 24 at which a former popcorn-plant worker from Missouri testified that, at age 35, he needs a double-lung transplant because his lung capacity has dropped to 18 percent. Eric Peoples won a \$20 million award in litigation against the company that makes the food additive, and the company has apparently been sued by more than 150 other workers in four states. There is apparently little science on whether diacetyl vapors are released when consumers make microwave popcorn; the Environmental Protection Agency has declined to release the results of its studies to the public. See *Milwaukee Journal Sentinel*, April 24, 2007; *The New York Times*, April 25, 2007.

Meanwhile, a Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* calls for employers to make minimizing worker exposure to flavoring chemicals such as diacetyl a priority. The [report](#), *Fixed Obstructive Lung Disease Among Workers in the Flavor-Manufacturing Industry – California, 2004–2007*, recommends engineering controls, including ventilation and

closed chemical transfers, as well as work practices like covering containers and minimizing spills.

Scientific/Technical Items

[12] Researchers Study Animal Feed Ingredients and Human Health Effects

A recent [study](#) of U.S. animal-feed production practices, animal-feed ingredients and potential human-health impacts has concluded that surveillance inadequacies make it difficult to identify the extent to which specific human-health risks are associated with animal-feeding practices. Amy Sapkota, et al., "What Do We Feed to Food-Production Animals? A Review of Animal Feed Ingredients and Their Potential Impacts on Human Health." *Environmental Health Perspectives* (May 2007). According to the authors, animal-feed ingredients, which include rendered animal products, animal waste, antibiotics, metals, and fats, "could result in higher levels of bacteria, antibiotic-resistant bacteria, prions, arsenic, and dioxin-like compounds in animals and resulting animal-based food products intended for human consumption." Such agents in feed, say the authors, "can affect the quality and safety of animal-based food products and pose potential risks to human health." Because there is "almost no biological or chemical testing" conducted on U.S. animal feeds, "insufficient testing is performed on retail meat products, and human health effects data are not appropriately linked to this information," researchers cannot identify whether increases in bacterial infections and the risk of developing certain chronic diseases can be linked to animal-feeding practices. The authors recommend a national reporting system for feed ingredients, the development of "farm to fork" surveillance systems and increased collaboration



among feed professionals, food-animal producers and veterinary and public-health officials.

[13] Two Studies Examine Impact of Ads and “Food Cues” on Appetite

A University of Liverpool study, presented last week at the European Congress on Obesity in Budapest, claims that overweight children double their food intake following TV food advertisements. Researchers followed 60 British children ages 9 to 11 as they watched toy and food advertisements, finding that after viewing the food ads, (i) the obese children increased their food intake by 134 percent; (ii) the overweight children by 101 percent; and (iii) the normal-weight children by 84 percent. The study also claims that the heavier children were more likely to choose products with higher fat content. *See University of Liverpool Press Release and Reuters, April 24, 2007.*

In a related development, University of Wisconsin researchers claim that food-related cues stimulated unique patterns of gene expression in rats. Craig Schiltz, et al., “Food-associated cues alter forebrain functional connectivity as assessed with immediate early gene and proenkephalin expression,” *BMC Biology*, April 26, 2007. Researchers studied the gene expression of rats pre-conditioned to expect treats in a certain setting that were then denied their reward. Their results “suggest that food-associated cues have a powerful influence on neuronal activity and gene expression in brain area mediating complicated function such as cognition and emotion, and more basic abilities such as arousal and energy balance,” according to one reviewer. *See Innovations Report.com, April 26, 2007.*



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LITIGATION UPDATE

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