

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Department of Health and Human Services (HHS)

[1] NTP Group Meets to Address Risks of Bisphenol A; Controversy Erupts over Contractor Personnel

The Center for the Evaluation of Risks to Human Reproduction panel met March 5-7, 2007, to discuss a draft [report](#) on the reproductive and developmental toxicity of bisphenol A, a chemical used in the production of polycarbonate plastic and several types of resins. The plastic and resins are ubiquitous in food containers, both plastic and metal, and the chemical is known to leach into the food and beverage products that contact materials containing it. *In vitro* and animal studies purportedly indicate that bisphenol A may mimic a natural female sex hormone and cause low birth weight, miscarriage, infertility, and cancer.

The center, which was created by the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS) in 1998, has become a magnet of controversy. Representative Henry Waxman (D-Calif.) and Senator Barbara Boxer (D-Calif.) [wrote](#) to NIEHS Director David Schwartz in February to raise concerns about personnel affiliated with the center. According to the letter, questions have been raised about the role of a

private consulting firm, Sciences International, Inc., in the center's review of bisphenol A. The Environmental Working Group (EWG), a nonprofit Washington, D.C.-based watchdog organization dedicated to protecting human health, is cited in the letter for its contention that Sciences International, not only prepared the bisphenol A draft report but also manages the center.

EWG sent its own [letter](#) to Schwartz to raise the issue of "whether or not government health assessments should be managed by private consulting firms with ties to the industry that manufactures the chemicals under review." EWG contends that Sciences International has "historic ties to the tobacco industry and a client base that appears to include manufacturers of substances that might be subject to [the center's] review, including the chemical up for review on March 5, 2007, bisphenol A."

EWG, which acknowledges contributions from a number of foundations and an organization of plaintiffs' lawyers, has issued its own bisphenol A [study](#), which was submitted to the center's review panel on March 5. According to the study, independent laboratory tests of canned goods found the highest levels of the chemical in infant formula, chicken soup and ravioli, and the substance has been detected in more than 95 percent of 400 people in the United States. To date, no governmental agency has set limitations on bisphenol A in consumer products, which EWG claims is toxic at low doses. News sources have indicated that some



scientists who have reviewed the center's draft report believe it makes critical mistakes, misrepresents government-funded studies, fails to note industry funding of some studies relied on, and downplays the chemical's risks. See *The Los Angeles Times*, March 4, 2007; and *The (New Jersey) Star-Ledger*, March 6, 2007.

[2] Surgeon General Urges Alcohol Advertisers to Exercise Restraint

Acting Surgeon General Kenneth Moritsugu, M.D., M.P.H., this week issued a "call to action" [report](#) urging alcohol manufacturers to voluntarily curb advertising, especially on college campuses. "Too many Americans consider underage drinking a rite of passage to adulthood," Moritsugu was quoted as saying. Moritsugu asked the alcohol and media industries to refrain from "glamorizing" underage drinking and advised universities to eliminate alcohol-sponsored events. He also encouraged companies to forgo commercials, Web sites and drink formulas that might appeal to young people in particular, although he did not recommend new legislative measures to address the youth alcohol issue. See *HHS News Release*, March 6, 2007.

U.S. Department of Agriculture (USDA)

[3] USDA Proposes Changes to List of Substances Approved for Organics

USDA has proposed [changes](#) to the list of substances approved for use in certified organics. This national list, according to USDA, "identifies synthetic substances that are exempted (allowed) and non-synthetic substances that are prohibited in organic crop and livestock production." The

proposed rule would renew directives for 166 of the 169 listed items, but would remove three exemptions: (i) non-organic milk replacers, because organic alternatives are now available to supplement baby animal diets; (ii) non-synthetic colors, an overly broad category erroneously included on the original list; and (iii) potassium tartrate made from tartaric acid, which is not formally recognized by the FDA for food processing. Comments on the revisions must be received by May 7, 2007. See *Federal Register*, March 6, 2007.

[4] USDA Considers Approval for Rice Engineered with Human Genes

USDA has released a [draft environmental assessment](#) that would permit a biotechnology firm to cultivate rice engineered with human genes. California-based Ventria Bioscience would plant GM rice on 3,000 acres in Kansas, where the crops could be isolated, and mill the seeds on-site to prevent cross-contamination. The rice expresses the human proteins lysozyme and lactoferrin, bacteria-fighting compounds found in breast milk, and serum albumin, a blood protein. See *Federal Register*, February 28, 2007.

The USDA's preliminary approval has renewed controversy over pharmaceutical crops, raising fears that active proteins will end up on the plate. "USDA's record is not good," said a Union of Concerned Scientists spokesperson. "We don't think they can enforce even the inadequate system that is in place." Proponents, however, say the rice could be used to treat childhood diseases like diarrhea, which kills 2 million children annually. USDA is accepting public comments on the assessment until March 30, 2007.



[5] APHIS Issues Hold on Clearfield CL131 Long-Grain Rice

The Animal and Plant Inspection Service (APHIS) this week issued “[emergency action notifications](#)” to prevent the planting of Clearfield CL131 long-grain rice, which might contain genetic material not approved for commercial use. Tests of CL131 reportedly revealed a GM strain developed by Bayer CropScience and similar to one that entered the food supply last year, disrupting international trade. A spokesperson for BASF Corp., which manufactures CL131, said the company alerted authorities to the situation and will “work cooperatively” to resolve the issue. APHIS has issued the hold while it confirms the results and conducts any appropriate risk assessments. *See Reuters*, March 6, 2007.

Food and Drug Administration (FDA)

[6] FDA Standardizes Food Ingredient and Packaging Terms

FDA recently published a [standardized vocabulary](#) for food ingredients and packaging terms such as (i) color additive, (ii) colorant, (iii) food additive, (iv) indirect food additive, and (v) secondary direct food additive.

According to FDA, color additives are dyes or pigments “capable of imparting color” to food, whereas a colorant “alters the color of a food-contact material, but does not migrate to food” in significant amounts. A food additive is described as any substance not Generally Recognized As Safe (GRAS) or sanctioned prior to 1958 that may, directly or indirectly, affect food characteristics through its use in any aspect of production, transport, preparation, or storage. Indirect food additives “come into contact with food as part of packaging,

holding or processing,” while secondary direct food additives have a “technical effect” in food processing but not the finished product.

The list also covers several databases, including (i) CEDI/ADI, which tracks Cumulative Estimated Daily Intakes and Acceptable Daily Intakes for food contact substances; (ii) EAFUS, an informational database for “Everything Added to Food in the United States”; and (iii) PAFA, the Priority-based Assessment of Food Additive database that monitors the toxicological effects of food ingredients. *See Food Navigator USA.com*, March 1, 2007.

State/Local Initiatives

[7] California Legislation Would Hold Companies Liable for Crop Contamination

California Assemblyman Jared Huffman (D-6th District) recently introduced [legislation](#) that would hold manufacturers liable if their genetically modified crops contaminated other fields. In addition to requiring registration for all GM products, the bill would prohibit “open-field” pharmaceutical crops of a species usually grown for human consumption. “Hopefully we can put a coherent policy in place before California experiences a cross-contamination disaster like the one that happened in Arkansas,” Huffman told the press, referring to an incident last year that disrupted rice exports.

The California Farm Bureau reportedly opposes the bill “as it stands now,” but is willing to negotiate with Huffman. Other trade groups, however, believe the bill does not go far enough to protect farmers. “The report we just put out said pretty clearly that our customers don’t want (genetically engineered crops) and that contamination in California would be much more severe than in the South,” opined a



Rice Producers of California spokesperson, who said the industry stands to lose 40 percent of the market if countries again ban U.S. rice. *See Associated Press*, February 28, 2007.

[8] **Fast Food Restaurants Take Steps to Avoid NYC's Menu Labeling Requirements**

According to news sources, Wendy's International, Quiznos and White Castle recently removed calorie information from their New York City locations and their Web sites to avoid being subjected to a city regulation that will require restaurants to provide calorie data on menus and menu boards if they voluntarily provide such information "on or after March 1." The regulation was adopted along with the city's *trans* fat ban and has been adamantly opposed by the industry, which asserts that it unfairly penalizes fast food and chain restaurants that have been providing nutritional information to customers.

Wendy's apparently replaced its nutrition posters with new ones that omit calorie data while still providing information about fats, carbohydrates and sugars. The city's health commissioner condemned the actions, stating "If some restaurants stop displaying calorie information to avoid making it useful to customers, we should wonder what they're so ashamed of."

City Councilman Joel Rivera has reportedly introduced a measure that would overturn the regulation and allow restaurants to provide the information in brochures or on posters rather than on their menu boards. He called the restaurants' action a "step in the wrong direction," but also

criticized the regulation, calling for the city to work with the industry because it had already been providing the information voluntarily. Public health advocates claim that Rivera's proposal will take the teeth out of a regulation designed to make calorie information obvious to customers before they make their selections. *See The New York Times*, March 2, 2007; *Rudd Center for Food Policy & Obesity News Summary*, March 5, 2007.

Litigation

[9] ***Pelman v. McDonald's Corp.*, No. 02 Civ. 7821 (S.D.N.Y. 9/19/06)**

U.S. District Court Judge Robert Sweet has issued a memorandum and opinion regarding discovery and trial in the obesity-related litigation pending against McDonald's Corp. since 2002. Entered March 1, 2007, the memorandum establishes the following schedule: (i) discovery is due by March 1 and June 13, 2007, and January 1, 2008; (ii) discovery disclosures and motions are due by July 16, 2007, with responses and replies due by August 13, 2007; (iii) trial is "due by" April 16, 2008. The materials subject to discovery will relate to the claims raised in the teenage plaintiffs' second-amended complaint, which alleges that the company's misleading and deceptive marketing caused their obesity and obesity-related health problems. Plaintiffs purport to represent a class of consumers under the New York Consumer Protection Act. Additional details about the most recent developments in the case appear in issues 155 and 186 of this Report.



[10] Court Dismisses FOIA Complaint Against USDA

A federal court in Wisconsin has dismissed claims that the U.S. Department of Agriculture (USDA) improperly withheld or redacted documents related to its administration of the National Organic Program. *The Cornucopia Inst. v. USDA*, No. 06-C-0182-C (W.D. Wisc., filed Feb. 22, 2007). The Cornucopia Institute brought the action after the USDA delayed responding to the organization's Freedom of Information Act (FOIA) requests for documents regarding pasture guidance and organic pasture rules for organic dairy cows. Some documents provided were redacted so that certain dairy farm data, like the number of cows and pasture acreage on a particular farm, were withheld. USDA released thousands of pages of documents after the lawsuit was filed and further provided some of the contested documents without redaction. Because it had done so, the court determined that the matter was moot. The court also refused to award attorney's fees or costs to either party, finding that neither could be considered a prevailing party.

The institute, which is dedicated to sustainable and organic agriculture, [contends](#) that the litigation was a success. Co-director Mark Kastel stated, "This lawsuit was what caused the USDA to release additional public documents that have given the organic community, farmers and consumers insight as to why the USDA has not enforced federal organic regulations that would have cracked down on a series of factory-farms, milking as many as 10,000 cows, and labeling the milk as organic." According to the institute, its FOIA request was designed to discover with whom USDA was communicating and why the agency had refused to investigate "a

number of formal legal complaints against the giant industrial-scale dairies." Details about the institute's plans to sue the USDA for its alleged failure to enforce the law appear in issue 203 of this Report.

[11] Monsanto Seeks to Intervene in GM Alfalfa Case

While a federal court in California is considering how to implement its decision that the U.S. Department of Agriculture (USDA) violated the law by failing to prepare an environmental impact statement before deregulating genetically engineered (GE) alfalfa, Monsanto Co., which created the crop, has filed a motion to intervene. Explaining its action in a [news release](#), Executive Vice President Jerry Steiner stated, "Monsanto is asking to intervene because we believe it is important for hay growers to have the choice to use this beneficial technology. Many alfalfa growers have expressed their desire to be heard, and we believe Monsanto's participation in the remedy phase will help bring forward important information that underscores how crucial this technology has become to forage operations from an economic and environmental point of view."

A coalition of alfalfa growers, the Sierra Club and other farmer and consumer organizations brought the litigation, contending that GE alfalfa will readily contaminate other alfalfa crops and eliminate their ability to grow and market conventional and organic alfalfa. Further details about the case appear in issue 202 of this Report. The parties had until February 26, 2007, to suggest to the court how its decision could be implemented, and the plaintiffs were expected to seek an injunction to halt commercial sales of GE alfalfa seeds. *See Food Navigator USA.com*, March 5, 2007.



[12] Family Court Judge Removes Obese Child from Parents' Custody

According to a newsletter published by the Centers for Disease Control and Prevention, a family law judge in New York has ordered that a 13-year-old girl be removed from her parents' custody because they have failed to follow court orders that required them to control the child's weight. *In re Kayla T. v. Linda T.*, No. 27078 (Chemung County, NY, Family Court, decided Feb. 23, 2007) The girl was apparently removed from her home in 2003 because of concerns about her health and was returned to her parents on condition that they take her to a gym and participate in a nutrition program. She weighs more than 250 pounds "due to excessive caloric intake and a sedentary lifestyle," which physicians involved in her care said were a "result of poor parental modeling and control of food intake." The court reportedly acknowledged the lack of precedent for basing a custody decision on morbid obesity; nevertheless, the child was placed in the custody of the county's Department of Social Services. *See CDC Public Health Law News*, March 7, 2007.

Media Coverage

[13] Rick Weiss, "FDA Rules Override Warnings About Drug," *The Washington Post*, March 4, 2007

"Cefquinome's seemingly inexorable march to market shows how a few words in an obscure regulatory document can sway the government's approach to protecting public health," charges *Washington Post* reporter Rick Weiss in this article about a cattle antibiotic on track for FDA approval. Manufactured by InterVet Inc., cefquinome would treat bovine respiratory disease, a common ailment

some industry consultants claim is the result of stress. Critics argue that veterinary applications of the potent drug will accelerate antibiotic-resistant infections in humans, as was the case 10 years ago when fluoroquinolones in poultry were allegedly linked to a rise in recalcitrant campylobacter cases seen in hospitals.

Weiss writes that although an FDA panel voted against the drug, a regulatory loophole will most likely override that decision. [Guidance for Industry #152](#), which formalizes the approval process, recommends rejection only if a drug would compromise front-line treatments for foodborne illness. In this instance, the diseases treated by cefquinome's human analogue are not considered foodborne. "We have to take a fairly legal interpretation," the head of FDA's Veterinary Medicine Center was quoted as saying. "If we have no evidence of a problem, or sparse evidence, we would not be able to make the prohibition prior to approval."



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