Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Occupational Safety and Health Administration (OSHA)

[1] Unions Seek Emergency Action on Artificial Butter Flavoring

Unions representing factory workers exposed to an artificial flavoring commonly used in microwave popcorn have filed a **petition** asking OSHA to adopt an emergency temporary standard (ETS) for diacetyl. The United Food and Commercial Workers International Union and the International Brotherhood of Teamsters claim that an ETS is needed "because workers will continue to be under grave danger of life-threatening illness during the time it would take for OSHA to set a Permanent Standard."

Diacetyl is a chemical used to give the taste of butter to popcorn, pastries, frozen foods, and candy. According to the petition, dozens of workers exposed to the substance in popcorn manufacturing facilities have developed occupational lung disease and "at least three have died." The unions claim that studies conducted by the National Institute for Occupational Safety and Health (NIOSH) have found an association between diacetyl and *bronchiolitis obliterans*.

Attached to the petition is a letter signed by scientists and occupational health experts, including former OSHA Director Adam Finkel and former Environmental Protection Agency (EPA) Assistant Administrator Lynn Goldman, expressing "strong support" for the union's request. The letter discusses the NIOSH research and contends that "[a]lthough the precise number of workers already suffering respiratory effects from exposure to diacetyl is unknown, the potential magnitude of the problem is sizeable." The unions claim that more than 8,000 workers are employed in the flavorings production industry while additional tens of thousands make the products that use the flavoring, which even appears in dog food.

According to a news source, the scientists who signed the letter also claim that EPA has withheld the results of a 2003 study about the purported health risks "from inhaling artificial butter flavor vapors from microwave popcorn." An EPA spokesperson has reportedly indicated that the study is undergoing internal review and could be submitted for publication in fall 2006. See Desert Morning News, July 28, 2006.

Information about a \$20 million jury verdict awarded for lung disease allegedly caused by diacetyl exposure to a popcorn plant worker in southwest Missouri appears in issue 72 of this Report, March 17, 2004.





Food and Drug Administration (FDA)

[2] FDA to Work on Conflict of Interest Rules

Amid continuing concerns about the integrity of its scientific advisory committees, the FDA has apparently undertaken the development of guidelines "to provide greater clarity and transparency in the disclosure of waivers of relationships that could present the appearance of conflicts of interest." The agency is also implementing new procedures to improve the transparency of advisory committee appointments.

FDA currently grants waivers to certain individuals to participate in meetings when they have a relationship to a particular issue that could present an appearance of bias. The waiver is granted when the benefit of their participation outweighs the conflict of interest. This process will be made more transparent with the agency more clearly identifying the conditions under which the waivers are granted and publicly disclosing the reasons for the waivers. FDA is also planning to provide better notice of advisory committee meetings to interest groups.

In a July 24, 2006, speech before the Center for Science in the Public Interest (CSPI), an FDA deputy commissioner suggested that concerns about the links between its scientific advisors and regulated industries are misplaced. Dr. Scott Gottlieb contended that while improvements can and will be made to the agency's waiver policies, most of the nation's scientific expertise resides among those who have some ties to industry and even the medical journals rely on them as peer reviewers.

"There are very few academic experts engaged in research who don't have some ties to industry," Gottlieb said. A CSPI spokesperson contested that claim, reportedly stating, "The idea that all the bright people in the medical world are working for industry is just not right." Claims that FDA action on specific drugs may have been influenced by advisory committee experts with industry links led to the passage of legislation in the House in 2005 and 2006 banning anyone with industry ties to serve on advisory boards.

Meanwhile, the Union of Concerned Scientists recently released survey results showing that one-fifth of FDA scientists "have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information" or their conclusions in an FDA scientific document. Sixty-one percent of scientists surveyed reportedly claimed that they knew of cases where political appointees "inappropriately injected themselves into FDA determinations or actions." See CQ Healthbeat News, July 20, 2006; The New York Times and FDA News Release, July 24, 2006.

[3] Feed Contaminants on FDA Meeting Agenda

FDA has announced that it will be holding a meeting to discuss the method the agency has been developing to rank animal-feed contaminants according to their "relative risks to animal and human health." Scheduled for September 12, 2006, the meeting will also give stakeholders the opportunity to provide input into changes that FDA has been making to its Animal Feed Safety System (AFSS) in recent years. According to the agency, AFSS "covers the entire spectrum of agency activities from preapproval of food additives and drugs for use in feed, to establishing limits for feed contaminants, providing education and training, and conducting inspections and taking enforcement actions for ensuring compliance with agency regulations." See Federal Register, August 1, 2006.





U.S. Congress

[4] House Bill Would Prohibit Carbon Monoxide Injection in Meat Products

Representative Rosa DeLauro (D-Conn.) has introduced a bill (H.R. 5991) that would amend the Federal Meat Inspection Act by adding text that would prohibit the use of "carbon monoxide in any meat or meat food products or the packaging of any meat or meat food products." According to DeLauro, this practice is already banned in Canada, the European Union and Japan. She further noted that while the gas itself is safe, "when the gas is injected to deceive customers into purchasing unsafe meat, then there is no doubt that it would be harmful to consumers."

The addition of carbon monoxide apparently prevents meat from turning brown and gives it the appearance of being fresh months after the "sell-by" date. The meat industry has reportedly indicated that while rancid meat may appear fresh, the sell-by date and a rancid odor will provide sufficient protection for consumers. DeLauro's bill has been referred to the House Committee on Agriculture. *See Meatingplace.com*, July 31, 2006.

Food Safety and Inspection Service (FSIS)

[5] Comments Sought for Processed Fruits and Vegetables in Preparation for Codex Meeting

FSIS has <u>announced</u> that it will be conducting a public meeting September 7, 2006, to prepare the U.S. position on matters that will be considered during the October meeting of the Codex Alimentarius Commission's Committee on Processed Fruits and Vegetables. Among the

discussion items are draft Codex standards on pickled fruits and vegetables; processed tomato concentrates; preserved canned tomatoes; certain canned citrus fruits and vegetables; and jams, jellies and marmalades. Written comments may be offered at the meeting or can be submitted in advance. See Federal Register, August 1, 2006.

In a related development, Codex, established in 1963 by the United Nations and the World Health Organization to ensure the soundness of the world's food supply, has made an <u>advance copy</u> of its 29th session report available online. Among the matters accomplished during the July 2006 session were the adoption of 26 new or revised standards and the splitting of the Codex Committee on Food Additives and Contaminants into two committees.

World Trade Organization (WTO)

[6] Consumer Rights Group Lauds Trade Negotiation Stalemate

Food & Water Watch, a Washington, D.C.-based nonprofit consumer rights organization, is claiming that the indefinite suspension of WTO trade negotiations "is a boon to U.S. consumers who could have lost vital food safety regulations." According to the watchdog group, which has issued a **report** titled "What's Cooking? Food Safety Gets Burned at the WTO," a number of existing food safety and labeling laws could have been invalidated by actions taken at the suspended WTO meetings in Geneva.

The report contains an appendix that details the domestic food safety rules in a number of countries that have apparently been subject to complaint and could be eliminated by WTO action. They include bovine spongiform encephalopathy (BSE), genetically modified organism (GMO) and bird flu regulations;





heavy metal limitations in seafood; and country-oforigin labeling for fish. Food & Water Watch claims that WTO trade representatives will not adequately protect consumers if they lower standards "to the lowest common denominator."

In a related development, Senator Chuck Grassley (R-Iowa) reportedly believes the WTO trade talks are dead, at least until the Bush administration's negotiating authority expires in July 2007. According to Grassley, the stalemate in Geneva was "the end of Doha," but that bilateral trade negotiations could continue without it and would be less complicated. He contends that Congress would be able to amend trade agreements without renewing the president's trade negotiating authority. *See Congress Daily*, August 1, 2006.

Legal Literature

[7] "Big Food Litigation" Included in Law School Casebook

Obesity-related litigation is discussed in a new casebook authored by George Washington University Law School Professor Alberto Benitez for non-U.S. and pre-law students. Titled *An Introduction to the United States Legal System: Cases and Comments*, the work contains a chapter on tort law that includes the case that was filed against McDonald's Corp. Additional information about the case, *Pelman v. McDonald's Corp.*, 02 Civ. 7821 (RWS) (S.D. N.Y.), appears in issue 155 of this report, January 11, 2006. The table of contents and first chapter of the casebook can be accessed at http://ssrn.com/abstract=920680.

Other Developments

[8] Boston Conference to Target Ways That Marketing Allegedly Undermines Children's Health, Values and Behavior

The Campaign for a Commercial-Free Childhood, a Boston-based coalition that "counters the harmful effects of advertising on children" is sponsoring a three-day summit on October 26-28, 2006, titled "Consuming Kids: Marketing in Schools and Beyond." Speakers at the event will include antitobacco attorney Richard Daynard and author Jean Kilbourne (Can't Buy My Love: How Advertising Changes the Way We Think and Feel.) The conference will be held on the campus of Wheelock College in Boston.



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LITIGATION UPDATE

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