

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Environmental Protection Agency (EPA)

[1] **Dioxin Reassessment Faces New Delays; Dioxin Levels in Babies Exceed Safety Limits**

The White House has reportedly put off an interagency workgroup meeting on EPA's dioxin reassessment to give agency officials time to address communication issues. Details about a deal worked out between the agency, the Office of Management and Budget and members of Congress appear in issue 4 of this Update, October 30, 2002. Some are apparently concerned that the latest delay represents an uphill battle for EPA to release the reassessment which has been under consideration for about 10 years. Livestock and dairy groups are reportedly tracking the issue due to fears that the risk data will alert the public to dioxin's presence in meat and dairy products. *See Inside EPA*, November 22, 2002.

Meanwhile, researchers in the United Kingdom have reportedly found that newborns are consuming 85 times the recommended limit of dioxin in breast milk. Britons apparently get 90 percent of their dioxin exposure from contaminated foods. British newborns are reportedly consuming 170,000 times the amount EPA has proposed as the limit to prevent cancer later in life. *See The Independent*, November 17, 2002.

U.S. Food and Drug Administration (FDA)

[2] **FDA Issues Agenda for Acrylamide Meeting**

FDA's Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee will meet December 4-5, 2002, in Adelphi, Maryland, to discuss various facets of the agency's action plan for acrylamide. The draft agenda for the meeting indicates that subcommittee members will address toxicology, analytical methods, formation, consumption/exposure, and consumer risk. *See <http://www.cfsan.fda.gov/~dms/acryage2.html>*.

[3] **Agency Reopens Comment Period for *Trans* Fatty Acid Labeling Proposal**

FDA has reopened the comment period for a proposed rule that would require manufacturers to disclose the amount of *trans* fatty acids in the Nutrition Facts panel of a food product's label. More specifically, the agency seeks comments on a proposed footnote that would state "Intake of *trans* fat should be as low as possible." Comments will be accepted until December 16, 2002. The agency evidently plans to publish a final rule in early 2003. *See Federal Register*, November 15, 2002.

[4] **FDA Launches Bioterrorism Act Web Site**

FDA has added a new page to its existing bioterrorism Web site that, among other matters, will allow the electronic submission of comments on proposed rules that will implement the agency's responsibilities under the Public Health Security and Bioterrorism Preparedness and Response Act



of 2002. Those proposals include (i) Registration of Food Facilities, (ii) Establishment and Maintenance of Records for Food Facilities, (iii) Prior Notice of Imported Food Shipments, and (iv) Administrative Detention Authority. The new page also contains links to guidance documents, other sources of information and a free subscription service to a directed e-mail list concerning FDA's bioterrorism-related activities. The site can be accessed at www.fda.gov.

U.S. Department of Agriculture (USDA)

[5] Comments Sought on Draft Codex Guidelines for Microbiological Risk Management

The U.S. delegate to the Codex Committee on Food Hygiene is soliciting comments on the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*, a document currently at step three of an eight-step process. Information about submitting the comments, which are due December 4, 2002, and a copy of the draft document can be obtained from the U.S. Codex Office at www.fsis.usda.gov. The document, which addresses "a framework for the management of risks arising from the occurrence of microbiological hazards in foods," has apparently been changed structurally since its last revision and incorporates concepts regarding the regional prevalence of foodborne pathogens. A "microbiological risk" is defined as "a risk arising from the presence in food of bacteria, viruses, yeasts, moulds and algae, parasitic protozoa and hemlinths, and their toxins or metabolites."

[6] USDA Seizes Nebraska Soybeans and Orders Destruction of Iowa Corn

Because genetically altered corn developed for use in pharmaceuticals by a biotechnology company apparently contaminated food crops in the nation's "corn belt," USDA has ordered Texas-based Prodi-

Gene to destroy corn in Iowa and soybeans in Nebraska. ProdiGene's corn was reportedly grown to produce trypsin for diabetes and another compound to treat diarrhea. The company is apparently being investigated to determine if it violated any federal regulations. Environmental groups and the food industry are reportedly calling for tougher regulations, sanctions and the use of non-food crops for the development of pharmaceuticals. According to a news source, ProdiGene's president has indicated the company will consider moving its operations to states with little commodity grain production. See *Reuters*, November 15, 2002; *PRNewswire* and *Greenwire*, November 18, 2002; *St. Louis Post-Dispatch*, November 21, 2002.

European Union (EU)

[7] EU Takes Action on Food Labeling and Irradiation; EFSA Launches Web Site

According to a press report, EU ministers have approved a proposal that would require food labels to list any ingredient constituting more than 2 percent of the finished product. Current law apparently requires such listings for those components comprising 25 percent of the product. Parliament's second reading is expected in early 2003, and if approved, the labeling directive amendment would have to be adopted by member states within the following year, said a news source. See *euractiv.com*, November 15, 2002.

Meanwhile, Parliament's Public Health Committee has reportedly voted against the inclusion of additional foods on the irradiation list pending scientific studies showing such processing is safe and efficient. Apparently, the only food category currently approved for irradiation consists of "dried aromatic herbs, spices and vegetable seasonings." In contrast, Canada's food authority has reportedly

proposed regulatory amendments that would permit the irradiation of ground beef, poultry, shrimp, prawns, and margarine. A Health Canada spokesperson was quoted as saying, "Our in-depth review ... concludes that this does not pose any danger to consumers." And in the U.S., the food industry is pressing for regulations that would permit irradiated products to be labeled as "pasteurized." See *washingtonpost.com*, November 5, 2002; *euractiv.com*, November 7, 2002; *just-food.com*, November 26, 2002.

In other developments, the European Food Safety Authority (EFSA) has launched a Web site at www.efsa.eu.int to provide information concerning development of the newly established, independent European Commission institution as it becomes operational. The authority is responsible for providing scientific advice and support to similar bodies in EU member states in addressing food safety risks, proposed legislation related to the food chain, and collection and analysis of data on exposure and dietary issues. The authority is composed of a management board, executive director, advisory forum, and eight scientific panels targeting particular issues, e.g., food additives.

Litigation

Fast Food

[8] McDonald's Seeks Dismissal of Obesity Lawsuit in Federal Court

The attorney who filed two obesity lawsuits in state court against fast-food companies has also apparently brought suit on behalf of obese teenagers in federal court, alleging deceptive business practices. At a November 20, 2002, hearing before U.S. District Judge Robert Sweet in New York, counsel for McDonald's Corp. reportedly argued that the

suit should be dismissed, calling it an abandonment of "common knowledge [and] common sense" and claiming that "McDonald's has no duty to warn people of fat, caloric content of commonly understood foods." The judge has not indicated when he will issue a ruling on the motion, said a news source.

Meanwhile, news of the lawsuit has found its way into numerous publications and programs as the litigants, attorneys and pundits debate the merits of such litigation. The editor of a men's health magazine, for example, has indicated that "the industry is vulnerable. Fast-food companies are marketing to children a product with proven health hazards and no warning labels." The president of the National Restaurant Association has responded to such claims by stating "Just because we have electricity doesn't mean you have to electrocute yourself." The issue has also been debated on NBC's *Today*, ABC's *Good Morning America*, CBS *Morning News*, CNN *Sunday Morning*, MSNBC's *The Abrams Report*, CNN *Crossfire*, and CNNFN's *Money & Markets*. See Dow Jones *Newswires*, November 20, 2002; *The New York Times*, November 21 and 23, 2002; CBS *Morning News*, November 22, 2002.

Food Poisoning

[9] Sickened Passengers File Class Action Complaint Against Cruise Operator

California-based law firm Norton and Melnick has reportedly filed a class action lawsuit against Holland America Cruise Lines seeking damages on behalf of more than 500 passengers and crew members recently sickened by the Norwalk virus during four consecutive cruises on the Amsterdam. Filed November 25, 2002, in Seattle, the complaint reportedly contends that Holland America "knew or should have known" that more passengers could be



infected with the virus by not taking the ship out of service to be sanitized. According to the Center for Food Safety & Applied Nutrition, Norwalk gastroenteritis outbreaks are often caused by contaminated water, shellfish and salad ingredients. See *CNN.com*, November 26, 2002.

Media Coverage

[10] Elizabeth Olson, “Fighting Fat by Going to the Source,” *The New York Times*, November 17, 2002

This brief interview with World Health Organization official Derek Yach focuses on a recent meeting in London between WHO officials and food and beverage manufacturers to discuss “the proliferation of salty, sugary and fatty foods.” Topics of discussion at the meeting evidently included advertising, labeling and public awareness issues. WHO officials reportedly assured the manufacturers that the organization does not intend to approach food issues as it has tobacco issues – i.e., by negotiating a treaty, – and will involve all major stakeholders in any policy decisions.

[11] Bonnie Liebman, “Big Fat Lies, The Truth About the Atkins Diet,” *Nutrition Action Healthletter*, November 2002

Addressing claims about low-carbohydrate diets made in July 2002 by a freelance writer, this article suggests that scientists were misquoted or ignored in the *New York Times Magazine* piece and that the Atkins diet may cause more harm than good in the long run. Obesity researchers have apparently stated that Gary Taubes’ article, “What if Fat Doesn’t Make You Fat?” “was written in bad faith” and “was irresponsible.” Ten claims made by Taubes are systematically discussed and dismissed as misleading or not true with quotes by some experts Taubes consulted in preparing his article. According to the

article appearing in the Center for Science in the Public Interest’s *Healthletter*, health experts agree that losing weight requires cutting saturated and *trans* fats, consuming carbohydrates in moderation, and choosing a weight-loss strategy that works for the individual. “Just make sure that you cut calories, and that the fats and carbs you do eat are healthy,” concludes the author.

Scientific/Technical Items

Cardiovascular Disease

[12] Foods Cooked at High Heat Linked to Inflammation

According to preliminary research, diabetics may be able to lower their risk of heart disease and other conditions by consuming foods cooked at low temperatures. Helen Vlassara, M.D., and colleagues at the Mount Sinai School of Medicine studied 24 diabetics, providing them with diets that differed only in the temperature at which the foods were prepared. Foods cooked at high temperatures are considered an environmental source of advanced glycation end products (AGEs); a percentage of those AGEs ingested are absorbed. While AGEs are normally produced in the body during glucose reactions, at high levels they can be toxic by triggering the production of inflammation-causing proteins in cells. Inflammatory proteins are believed to weaken fatty buildups, or plaque, in blood vessels. Vlassara and her team confirmed that those subjects eating a diet high in AGEs had higher AGE-blood levels and higher levels of inflammatory chemicals; restricting dietary AGEs suppressed these effects. Such chemicals are of particular concern to diabetics because they have been linked with the progression of heart disease and damage caused by diabetes, including blindness, nerve and kidney damage.



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Food & Beverage Litigation Update is distributed by Dale Walker and Mary Boyd in the Kansas City office of SHB. If you have questions about the Update or would like to receive back-up materials, please contact us by e-mail at dwalker@shb.com or mboyd@shb.com. You can also reach us at 816-474-6550. We welcome any leads on new developments in this emerging area of litigation.

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