Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

110th Congress

[1] U.S. Senate Holds Hearing on Pet Food Contamination

The Senate Agriculture Appropriations Subcommittee held a hearing this week on the pet food industry, which recently issued a nationwide recall of products containing adulterated wheat gluten from China. The subcommittee heard testimony from FDA officials, industry experts and veterinarians on the regulatory gaps that allowed melamine-tainted gluten to enter the pet food supply, where the plasticizer allegedly caused kidney failure in animals. Senator Richard Durbin (D-Ill.), who requested the hearing, reportedly responded to FDA testimony that all adulterated food may not be off store shelves by stating "This in inexcusable. The FDA's response to this situation has been wholly inadequate." He also linked the pet food imbroglio to the nation's food supply, claiming, "It's the same broken food safety system."

Subcommittee Chair Herb Kohl (D-Wis.) pointed out how confusing FDA's Web site was about the recall, and an agency representative agreed that it could be improved. Senator Robert Byrd (D-W.Va.) made an unexpected appearance at the hearing to talk about his dog, "As a pet owner and dog-lover, I join with many millions of Americans in anxiously hoping I didn't poison my dog with a special snack or serving of food."

The FDA was asked to address (i) the delay between when the first company suspected a problem and when it notified FDA; (ii) the lack of FDA inspections at processing facilities; and (iii) incomplete reporting and data. Congressional concerns about the issue are bipartisan; when an industry representative contended that only 1 percent of the pet food on the market was recalled as tainted, Republican Senator Robert Bennett (Utah) said "I'd like to know how lethal that 1 percent really is."

"Many cats, dogs and other pets, considered members of the family are now suffering as a result of a deeply flawed pet food inspection system," said Durbin in a **press release**. "The FDA's response to this situation has been tragically slow. Pet owners deserve answers." Industry representative who testified reportedly asserted that pet food is already "highly regulated" and "safe" and that further regulation should be left to market forces. *See Reuters* and *The New York Times*, April 12, 2007; *The Washington Post*, April 13, 2007.

In a related development, Menu Foods, Inc. has expanded its pet food recall to include products manufactured at its Streetsville, Ontario, plant. "After being repeatedly assured by Menu Foods, as reinforced by FDA public statements, that none of the contaminated wheat gluten had made its way to Canada, we were completely shocked to learn

yesterday that this was not the case," said the spokesperson of a company affected by the recall. In the United States, a major veterinary hospital chain reported a 30 percent increase in the number of cats seen for kidney failure in recent months. *See Associated Press*, April 9 and 11, 2007.

Meanwhile, legal analysts are expecting pet owners to seek damages for pain and suffering, despite a precedent that values animals strictly as property. "Some of the lawyers who have filed the lawsuits say they'll argue that pets are 'special property' that have an intrinsic value beyond market worth," according to *National Law Journal* reporter Lynne Marek. On the **Products Liability Prof Blog**, however, Michael Steenson, J.D., points to an article on pet litigation by Shook, Hardy & Bacon attorneys Victor Schwartz and Emily Laird, who argue in *Non-Economic Damages in Pet Litigation: The Serious Need to Preserve a Rational Rule*, 33 Pepp. L. Rev. 227 (2006), that the prevailing rule should be maintained. *See The National Law Journal*, April 10, 2007.

U.S. Department of Agriculture (USDA)

[2] National Organic Standards Board Approves Recommendation on Cloned Animals

According to the Organic Consumers Association, the USDA's National Organic Standards Board (NOSB) has unanimously approved a **recommendation** that would exclude the progeny of cloned animals from organic production.

The Food and Drug Administration sought public comments on a draft risk assessment on meat and milk from cloned animals in January 2007; thereafter, the National Organic Program (NOP) posted material on its Web site indicating that cloning technology is prohibited in organic production and that it would be working with NOSB to determine the organic status of cloned progeny. The NOSB apparently concurs with NOP and "believes that the existing federal organic rules prohibit animal cloning technology and all its products. To strengthen and clarify the existing rules, the NOSB recommends that the NOP amend the regulation to ensure animal cloning technology, and all products derived from such organisms be excluded from organic production."

While neither the USDA nor the NOSB has posted any information relating to the March 29 vote on the cloning recommendation, the Organic Consumers Association reports that the NOSB voted 12-0 to approve the recommendation. *See Organic Consumers Association Sustainable Food News*, March 29, 2007.

Food and Drug Administration (FDA)

[3] FDA Issues Warning Letter Against Makers of "Cocaine" Energy Drink

The Food and Drug Administration has issued a warning **letter** to Redux Beverages, LLC stating that its product, Cocaine®, is "marketed as an alternative to an illicit street drug, and certain ingredients therein are intended to prevent, treat, or cure disease conditions." In marketing statements and on the beverage container, the company refers to the product as "The Legal Alternative," "Speed in a Can," "Liquid Cocaine," and "Cocaine – Instant Rush." On its Web site, the company discusses one of the product ingredients, Inositol, as a substance that "reduces cholesterol in the blood; it helps prevent hardening of the arteries and may protect nerve fibers from excess glucose damage."

The FDA's letter states, "Your product, Cocaine, is a drug" under the law because of its intended use. "Moreover, this product is a new drug . . . because it is not generally recognized as safe and effective for its labeled uses." According to FDA, "a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of Cocaine without an approved application violates these provisions of the Act." The agency also said the product was "misbranded" because its "labeling fails to bear adequate directions for its intended uses." FDA calls on the company to correct these violations or be subject to an enforcement action without further notice, including product seizure.

A company spokesperson reportedly said its attorneys are already discussing with FDA how it can comply with federal law, but she contended "Obviously, we're not a drug. We pretty much have the identical ingredients of every other energy drink out there." She also called the company "naïve" and indicated that the marketing campaign was intended to be "tongue-in-cheek." *See Seattle Post-Intelligencer*, April 11, 2007.

Environmental Protection Agency (EPA)

[4] EPA Re-Issues Food Packaging Pesticide Rule; This Time for Public Comment

EPA has issued a proposed **rule** that would essentially eliminate duplicative regulation of pesticides in food packaging under the Federal Food, Drug, and Cosmetic Act. Instead of being regulated as a pesticide chemical residue and as a food contact substance, such packaging additives would be regulated simply as the latter. EPA issued the proposal as a direct final rule in December 2006, but withdrew it after receiving several opposing comments. Consistent with agency policy, EPA has now issued the rule as a proposal; public comment must be submitted on or before April 23, 2007. Previous commenters "were concerned about the inclusion of pesticides in food packaging" altogether and appeared to believe that EPA was relinquishing authority to regulate that activity. EPA emphasizes in the notice that "nothing in today's proposal relieves EPA of the obligation to regulate pesticides in food packaging, nor does today's action serve to approve the use of any pesticides in food packaging. Accordingly, these comments are not relevant to the action EPA is today proposing to take." *See Federal Register*, April 6, 2007.

World Health Organization (WHO)

[5] World Health Organization Releases Report on Reducing Salt Intake

WHO has issued a **report** from a forum and technical meeting convened in October 2006 to address concerns about the purported link between excessive salt consumption and health. The report, titled *Reducing Salt Intake in Populations*, recommends that governments take action to reduce salt consumption as a cost-effective way to lower blood pressure and thereby reduce chronic disease incidence. Meeting participants agreed that salt consumption should be reduced to an average 2,000 milligrams per day and that other ways be found to provide sufficient iodine in the diet. They also agreed that food manufacturers must be engaged in salt reduction strategies to ensure their success and that consumers must be better educated about the "adverse effects of excessive salt consumption on health" and how to read labels and choose healthier foods. The WHO report calls for

product reformulation, the adoption of Codex Alimentarius Commission labeling recommendations and the development of national standards for restaurant or meal producers "to ensure compliance of served meals with national dietary recommendations. This is particularly critical for those companies/caterers/food providers for school and worksite canteens."

European Parliament

[6] European Parliament Committee Votes to Amend Food Additive Legislation

The European Parliament Committee on the Environment, Public Health and Food Safety this week approved amendments to **food additive legislation** initiated by the European Commission, which proposes to simplify the existing laws into four major rules. One rule would determine "a common authorization procedure for additives, enzymes and flavorings," and three would break down these categories into lists of authorized products, their conditions of use, and labeling restrictions, according to *Food Quality News*. After reviewing **two reading reports**, the committee voted to adopt amendments that would (i) require transparency in the authorization process; (ii) prevent unilateral decisions regarding the list of authorized products; and (iii) add a condition that approved additives not harm the environment. Committee members also backed amendments to limit nanotechnologies and to label additives with genetically modified components. If approved by the Parliament this summer, the amended regulations could reportedly affect more than 300 sweeteners, colorings and flavor enhancements already on the market. *See Food Quality News*, April 12, 2007.

Litigation

[7] Sugar-Substitute Trial Begins in Philadelphia Courtroom

Opening statements were made to a federal jury in Philadelphia on April 11, 2007, in a case that pits the maker of Equal® against the maker of Splenda® in a contest over the latter's advertising claims. Further details about the sugar-substitute lawsuit appear in issue 209 of this Report. According to news sources, Merisant Co., which makes Equal® and NutraSweet,® told the 10-member jury that the advertising campaign for its rival was intended to mislead the public and falsely suggests that the product contains sugar. Jurors will hear about the complex chemical process that produces sucralose, the synthetic compound that gives Splenda® its sweet taste.

Lawyers for McNeil Nutritionals told the jury that Merisant filed suit only because Splenda has overtaken its products in the marketplace and that the evidence will show all advertising claims to be completely true. Splenda® reportedly has 62 percent of the U.S. market and had sales of $212 million in 2006, compared to sales for Equal® of $49 million. Trial is expected to last three weeks. McNeil is also reportedly defending its advertising claims in federal court in Los Angeles against a group of sugar manufacturers. Trial in that case is expected to begin in November. *See The New York Times*, April 6, 2007; *Associated Press*, April 10, 2007; *The Legal Intelligencer*, April 11, 2007.

In a related development, Tate & Lyle Sucralose, Inc. has reportedly filed a U.S. International Trade Commission case in Washington, D.C., alleging that its patent for the manufacture of sucralose has been infringed by three Chinese manufacturing groups

and 18 importers and distributors. A company spokesperson was quoted as saying, "Our sucralose manufacturing technology is protected by a robust and sophisticated patent estate, which we will defend vigorously. This action follows the filing with the U.S. Federal District Court in May 2006, which so far has resulted in favorable settlements with three of the 10 defendants cited in that case." *See Tate & Lyle Press Release*, April 10, 2007.

[8] Pet-Food Plaintiffs Seek Consolidation of Cases Before MDL Judge

Three plaintiffs who filed lawsuits against Menu Foods, Inc. and other defendants in federal district court in New Jersey for harm allegedly caused by tainted pet food have filed a motion before the Judicial Panel on Multidistrict Litigation seeking to consolidate similar actions from across the nation in one court. *In re Pet Foods Product Liability Litigation*, MDL No. 1850 (Judicial Panel on Multidistrict Litigation, filed April 5, 2007). They seek an order transferring 13 putative class actions already filed as well as any subsequently filed cases to the District of New Jersey and coordinating these actions with 15 similar actions pending in that court. According to the motion, the claims in all cases are virtually the same, "Each action is brought on behalf of a class of purchasers of dog or cat food manufactured by Menu Foods and sold under various labels and alleges that Menu Foods produced contaminated or tainted pet food that sickened their dogs or cats and caused the death of many of them."

The plaintiffs contend that common questions include (i) "whether the Defendants' dog and cat food was materially defective and unfit for use as dog or cat food"; (ii) "whether Defendants breach any warranties"; (iii) "whether Defendants' dog and cat food caused Plaintiffs' and other Class members' pets to become ill and die"; and (iv) "whether Plaintiffs and other Class members have been damaged, and, if so, what is the proper measure thereof." They suggest that coordinated pretrial proceedings "will promote the just and efficient conduct of these actions, will serve the convenience of all parties and witnesses and will promote the interests of justice."

Defendants in the pending cases include various Menu Foods entities, pet-food producers and distributors, and two Chinese companies.

Legal Literature

[9] Michele Simon and Ellen Fried, "State School Vending Laws: The Need for a Public Health Approach," *Food and Drug Law Journal* (2007)

In this article, activist Michele Simon blames a beverage industry trade association with overturning federal regulations that would have restricted the sales of soft drinks and foods of minimal nutritional value in schools. She and co-author Ellen Fried, a nutrition professor, discuss the recent legislative activity in many states related to fast food, sugary drinks and snack foods in schools and explore the variations among the bills enacted. They discuss the obstacles legislators face when trying to adopt such measures and specifically identify "intensive corporate lobbying" and "resistance from local school boards" as impediments. Contending that slow, incremental changes are "unacceptable given increasing rates of childhood obesity, diabetes, and other chronic conditions previously relegated to adulthood," the authors call for a strong national approach to the issue. Alternatively, they suggest that (i) local initiatives involve nutritionists, lawyers, food service staff, and politicians; (ii) mean-

ingful enforcement mechanisms be adopted; and (iii) lawyers with expertise in school food procurement and contract analysis serve as consultants to assess the affect any state legislation has on existing and future "pouring" contracts.

Other Developments

[10] ConAgra to Reopen Peanut Butter Processing Plant

ConAgra Foods recently announced plans to reopen the Sylvester, Ga., peanut butter plant implicated in a nationwide *Salmonella* outbreak. The company, which recalled Peter Pan Peanut Butter products earlier this year, has reportedly attributed the incident to dormant *Salmonella* in raw peanut dust that may have combined with excess moisture during the production process. In addition to renovating the facility with state-of-the-art technology, ConAgra has hired microbiology expert Paul Hall, Ph.D., to serve as Global Food Safety vice president, a new leadership position designated to handle food safety initiatives. It has also formed the Food Safety Advisory Committee, a panel of independent experts chaired by Michael Doyle, Ph.D., director of the University of Georgia's Center for Food Safety, to help the company invest in foodborne pathogen research. ConAgra plans to reopen the facility this August. *See ConAgra Press Release*, April 5, 2007.

Meanwhile, plaintiffs' lawyers suing ConAgra reportedly inspected the Georgia peanut butter plant this week. "When you do have a factory that's manufacturing this much product, there's some small glitch in the system and it gets amplified," trial lawyer Bill Marler was quoted as saying. Marler, who represents more than 5,000 clients in the *Salmonella* outbreak, apparently estimated that more than 250 law firms will eventually file claims. *See AFX International ProFeed*, April 9, 2007.

[11] Harvard Conference to Address Ethics and Public Health

The Harvard University Program in Ethics and Health has announced a **conference**, titled "Responsibility for Health: Ethical Issues," that will "[seek] to clarify the issues at stake in debates over responsibility for health and to enlist the methods and theories from a number of disciplines in forging a coherent response to the issues." The organizers also aim to address how "the profitability of leading industries, such as tobacco, food, and alcohol" affects public health outcomes. Slated for April 26-27, 2007, the first day will cover theoretical approaches and the second will focus on legal and policy responses.

Scientific/Technical Items

[12] Studies Link Red Meat and High-Fat Diets to Breast Cancer

A University of Leeds study contends that older women who ate 2 ounces of red meat per day increased their risk of developing breast cancer by 56 percent. E.F. Taylor, et al., "Meat consumption and risk of breast cancer in the UK Women's Cohort Study," 96 *British Journal of Cancer*, 2007. The study, which monitored 35,000 women over seven years, also concludes that those who ate the most processed meat increased their breast cancer risk by 64 percent. Researchers reportedly speculated that saturated fats, cholesterol or carcinogenic compounds developed during cooking might contribute to the apparent risk increase, although growth hormones are no longer used in U.K. animals. *See BBC News*, April 4, 2007.

In a related development, a National Cancer Institute study claims that high fat intake may also increase a woman's risk of developing breast cancer. Marina S. Touillaud, et al. "Dietary Lignan Intake and Postmenopausal Breast Cancer Risk by Estrogen and Progesterone Receptor Status," *Journal of the National Cancer Institute*, March 21, 2007. Researchers found that women consuming 40 percent of their total energy intake in fats had an 11 percent increase in breast cancer cases, compared with those women for whom fat constituted less than 20 percent of their diets. "In this large cohort of postmenopausal U.S. women, we detected a direct association between dietary fat intake and the risk of invasive cancer," the lead author was quoted as saying, although the study noted that women with the highest fat intake were also more likely to take hormone replacement therapy. *See BBC News*, March 21, 2007.

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