

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

U.S. Food and Drug Administration (FDA)

[1] FDA Issues Acrylamide Level Test Results; Studies Proceed in Other Countries

FDA has released its test results for acrylamide levels in some 300 purchased food items, ranging from potato chips to breads and coffee. The data can be accessed electronically from <http://www.cfsan.fda.gov/list.html>. Overall, FDA scientists note that levels increase in starchy foods the longer they are cooked and at higher temperatures. Because only animal studies have shown associations between acrylamide consumption and cancer, the FDA, food-industry trade groups and public interest organizations are urging the public not to be overly alarmed. Yet, the FDA, in collaboration with other agencies, international partners, academia, consumers, and the food-processing industry, has made acrylamide research a priority for the coming year.

In related developments, researchers in Germany have reportedly found high levels of acrylamide in gingerbread, and the Food Safety Authority of Ireland recently conducted a conference to discuss current data on the acrylamide issue. A report prepared by the United Kingdom's Food Standards Agency summarizes all known international activity on acrylamide in food. It can be accessed from the Institute of Food Science & Technology Web site at www.ifst.org. The report contains links to other sources and information about current research projects and upcoming scientific meetings. See *foodproductiondaily.com*, December 2, 2002;

reutershealth.com, December 3, 2002; *The New York Times*, *nfpa-food.org*, *gmabrands.com*, and *acsh.org*, December 4, 2002.

U.S. Department of Agriculture (USDA)

[2] USDA Releases Semiannual Regulatory Agenda; Changes to Organic Rules Pending

USDA published its semiannual regulatory agenda in the *Federal Register* on December 9, 2002. Among the agenda items are several proposed changes to the agency's national organic program, including the addition of standards for mushroom, apiculture, greenhouse, and hydroponic production systems and the amendment of the national list of allowed and prohibited substances. Among those items in the final rule stage is a food labeling standard that would require meat and poultry products labeled as "healthy" to contain no more than 360 mgs. of sodium.

In a related development, an environmental group is reportedly calling on USDA to label organic foods as safer than their conventional counterparts. Citing a study recently published in *Environmental Health Perspectives*, the Environmental Working Group apparently claims that children who eat organic foods have fewer organophosphate pesticide metabolites in their urine than children fed a conventional diet. An industry spokesperson reportedly criticized the study saying "you can't tell from this research whether the child consumed pesticide residues directly or metabolites," which he claimed are nontoxic and also present on food. See *BNA Daily Environment Report*, November 25, 2002.



[3] **Consent Decree Entered with Biotechnology Company for Plant Protection Act Violations; GM Issue Flares Globally**

According to press reports, USDA entered a consent decree with ProdiGene, Inc., whose genetically modified (GM) corn contaminated corn and soybeans in Iowa and Nebraska. Under the agreement, ProdiGene did not apparently admit or deny any violations of the Plant Protection Act, but did agree to pay a civil penalty of \$250,000 and will reimburse USDA for the more than \$2 million in costs associated with acquiring, storing and destroying some 500,000 bushels of soybeans in Nebraska. ProdiGene also reportedly agreed to post a \$1 million bond and comply with higher standards, including securing additional approvals before field testing and harvesting genetically modified plant material. The fine has been called the first of its kind, said a news source.

Meanwhile, scientists championing advancements in the development of plant-derived drugs for treating serious diseases face increasing opposition from environmentalists and activists in other countries such as India who fear the “pharma-crops” will contaminate food crops. Powerful food industry associations are also reportedly calling for stricter government regulation to prevent such incidents. Yet, according to a recent article, inexpensive products that can be and are being grown by intermingling human and plant DNA include a Hepatitis-B vaccine, a topical treatment for herpes, human insulin, an HIV vaccine, and a drug to control blood clotting in heart surgeries. USDA Secretary Ann Veneman has reportedly indicated that tougher regulations are on the horizon. She was quoted at a farm journal forum as saying, “We are proposing additional restrictions.”

In related developments, the European Union has reportedly established a network of laboratories

across member states that will cooperate in tracing GM organisms in food and feed. Biotechnology industries will apparently be voluntarily collaborating with the network by providing details on DNA sequences that will be needed to detect GM material. And in China, Nestle has apparently been criticized for selling products with GM ingredients. The Swiss food giant has reportedly responded by denying the claims and stating that its products in China are in strict compliance with national and international regulations and standards. A spokesperson was quoted as saying “The rules on labeling of [GM] food products issued in March of this year apply to imported agricultural products. Nestle’s products are processed final-use food products and aren’t covered by these rules.” See *euractiv.com*, December 4, 2002; *just-food.com*, December 2 and 5, 2002; *PR Newswire*, December 6, 2002; *The New York Times*, December 7, 2002; and *Greenwire* and *Reuters*, December 9, 2002.

[4] **Nutrition Center Seeks Comments on Information Collection Instruments**

USDA’s Center for Nutrition Policy and Promotion (CNPP) is seeking public comments on information collection instruments designed to gauge consumers’ understanding of revised nutrition education messages. A *Federal Register* notice indicates that the increased prevalence of overweight and obesity in the United States has led to proposed revisions in the educational messages and materials that support the federal government’s Dietary Guidelines for Americans and Food Guide Pyramid. Draft materials for the revised initiatives will evidently be tested using focus groups, qualitative interviews and Web-based surveys. Written comments on the proposed instruments used to collect consumer feedback must be submitted by February 7, 2003; requests for additional information should be directed to Carole Davis at (703) 305-7600.

Any comments received will be included in CNPP's request for approval of the information collection instruments to the Office of Management and Budget. See *Federal Register*, December 9, 2002.

Codex Alimentarius Commission

[5] Public Meeting Announced to Prepare for Meat and Poultry Hygiene Committee Session

The U.S. delegate to the Codex Committee on Meat and Poultry Hygiene has announced that a public meeting will be held December 19, 2002, in Washington, D.C., to prepare for the committee's 9th session to be held in New Zealand during February 2003. Further information can be obtained from the Food Safety and Inspection Service Web site at www.fsis.usda.gov/OA/codex/new.htm.

Litigation

Fast Food

[6] *Domingue v. McDonald's Corp.*, No. 02-1046-C-M3 (U.S. District Court, Middle District, Louisiana) (unknown filing date; notice of removal filed November 6, 2002)

McDonald's Corp. has filed its answers and defenses in federal district court in Louisiana to a complaint that apparently alleges injuries from the consumption of its french fries. According to McDonald's, plaintiffs' claims should be dismissed because they failed to "opt out of an approved class action settlement for all claims against McDonald's Corporation relative to alleged injuries and damages from the consumption of McDonald's french fries." Press reports have indicated that the settlement resolved a dispute about the use of beef flavoring in

french fries. A scheduling conference has been set for February 6, 2003.

McDonald's further avers that "plaintiffs' injuries or damages, if any, had nothing to do with the ingestion of a flavoring used in preparation of McDonald's french fries, but were related to the ingestion of other foods not purchased from a McDonald's Restaurant, and that these other foods caused the minor plaintiffs' alleged injuries and/or damages." In addition, McDonald's suggests that plaintiffs' damages "are the result of their genetic condition, Phenylketonuria ('PKU'), and the ingestion of a flavoring used in preparation of McDonald's french fries prior to delivery and cooking in a McDonald's Restaurant did not cause and/or contribute to the minor plaintiffs' alleged injuries and damages." Plaintiffs have since filed a motion to remand the case to state court.

E Coli

[7] *Almquist v. Finley S.D.*, No. 21091-0-III (Washington Court of Appeals) (decided November 21, 2002)

A Washington appeals court has upheld a jury verdict against a school district for the sale of beef tacos that allegedly resulted in the *E. coli* infection of children who consumed the tacos and another child whose infection was caused by contact with those children. While the beef supplier settled with the plaintiffs, the jury did not assign any liability to it for their injuries. At issue in the appeal was whether the state's product liability law applied to the school district as the beef seller and whether the law imposes liability for a "secondary victim." Answering both questions in the affirmative, the court ruled that (i) the school district, which processed the beef for sale in the tacos, was a product manufacturer and could be found negligent for not cooking the beef



properly, and (ii) the 2-year-old injured by contact with infected children could bring a claim because the law does not limit “claimants” to those who have direct contact with the product.

Other Developments

[8] CSPI Targets Kraft Pasta Products in Monthly Newsletter

Center for Science in the Public Interest (CSPI) presented three It’s Pasta Anytime products with the Food Porn of the Month award in the December 2002 issue of the group’s *Nutrition Action Newsletter*. According to CSPI, Kraft’s Rotini with Three Cheese Sauce, Rotini with Mild Cheddar Cheese Sauce and Fettucine with Roasted Garlic Alfredo Sauce average 600 calories, 15 grams of saturated fat and 2,100 mgs. of sodium. “Leave it to the good people at Kraft to take what could be a perfectly healthful food – pasta – and weigh it down with three-quarters of a day’s worth of saturated fat and almost a day’s worth of sodium,” CSPI Director Michael Jacobson was quoted as saying. CSPI is a Washington, D.C.,-based nonprofit education and advocacy organization. See *CSPI Newsroom*, November 29, 2002.

Scientific/Technical Items

Obesity

[9] Obesity Alone Can Damage Arteries

New research suggests that obesity, particularly extra weight around the abdomen, is associated with carotid artery damage independent of other cardiovascular risk factors. A group of Italian researchers compared two measures of obesity, body mass index (BMI) and waist-to-hip ratio, to carotid artery thickness in 310 middle-age women. They found

that obese women and women with the highest waist-to-hip ratios had the thickest carotid arteries, a thickening that increases the risk of stroke and is said to be an early sign of disease in other arteries. After adjusting for other cardiovascular risk factors (e.g., age, blood pressure, lipid abnormalities, and fasting insulin), the authors found that obesity was still directly related to artery thickness. They recommend that “obesity should be treated in its own right for cardiovascular prevention.” See “Association of Obesity and Central Fat Distribution with Carotid Artery Wall Thickening in Middle-Aged Women,” M. De Michele, et al., *Stroke* 2002 (published online before print November 14, 2002).

Alcoholic Beverages

[10] Study Identifies SIDS Risk Factors Among Native American Infants

A new study of Northern Plains Indians has found that binge drinking (five or more drinks at one time) during the mother’s first trimester of pregnancy made it eight times more likely that her infant would die of sudden infant death syndrome (SIDS) and that any maternal drinking during the periconceptual period (three months before pregnancy or during the first trimester) was associated with a six-fold increased risk of SIDS. The research, published recently in the *Journal of the American Medical Association*, also found that infants born to women who received visits from public health nurses before and after giving birth were less likely to die of SIDS.

The SIDS rate among Native Indians is the highest of any population group. Press accounts of this study suggest that “strengthening public health nurse visiting programs and programs to reduce alcohol consumption among women of childbearing age could potentially reduce the high rate of SIDS.”

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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 supporting documentation, 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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