

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

- [1] Alcohol Bureau Proposes New Rules to Regulate
"Alcopop" Beverages1
- [2] CFSAN Updates Acrylamide Data1
- [3] Agency Seeks Comments on Food and Cosmetic Security
Guidance; GAO Issues Report on Food Security Issues1
- [4] Recalled and Imported Meat Issues Raise Concerns About
USDA Policies2

Litigation

- [5] European Court Allows Danes to Impose More Stringent
Food-Additive Standards2

Legal Literature

- [6] Michael I. Krauss, "Suits Against 'Big Fat' Tread on Basic
Tort Liability Principles," *Washington Legal Foundation*,
March 14, 2003.....3

Other Developments

- [7] Surveys Reveal Public Attitudes About Obesity3

Scientific/Technical Items

- [8] Defective Gene May Be Responsible for Binge Eating.....4
- [9] Alcohol Consumption May Affect Likelihood of Dementia4

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Legislation, Regulations and Standards

Treasury Department

[1] Alcohol Bureau Proposes New Rules to Regulate “Alcopop” Beverages

Citing concerns raised by the states and others, the Treasury Department’s Alcohol and Tobacco Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco and Firearms or ATF) has proposed new regulations that would affect many “malt alternative drinks” (otherwise known as alcopops), such as Smirnoff Ice, Mike’s Hard Lemonade and Zima. Information about a Center for Science in the Public Interest initiative involving these beverages appears in issue 6 of this Report, November 13, 2002. The proposal would change product labels, taxes and advertising by reclassifying as distilled spirits those products with more than 10 percent alcohol or 0.5 percent flavoring coming from distilled spirits. According to the Treasury Department, of the 114 “malt alternatives” on the market, only four would not have to be re-classified. Comments on the proposal, which would amend 27 C.F.R. Parts 7 and 25 and can be obtained from www.ttb.gov, must be submitted by June 23, 2003. See *Federal Register*, March 24, 2003.

U.S. Food and Drug Administration (FDA)

[2] CFSAN Updates Acrylamide Data

FDA’s Center for Food Safety and Applied Nutrition (CFSAN) is continuing to add test results to its list of products containing acrylamide. <http://www.cfsan.fda.gov/~dms/acrydat2.html>. The

most recent update contains information about breads and bakery products, cereals, coffee, cookies, canned fruits and vegetables, snack foods, jams, and jellies. The highest acrylamide levels were reported for a toasted wheat cereal, some brands of crackers and potato chips. The lowest levels were reported for canned fruits and vegetables. And while coffee grounds apparently have acrylamide levels ranging from 37 parts per billion (ppb) to 374 ppb, the brewed coffees tested had less than 11 ppb. The data in the most recent update were collected between November 16, 2002, and February 7, 2003.

CFSAN also recently issued the program’s priorities for 2003. <http://www.cfsan.fda.gov/~dms/cfsan303.html>. The work plan includes goals related to food security, labeling and health claims.

[3] Agency Seeks Comments on Food and Cosmetic Security Guidance; GAO Issues Report on Food Security Issues

FDA has decided to supplement the food security guidance documents it developed after the September 11, 2001, terrorist attacks, and is requesting public comment on two new drafts. Titled “Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance” and “Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance,” the new documents “take the operators of food and cosmetic establishments through each segment of the system within their control, in order to minimize the risk that the foods or cosmetics under their control are subject to tampering, or other malicious criminal or terrorist actions.” The guidance is not mandatory,



but apparently represents “FDA’s current thinking on appropriate and flexible food and cosmetic security preventive measures.” The original guidance documents have been revised in response to public comments since they were promulgated January 6, 2002; they address issues involving food producers, processors, transporters, importers, and filers. *See Federal Register*, March 21, 2003.

In a related development, the U.S. General Accounting Office (GAO) has issued a report to congressional requesters addressing food-processing security issues. According to GAO, neither the FDA nor the U.S. Department of Agriculture has clear statutory authority to impose security requirements and thus cannot fully assess whether voluntary guidance is being implemented. GAO recommends that these agencies (i) “identify what additional authorities they may need relating to security measures at food-processing facilities to reduce the risk of deliberate contamination of the food supply” and seek additional authority from Congress, if needed; and (ii) “provide training for all food inspection personnel to enhance their awareness and ability to discuss security measures with plant personnel.” The GAO report is available online at www.gao.gov.

U.S. Congress

[4] Recalled and Imported Meat Issues Raise Concerns About USDA Policies

Some members of Congress have reportedly called into question U.S. Department of Agriculture (USDA) policies on meat recalls, claiming that consumers would be better served if the agency reported where recalled meat had been sold. The Bush administration apparently opposes such action, claiming that companies would resist sharing proprietary information, leaving more people at risk of getting sick. In addition, a group of Democratic lawmakers has requested that USDA open an

investigation into the ConAgra Beef Co., claiming that the company was aware of *E. coli* contamination at its Greeley, Colorado, meat-packing plant weeks before it contacted the government, prompting the second-largest meat recall in the country, said a news source. Meanwhile, with many lawsuits still pending, ConAgra has reportedly settled a number of claims filed by those who became ill after eating *E. coli*-contaminated meat.

In a related development, USDA’s inspector general has apparently issued a report indicating that the safety of the U.S. food supply was jeopardized when USDA permitted the import of meat from foreign plants in countries with foot-and-mouth disease outbreaks. The auditors also reportedly requested agency records about where the meat originated. According to a news source, USDA has responded by stating that the agency is working on correcting the problems the auditors identified, but cannot provide the requested meat-processing records because only current records are retained. The agency’s meat-tracking system will apparently be improved by September 2003. *See CongressDaily*, March 12, 2003; *Associated Press*, March 13 and 14, 2003; *Denver Post*, March 13, 2003; and *The New York Times*, March 25, 2003.

Litigation

[5] European Court Allows Danes to Impose More Stringent Food-Additive Standards

Challenging a European Commission’s ruling that refused to authorize Denmark to maintain national food-additive standards that differ from a European Union (EU) directive, the Danes have reportedly scored a partial victory before the European Court of Justice. Noting that member states may adopt “derogating national provisions” where they can show that their assessment of risk to public health is different from that of the EU, the court apparently upheld



Danish restrictions regarding nitrites and nitrates, but found the stricter Danish standards on sulphites not authorized. In its ruling, the court reportedly acknowledged that divergent risk assessments are to be expected given inherent uncertainties in assessing public-health risks. Nonetheless, the court required member states to prove that their more stringent controls ensure a level of health protection higher than the EU directive without going beyond what is necessary to attain that goal. See *meatnews.com*, March 21, 2003.

Legal Literature

- [6] Michael I. Krauss, "Suits Against 'Big Fat' Tread on Basic Tort Liability Principles," *Washington Legal Foundation*, March 14, 2003

Concluding that "suing Big Fat is a big fat mistake," George Mason University professor of law Michael Krauss explores the recent trend in litigation of bringing lawsuits against the food industry for obesity-related injury. According to Krauss, "plaintiffs' lawyers' litigation campaigns against 'Big Tobacco,' gun makers, and the lead paint industry [like suits against the food industry],... [transform] tort law from a tool of private ordering (rectifying individual wrongs inflicted by one person on an unwilling victim) to a technique of public policy on the same level as taxation or regulation."

Krauss claims that such suits have no legal foundation because (i) "there is absolutely no proof that the food sold by the defendants in these suits is 'defective and unreasonably dangerous'; (ii) *even if the defendants' food was legally 'defective'* (which it is not – as argued above), there is absolutely no proof that it is the *legal cause* of any of the plaintiffs' maladies"; (iii) "*when plaintiffs do try to make legal arguments against Big Fat, they rely on scandalous 'junk science'*"; and (iv) "the lawsuits against Big Animal Fat are in reality lawsuits against parental responsi-

bility." (emphasis in original)

Krauss challenges the validity of reports from the Center for Science in the Public Interest and the National Academy of Sciences on acrylamide and *trans* fats; he also accuses lawyers like John Banzhaf of using litigation, "before unelected and non-responsible judges, to obtain what we can't get using the proper constitutional principles," and thus sending "the basic principles of tort law... down the drain with the bathwater."

Other Developments

- [7] Surveys Reveal Public Attitudes About Obesity

A recent survey of 1,000 jury-eligible adults reportedly found that 80 percent of those polled believed that parents and caretakers, not restaurants, should be held responsible for overweight children who frequently eat fast food. When asked whether they would vote for a plaintiff or a fast food retailer if they were jurors in a case involving false nutritional claims, 56.5 percent of respondents would reportedly side with the fast food company and 24.4 percent with the plaintiff, with 19 percent undecided. The survey was conducted by the litigation research firm Bowne DecisionQuest and has a margin of error of plus or minus 3 percent.

Meanwhile a recent survey in Michigan reportedly revealed that two-thirds of the 1,000 adult residents questioned believed that overweight and obesity were not matters of public health. "The health community and the government are saying this is a huge public problem, but people see this as more of a personal concern, not something that impacts all of us," a survey investigator was quoted as saying. "That's a disconnect. When we approach the public to address the problem, we need to educate them that this affects society at large, and that many of the things we need to do probably have to



be done in the public health arena." Adult obesity in Michigan has reportedly increased by 41 percent in the past decade. The 26th State of the State Survey was conducted by the Institute for Public Policy and Social Research and has a margin of error of plus or minus 3.2 percent. See *Reuters*, March 19, 2003; *Michigan State University Press Release*, March 20, 2003.

Scientific/Technical Items

Obesity

[8] Defective Gene May Be Responsible for Binge Eating

Genetics, not ineffective will power, may be responsible for binge eating. "Clinical Spectrum of Obesity and Mutations in the Melanocortin 4 Receptor Gene," I.S. Farooqi, J.M. Keogh, G.S.H. Yeo, E.J. Lank, T. Cheetham, and S. O'Rahilly, *The New England Journal of Medicine* 348(12): 1085-1095, 2003. Data from a collaborative Swiss-German-American study focused on the melanocortin 4 receptor gene, which produces a protein that signals the brain's hunger-regulating region. If mutated, the gene makes too little protein, thereby triggering signals that the brain interprets as hunger. In examining nearly 500 severely obese adults, one-quarter of whom were binge eaters, the researchers found the disorder to be much more common in those 5 percent with the genetic mutation. In fact, those individuals with the mutated gene were all binge eaters, while only 14 percent of those without the mutation suffered from the disorder.

Alcoholic Beverages

[9] Alcohol Consumption May Affect Likelihood of Dementia

Older adults who drink moderately are less likely to develop dementia than those who abstain, while those who drink more heavily increase their risk, according to a study published recently in *The Journal of the American Medical Association*. "Prospective of Alcohol Consumption and Risk of Dementia in Older Adults," K.J. Mukamal, L.H. Kuller, A.L. Fitzpatrick, W.T. Longstreth, M.A. Mittleman, and D.S. Siscovick, *JAMA* 289(11): 1405-1413, 2003. Researchers involved in the study examined 373 elderly dementia patients and a like number of control subjects, finding the lowest rates of dementia among subjects who drank one to six alcoholic beverages per week. Those at this level of consumption had approximately one-half the risk of those who abstained. The researchers note, however, a trend toward greater risk of dementia with consumption beyond six drinks per week. Those individuals who consumed 14 or more drinks per week were at a 22 percent increased risk.



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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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