

Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

- [1] Rocket-Fuel Concentrations Found in Commercial Lettuce Samples; Regulatory Approaches Muddled1
- [2] Agency Asked to Take Fungus-Based Meat Substitute Off Market2
- [3] California Agency Issues Preliminary Agenda for Acrylamide Workshop2

Litigation

- [4] Supermarket Chains Sued for Failing to Notify Public About Dye in Salmon2

Other Developments

- [5] Food-Industry Critic Publishes Book on Food Safety2
- [6] Pew Report Addresses Biotechnology Regulation3
- [7] State PIRGs Warn Kraft About Use of GM Ingredients in Food Products3

Media Coverage

- [8] John Stossel, "I Can't Help Myself: Is Addiction a Matter of Choice?," *abcnews.com*, April 21, 20034

Scientific/Technical Items

- [9] Obesity Blamed for 90,000 Cancer Deaths Annually4

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LITIGATION UPDATE

Legislation, Regulations and Standards

Federal Initiatives

[1] Rocket-Fuel Concentrations Found in Commercial Lettuce Samples; Regulatory Approaches Muddled

With Senator Barbara Boxer (D-Calif.) calling for an immediate government investigation, the Food and Drug Administration claiming it is developing new testing procedures, and the Bush administration ordering Environmental Protection Agency (EPA) officials not to discuss the matter, the rocket-fuel contamination of lettuce grown in California has hit the media with a resounding blast. The Environmental Working Group (EWG), a non-profit environmental research organization dedicated to improving public health and protecting the environment, has released the results of its tests for perchlorate in supermarket produce.

According to EWG's report, [*Suspect Salads, Toxic Rocket Fuel Found in Samples of Winter Lettuce*](#), 18 percent of lettuce samples contained detectable levels of perchlorate, and an average of these contaminated samples contained 4 times the level EPA has established as safe for drinking water. The source of the perchlorate in drinking and irrigation water is said to include military sites and other government and industrial facilities. Charts and diagrams in the report identify specific source locations and the entities that either manufacture or use perchlorate throughout the United States.

Concerns about the chemical's effect on the production of thyroid hormones and its potential to cause Graves' disease, cancer in adults, and damage to fetuses and newborns apparently put perchlorate high on EPA's research priority list in the late 1990s. Pregnant women are advised to avoid the substance because it can cause lowered IQ, mental retardation, loss of hearing and speech and motor skills deficits in fetuses and infants. EPA's preliminary research shows that perchlorate concentrates in outer lettuce leaves at levels higher than the water used for irrigation. Delays in finalizing the study on perchlorate pollution of the food supply will evidently be exacerbated by an Office of Management and Budget request that the National Academy of Sciences (NAS) study the issue. EPA has apparently been ordered to refrain from taking any regulatory action until the NAS study is completed; this could take another six to 18 months.

According to the EWG report, government officials have confirmed perchlorate contamination of more than 500 drinking water sources in 20 states that serve more than 20 million people in California, Arizona and Nevada, and unknown millions elsewhere. EWG bought 22 lettuce samples in January and February 2003 and submitted them to scientists at Texas Tech University for analysis. The highest levels of perchlorate were detected in mixed organic baby greens and conventional adult butter lettuce and radicchio. EWG calls for cleaning up perchlorate contamination and stopping the Bush administration's current proposal to exempt Department of Defense sites from environmental regulations. See *Greenwire*, *Reuters*, *The Desert Sun*, *The Kansas City*



Star, and *San Bernardino County Sun*, April 28, 2003; *Mercury News* and *Greenwire*, January 29, 2003.

Food and Drug Administration (FDA)

[2] Agency Asked to Take Fungus-Based Meat Substitute Off Market

The Center for Science in the Public Interest (CSPI) has requested that the FDA deny the “generally recognized as safe” (GRAS) classification of a food ingredient derived from fungus and used as a meat substitute. This mycoprotein, known as Quorn, purportedly causes vomiting and other gastrointestinal symptoms in a percentage of consumers. According to FDA, no evidence indicates that Quorn poses a serious threat to consumers, but the agency is continuing to review the product to decide whether to approve its use as a food additive. CSPI claims that FDA accepted the GRAS designation for Quorn from its manufacturer despite knowing that 100 adverse-reaction reports were being filed annually in the United Kingdom where the product has been available since the mid 1980s. CSPI is also asking that FDA order Quorn foods off the market without delay. See *Reuters* and *www.cspinet.org*, April 23, 2003.

[3] California Agency Issues Preliminary Agenda for Acrylamide Workshop

The California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment has issued a [preliminary agenda](#) for a May 12, 2003, public workshop focusing on Safe Drinking Water and Toxic Enforcement Act (Prop. 65) regulatory options for acrylamide. The byproduct of high-temperature cooking processes is currently listed as a carcinogen “known to the state to cause cancer” under Prop. 65. Discussions at the workshop will target ways of modulating acrylamide through cooking practices, assessing acrylamide cancer potency and determining sensitive populations.

Litigation

[4] Supermarket Chains Sued for Failing to Notify Public About Dye in Salmon

Three lawsuits have been filed in a Washington state court on behalf of a proposed class of shoppers who seek unspecified damages for past purchases from the country’s three largest grocery chains, civil penalties and a court order requiring that the chains inform shoppers that the farm-raised salmon they sell are artificially colored. According to news sources, the suit, filed April 23, 2003, claims that the artificial coloring should be declared under existing federal Food and Drug Administration (FDA) regulations. Farm-raised salmon, which have a gray-colored flesh, are evidently fed the pigment canthaxanthin and other chemicals to mimic the pink color of wild salmon that obtain their coloring from food sources such as shrimp. The European Union has been concerned about the pigment and lowered permissible intake levels to one-third of FDA levels after studies linked the chemical to retinal problems. More information about the EU initiative appears in issue 16 of this Update, February 5, 2003. Defendants in the suit are Safeway, Albertsons and the Kroger Co., which indicated it would begin adding “color added” to all farm-raised salmon and trout labels. See *Associated Press*, April 23, 2003; *Greenwire*, *Seattle Post-Intelligencer* and *San Francisco Chronicle*, April 24, 2003; *Food Ingredients First*, April 29, 2003.

Other Developments

[5] Food-Industry Critic Publishes Book on Food Safety

Marion Nestle, Ph.D., chair of the nutrition and food studies department at New York University, has added a new book to her body of work critical of the

food industry. Titled *Safe Food: Bacteria, Biotechnology and Bioterrorism*, the book condemns industry for choosing profits over safety and points to irrational allocations of jurisdiction among government agencies for the lack of effective food-safety regulation in the United States. According to Nestle, "For reasons of history, inertia, turf disputes and just plain greed, government oversight of food safety has long tended to provide far more protection to food producers than to the public." She notes that 35 separate laws, administered by 12 agencies in six cabinet-level departments result in cheese pizza being regulated by the Food and Drug Administration, while pepperoni pizza is regulated by the Department of Agriculture. Nestle concludes that the failure of industry, scientists and federal agencies to address the beliefs people hold and concerns such as unintended consequences, effect on rural life and environmental concerns, leads to widespread distrust. According to Nestle, "When officials and experts dismiss dread-and-outrage concerns as emotional, irrational, unscientific, and indefensible, they raise questions about their own credibility and competence." See *The New York Times*, April 23, 2003.

[6] **Pew Report Addresses Biotechnology Regulation**

A new report issued by the Pew Initiative on Food and Biotechnology analyzes issues related to genetically modified (GM) food products after they enter the marketplace. Titled [*Post-Market Oversight of Biotech Foods: Is the System Prepared?*](#), the report acknowledges that the current system of post-market oversight by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service, Environmental Protection Agency and Food and Drug Administration, has not resulted in "any documented harms to human health or the environment. Recent experiences, however, with StarLink corn and

Prodigene's vaccine-producing plant demonstrated the importance of post-market oversight, not only for achieving traditional food safety and environmental objectives but also for ensuring the orderly working of food and commodity markets and maintaining public confidence in the food supply."

Specific issues addressed by the report include how post-market oversight issues posed by biotech crops and foods differ from those posed by conventionally produced products and the degree to which government should be involved in such matters. A biotechnology trade group responded negatively to release of the Pew report, claiming "there are zero cases of any proven health issues associated with the food products of biotechnology." See *The Washington Post*, April 25, 2003.

[7] **State PIRGs Warn Kraft About Use of GM Ingredients in Food Products**

The National Association of State Public Interest Research Groups (PIRGs) and As You Sow, a non-profit organization dedicated to promoting corporate social responsibility and shareholder advocacy, have released a report warning that Kraft Foods' continued use of genetically modified ingredients poses financial risk to the company and its shareholders. Titled [*Risky Business: Financial Risks That Genetically Engineered Foods Pose to Kraft Foods, Inc. and Shareholders*](#), the report raises the specter of product recalls, liability lawsuits, loss of competitive advantage, consumer rejection of Kraft products, and damage to reputation as the risks the company faces for failing to phase out genetically modified ingredients from its product line. The report also cites biopharm contamination as a potential risk for the company. According to the report, it is difficult and costly to screen for the presence of biopharm contamination in products that consist of genetically modified ingredients. Biopharm food crops are used



to produce industrial chemicals and prescription drugs, and they have been known to contaminate food crops. The report claims that Kraft could be held liable for this contamination, especially because it was aware that such contamination can occur.

Media Coverage

- [8] **John Stossel, "I Can't Help Myself: Is Addiction a Matter of Choice?,"**
abcnews.com, April 21, 2003

This program discussed the scientific debate over whether addiction is a brain disease characterized by loss of control or whether drug, alcohol, shopping, gambling, food, and tobacco excesses are a matter of choice. The National Institute on Drug Abuse claims that the loss-of-control model is the U.S. government's official policy; apparently, government-funded researchers tend to agree with this position. Some physicians, addiction experts and researchers, however, believe that stigmatizing addicts by characterizing their behavior as a matter of free will remains a useful tool in combating the problem because the vast majority of tobacco and drug "addicts" have recovered without professional help. They assert that characterizing addiction as a disease (i) profits treatment centers that claim addicts need professional help to beat their addictions, and (ii) permits consumers to slam industries with multi-million dollar claims. They also note that if addiction is viewed as an issue of choice, insurance companies will not be required to reimburse the costs of treatment.

Scientific/Technical Items

Obesity

- [9] **Obesity Blamed for 90,000 Cancer Deaths Annually**

American Cancer Society researchers now estimate that obesity may cause more than 90,000 cancers deaths each year in the United States. "Overweight, Obesity, and Mortality from Cancer in a Prospectively Studied Cohort of U.S. Adults," E.E. Calle, et al., *The New England Journal of Medicine* 348(17): 1625-1638, 2003. Over a 16-year period, Dr. Eugenia Calle and colleagues examined the relationship between body mass index and cancer development and death in a population of more than 900,000 adults. They determined that those individuals who were heaviest, with body mass indices of at least 40, were significantly more likely to die from cancer than those of normal weight, with body mass indices ranging from 18.5 to 24.9. Specifically, the heaviest men and women had death rates from all cancers that were 52 percent and 62 percent higher, respectively, than rates in men and women of normal weight. Based on the increased risks identified and current patterns of overweight and obesity in the United States, the researchers estimate that excess weight may account for 14 percent of all cancer deaths in men and 20 percent of those in women.

Dr. Calle noted that the study was also large enough to identify any relationship between body mass index and risk of death from cancers at individual sites. Her findings confirm previous reports of associations between excess weight and increased risk of cancers of breast, uterus, colon, rectum, kidney, esophagus, and gall bladder.



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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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