

# Food & Beverage

## LITIGATION UPDATE

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### Table of Contents

#### Legislation, Regulations and Standards

- [1] Washington Legal Foundation Urges EPA to Revise Cancer Risk Assessment Guidelines .....1
- [2] Public Health Group Solicits Consumer Complaints About Dairy Industry's Weight-Loss Claims .....2

#### Litigation

- [3] Seeking Acrylamide Warnings on Potato Products, California Attorney General Files Lawsuit Against Nine Companies .....2
- [4] California Court Approves Settlement of McDonald's *Trans* Fats Cases .....3

#### Other Developments

- [5] Discussions of Alcohol Marketing and Youth Featured in Public Health Journal .....3
- [6] Food Marketing Aimed at Children to Be Topic of Loyola Law School Symposium .....4

#### Scientific/Technical Items

- [7] New Study Champions Coffee as Excellent Source of Antioxidants .....4

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## LITIGATION UPDATE

### Legislation, Regulations and Standards

#### Environmental Protection Agency (EPA)

##### [1] Washington Legal Foundation Urges EPA to Revise Cancer Risk Assessment Guidelines

In a [petition](#) filed last week on behalf of itself and the American Council on Science and Health, the Washington Legal Foundation (WLF) asserts that EPA violated the Information Quality Act (IQA) in its March 2005 *Guidelines for Carcinogen Risk Assessment* by failing to rely on sound science in determining the human carcinogenicity of environmental hazards. More specifically, WLF asks the federal agency to remove statements in the cancer guidelines that indicate a substance “may properly be labeled as ‘likely to be carcinogenic to humans’ based solely or primarily on the results of animal studies” and argues that most toxicologists believe such statements are scientifically unsound.

Enacted in December 2000, the Information Quality Act (aka Data Quality Act) directed the Office of Management and Budget (OMB) to issue guidance to federal agencies for ensuring the “quality, objectivity, utility, and integrity” of information disseminated to the public. The Act also directed agencies to establish their own information quality guidelines and administrative mechanisms by which affected stakeholders could seek correction of

information they considered noncompliant with the OMB guidance.

According to WLF’s petition, “animal studies have lead to numerous substances being deemed ‘likely’ human carcinogens, despite the absence of evidence that the substances have caused any cancer in humans. The law permits EPA, if it so chooses, to adopt policies that err on the side of caution when faced with equivocal evidence regarding a substance’s carcinogenicity; but the IQA does not permit EPA to distort the scientific evidence in furtherance of such policies.” Such scientific distortion, says WLF, results from EPA’s use of a “health-protective” default option – i.e., the assumption that, because laboratory animals exposed to massive doses of a substance develop cancer, humans exposed to smaller doses of the substance could similarly develop the disease. WLF contends that, even though EPA is at liberty “to err on the side of caution,” the agency “should not be permitted to skew the policy debate by attaching scientifically unwarranted ‘likely to be carcinogenic to humans’ labels to substances that may very well provide significant benefits to society.” See *WLF News Release*, August 23, 2005.



## Food and Drug Administration (FDA)

### [2] Public Health Group Solicits Consumer Complaints About Dairy Industry's Weight-Loss Claims

The Physicians Committee for Responsible Medicine (PCRM) has issued an ["action alert"](#) that provides consumers with suggested substantive content for complaints to FDA requesting an investigation of three manufacturers' claims that dairy consumption promotes weight and fat loss. In a consumer complaint filed on July 29, 2005, the activist group urged FDA to (i) declare as misbranded certain Dannon, General Mills' and McNeil Nutritionals' products labeled with weight-loss claims; (ii) initiate a voluntary recall, court-ordered injunction or seizure of such products; and (iii) require corrective advertising and labeling. In filing the consumer complaint, PCRM formally withdrew a similar citizen petition dated June 9, but asked FDA to "incorporate the contents of the withdrawn petition and its exhibits as supporting documentation" to the complaint. PCRM has made parallel accusations against the dairy industry in a petition to the Federal Trade Commission and in two recent lawsuits filed in Virginia state court. *See PCRM Action Alert*, August 24, 2005.

## Litigation

### Warnings

### [3] Seeking Acrylamide Warnings on Potato Products, California Attorney General Files Lawsuit Against Nine Companies

Acting under California's Proposition 65 (Prop. 65), the Safe Drinking Water and Toxic Enforcement Act of 1986, Attorney General Bill Lockyer last Friday [sued](#) nine companies for failure to warn consumers of potentially dangerous levels of acrylamide in the companies' potato products. *People of the State of California v. Frito-Lay, Inc., et al.*, No. BC338956 (Superior Court of Los Angeles County) (filed 8/26/05).

"In taking this action, I am not telling people to stop eating potato chips or french fries," Lockyer said. "I know from personal experience that, while these snacks may not be a necessary part of a healthy diet, they sure taste good. But I, and all consumers, should have the information we need to make informed decisions about the food we eat," he said. Named defendants in the lawsuit include Frito-Lay, Inc./PepsiCo., Inc. for Lay's chips; Burger King Corp. for french fries; Lance Inc. for Cape Cod chips; H.J. Heinz, Inc. for Ore-Ida frozen potato products; Kettle Foods, Inc. for Kettle chips; KFC Corp. for Potato Wedges; McDonald's Corp. for french fries; Procter & Gamble for Pringle's chips; and Wendy's International, Inc. for french fries. *See News Release of the Office of the Attorney General*, August 26, 2005.

Prop. 65 requires warnings to the public about exposure to chemicals "known to the state to cause cancer or reproductive toxicity"; the law does not apply to chemicals that occur naturally in food.



Acrylamide forms as a byproduct of high-temperature cooking processes in many high-carbohydrate foods and is reported to cause cancer in laboratory rodents. The chemical has been listed as a carcinogen under Prop. 65 since 1990, and the current no-significant-risk-level (NSRL) of 0.2 micrograms per day was based on occupational exposures unrelated to food consumption.

Cal/EPA is currently evaluating whether to (i) exempt acrylamide in foods from Prop. 65 warning requirements, (ii) establish a new NSRL for acrylamide of 1.0 microgram per day, (iii) set an NSRL for acrylamide in breads and cereals of 10.0 micrograms per day, or (iv) establish new warning requirements for stores and restaurants if products sold by those establishments exceed any new NSRLs for acrylamide. Such warnings would be required only at the point of sale or point of display of the affected food products, not on individual package labeling.

## Deceptive Trade Practices

### [4] California Court Approves Settlement of McDonald's *Trans* Fats Cases

Marin County Superior Court Judge John Sutro last week approved a settlement in which McDonald's Corp. agreed to pay \$8.5 million to settle a purported class action alleging the company deceived consumers by failing to switch to a lower-*trans*-fat cooking oil by the date mentioned in a 2002 public statement. *Fettke v. McDonald's Corp.*, No. CV04-02754-WHA (U.S. District Court, Northern District, California) (filed 7/8/04). The settlement also resolves an October 2003 lawsuit filed by

plaintiffs' lawyer Stephen Joseph on behalf of BanTransFats.com, Inc., an organization he founded. Under terms of the settlement, McDonald's will donate \$7 million to the American Heart Association to fund public education programs about *trans* fats and spend \$1.5 million on a campaign to keep the public apprised of the company's progress in switching to non-partially hydrogenated cooking oil. McDonald's will also reportedly pay some \$2 million in attorney's fees and other costs. *See Associated Press*, August 25, 2005.

## Other Developments

### [5] Discussions of Alcohol Marketing and Youth Featured in Public Health Journal

"The global alcohol industry has become increasingly concentrated and dominated by a small number of large transnational companies, resulting in global branding and the development of global marketing strategies" that lead underage consumers to drink, according to an editorial introducing a [special section](#) of the September 2005 issue of the *Journal of Public Health Policy*. The section includes articles that discuss regulatory options aimed at reducing youth exposure to alcohol ads, product categories that allegedly appeal to teens and relevant provisions of global trade agreements. Georgetown University's Center on Alcohol Marketing and Youth coordinated production of the articles. *See CAMY News Release*, August 26, 2005.



**[6] Food Marketing Aimed at Children to Be Topic of Loyola Law School Symposium**

“Food Marketing to Children and the Law” is the title of a [free symposium](#) slated for October 21, 2005, at Loyola Law School in Los Angeles.

Organized by public health lawyer Michele Simon of the Oakland-based Center for Informed Food Choices, the event will feature sessions about product placement practices, the commercial speech doctrine and the efficacy of self-regulation. Speakers will include Susan Linn of the Campaign for a Commercial-Free Childhood; Jason Smith of the Public Health Advocacy Institute; and Stephen Gardner, litigation director of the Center for Science in the Public Interest.

## Scientific/Technical Items

### Coffee

**[7] New Study Champions Coffee as Excellent Source of Antioxidants**

Coffee is the No. 1 source of antioxidants in the American diet, according to a study presented this week at the 230th National Meeting of the American Chemical Society. (J. Vinson, “Polyphenols: Total Amounts in Foods and Beverages and U.S. Per Capita Consumption,”

Abstract/Presentation, American Chemical Society, Washington, D.C., August 28, 2005.) In the current study, researchers analyzed the antioxidant content of more than 100 food items, including vegetables, fruits, nuts, and various beverages. The data for each food item was then compared to existing agriculture department data on the contribution of each type of item to the average estimated U.S. per capita consumption. Based on both the amount of antioxidants per serving and the frequency of consumption, coffee ranked No. 1 over other popular sources of antioxidants such as tea, chocolate and cranberries. The American Cocoa Research Institute provided primary funding for the study. Other recent research has suggested that coffee consumption could lower the risk of developing liver and colon cancer, Type II diabetes and Parkinson’s disease. *See American Chemical Society News Service and Associated Press, August 28, 2005.*



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## LITIGATION UPDATE

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