

Food & Beverage

LITIGATION UPDATE

Issue 65 • January 28, 2004

Table of Contents

Legislation, Regulations and Standards

- [1] Lawmakers Introduce BSE-Related Legislation.....1
- [2] Daschle Promises Continued Fight over COOL Regulations.....1
- [3] FDA Announces New BSE Safeguards; Schedules
Related Meeting1
- [4] FDA Extends Comment Period for ANPRM on Qualified
Health Claims2
- [5] Virginia House of Delegates Bill Would Exempt Food
Companies from Obesity-Related Lawsuits2

Litigation

- [6] Environmental Groups Seek California Prop. 65 Enforcement
Action over Lack of Warnings for Farmed Salmon2
- [7] Parents Blame Son's Death on Alleged Emulation of Pepsi Ad.....3

Other Developments

- [8] D.C. Conference Targets Prevention and Defense of
Obesity Claims3

Media Coverage

- [9] "The Sweet and Lowdown on Sugar," Kelly Brownell and
Marion Nestle, *The New York Times*, January 23, 2004.....4

Scientific/Technical Items

- [10] Study Cohort Loses Weight on High-Carb, Low-Fat Diet4

Shook,
Hardy &
Bacon L.L.P.

www.shb.com

Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Congress

[1] Lawmakers Introduce BSE-Related Legislation

Legislation introduced last week in both the House ([H.R. 3714](#)) and Senate ([S. 2007](#)) takes aim at bovine spongiform encephalopathy (BSE) and other prion diseases. Among other things, provisions of the “BSE and Other Prion Disease Prevention and Public Health Protection Act” would mandate (i) bans on the importation and exportation of articles containing “animal-derived material from a ruminant that was in any country at a time there was a risk of transmission of BSE in the country,” (ii) annual Department of Agriculture reports regarding surveillance programs to assess the prevalence of prion diseases in the United States, (iii) establishment of a ruminant identification program “capable of tracing, within 48 hours, after an animal is diagnosed with any reportable animal disease or any condition that can cause disease in humans, the movements of all exposed animals from birth to slaughter,” and (iv) establishment of a multi-agency task force on prion diseases.

Related legislation ([H.R. 3705](#)) would amend the federal Meat Inspection Act by requiring the testing of all cattle for BSE at the time of slaughter, while a measure ([S. 2008](#)) introduced by Senators Arlen Specter (R-Pa.) and Patrick Leahy (D-Vt.) would require the agriculture secretary to establish an electronic nationwide livestock identification system.

[2] Daschle Promises Continued Fight over COOL Regulations

In light of passage of the contentious omnibus appropriations bill that contained a rider delaying implementation of country-of-origin labeling (COOL) on meat, seafood and produce until 2006, Senate Minority Leader Tom Daschle (D-S.D.) has vowed that supporters of the labeling rules will amend upcoming legislation whenever possible to reinstate their implementation during 2004 or offer a resolution to veto the regulations that impose their delay. “We will take both tracks and apply them whenever and wherever we can,” Daschle said. Daschle claims the two-year delay is “tantamount to killing the program,” while Department of Agriculture Secretary Ann Veneman claims it will allow time for further refinements, calling the COOL rules a “targeted marketing tool, not a food safety or animal health program.” See *The New York Times*, January 22, 2004; *Associated Press*, January 23, 2004.

Food and Drug Administration (FDA)

[3] FDA Announces New BSE Safeguards; Schedules Related Meeting

Department of Health and Human Services Secretary Tommy Thompson has announced new safeguards to further protect the U.S. food supply from the risk of bovine spongiform encephalopathy (BSE). Interim final rules soon to be issued and made effective upon publication in the *Federal Register* will target the use of bovine-derived materials from human food and cosmetics as well as a ban on feeding



cow blood and poultry waste to cattle. More specifically, the first rule will ban from FDA-regulated human food and cosmetics (i) any material from downer cattle, (ii) any material from cattle that die on the farm (before reaching a slaughtering facility), (iii) specified risk materials “known to harbor the highest levels of the infectious agent for BSE,” and (iv) mechanically separated beef. The second interim rule will prohibit (i) the feeding of mammalian blood and blood products to other ruminants as a source of protein, (ii) the use of “poultry litter” (e.g., fecal matter, spilled feed, feathers) as an ingredient in feed for ruminant animals, and (iii) the use of “plate waste” (i.e., restaurants’ uneaten meat scraps that are rendered into meat and bone meal) as a feed ingredient for ruminants. It will also mandate dedicated equipment, facilities or production lines for cattle feed to prevent cross-contamination of ruminant and non-ruminant feed. *See FDA Press Release*, January 26, 2004.

The agency has also announced a meeting of its Transmissible Spongiform Encephalopathies (TSE) Advisory Committee for February 12-13, 2004, in Silver Spring, Maryland. The agenda will include discussions of a presumptive transfusion-transmitted case of variant Creutzfeldt-Jakob disease, human and animal TSEs, and risk-based approaches to sourcing of bovine derivatives used in the manufacture of medical products. *See Federal Register*, January 26, 2004.

[4] FDA Extends Comment Period for ANPRM on Qualified Health Claims

Citing the complexity and importance of the rulemaking, FDA has extended until February 25, 2004, the comment period for the advanced notice of proposed rulemaking (ANPRM) on qualified health claims – those not supported by significant scientific agreement (SSA) – and “other potential initiatives to

help consumers choose a healthy diet.” The broad areas of FDA inquiry include (i) alternatives for regulating health claims not meeting the SSA standard, (ii) data and research on a substance/disease relationship, (iii) the use of phrases such as “FDA authorized” in qualified and unqualified health claims, (iv) consumer education about qualified health claims, and (v) dietary guidance statements on conventional food and dietary supplement labels. *See Federal Register*, January 27, 2004.

State/Local Initiatives

[5] Virginia House of Delegates Bill Would Exempt Food Companies from Obesity-Related Lawsuits

Virginia Delegate Bill Janis (R) has introduced product liability legislation that would limit lawsuits against manufacturers or sellers of products containing “patent hazards.” Under [H.B. 1372](#), products containing patent hazards include foods made with sugar, butter, hydrogenated oils, and *trans*-fats; alcoholic beverages; tobacco; and firearms. The bill’s provisions exclude actions based on manufacturing defects or breach of an express warranty. Louisiana enacted similar legislation in 2003, and like-minded bills are now pending in various states.

Litigation

Warnings

[6] Environmental Groups Seek California Prop. 65 Enforcement Action over Lack of Warnings for Farmed Salmon

Acting under California’s Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of



1986, two environmental groups have served notice of their intent to sue 50 grocery chains, salmon farms, and fish processors worldwide for failure to warn consumers of potentially dangerous levels of polychlorinated biphenyls (PCBs) in farmed salmon. Prop. 65 requires warnings to the public about exposure to chemicals “known to the state to cause cancer or reproductive toxicity” and provides 60 days for the state attorney general to decide whether to join or take over the lawsuit.

The Center for Environmental Health and the Environmental Working Group (EWG) want the salmon farming industry to discontinue feeding practices that purportedly result in high levels of PCBs in the fish. “The salmon farming industry can and must produce a heart-healthy food without the PCB risks that farmed salmon currently pose,” an EWG spokesperson was quoted as saying. The proposed enforcement action comes on the heels of a recently published study in the journal *Science* which contended that PCBs in the highly concentrated feed given to farmed salmon result in PCB levels seven times higher than those found in wild salmon. Industry representatives, however, assert that PCB levels in farmed salmon fall well below safety levels set by the Food and Drug Administration. See *Environmental Working Group Press Release and The San Francisco Chronicle, January 22, 2004; Associated Press, January 23, 2004.*

Negligence

[7] Parents Blame Son’s Death on Alleged Emulation of Pepsi Ad

A federal court in New Hampshire has dismissed a case brought against PepsiCo and bottlers by parents who attributed their son’s death to a Pepsi advertisement purportedly depicting consumption of the beverage through “shotgunning” – punctur-

ing the can. [*Estate of Thomas Noah Sullivan v. Pepsi-Cola Metropolitan Bottling Co., No. 03-361-JD, \(D.N.H. 1/15/04\)*](#). Thomas Sullivan died after a pushpin was propelled into his throat by the pressurized contents of a can of Pepsi. The pushpin lodged in his vocal cords and triggered a seizure that led to a coma, loss of neurological function and death. The court found plaintiffs’ original claims of negligence, strict product liability and violations of a state consumer protection statute to be time-barred. A second suit involving the same cause of action, but seeking recovery through breach of express and implied warranty claims, failed on *res judicata* grounds.

Other Developments

[8] D.C. Conference Targets Prevention and Defense of Obesity Claims

Starting tomorrow, prominent lawyers and scientists on both sides of the issue will convene in Washington, D.C., for a [national forum](#) on preventing and defending obesity claims. Longtime tobacco-control proponent John Banzhaf will advocate “Using Legal Action as a Weapon Against the Public Health Problem of Obesity.” Shook, Hardy & Bacon partner [Victor Schwartz](#) will offer insight on the question “Will Resolution Come from The Hill?” as he updates attendees on legislation to protect restaurants and food manufacturers from obesity lawsuits. Other speakers will address the science behind obesity causation claims, effective marketing in a litigious environment, lessons learned from diet drug litigation, and “preemptive tools for success in the face of litigation.”

The two-day forum is sponsored by Faegre & Benson and produced by the American Conference Institute. The target audience includes products-liability



attorneys, food-regulatory attorneys, advertising attorneys, in-house counsel for potential defendants, and advertising and marketing executives. After the conference, materials will be available for purchase from the American Conference Institute.

At another location in Washington, D.C., the [National Health Policy Conference 2004](#), scheduled for today and tomorrow, will include a breakout session on strategies to combat obesity. Anticipated panelists include Jessie Gruman of the Center for Advancement of Health; Michael Mudd of Kraft Foods, Inc.; Marion Nestle of New York University; and John Peters of Procter and Gamble Nutrition Science Institute.

Media Coverage

- [9] **“The Sweet and Lowdown on Sugar,” Kelly Brownell and Marion Nestle, *The New York Times*, January 23, 2004**

In this editorial, Yale University’s Kelly Brownell and New York University’s Marion Nestle call recent Bush administration criticism of the World Health Organization’s (WHO’s) *Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases* “blatant pandering to American food companies that produce much of the world’s high-calorie, high-profit sodas and snacks, especially the makers of sugars, the main ingredients in many of these products.” They further assert the administration’s allegations of faulty science in the WHO report “undermine the efforts of more forward-thinking food companies and threaten public health.” See [issue 64](#) of this Update, January 21, 2004.

Scientific/Technical Items

Overweight/Obesity

- [10] **Study Cohort Loses Weight on High-Carb, Low-Fat Diet**

Those consuming a diet high in carbohydrates and low in fat might be able to lose weight without actually cutting calories or exercising. N.P. Hays, et al., “Effects of an Ad Libitum Low-Fat, High-Carbohydrate Diet on Body Weight, Body Composition, and Fat Distribution in Older Men and Women,” *Archives of Internal Medicine* 164(2): 210-217, 2004. Over a 12-week period, researchers put 34 overweight individuals in one of three groups: those provided a high-carbohydrate/low-fat diet, those provided that same diet and instructed to exercise regularly, and those allowed to maintain their regular diet. To more accurately count calories, meals were provided, and participants were instructed to eat as much as they wanted. In the end, all three groups were shown to have consumed essentially the same number of calories. On average, however, those who consumed the recommended diet, either alone or in combination with exercise, lost more weight and a larger percentage of body fat. The researchers attribute the weight loss to differences in the way people metabolize fats and carbohydrates.



Food & Beverage

LITIGATION UPDATE

Food & Beverage Litigation Update is distributed by Mark Cowing 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 mcowing@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.

Shook,
Hardy &
Bacon_{L.L.P.}TM

Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

New Orleans, Louisiana

Orange County, California

Overland Park, Kansas

San Francisco, California

Tampa, Florida

Washington, D.C.

