

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

FTC Seeks Comment on Self-Regulatory Guidelines to Protect Children's Online Privacy

The Federal Trade Commission (FTC) has issued a [notice](#) seeking public comments on a proposed set of self-regulatory guidelines submitted by i-SAFE, Inc. under the safe harbor provision of the Children's Online Privacy Protection Rule. Comments must be submitted by March 1, 2010.

The organization that prepared the proposed guidelines is a non-profit that for some years has partnered with industry to provide educational programs for children about online safety issues. It recently determined that it would become involved in assisting and licensing online "operators" with children's online privacy issues. Among other matters, the i-Safe guidelines would (i) provide notice to parents about the information collected from children by i-Safe licensees, (ii) require verifiable parental consent for the collection of personal information from children; and (iii) provide parents with an opportunity to view the information collected and prevent its further dissemination. *See Federal Register*, January 13, 2010.

In recent years, consumer advocates concerned about youth marketing have raised concerns about the online initiatives, including games and personalized digital marketing, that some food companies have used to increase brand awareness among children.

EPA Special Communications Committee to Address Food Safety Concerns

The Environmental Protection Agency (EPA) has reportedly created a special communications committee to address food safety concerns related to dioxin. According to a January 15, 2010, *Inside EPA* article, a forthcoming EPA reassessment is expected to identify dioxin "as highly toxic and bioaccumulative with most exposure occurring through the food supply." The agency apparently undertook the reevaluation after a 2006 National Academy of Sciences report advised EPA to update its risk assessment of 2,3,7,8 Tetrachlorodibenzo-p-Dioxin (TCDD), a byproduct of combustions and other industrial processes. *Inside EPA* has anticipated that the pending EPA report will intensify public concerns "given existing data from the Food & Drug Administration (FDA)," which in 2009 reported that "over 95 percent of exposure arises from dietary intake of animal fats." In addition, an EPA source has

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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purportedly indicated that human body burdens are "probably" at levels higher than any reference dose recommended by the agency.

Inside EPA nevertheless noted that new data from the U.S. Department of Agriculture "shows declining levels of dioxins in the food supply and in humans." "It's a classic communication problem because most dioxin emissions are greatly reduced," the EPA source was quoted as saying. "It's a big legacy problem instead of a current emissions problem."

In a related development, the Center for Biological Diversity (CBD) has [petitioned](#) EPA "to establish water-quality criteria for numerous endocrine-disrupting chemicals under the Clean Water Act." In a January 11 press release, CBD claims that "A wide variety of substances, including pharmaceuticals, dioxins, polychlorinated biphenyls, DDT and other pesticides, solvents and plasticizers can cause endocrine disruption." The group has urged EPA to fill the "regulatory void for controlling endocrine disruptors," calling on the agency to "completely eliminate or dramatically reduce the 'acceptable' levels of these pollutants in the waterways." See *Inside EPA*, January 15, 2010.

APHIS Issues *Federal Register* Notice on GM Alfalfa

The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has [published](#) its notice about the availability of a draft environmental impact statement (EIS) for genetically modified (GM) alfalfa. The agency was required to prepare the EIS by a Ninth Circuit Court of Appeals ruling finding that APHIS violated the National Environmental Protection Act by failing to do so in connection with its determination that the crop could be deregulated. Comments must be submitted by February 16, 2010, and public meetings will be held on January 19 in Las Vegas; February 3 in Kearney, Nebraska; February 4 in Lincoln, Nebraska; and February 9 in Riverdale, Maryland. See *Federal Register*, January 12, 2010.

Meanwhile, Food & Water Watch, a consumer advocacy organization, is calling on supporters to take action on the EIS by telling the USDA "loud and clear that consumers want foods that are free from genetic engineering." According to the organization's online alert, the USDA is getting closer to approving the GM crop "despite the fact that it's likely to contaminate other crops, including organic alfalfa. Almost all organic dairies are dependent on organic alfalfa, and organic standards don't allow the use of GE crops." Food & Water Watch claims that USDA has admitted there could be cross-contamination problems but does not know "if the contamination of organic alfalfa would matter to consumers of organic food." See *food&waterwatch Online Alert*, January 14, 2010.

Soybean Interests Call for USDA to More Closely Examine Competition in Agriculture

The American Soybean Association has reportedly submitted comments expressing concerns about agribusiness concentration to the Department of Justice and the U.S. Department of Agriculture (USDA) in response to their recent initiative

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on competition and regulatory issues in the agriculture industry. According to ASA President Rob Joslin, "In recent years, we have seen increased consolidation in various agricultural industries. Many farmers have questioned why high levels of concentration have not been more thoroughly reviewed and analyzed by the federal government to determine their impact on competition." *See Southeast Farm Press*, January 11, 2010.

The agencies announced that they would be holding a number of joint public workshops to explore these issues in a November 2009 news release. Discussions about issues for crop farmers, "including seed technology, vertical integration, market transparency and buyer power" will take place in Ankeny, Iowa, on March 12, 2010; production contracts, concentration and buyer power in the poultry industry will be discussed in Normal, Alabama, on May 21; similar issues in the dairy industry will provide the focus for a public workshop in Madison, Wisconsin, on June 7; "enforcement of the Packers and Stockyards Act and concentration" will be addressed for the livestock industry in Fort Collins, Colorado, on August 26; and "discrepancies between the prices received by farmers and the prices paid by consumers" will be discussed in Washington, D.C., on December 8.

National Organic Program Proposes Amendments to National List of Allowed and Prohibited Substances

The U.S. Department of Agriculture's Agriculture Marketing Service has [issued](#) a proposed rule that would amend the National List of Allowed and Prohibited Substances (National List) to reflect the recommendations of the National Organic Program Board (NOPB). The National List "identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production," as well as identifying "synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling." The proposed rule would alter the National List to "amend the annotation for one exempted material (tetracycline) and add one substance (sulfurous acid) for use in organic crop production." AMS will accept comments on the proposed rule until March 15, 2010. *See Federal Register*, January 12, 2009.

National Salt Reduction Initiative Unveils Proposed Dietary Targets

The National Salt Reduction Initiative (NSRI) has called on companies "to reduce the salt levels in 61 categories of packaged food and 25 classes of restaurant food," issuing a [list of proposed targets](#) designed to cut the salt in these foods by 25 percent over five years. Led by the New York City Health Department, this partnership of cities, states and national health organizations apparently solicited input from the food industry in developing the proposed targets. NSRI will also [accept](#) additional comments until February 1, "especially from companies that have not yet participated in the target-setting process, as well as consumer organizations and other interested parties."

"Americans consume roughly twice the recommended limit of salt each day – causing widespread high blood pressure and placing millions at risk of heart attack and stroke – in ways that they cannot control on their own," stated a January 11,

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2010, press release, which noted that “some popular products already meet the [proposed] targets – a clear indication that food companies can substantially lower sodium levels while still offering foods that consumers enjoy.”

Meanwhile, the Center for Science in the Public Interest (CSPI) has issued a statement praising the initiative. According to the group, “Reducing sodium by 25 percent over the next 5 years could also save the federal government billions in direct medical expenditures.” As *The Wall Street Journal* has reported, however, food makers are already “taking a new tack in their long-running effort to sell products with less salt,” reformulating their products to contain less salt but “not making a big fuss about it on the label.” Instead of cutting salt all at once, companies have apparently learned to “decrease sodium slowly so that customers don’t notice it.” See *CSPI Press Release, The Wall Street Journal and The New York Times*, January 11, 2009.

American Meat Institute Deems Mandatory COOL a Violation of Trade Obligations

The American Meat Institute (AMI) has apparently submitted comments to the Office of U.S. Trade Representative contending that country-of-origin labeling (COOL) requirements violate U.S. international trade obligations. According to AMI, the nation’s “credibility is undermined when U.S. legislation violates America’s commitments” under international agreements. AMI claims that the COOL requirements “are not consistent with U.S. obligations” under World Trade Organization (WTO) and North American Free Trade Agreement obligations or the General Agreement on Tariffs and Trade.

The organization apparently characterizes COOL as “*de facto* discrimination against foreign products, a result even contemplated by sponsors of the legislation who declared that it would be ‘helpful to a lot of American agricultural producers’ and force companies to rely ‘on our independent producers here in this country.’” Canada and Mexico have asked the WTO to rule on the legality of the COOL law. See *AMI Press Release*, January 8, 2010; *meatingplace.com*, January 11, 2010.

LITIGATION

First Circuit Strikes Down Massachusetts Wine Shipping Law Under Commerce Clause

The First Circuit Court of Appeals has upheld an injunction against the enforcement of a Massachusetts law that regulated wine shipments in a manner that changed “the competitive balance between in-state and out-of-state wineries in a way that benefits Massachusetts wineries and significantly burdens out-of-state wineries.” [*Family Winemakers of Cal. v. Jenkins, No. 09-1169 \(1st Cir., decided January 14, 2010\)*](#).

The statute at issue gave small wineries (those producing 30,000 gallons or less of grape wine annually) the most options for selling to consumers, either by direct shipment or through wholesalers and retailers. According to the court, most Massachusetts wineries are small wineries. Large wineries could sell either through wholesalers or by applying for a special license to ship directly to consumers; they

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could not do both. Apparently, Massachusetts has no large wineries. A group of California wineries and Massachusetts residents challenged the law, claiming it violated the Commerce Clause by effectively giving Massachusetts wineries a competitive advantage and thus discriminating against interstate commerce. The district court agreed and enjoined the law's enforcement.

The state appealed, and the First Circuit determined that, while the law was neutral on its face, "the effect of its particular gallonage cap" was discriminatory and the legislature intended to discriminate against out-of-state wineries. The court also determined that the Twenty-First Amendment, which gives states certain limited authority to regulate the transportation, importation and use of alcohol within their borders regardless of effects on interstate commerce, does not protect facially neutral laws from invalidation under the Commerce Clause.

Federal Court Certifies Class Action Against Yogurt Maker

A federal court has certified class claims against General Mills alleging that the company's advertising for its premium-priced Yo-Plus® yogurt violates the Florida Deceptive and Unfair Trade Practices Act because the product does not provide any digestive health benefits that cannot be obtained from eating normal yogurt. *Fitzpatrick v. General Mills, Inc.*, No. 09-CV-60412 (U.S. Dist. Ct., S.D. Fla., decided January 11, 2010).

The named plaintiff claimed that the company's ads and promotional materials convinced her to try the product and that she consumed it on a regular basis for about a year. She claimed that her digestive health was the same before, during and after eating Yo-Plus® and thus, the company's claims for digestive health benefits beyond those provided by normal yogurt are false, misleading and likely to deceive the public. She also alleged breach of express warranty and sought to certify a class of "[a]ll persons who purchased YoPlus in the State of Florida."

The court's legal analysis focuses primarily on the predominance requirement of Federal Rule of Civil Procedure 23(b)(3). General Mills argued that common issues do not predominate because (i) each plaintiff was exposed to a mix of advertising statements, and the truthfulness of each must be separately assessed; (ii) different plaintiffs may have purchased the product for different reasons, including those completely unrelated to its purported health benefits; and (iii) the scope of damages will vary among plaintiffs, some of whom may have experienced the expected digestive health benefit. The court disagreed with each contention and concluded that individual issues do not predominate as to the claim raised under the state consumer protection statute. Finding that the express warranty claim requires individualized proof, however, the court refused to certify it.

According to the court, "the dispute centers on the scientifically complex question of whether Yo-Plus provides a digestive health benefit, and if General Mills had an adequate basis to disseminate that message to Florida consumers. It is this thorny issue—rife with contested, bleeding-edge scientific evidence—that would overwhelmingly dominate (and hence preclude) every plaintiff's case were they forced to litigate independently."

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Chicken Producer to Settle Claims over “Raised Without Antibiotics” Ad Campaign

Multidistrict litigation (MDL) plaintiffs who challenged claims that Tyson products were made from “chickens raised without antibiotics” have sought approval of a settlement reached with the company. *In re: Tyson Foods Inc., Chicken Raised Without Antibiotics Consumer Litigation*, MDL No. 1982 (U.S. Dist. Ct., D. Md., N. Div., motion filed January 12, 2010).

Under the terms of the settlement, Tyson will pay up to \$5 million to three tiers of plaintiffs: those who can provide receipts (they can recover up to \$50); those who can estimate how much they spent on the products, how often they purchased them and where the purchases were made (they can recover up to \$10) and those who simply claim they purchased the product at least once and submit a claim for a \$5 coupon instead of cash. Four named plaintiffs in the suits consolidated before the MDL court for pre-trial proceedings and four class members who were deposed will receive incentive awards not to exceed a total of \$20,000 if the settlement is approved.

Attorney’s fees not to exceed \$3 million will be paid separately by the company, and any unclaimed funds will be used for in-kind donations of Tyson products to food banks. According to a news source, a hearing for the court to review the settlement and the request to certify a settlement class was scheduled to be held January 15, 2010. A company spokesperson was quoted as saying, “Our Raised Without Antibiotics chicken initiative, which we started in 2007, was suspended in 2008 due to labeling challenges. While we believe our company acted appropriately, we also believe it makes sense for us to resolve this legal matter and move on.” *See meating-place.com*, January 13, 2010.

Additional information about related litigation filed by Tyson competitors appears in issues 256, 257 and 258 of this Update. More details about the consumer litigation that led to the proposed settlement appear in issues 259 and 265 of this Update. A challenge that Tyson filed against the U.S. Department of Agriculture’s antibiotic labeling regulations appears in issue 264.

California Court Declares Prop. 65 Warnings for Meat Products Preempted

A California court of appeal recently determined that the Federal Meat Inspection Act (FMIA) preempts point-of-sale or other warning labels on meat products under Proposition 65 (Prop. 65). *Am. Meat Inst. v. Leeman*, No. D053325 (Cal. Ct. App., 4th Dist., Div. One, decided December 22, 2009).

In 2004, Whitney Leeman notified a number of meat processors and retailers in California that she intended to file a citizen suit against them alleging violations of Prop. 65 for their failure to provide warnings that their beef products contained dioxins and PCBs, chemicals known to the state to cause cancer or reproductive toxicity. The companies’ trade association filed a complaint seeking declaratory relief, and the trial court, finding implied, but not express, federal preemption, granted the association’s motion for summary judgment.

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The court of appeal focused for the most part on defining “labeling,” because Leeman argued that point-of-sale warnings do not constitute labeling under the FMIA, which contains an express preemption provision for “labeling” requirements “in addition to, or different than, those made under this chapter.” Finding that labeling encompasses point-of-sale warnings, the court affirmed the lower court’s preemption ruling.

The American Meat Institute’s president expressed the organization’s satisfaction with the ruling, stating “Federal labeling requirements provide the necessary information to inform consumers about the meat products they purchase. The court has agreed with our view that state laws that conflict with federal laws will confuse the consumer and should be preempted.” See *American Meat Institute Press Release*, December 23, 2009.

LEGAL LITERATURE

SHB Attorney Co-Authors ABA Article on ANSI Draft National Standard for Sustainable Agriculture

Shook, Hardy & Bacon Of Counsel [Jim Andreasen](#) has co-authored an article providing an update on the American National Standards Institute’s (ANSI’s) draft national standard for sustainable agriculture. The article appears in the January 2010 issue of the American Bar Association’s (ABA’s) *Agricultural Management Committee Newsletter*. This committee is part of the ABA’s Section of Environment, Energy, and Resources.

The article outlines the draft standard’s development to date and the potential impact it could have once finalized. According to the article, the draft “as initially proposed would promote a non-GMO [genetically modified organism], organic, and fair trade (i.e., fair labor) standard for agriculture that exceeds nearly all existing organic and nonorganic practices in U.S. agriculture.” The draft has undergone a number of changes, including a narrowing of its scope, since its introduction, and the committee working to develop it has expanded to include some industry interests.

The article also discusses the appeals that various interested stakeholders have filed, mostly challenging the composition of the standards development committee, and reports that the draft will be further refined in March 2010 during a meeting at the University of Arkansas. ANSI standards, once finalized, have the potential to be adopted as international standards under the International Organization for Standardization in Geneva, Switzerland. They are also often adopted by federal and state regulators in this country.

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OTHER DEVELOPMENTS

Food Health Claims in Canada Topic of Upcoming Webcast

The Canadian government has announced a January 20, 1010, Webcast titled "Health Claims in Canada: An Update on Function Claims and Probiotic Claims for Food." Presented by Agriculture and Agri-Food Canada, Health Canada and the Canadian Food Inspection Agency (CFIA), the Webcast will (i) "provide an update on the development of a modernized framework for health claims for food and the future directions for managing health claims"; (ii) "present new guidance on function claims and probiotic claims, and the requirements for scientific evidence to validate claims" and (iii) provide insights into CFIA's enforcement approach. For more information and to register, please click [here](#).

SCIENTIFIC/TECHNICAL ITEMS

Heart Disease Allegedly Linked to Higher Urinary Concentrations of BPA

A recent study has claimed that "higher urinary concentrations of bisphenol A [BPA] are associated with an increased prevalence of coronary heart disease." David Melzer, et al., "Association of Urinary Bisphenol A Concentration with Heart Disease: Evidence from NHANES 2003/06," *PLoS ONE*, January 2010. Using data from the National Health and Nutrition Examination Survey (NHANES) 2003/04 and 2005/06, researchers examined the urinary BPA concentrations of participants aged 18-74 years, "representative of the general adult population of the United States." According to the authors, "Associations have previously been reported between urinary BPA concentrations and heart disease, diabetes and liver enzymes in adults participants of [NHANES] 2003/04."

The 2005/06 NHANES data purportedly confirmed that "higher BPA exposure, reflected in higher urinary concentrations of BPA, is consistently associated with reported heart disease in the general adult population of the USA." The study noted, however, that "Associations between urinary BPA concentrations and diabetes or liver enzyme increases were not statistically significant." In addition, participants' urinary BPA concentrations in 2005/06 were "substantially lower" than in 2003/04. The authors recommended further study "to clarify the mechanisms explaining the statistical association between BPA and adult morbidity." See *ScienceNews*, January 13, 2009.

CDC Data Suggest Obesity Rates Leveling Off

Two recent studies have reportedly suggested that obesity rates in America have remained constant for at least five years among men and closer to 10 years for women and children. Using data obtained from the Centers for Disease Control and Prevention's (CDC's) National Health and Nutrition Examination Survey (NHANES), researchers [concluded](#) that although approximately 32 percent of men and 35 percent of women are obese, "the increases in the prevalence of obesity previously observed do not appear to be continuing at the same rate over the past 10 years, particularly for women and possibly for men." In addition, a separate [study](#) apparently found a similar plateau in obesity rates for children.

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"Right now we've halted the progress of the obesity epidemic," William Dietz, CDC's Director of Nutrition, Physical Activity and Obesity, was quoted as saying. "The data are really promising. That said, I don't think we have in place the kind of policy or environmental changes needed to reverse this epidemic just yet." Dietz, who theorized that the findings reflected an increased awareness of the nation's obesity problem, told a news source that he hoped the obesity data would follow what happened with smoking rates. See *The New York Times*, January 14, 2010.

Study Claims Soda Fountains May Dispense Fecal Bacteria

A study of microbial contamination in soda fountains within a 22-mile radius of Roanoke, Virginia, claims that nearly one-half of them harbored "coliform bacteria" that could contain fecal matter. Amy S. White, et al., "Beverages obtained from soda fountain machines in the U.S. contain microorganisms, including bacteria," *International Journal of Food Microbiology*, January 2010. Researchers studied 90 beverages of three types (sugar sodas, diet sodas and water) from 30 soda fountains (both self-serviced and staff-operated) to analyze and evaluate microorganisms with respect to U.S. drinking water regulations. They found that 48 percent of the beverages harbored coliform bacteria, 11 percent contained *E. coli* and 17 percent had *Chryseobacterium meningosepticum*. The authors speculated that the contamination could have come from "dispensing with a hand that wasn't clean or using wet rags to wipe down the machine."

"These findings suggest that soda fountain machines may harbor persistent communities of potentially pathogenic microorganisms which may contribute to episodic gastric distress in the general population and could pose a more significant health risk to immunocompromised individuals," according to the study's abstract. "These findings have important public health implications and signal the need for regulations enforcing hygienic practices associated with these beverage dispensers." See *CNN.com*, January 8, 2010.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

