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LEGISLATION, REGULATIONS AND STANDARDS

House Approves Bill Overhauling Food Safety Laws

By a 283-142 vote, the U.S. House of Representatives has passed the "Food Safety Enhancement Act of 2009" (H.R. 2749). The day before its passage, the measure failed to garner the two-thirds majority vote needed to approve legislation submitted under "suspension of the rules," which would not have allowed any floor amendments. The second submission, on July 30, 2009, needed only a simple majority vote, which was handily achieved. According to news sources, farm-state lawmakers were able to insert several last-minute changes that would exempt some growers from the new farming standards and restrict recordkeeping requirements for livestock farmers. The pork industry apparently kept some proposed restrictions on antibiotic use out of the final bill.

Heralded by some as an historic moment for food safety, the bill would provide for more frequent inspections of processing plants and would give the Food and Drug Administration (FDA) the authority to order the recall of tainted foods. The increased inspections would be financed with a yearly \$500 fee imposed on food processing plants, although a cap of \$175,000 would apply to large companies with numerous facilities. The measure also contains provisions for the adoption of processing-plant safety standards, food traceability, criminal and civil penalties, inspection protocols for imported foods, and restrictions on bisphenol A in food and beverage containers.

Similar legislation will be considered in the U.S. Senate, although that body is not expected to take up the proposal until fall 2009. While industry groups, such as the Grocery Manufacturers Association, and consumer organizations reportedly supported the House bill, others were concerned that it will, if ultimately enacted, raise food prices and burden small farms and processors. Still, the bill's current registration requirements do not "include farms; private residences of individuals, restaurants, other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer." Nor do they apply to farms that sell primarily through farmers' markets. *See The Des Moines Register* and *CQ Today*, July 29, 2009; *The New York Times* and *FoodProductionDaily.com*, July 31, 2009.



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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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); Meanwhile, Representative Steve Israel (D-N.Y.) has introduced legislation (H.R. 3317) that would require food producers to label their products with a notation that they contain less than 0.5 grams of *trans* fat, rather than continuing to use a "zero" *trans* fat label for foods with less than 0.5 grams of the substance. Titled the "Trans Fat Truth in Labeling Act of 2009," the bill has been referred to the House Committee on Energy and Commerce.

CDC's "Weight of the Nation" Conference Addresses Obesity Epidemic

The Centers for Disease Control and Prevention (CDC) hosted a "Weight of the Nation" conference July 27-29, 2009, in Washington, D.C., to explore ways of tackling the nation's escalating rates of obesity. Treating obesity-related conditions such as diabetes, heart disease and arthritis reportedly costs some \$147 billion annually.

Speakers at the inaugural event included CDC Director Thomas Frieden, who was quoted as saying that taxing sugary drinks at \$.01 per ounce could produce \$100 billion to \$200 billion over the next decade. "Anything that decreases the availability and increases the cost is likely to be effective. The challenge, I think, is a political one of getting that approved," he said. Frieden further asserted that average American adults are 23 pounds overweight, consume 250 more calories daily than 10 years ago and that about 120 of those calories are from sugary beverages.

In a related development, CDC issued a <u>report</u> on July 17 that claims the obesity epidemic most adversely affects African-Americans and Hispanics. Of the three groups studied, blacks had the highest rate of obesity at 36 percent, followed by Hispanics at 29 percent, and whites at 24 percent. "Evidence suggests that neighborhoods with large minority populations have fewer chain supermarkets and produce stores and that healthful foods are relatively more expensive than energy-dense foods, especially in minority and low-income neighborhoods," the report stated. *See Reuters; MedPage Today*, July 27, 2009.

FDA Committee Plans Meeting to Assess BPA, Discuss Science Upgrades

The Food and Drug Administration's (FDA's) Science Board has <u>scheduled</u> an August 17, 2009, public meeting to review the agency's continuing assessment of the packaging chemical bisphenol A (BPA) in FDA-regulated products and discuss plans to increase research reviews at the Center for Food Safety and Applied Nutrition (CSFAN). *See Federal Register*, July 28, 2009.

ANSI Nanotechnology Standards Panel to Meet in Chicago

The Nanotechnology Standards Panel of the American National Standards Institute (ANSI) will meet September 9, 2009, in Chicago. The meeting will be held during the Nanobusiness Alliance Conference. The panel has been working to develop nanotechnology-related standards involving nomenclature/terminology; materials properties; and testing, measurement and characterization procedures. ANSI's efforts are in support of international nanotechnology standards initiatives and could result in federal regulation. Nanomaterials are used in hundreds of products including food packaging.



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LITIGATION

Federal Court Dismisses Challenge to Animal ID System

A federal court in the District of Columbia has dismissed claims that the National Animal Identification System (NAIS) violates a number of federal and state laws, including a religious freedom statute and constitutional protections. *Farm-to-Consumer Legal Defense Fund v. Vilsack*, No. 08-1546 (U.S. Dist. Ct., D.D.C., decided July 23, 2009). Dubbed in the press as the "mark of the beast" lawsuit, the complaint, brought by farmers "who raise livestock in a sustainable manner," contends that the U.S. Department of Agriculture (USDA) coerced Michigan's Department of Agriculture to adopt uniform NAIS requirements that threaten their way of life by gathering information into a national database against their wills and in violation of their religious beliefs.

Among the complainants are Amish farmers who apparently believe (i) they have been given dominion and control over animals, and that control has now been given to state and federal agencies; (ii) they are not permitted to take the NAIS "mark," and the imposition of premises identification numbers (PINs) and radio frequency identification devices (RFIDs) violates this religious tenet; (iii) they must farm but will be forced out of business by prohibitive NAIS compliance costs; and (iv) they must eschew technology, "directly contrary to the use of RFIDs, scanners and computer programs," and discourage outside contact, "yet their private data is stored in a national database."

The court dismissed the claims against the USDA because they erroneously asserted that NAIS requires the registration of PINs and the use of RFID tags. According to the court, NAIS regulations are not mandatory and, in any event, allow the use of other identification methods. According to the court, Michigan adopted many of the challenged practices in response to a bovine tuberculosis emergency in the late 1990s and not as a matter of USDA dictate. The court rejected the claims against the state department of agriculture because they involved federal statutes that do not apply to state actors implementing state law, and the court lacked supplemental jurisdiction over the remaining state law claims.

The Farm-to-Consumer Legal Defense Fund has expressed its disappointment in the court's decision and indicated that it is considering its options, "including the filing of an appeal, the filing of a request to reconsider the evidence and the law, or bringing a case in state court against Michigan." *See The BLT: The Blog of the Legal Times*, July 24, 2009; *Farm-to-Consumer Legal Defense Fund Press Release*, July 27, 2009.

Federal Judge Denies Class Certification in Frozen Waffle Litigation

A federal court in California has denied the request for class certification filed by plaintiffs who allege that Van's International Foods falsely advertised its frozen waffle products by listing incorrect nutritional information in their labels. *Hodes v. Van's Int'l Foods*, No. 09-1530 (U.S. Dist. Ct., C.D. Cal, decided July 23, 2009). While the court found that the claims met the numerosity, commonality, typicality, and



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adequacy of representation requirements of Rule 23(a) of the Federal Rules of Civil Procedure, it found that the named plaintiffs failed to satisfy Rule 23(b)(3). According to the court, common questions of law and fact do not predominate over individualized issues, and the class action device is not superior to other methods for adjudicating the controversy.

The named plaintiffs had sought to certify a nationwide class of consumers, and the court was concerned about the manageability of the class action, stating, "the Court has concerns about how Plaintiffs will identify each class member and prove which brand of Van's frozen waffles each member purchased, in what quantity, and for what purpose. The likelihood that tens of thousands of class members saved their receipts as proof of their purchase of Van's waffles is very low."

The court also observed that the plaintiffs had not "presented the Court with any indication of how to determine the amount of damages suffered by each class member. The Court will not engage in its own investigation as to which of Van's 19 frozen waffle varieties class members purchased, how much each class member spent, and whether those particular varieties contained nutritional inaccuracies." Additional details about the litigation appear in issues 295 and 308 of this Update.

Pomegranate Juice Dispute Allowed to Proceed

A federal court in California has denied the motion to dismiss filed by Ocean Spray Cranberries, Inc. in litigation filed by Pom Wonderful LLC alleging that the company's false advertising for a cranberry-pomegranate juice violates federal and state law and constitutes unfair competition. *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, No. 09-00565 (U.S. Dist. Ct., C.D. Cal., decided July 16, 2009). Pom Wonderful alleges that Ocean Spray's product contains little pomegranate juice, costs less to produce and thus unfairly competes with its own and other competitors' pomegranate juices. The complaint also contends that marketing the Ocean Spray product as high in antioxidants misrepresents the product because "in fact the Beverage does not contain high levels of antioxidants."

The court rejected Ocean Spray's assertions that (i) the false advertising claims brought under the Lanham Act are precluded or barred by the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration (FDA) regulations; (ii) federal law expressly or impliedly preempts Pom Wonderful's state law claims; and (iii) the complex labeling issues raised fall within the FDA's jurisdiction and should therefore be referred to that agency for resolution under the primary jurisdiction doctrine. The court examined the respective interests protected under the two federal laws and concluded that, while the laws overlap, plaintiff's essential claim—that Defendant's label misrepresents the primary ingredients of the beverage—does not rely "on a determination by the FDA or an interpretation of its regulations."

Chicken Growers Lawsuit to Be Heard by En Banc Court of Appeals

The Fifth Circuit Court of Appeals has decided to rehear a case involving the interpretation of the Packers and Stockyards Act as applied to contracts between chicken growers and a processor. *Wheeler v. Pilgrim's Pride Corp.*, No. 07-40651 (5th



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Cir., decided July 27, 2009). In 2008, a three-judge circuit panel decided that the law does not require proof of an adverse effect on competition, creating a split with other circuit courts that had considered the question. The issue arose when chicken growers complained that the processor for whom they raised chickens gave preferential treatment and thus greater compensation to one grower. According to the earlier opinion, the other circuit courts have mistakenly looked to legislative history and policy issues to interpret the law, which the Fifth Circuit panel believed was clear and unambiguous. The case will be considered by the entire Fifth Circuit court on rehearing.

Environmental Group Notifies EPA of Intent to Sue over Pesticide Effects on Polar Bears

The Center for Biological Diversity has sent a 60-day notice of intent to sue letter to the Environmental Protection Agency (EPA) claiming that the agency has failed to take required action under the Endangered Species Act (ESA) to further the polar bear's conservation when making decisions about the use of pesticides and herbicides under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA). According to the July 8, 2009, letter, the polar bear was designated an endangered species in May 2008, and the ESA requires the EPA to consider protected species when registering pesticides under FIFRA.

The center contends that many of the pesticides registered in the United States "are known likely to affect the polar bear" and that EPA has failed to comply with its consultation and review obligations as to more than 35 organophosphates, many of which have apparently been detected in the Arctic. Listed are chlorpyrifos, diazinon, disulfoton, fenitrothion, methyl-parathion, and terbufos. Among the non-organophosphates the center discusses in the letter are atrazine, alachlor, DCPA, and endosulfan.

The center concludes by calling on EPA to "initiate formal consultation under ESA Section 7 regarding the effects of these pesticides on polar bears, including analyzing the cumulative effects of these pesticides in the context of a warming climate," and to "rescind or suspend registration of all pesticides that 'may affect' the polar bear pending the completion of such consultation."

Proposed Prop. 65 Styrene Listing Challenged

An industry trade group has sued Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) to stop it from listing styrene as a carcinogen under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). *Styrene Info.* & *Research Ctr. v. OEHHA*, No. 09-53089 (Cal. Super. Ct., Sacramento County *filed* 07/15/09). According to the complaint, styrene does not cause human cancer, and its proposed Prop. 65 listing would cause the \$28-billion-a-year industry "irreparable harm" by stigmatizing the chemical. It also alleges that OEHHA failed to comply with administrative procedures in interpreting and implementing Prop. 65, created secret interpretative standards and refused to consider new scientific evidence indicating that styrene is not "known to cause cancer."



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Styrene is used in milk and egg cartons, berry baskets, produce shipping crates, foodservice containers, plastic pipes, automobile parts, medical equipment, countertops, and many other products. To support its proposed styrene listing, OEHHA cited a 2002 International Agency for Research on Cancer monograph that called styrene "possibly carcinogenic to humans." The Environmental Protection Agency has classified it as a suspected carcinogen, and the Occupational Safety and Health Administration says that exposure to styrene may affect the central nervous system and result in headaches, fatigue and dizziness. While the court has denied the industry's request for a temporary restraining order, it has reportedly scheduled an August 12, 2009, hearing on its request for injunctive relief. *See Inside EPA*, July 24, 2009.

OTHER DEVELOPMENTS

Report Urges Lawmakers to Look at Anti-Tobacco Campaigns in the Fight Against Obesity

The Urban Institute and the University of Virginia have issued a <u>report</u> claiming that lawmakers should study anti-tobacco campaigns as they consider taxing fattening foods and sugary drinks to curb the nation's obesity problem.

Titled "Reducing Obesity: Policy Strategies from the Tobacco Wars," the report asserts that increased education about smoking and taxing tobacco products brought the percentage of U.S. smokers down from 42.4 percent of the population in 1965 to less than 20 percent in 2007. Matthew Myers, president of the Campaign for Tobacco-Free Kids, was quoted as saying that raising taxes "brings about the quickest, most measurable, and most pronounced decline in use."

Policies suggested in the report include (i) the adoption of excise or sales taxes on "fattening food," such as ice cream, sugary drinks and candy; (ii) the placement of "clear and simple labels," such as traffic-light signpost labels, "conveying the health risks of fattening foods" on food packages, (iii) the posting of nutritional information on chain restaurant menus; and (iv) a ban on advertising and restrictions on the marketing of foods with little nutritional value.

The report claims that a 10 percent tax on less-healthy food could generate more than \$500 billion over 10 years, and if combined with a subsidy that lowered the price of fruits and vegetables by 10 percent, the net revenue would exceed \$350 billion. *See CBSNews.com/blogs*, July 28, 2009.

Canadian Study Reveals Higher Levels of Folic Acid in Foods Than Claimed on Labels

According to a news source, the *Canadian Journal of Public Health* has published research showing that folic-acid fortified foods often contain, on average, 50 percent more of the vitamin than listed on product labels. Some foods apparently contain 377 percent of the folic acid declared. The federal government reportedly adopted a folic-acid fortification program in the late 1990s affecting products ranging from breads, cookies, crackers, and pastas to desserts and ready-to-eat



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cereals. The incidence of certain birth defects in Canada has dropped by more than half since then, and the program is also credited with reducing heart defects and neuroblastoma, a type of childhood cancer.

Some in Canada have reportedly called for adding folic acid to other foods, but caution has been urged in light of the new research because too much folic acid can mask vitamin B12 deficiency, a problem for seniors with anemia. Excess levels can also apparently interfere with drugs used for rheumatoid arthritis, psoriasis and malaria. *See The Globe and Mail*, July 27, 2009.

MEDIA COVERAGE

Sherry Colb, "Child Obesity as Child Neglect: Is the Standard American Diet Dangerous?," *FindLaw.com*, July 22, 2009

Cornell Law School Professor Sherry Colb discusses the recent incident involving the removal of a morbidly obese teen from the custody of his mother for child neglect. Colb questions the wisdom of South Carolina's decision to place the child in the state's protective custody, suggesting, "the government could spend considerably less money providing [the mother] with healthy food and information about nutrition."

Noting that the mother works long hours at more than one job and relies on fast food to feed her child, Colb points out that she only lacks resources, "not love or concern for her son." She considers whether the government could take custody of a child with anorexia nervosa and thus, "needlessly add psychological trauma to an already fragile child's life." She also considers the typical diet offered in the nation's school lunch programs, involving high-fat and processed carbohydrates.

Colb concludes, "We should not be arresting people and taking away their children for simply following the pack on dietary matters. What we should do, instead, is educate everyone and demand that government—in the form of public schools—begin to serve as a model for healthful nutrition, rather than as a parody of American over-indulgence.

Bijal Trivedi, "The Calorie Delusion: Why Food Labels Are Wrong," *New Scientist,* July 15, 2009

This article explores how the method of estimating the calories in food, developed in the late 19th century, may provide misleading information on the amount of energy people actually get from a food. The calorie counts are calculated by burning small samples of food, and science writer Bijal Trivedi observes, "Nutritionists are well aware that our bodies don't incinerate food, they digest it. And digestion from chewing food to moving it through the gut and chemically breaking it down along the way—takes a different amount of energy for different foods."

Trivedi compares the nutrients in a health-food bar and a chocolate brownie and discusses research showing that more highly refined, cooked and softer ingredients tend to be absorbed more readily when eaten, thus contributing higher actual





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caloric intake than raw or chewy foods. Despite the acknowledged inaccuracies in calorie counts, most nutritionists have apparently decided that the measuring system should not be changed because "the problems and burdens ensuing from such a change would appear to outweigh by far the benefits."

CONFERENCES AND SEMINARS

SHB Partner to Speak During Foreign Corrupt Practices Act Conference

Shook, Hardy & Bacon Corporate Law Partner **Nate Muyskens** will join a panel of distinguished speakers in Washington, D.C. at a Legal iQ Foreign Corrupt Practices Act (FCPA) <u>conference</u>, September 21-23, 2009. Co-sponsored by SHB, the conference brings together counsel from global corporations and federal enforcement agencies to address FCPA issues with a specific focus on "Defining New Strategies in Global Anti-Corruption for 2009 and Beyond."

Muyskens will share a podium with representatives of Siemens Corp., Coca-Cola Ltd. and Morgan Stanley to discuss "Conducting Due Diligence of Foreign Third Parties to Minimize Liability Risks." Conference organizer Legal iQ is a division of the International Quality & Productivity Center.

OFFICE LOCATIONS

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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.

FOOD & BEVERAGE LITIGATION UPDATE

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.



