

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] USDA Releases GAIN Report on EU Food Laws

The USDA Foreign Agricultural Service recently published its annual [Global Agriculture Information Network \(GAIN\) Report](#) on the current status of European Union (EU) food laws. Billed as “a complete overview of food laws currently in force in the EU-27,” the report notes that in 2007-2008 the EU updated regulations pertaining to: (i) labeling requirements for allergens, nutrition and health claims; (ii) packaging; (iii) pesticides; (iv) contaminants; (v) specific standards for genetically modified foods, novel foods, wine and spirit drinks, organic foods, beef labeling, and egg marking; and (vi) import procedures. The report also covers European Commission proposals that may affect U.S. exports and includes an annex of Web site links and guidance documents. USDA nevertheless advises domestic companies to “verify import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any food is shipped.”

Food and Drug Administration (FDA)

[2] FDA Schedules Public Meeting on Products Containing Nanoscale Materials

The Food and Drug Administration (FDA) will hold a [public meeting](#) on September 8, 2008, to gather information to be used in developing agency guidances on products containing nanoscale materials. Written or electronic comments must be submitted by October 24. According to FDA, the primary purpose of the meeting is “to determine what factors the agency should consider in providing guidance on: 1. The information and data that may be needed to demonstrate the safety and effectiveness of FDA-regulated products containing nanoscale materials; and 2. The circumstances under which a product’s regulatory status might change due to the presence or use of nanoscale materials (for example, making a device no longer exempt from 510(k) submission requirements.)”

Breakout sessions during the meeting will be organized around product categories that include food and color additives, food contact substances, and dietary supplements. The sessions will focus on (i) the nanoscale material characteristics that should be identified and evaluated to ensure product safety; (ii) the available assessment tools to evaluate nanoscale material characteristics that may affect product safety, effectiveness and quality; (iii) any unique features of manufacturing processes for products containing nanoscale materials; (iv) particular aspects of product formulation, processing or storage that can affect



product quality, safety or effectiveness; (v) manufacturers' experience with products containing nanoscale materials; and (vi) "additional questions focusing on characterization (including stability) and manufacturing aspects of products containing nanoscale materials [that] should be addressed in this forum."

The agency is also requesting available data and information that identify nanoscale versions of previously approved food and color additives, the effects that nanoscale versions of larger sized materials have on bioavailability and the effects of nanoscale materials on manufacturing processes. See *Federal Register*, August 7, 2008.

European Union

[3] EFSA Redrafts Opinion on Foodborne Antimicrobial Resistance

The European Food Safety Authority (EFSA) has adopted a [redrafted opinion](#) suggesting that the increased use of antimicrobial agents in food could be affecting human resistance to bacteria. According to EFSA's panel on biological hazards, "foodborne bacteria, including known pathogens and commensal bacteria, display an increasing, extensive and diverse range of resistance to antimicrobial agents of human and veterinary importance, and any further spread of resistance among bacteria in foods is likely to have an influence on human exposure." EFSA found that "[r]esistant *Salmonella* and *Campylobacter* involved in human disease are mostly spread through foods" and "[a]nimal-derived products remain a potential source of meticillin-resistant *Staphylococcus aureus* (MRSA)."

The opinion calls for limiting antimicrobial usage and recommends "[t]he development and application of new approaches to the recognition and control of food as a vehicle for AMR [antimicrobial resistant] bacteria and related genes based on epidemiological and source attribution studies directed towards fresh crop-based foods, raw poultry meat, raw pig meat and raw beef." According to EFSA, the problem "requires a response from all stakeholders to acknowledge their responsibilities for preventing both the development and spread of AMR, each in their own area of activity including medicine, veterinary medicine, primary animal food production, food processing and food preparation, as well as in the regulation of food safety."

United Kingdom

[4] FSA Seeks Views on EC Proposal to Regulate Food Contact Materials

The U.K.'s Food Standards Agency (FSA) has [invited](#) interested parties to provide comment on a European Commission (EC) proposal to regulate active and intelligent materials and articles intended to come into contact with food. Comments should be submitted by August 31, 2008, but can be sent until October 17, when the consultation closes.

According to the notice, the EC defines "active food contact materials and articles" as "materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food." "Intelligent food contact materials and articles" are defined as "materials and articles which monitor the conditions of packaged food or the environment surrounding the food." Such materials



could be placed on the market only if the substances in them are included on a list of allowable components; they do not migrate into foods at a rate exceeding 0.01 mg/kg; and they are not classified as proved or suspected carcinogenic, mutagenic or toxic-to-reproduction substances. The EC proposal will also cover conditions for placing such materials on the market, rules on labeling, compliance, and the establishment of the initial list of allowable substances.

FSA seeks information about the numbers of companies likely to be affected by the proposal, its potential financial impact, identifiable benefits, likely administrative costs, impact on sustainable development, and possible costs to the environment, among other matters.

State and Local Governments

[5] Industry Groups Oppose Draft OEHHA Regulation on Labor Code Mechanism

Diverse industry interests have filed comments on the [draft](#) regulation published in May 2008 by California's Office of Environmental Health Hazard Assessment (OEHHA) proposing how substances identified under the Labor Code as toxic and hazardous shall be added to the state's Proposition 65 (Prop. 65) list of those chemicals known to the state to cause cancer or reproductive toxicity. The California Chamber of Commerce, Grocery Manufacturers Association, Personal Care Products Council, American Beverage Association, Western Growers, and others contend that OEHHA has misread the law that describes how substances are added to the list. The proposed regulations indicate that Prop. 65 mandates an automatic listing of chemicals without any requirement of public input

or opportunity for OEHHA to consult with the state's qualified experts on scientific issues before a listing decision is made.

The industry commenters assert that the Labor Code reference substances were to be listed automatically when the list was initially established in 1987, but that any substances proposed for listing thereafter have to undergo scientific review and public comment. Reference chemicals under the Labor Code are derived from the hazardous chemical lists of the U.N.'s International Agency for Research on Cancer (IARC), the federal Hazard Communications Standard, the National Toxicology Program, and the federal Occupational Safety and Health Act.

The commenters also note that OEHHA only recently switched positions on how it uses the Labor Code as a listing method. According to a California Chamber of Commerce representative, "In the years since the initial adoption of the list, OEHHA has appropriately ignored the Labor Code Mechanism in adding substances to the Prop. 65 list—until quite recently. This agency practice amply demonstrates that OEHHA agreed until quite recently that the Labor Code Mechanism is no longer available. There has been to date a failure to justify, or even explain, why this long-standing interpretation has changed."

OEHHA has reportedly defended its action by claiming the agency has been using this mechanism "since about 2000." An agency spokesperson reports that the industry group comments have failed to focus on the draft proposal, stating "OEHHA is still reviewing the comments, but most of them do not relate at all to the draft regulatory language, instead making general legal and policy arguments



concerning OEHHA's authority to list chemicals through this mechanism." See *InsideEPA.com*, August 1, 2008.

[6] Oregon County Adopts Menu Labeling Requirements for Chain Restaurants

County officials in Portland, Oregon, this week approved legislation that would require chain restaurants with 15 outlets or more nationwide to supply calorie content and nutritional information on menus. The Multnomah County Board of Commissioners voted 4-1 to adopt the measure after hearing from Senator Margaret Carter (D-Portland) and Representative Tina Kotek (D-North/Northeast Portland), who announced their joint campaign for a statewide menu labeling initiative next year. In addition, Commissioner Lisa Naito urged the board to prohibit *trans* fats in all restaurants and to expand the menu labeling regulation to prepared foods in schools, health care facilities and grocery stores. Although her amendments ultimately failed to gain the board's approval, Naito joined her peers in sending a policy directive to the county's health department, which will spend two months hashing out implementation guidelines for the menu labeling plan. If the health department's version is officially adopted by the Board of Commissioners later this year, the rule would take effect in January 2009 with a six-month grace period for compliance. See *The Oregonian*, August 1, 2008.

In a related development, Los Angeles County Supervisor Zev Yaroslavsky reportedly announced a similar proposal that would compel chain restaurants in unincorporated parts of the city to list calorie information on menus. County municipalities and Los Angeles itself could also "opt in" and adopt the initiative if passed by the Board of Supervisors next week. Although the California Restaurant

Association has not opposed the plan, it has stressed a need for implementation guidelines and uniform regulations to reduce consumer confusion. See *Los Angeles Times*, August 7, 2008.

Litigation

[7] Federal Prosecutors Probe Alleged Price-Fixing in Packaged Ice Industry

With three companies dominating the national market for the packaged ice typically sold at supermarkets, gas stations and convenience stores, federal prosecutors are reportedly investigating whether they conspired to illegally fix prices for the product. According to information recently filed in a federal court in Detroit, a former executive of one of the companies has been assisting in the investigation and provided evidence that the alleged collusion forced up ice prices for consumers and businesses.

Home City Ice Co., which makes 4,400 tons of ice daily and leads the Midwest market, is apparently negotiating a plea to charges unsealed against it in June 2008. While it is cooperating with the investigation, Home City could ultimately face \$100 million in fines. The other companies reportedly targeted in the probe are Reddy Ice Holdings, Inc. and Arctic Glacier, Inc.

According to a news source, the three companies not only face criminal charges—dozens of civil suits filed by consumers alleging they were overcharged are apparently pending across the country, with the most recent filed in July by Boies Schiller on behalf of a New York pub and a beverage retailer. The whistleblowing former executive has also filed a lawsuit seeking back pay and other damages from the alleged co-conspirators. See *The Wall Street Journal*, August 7, 2008.



[8] California AG Reaches Settlement in Prop. 65 Acrylamide Claims

California Attorney General Edmund Brown Jr. has reportedly settled claims filed in 2005 against snack food manufacturers for failure to warn consumers of potentially dangerous levels of acrylamide in their fried potato products. *Cal. v. Frito-Lay, Inc.*, No. BC338956 (Super. Ct. of Los Angeles County, settlement approved Aug. 1, 2008). Further details about the suits, filed under California's Proposition 65 (Prop. 65), the Safe Drinking Water and Toxic Enforcement Act of 1986, appear in issues 132, 140 and 212 of this Update. This agreement with Frito-Lay, Inc., Kettle Foods, Inc. and Lance, Inc., which concludes the litigation, follows a similar settlement in July 2008 with H.J. Heinz Co. Claims against fast food companies were settled in 2007, when they agreed to post acrylamide warnings in their restaurants and pay civil penalties and costs.

Prop. 65 requires warnings to the public about exposure to chemicals "known to the state to cause cancer or reproductive toxicity." Acrylamide forms as a byproduct of high-temperature cooking processes in many high-carbohydrate foods and is reported to cause cancer in laboratory rodents. Under the agreement, Frito-Lay, Kettle Foods and Lance will reduce the acrylamide in their products to 275 parts per billion over the next three years. If they cannot do so, they will either withdraw the products from the California market or place warnings on product packaging. Frito-Lay will pay \$1.5 million in penalties and costs, \$550,000 of which will be forgiven if the company reduces the acrylamide in its products in half the time; an additional \$2 million in penalties will be required if the company fails to meet the deadline. Kettle Foods will pay \$350,000 in penalties and costs, and Lance will pay \$95,000.

A number of companies are reportedly researching the use of enzymes to reduce acrylamide levels in foods, and several have obtained application intellectual property rights and GRAS [generally recognized as safe] status for their enzymes. Washing and soaking potatoes at home before cooking, also apparently reduces the risk of acrylamide formation.

Representatives from the California attorney general's office reportedly characterized the litigation as "frustrating." The companies apparently fought the claims "tooth and nail," trying repeatedly to get them dismissed, arguing a lack of scientific proof of danger, federal preemption and jeopardy to First Amendment rights. The case was apparently scheduled to go to trial on July 28 after the defendants' motions for dismissal were rejected. According to a deputy attorney general, "It became clear that we'd be going to trial and that this was a case we could win." None of the companies admitted wrongdoing in settling the case. *See Office of the Attorney General Press Release*, August 1, 2008; *FoodUSANavigator.com*, August 4, 2008; *The Los Angeles Times*, August 6, 2008.

[9] BASF Sues EC for Delay in Approving Genetically Modified Potato

According to a news source, BASF has filed suit against the European Commission (EC) in the European Court of First Instance for delaying its approval of the company's genetically modified (GM) Amflora potato. While the European Food Safety Authority (EFSA) apparently concluded in 2006 that this GM crop was no more likely to cause adverse effects than conventional potatoes, the EC is concerned about BASF using antibiotic resistance marker genes in its process to produce a potato with pure starch for use in the paper



industry; the possibility of gene transfer into animals and humans is reportedly holding up the approval. EFSA is working on a new report about the safety of the technology BASF is using, but it will not be available before December 15, 2008. A BASF spokesperson was quoted as saying, “We have nothing against the strict approval process, but we want politicians to stick to it. We fear that, for political reasons, the commission is not acting according to the science.” See *Chemical & Engineering News*, August 2008.

Media Coverage

[10] Shmuel Herzfeld, “Dark Meat,” *The New York Times*, August 6, 2008

“Unfortunately, this year kosher meat has become a different type of symbol, one not of mourning and spiritual devotion but of ridicule, embarrassment and hypocrisy,” writes Shmuel Herzfeld, rabbi of Ohev Sholom-The International Synagogue, in this op-ed article about a recent “immigration sting” at Agriprocessors Inc., a kosher meatpacking company in Postville, Iowa. “News reports and government documents have described abusive practices at Agriprocessors against workers, including minors,” according to Herzfeld. “Children as young as 13 were said to be wielding knives on the killing floor; some teenagers were working 17-hour shifts, six days a week.”

Herzfeld argues that the allegations call into question the kosher status of the plant and criticizes both the Rabbinical Council of America and the Orthodox Union for failing to actively investigate the charges. In particular, Herzfeld proposes that the groups “appoint an independent commission whose members have not in the past been paid by either

the Orthodox Union or Agriprocessors.” This commission would then select a team of rabbinical experts to “make sure the plant upholds basic standards of kashrut and worker and animal treatments—and that it is in full compliance with the laws of the United States.”

Other Developments

[11] CSPI Report Claims Children’s Meals Laden with Calories

The Center for Science in the Public Interest (CSPI) this week released the results of an investigation alleging that 93 percent of 1,474 kids’ meal food combinations at 13 chains exceeded 430 calories, that is, one-third of the Institute of Medicine’s recommended daily caloric intake for children ages 4 to 8. The consumer watchdog singled out popular restaurants like Chili’s, KFC, Burger King, and McDonald’s for offering kids’ meals that approached or surpassed the 1,000 calorie mark. In addition, CSPI alleged that 45 percent of these menu options were “too high” in saturated and *trans* fats, and 86 percent were “too high” in sodium. The study only examined chain restaurants with a dedicated children’s menu that made nutritional information available to the consumer on Web sites or elsewhere.

CSPI has called on lawmakers to adopt regulations requiring restaurants to list calorie counts on menus and menu boards to help parents make healthier selections for their children. “Parents want to feed their children healthy meals, but America’s chain restaurants are setting parents up to fail,” opined CSPI Nutrition Policy Director Margo Wootan. “McDonald’s, Burger King, KFC, and other chains are conditioning kids to expect burgers, fried chicken, pizza, French fries, macaroni and cheese,



and soda in various combinations at almost every lunch and dinner.” See *CSPI Press Release, The Associated Press, USA Today, and CQ Healthbeat News*, August 4, 2008; *Reuters*, August 5, 2008.

Meanwhile, the National Restaurant Association has issued a statement urging parents to take advantage of the nutrition information already available at most chain restaurants. The association stressed that the nation’s restaurant industry has consistently shown a significant commitment to helping patrons make smart eating decisions when dining out. “Exercising parental responsibility is key to childhood nutrition,” the association stated. “Indeed, CSPI fails to acknowledge the essential role of nutrition education, physical activity and parental responsibility in childhood nutrition—good eating habits and healthy living must be established at home.” See *National Restaurant Association Press Release and Business & Media Institute*, August 4, 2008.

[12] NCAA Officials Decline to Eliminate Alcohol Advertising Despite Coaches’ Petition

More than 100 basketball and football coaches affiliated with Division I of the National Collegiate Athletic Association (NCAA) this week petitioned the organization to prohibit alcoholic beverage advertisements during all televised college competitions. The coaches were joined by 240 college athletic directors and 60 college presidents, according to the Center for Science in the Public Interest, which also urged the NCAA to adopt more stringent marketing policies. NCAA currently restricts alcohol advertising to products with less than 6 percent alcohol by volume and allows these beverages only 60 seconds of commercial airtime per broadcast hour.

In a [letter](#) dated August 4, 2008, coaches, athletic directors and college presidents called on NCAA President Myles Brand and Executive Committee Chair Michael Adams to raise the issue at an August 7 meeting. The authors specifically cited NCAA’s advertising and promotional standards, which aim to “exclude those advertisements and advertisers ... that do not appear to be in the best interests of higher education and student-athletes.” “Advertising beer to a large number of collegians in the TV audience, many of them underage, betrays the intent of those policies, whether or not the advertising occurs between tip-off and final buzzer or during other parts of the same sports program,” the signatories concluded. See *CSPI Press Release and Advertising Age*, August 5, 2008.

The NCAA Division I Executive Committee, however, has reportedly declined to change the advertising policy. The committee announced its decision at its annual meeting in Indianapolis, where officials apparently agreed that the current restrictions were sufficient. “I think we’ve taken a very sensible, very rational, very conservative approach and we’ve asked that any company that advertises [alcohol] during our games continue to include the message ‘drink responsibly’ on its ads,” Adams was quoted as saying. “I think we’ve taken about as conservative an approach as any sport in the country. While not everyone agrees 100 percent, I think we represent what is a good balance in that opinion.” See *The Associated Press and Advertising Age*, August 7, 2008.



**[13] Fifth Annual PHAI Conference on Obesity
Set for September 2008**

The Public Health Advocacy Institute (PHAI) and Public Health Law & Policy will hold the [Fifth Conference on Public Health, Law and Obesity](#) at Northeastern University in Boston, Massachusetts, September 19-21, 2008.

Among the topics that will be addressed are (i) economic and social aspects of dietary behavior; (ii) the farm bill's implications for food reform, food marketing and potential regulatory strategies; (iii) menu labeling; (iv) regulatory solutions to increase physical activity; (v) major policy implications between childhood and adult and family obesity prevention; and (vi) disparity issues to be considered when making policy recommendations.

While meeting information is sparse, scheduled speakers include Professor of Nutrition Marion Nestle; Neville Rigby, Director of Policy and Public Affairs, International Obesity Task Force; Michel Chauliac, French Ministry of Health; and Paul Simon, Los Angeles County Department of Public Health. A discounted registration rate is available until August 15. The last PHAI obesity conference was held in late 2006; additional details appear in issue 192 of this Update.



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