Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

White House

[1] New Administration Puts Freeze on COOL Regulations

Among the first official acts of the Obama administration was a directive from White House Chief of Staff Rahm Emanuel to all federal departments and agencies not to finalize any pending rule and to extend final-rule effective dates for 60 days. According to a news source, the block affects a Department of Agriculture rule that established requirements for country-of-origin labeling (COOL) on meat and other perishable foods. A regulatory analyst for a Washington-based government watchdog group reportedly observed that the freeze would "give USDA an opportunity to tighten up the rule." Critics have apparently said that the Bush rule could weaken distinctions between U.S. and imported meats by allowing domestic facilities that process domestic and imported animals to carry a multi-country label. *See Bloomberg.com*, January 21, 2009.

U.S. Department of Agriculture (USDA)

[2] USDA Publishes Voluntary Standard for "Naturally Raised" Livestock Marketing Claim

The Agricultural Marketing Service (AMS) has issued a voluntary **standard** that livestock producers can use to verify "naturally raised" marketing claims with USDA. The standard apparently took into account more than 44,000 public comments from consumers, veterinarians, trade and professional organizations, national organic associations, consumer, agriculture and animal advocates, and retail and meat companies. AMS concurred with the majority of comments requesting "that the three core criteria proposed (animals raised without growth promotants and antibiotics and have never been fed mammalian or avian byproducts) should be a part of a naturally raised marketing claim standard," but declined to further narrow the scope of the standard because the agency felt additional restriction would limit its usefulness.

"A number of livestock producers make claims associated with production practices in order to distinguish their products in the marketplace," according to AMS. "This voluntary standard will allow livestock producers to utilize AMS' voluntary, third party verification services to provide validity to such naturally raised livestock claims and, in certain cases, access to markets which require AMS verification."

Food & Drug Administration (FDA)

[3] FDA Issues Final Guidance on Regulating GE Animals

The FDA has issued its final **guidance** on regulating genetically engineered (GE) animals under the new animal drug provisions of the Food, Drug and Cosmetic Act. The guidance clarifies FDA's regulatory authority "and provides recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law." It is intended to apply to GE animals with heritable rDNA constructs. According to the guidance, GE animals are being developed for a number of purposes, including the enhancement of production or food quality traits, improvements to animal health, the production of products for human therapeutic uses, and enhancement of animals' interactions with humans (e.g. hypo-allergenic pets). The FDA explains when GE animal producers must comply with labeling and record-keeping requirements or submit information for agency approval.

[4] Net Health Effects of Commercial Fish Consumption Topic of New FDA Risk Assessment

FDA this week published a draft **assessment** weighing the risks and benefits of fish consumption for children and the general population. The assessment considers the net health effects of fish consumption on fetal neurodevelopment, as well as fatal heart disease and stroke risk in the general population. FDA is seeking "to understand the relationship between the risk of not eating fish (and thus losing any health benefits fish may provide) and the risk of eating fish that contains methylmercury at the levels currently found in the commercial fish available to consumers."

The draft concludes that in respect to neurodevelopment, maternal consumption of fish species low in methyl mercury "has a significantly greater probability of resulting in a net benefit, as measured by verbal development." Although results also indicated "a significant probability of a net adverse effect for one-tenth of one percent of children," the FDA assessment finds that the highest net benefit and net adverse effect are "modest." In addition, "[f]or fatal coronary heart disease and stroke, commercial fish baseline consumption is averting a central estimate of over 30,000 deaths per year from coronary heart disease and over 20,000 deaths per year from stroke," according to FDA. The agency will accept public comments on the draft until April 21, 2009. *See Federal Register*, January 21, 2009; *InsideEPA.com*, January 23, 2009.

[5] FDA Seeks Comments on *Listeria* Risk Assessment

FDA has published a notice requesting comments, scientific data and information "that would assist the agency in its plans to conduct a risk assessment of the public health impact of foodborne *Listeria monocytogenes* in some ready-to-eat foods, sliced, prepared, and/or packaged in retail facilities." According to the notice, "[l]ittle is known about how *Listeria* contamination occurs in retail facilities. . . . There is thus a need to identify potential sources and practices that may increase *L. monocytogenes* contamination in retail settings and practices or interventions that could reduce or eliminate *L. monocytogenes* contamination of food products (sold to consumers at the retail level) and resulting human illness."

Comments and materials relevant to FDA's risk assessment must be submitted by April 21, 2009. The agency specifically requests data and information about (i) ready-to-eat food markets in the

United States; (ii) deli department characteristics; (iii) product contamination data; (iv) factors influencing the growth of the bacteria in cheese, deli meat and deli-type salad; (v) environmental contamination; (vi) factors influencing the environmental contamination and cross-contamination of food by *L. monocytogenes* in retail facilities; and (vii) identity and effectiveness of control measures. A 2003 risk assessment apparently found that among ready-to-eat foods, deli meats presented the highest risk per serving and the highest risk per annum for *Listeria* contamination. Unpublished USDA data evidently "estimated that most of the listeriosis cases attributed to ready-to-eat meat and poultry deli meats are from products sliced and packaged at retail." *See Federal Register*, January 21, 2009.

Occupational Safety and Health Administration (OSHA)

[6] OSHA Proposed Rulemaking Targets Diacetyl and Related Flavorings

OSHA has published an advance notice of proposed rulemaking, seeking data, information and comments about occupational exposure to diacetyl and food flavorings containing diacetyl. Diacetyl is a chemical used as a butter flavoring in products such as microwave popcorn, margarine, cooking sprays, snack foods, confectionaries, and other foods with dairy, butter and cheese flavors. Workers exposed to the chemical have reportedly developed respiratory impairments including a potentially fatal disease known as *bronchiolitis obliterans*. OSHA is considering developing a health standard regulating occupational exposure to diacetyl and food flavorings containing diacetyl and will accept comments until April 21, 2009.

The agency requests that commenters focus on more than 60 specific questions concerning levels of exposure, number of employees exposed, symptoms and diseases found in exposed employees, exposure mitigation measures, employee training, risk assessments, and potential costs of an exposure standard, among other matters. According to OSHA, which is also seeking information about related potential airway reactive substances often used in conjunction with diacetyl, such as acetoin, acetaldehyde, acetic acid, and furfural, "[a] number of studies, including several occupational investigations and case reports, have documented obstructive airway disease among employees exposed to airborne butter flavoring chemicals."

Information provided by the Flavor and Extract Manufacturers Association indicated that the U.S. flavorings industry uses some 228,000 pounds of diacetyl annually, and OSHA has "identified 139 establishments, employing an estimated 8,972 employees, that produce flavorings containing diacetyl." The *Federal Register* notice discusses investigations into popcorn factory employee illnesses and animal exposure studies. It also mentions several reports, including one from California's OSHA, that the agency is considering incorporating into its standard. Among the potential approaches to regulation that OSHA is considering are (i) permissible exposure limits, (ii) engineering controls, and (iii) respiratory protection. *See Federal Register*, January 21, 2009.

State and Local Governments

[7] Twin Cities Propose *Trans* Fat Bans and Menu Labeling Ordinances

Minneapolis and St. Paul are reportedly developing ordinances to require some restaurants to remove *trans* fats from their menus and to list calo-

ries alongside portions. St. Paul would require chain restaurants with 15 or more locations nationwide to abide by both proposed ordinances, while Minneapolis would apply its menu labeling regulation only to chain restaurants and its *trans* fat ban to all restaurants, groceries and bakeries. The city councils could take both measures under consideration as early as February.

Meanwhile, the executive president of the Minnesota Restaurant Association, David Siegel, told reporters that most restaurants have already phased out *trans* fat in response to public demand. In addition, he noted a growing desire for a federal benchmark with respect to menu labeling laws. "Let's give information to consumers and create a national standard like we did in grocery stores," said Siegel, pointing to the cost and frustration of navigating the current patchwork of localized regulations. *See The Star Tribune*, January 18, 2009.

Litigation

[8] Plaintiffs' Bar Prepares Litigation in National *Salmonella* Outbreak

With hundreds of foods containing potentially contaminated peanut butter being recalled daily, plaintiffs' lawyers across the nation have begun to file claims against producers, suppliers, retailers, and others in the supply chain. Food claims lawyer William Marler has reportedly brought an action against the Virginia-based Peanut Corp. of America on behalf of Vermont residents Gabrielle and Daryl Meunier whose 7-year-old son was among the nearly 500 people purportedly sickened by the *Salmonella Typhimurium* traced to a Peanut Corp. processing plant in Georgia. According to a news source, the Meunier's son spent six days in the hospital after consuming cheese and peanut butter crackers. A Minnesota-based food safety lawyer reportedly plans to file a claim against Peanut Corp. and its distributor, King Nut Companies, on behalf of the family of a 72-year-old woman who allegedly died in December 2008 after eating *Salmonella*-contaminated peanut butter served at a long-term care facility in Minnesota.

In recent days, foods that contain peanut butter and peanut paste, such as candies, cookie dough, ice cream, cereal, energy bars, ready-to-eat meals with peanut sauce, crackers, and even dog treats, have been subject to nationwide recalls. The Food and Drug Administration maintains a **list** of affected products and notes that, while animals will not likely be affected if they eat tainted products, people could ingest *Salmonella* if they do not wash their hands after handling the treats. Apparently, some 85 companies purchased peanut butter and peanut paste produced in the Georgia facility, and the *Salmonella* strain linked to the outbreak has reportedly been found in a package of crackers with peanut butter. The Center for Science in the Public Interest cited the peanut butter outbreak in a statement calling on the Obama administration to give the FDA more authority and resources. *See USA Today*, January 17, 2009; *The Wall Street Journal*, January 20, 2009; *Newsday*, *U.S. Food Law Report*, and *The Washington Post*, January 21, 2009; *CSPI Press Release,* January 22, 2009.

[9] Whole Foods Takes Due Process Claims Against FTC to Appeals Court

Whole Foods Market, Inc. has reportedly withdrawn from U.S. district court its due process challenge to the Federal Trade Commission's (FTC) antitrust proceedings against the company's merger with Wild Oats Markets, Inc. The case was then refiled before the D.C. Circuit Court of Appeals.

According to a Whole Foods executive, "Whole Foods Market is interested in getting to the merits of this case as quickly as possible rather than spending everyone's valuable time and resources arguing about jurisdiction. Filing with the Court of Appeals, which the FTC concedes has jurisdiction over the case, saves time and we want to move this case forward in the most expeditious manner for all concerned." Additional details about Whole Foods' petition appear in issue 285 of this Update. The FTC's administrative hearings are scheduled to begin April 6, 2009, and Whole Foods claims that the commission has already prejudged the case. *See PR Newswire*, January 15, 2009.

[10] Beef Hormone Dispute Headed to WTO

The European Commission has reportedly indicated that it will file a World Trade Organization (WTO) challenge to the U.S. decision to impose new tariffs on European Union (EU) products involved in sanctions stemming from a dispute over beef hormones. The EU has banned hormone-treated beef since the early 1980s, and the WTO ruled in 1998 that the ban violated trade rules, thus opening the door for U.S. and Canadian trade sanctions. While the EU contends that it has scientific grounds to support the ban, the United States and Canada have maintained their trade sanctions against the European bloc.

According to a French Roquefort cheese producer, 100 percent tariffs have been imposed on his products for nine years; a new sanctions update has increased the penalty to 300 percent. "Sales of Roquefort to the United States will be finished," he reportedly said. At issue is a Bush administration decision to suspend the existing sanctions, thus allowing Washington to revise its list of targeted products every six months. A commission spokesperson reportedly said this action would increase uncertainty for exporters and "is most regrettable in view of many attempts by the EU to find a solution to the long-standing trade dispute over hormone-treated beef. A large number of EU exporters will be hit by these illegal sanctions. We look forward to working with the new administration to address this situation." *See Agence France Presse*, January 15, 2009.

[11] Mass Tainted-Milk Action Filed in Chinese Court; Responsible Producers Sentenced to Death

More than 200 Chinese families whose children were sickened after consuming melamine-contaminated milk products have reportedly filed suit against a group of 22 milk producers before the Supreme People's Court in Beijing. Earlier class-action suits filed in Chinese courts were not accepted, so it is unclear whether this action will proceed. According to Lin Zheng, who is coordinating the litigation for a group of volunteer lawyers, this lawsuit includes four dead children not previously accounted for in government statistics. Lin also indicated that the lawyers will file another lawsuit on behalf of the survivors of a fifth unacknowledged dead child. The government reported that six children died and nearly 300,000 became ill with kidney stones and other problems. The latest action includes a demand for more than $5.2 million in compensation.

In a related development, a dairy middleman, convicted of selling 600 tons of melamine-tainted

"protein powder" to dairy companies, and another dairy producer were sentenced to death for their role in the scandal, according to news sources. A third man was also sentenced to death, but, with a two-year reprieve, he could be spared. The former chairwoman of the Sanlu Group, one of China's largest dairy companies and allegedly at the epicenter of the milk-contamination scandal, was sentenced to life in prison. She pleaded guilty for her failure to stop producing and selling the milk products even after learning they were defective and was also fined about US$3 million. Some of the victim's relatives reportedly thought she had gotten off lightly for her conduct and "should be shot."

The Intermediate People's Court in Shijiazhuang reportedly sentenced other company executives to five to 15 years in prison and imposed a fine of US$7.3 million on the company which recently filed for bankruptcy protection. Parents protesting outside the courtroom where the sentencing occurred were apparently dissatisfied with the outcome, calling for government officials to take responsibility. *See Product Liability Law 360*, January 20, 2009; *Associated Press*, January 20 and 22, 2009; *The New York Times*, January 21 and 23, 2009; and *GMA Food Safety Daily Digest* and *The Seattle Times*, January 22, 2009.

Other Developments

[12] Consumer Watchdog Criticizes NCAA for Alcohol Advertising Policy

The Center for Science in the Public Interest (CSPI) has criticized the National Collegiate Athletic Association's (NCAA's) policy on alcohol marketing during sanctioned events, claiming that beer was the "second most-advertised product" in the Final Four basketball tournament. CSPI allegedly found that beer promotions constituted 12 percent of all advertisements during the Final Four, but only 6 percent of those featured during the Bowl Championship Series, where "beer was the seventh most-advertised product."

The consumer watchdog has purportedly sent a letter to NCAA President Myles Brands, reiterating its long-standing request for NCAA to prohibit all alcohol advertising during its games. In addition, CSPI noted that hundreds of college presidents, athletic directors and coaches last year petitioned the association to further restrict its alcohol marketing policies. "The NCAA lags far behind other organizations when it comes to protecting its young audience from beer ads," stated CSPI's George Hacker. *See CSPI Press Release*, January 16, 2009.

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