

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Interagency Working Group on Import Safety

[1] Interagency Working Group Publishes Strategic Framework to Promote Import Safety

The Interagency Working Group on Import Safety has [announced](#) a public meeting slated for October 1, 2007, to “explore actions that public and private stakeholders can take to promote the safety of products imported into the United States.” Established by Executive Order on July 18, 2007, the working group is chaired by Department of Health and Human Services Secretary Michael Leavitt and includes officials from the departments of State, Treasury, Justice, Agriculture, Commerce, Transportation, and Homeland Security; the Office of Management and Budget; the Office of the U.S. Trade Representative; the Environmental Protection Agency; and the Consumer Product Safety Commission. The group has also released a report titled “[Protecting American Consumers Every Step of the Way: A strategic framework for the continual improvement in import safety](#),” which recommends increased interoperability as the “key” to developing more effective safety practices. In addition, the report concludes that an expansion of existing public-private partnerships and increased

international cooperation are critical to creating a safety environment based on three organizing principles: “Prevention, Intervention, Response.” “This will require shifting from reliance on ‘snapshots’ at the border to interdict unsafe products, to a cost-effective, prevention-focused ‘video’ model that identifies and targets those critical points in the import life cycle where the risk of unsafe products is at its greatest,” stated Leavitt in an introductory letter to President George W. Bush. The panel will release a follow-up report in November that describes agency-specific details. *See CQ HealthBeat News*, September 10, 2007.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

[2] TTB Proposed Changing Alcohol Labeling Requirements

TTB has issued a [notice](#) of proposed rulemaking to bring current labeling regulations for wines, distilled spirits and malt beverages into conformity with a World Wine Trade Group Agreement. The only change contemplated is to allow alcohol content to appear on “other labels affixed to the container rather than on the brand label as currently required.” Comments on the proposed rule must be submitted on or before November 13, 2007. *See Federal Register*, September 11, 2007.



Food and Drug Administration (FDA)

[3] FDA Addresses Sugar-Free Labeling in Industry Guidance Letter

FDA this week issued a [guidance letter](#) to the food industry urging companies to review their labeling practices for products marketed as “sugar-free,” “free of sugar,” “zero sugar,” or “sugarless.” Products that are not low or reduced in calories but purport to be sugar-free must also display a disclaimer (“not a reduced calorie food,” “not a low calorie food” or “not for weight control”) in prominent lettering at least 1/16-inch in height. In addition, labels must note a sugar-containing ingredient with one of the following statements: “adds a trivial amount of sugar,” “adds a negligible amount of sugar,” or “adds a dietarily insignificant amount of sugar.” FDA, which has already sent a [warning letter](#) to Oberlander Baking Co., stated that it “intends to take appropriate action against products” that “fail to meet each of the requirements of the regulation that defines ‘sugar-free.’” The agency expressed particular concern that mislabeled sugar-free products might deceive consumers who are looking for weight-control aids. *See FoodNavigator-USA.com*, September 6, 2007.

In a related development, FDA recently held a [public hearing](#) to gather information about supplemental symbols currently used by some U.S. food manufacturers and overseas governments to categorize the healthfulness of their products. The British government, for example, recently instituted a “traffic light” system that uses red, yellow and green dots to signify the relative nutritional value of a food product. FDA is reportedly considering whether a similar nationwide program would alleviate any confusion caused by competing campaigns, such as PepsiCo, Inc.’s Smart Spot™ and Hannaford Bros.

three-star rating, but has stressed that the agency is still in the information-gathering stage. Meanwhile, lawmakers and consumer advocate groups have urged Congress to enact legislation compelling the agency to implement a federally approved system. “The proliferation of different nutrition symbols on food packaging, well-intended as it may be, is likely to further confuse, rather than assist, American consumers who are trying to make good nutrition choices for themselves and their families. FDA should take meaningful steps to establish some consistency to these many different nutrition symbols,” U.S. Senator Tom Harkin (D-Iowa) was quoted as saying. *See Associated Press*, September 10, 2007.

[4] FDA Evaluates Consumer Risk from Common Popcorn Additive

FDA has reportedly started evaluating whether the butter-flavoring agent diacetyl poses a risk to consumers when inhaled. Diacetyl has been linked to bronchiolitis obliterans, a lung disease characterized by scarred and swollen airways, in popcorn plant workers routinely exposed to the heated form of the chemical. In a July [letter](#) to FDA, a pulmonary specialist with Denver’s National Jewish Medical and Research Center identified the first possible case of “popcorn worker’s lung” in a 53-year-old man who ate multiple bags of popcorn daily and often inhaled “the fragrance because he liked it so much.” “That’s heated diacetyl, which we know from workers’ studies is the highest risk,” said Dr. Cecile Rose, who also found that the man’s home was saturated with popcorn-factory levels of diacetyl. “This is not a definitive causal link, but it raises a lot of questions and supports the recommendation that more work needs to be done.” *See Associated Press and The New York Times*, September 5, 2007.



Meanwhile, several popcorn manufacturers, including ConAgra Foods Inc., have announced plans to phase out the chemical. “While we are fully confident that microwave popcorn is safe for consumers to prepare and consume, we plan to eliminate the use of added diacetyl in products in order to eliminate even the perception of risks for consumers and to provide our employees who handle large quantities of diacetyl with the safest possible work environment,” a ConAgra spokesperson was quoted as saying. In addition, the U.S. Centers for Disease Control and Prevention last April concluded that workers at food-flavoring factories are equally at risk of contracting the condition, a conclusion backed by a recent Dutch study that allegedly discovered bronchiolitis obliterans in workers from a diacetyl manufacturing plant. *See FoodNavigator-USA.com*, September 3, 2007; *The Wall Street Journal*, September 6, 2007.

Environmental Protection Agency

[5] EPA Workshop to Address Draft Document on Child-Specific Exposure Factors

EPA this week [announced](#) that independent contractor Eastern Research Group, Inc. will convene an expert panel and peer-review workshop on September 19-20, 2007, to review the draft document titled “Child-Specific Exposure Factors Handbook.” Prepared by the EPA’s National Center for Environmental Assessment, the handbook summarizes “statistical data on various exposure factors used in assessing children’s exposures, including: Drinking water consumption; soil ingestion and mouthing behavior; inhalation rates; dermal factors including skin surface area and soil adherence factors; consumption of retail and home-grown products; breast milk intake; and human

activity pattern data.” In its final form, the document will aid exposure assessors in estimating children’s exposures. EPA will consider the expert panel review and public comments received at the workshop in preparing its final report on the handbook.

European Union (EU)

[6] EU Delays Reinstatement of British Meat Exports After Recurrence of Foot-and-Mouth Disease

The EU has reportedly suspended its decision to lift an export ban on British meat, dairy products and livestock after U.K. officials this week confirmed a new case of foot-and-mouth disease (FMD) in Engham, Surrey. An outbreak in July and August 2007 first caused EU veterinary experts to issue the quarantine, but they had agreed to declare Britain FMD-free as of November 9 if no new cases were reported. The country’s Health and Safety Executive had also concluded that it was “highly likely” the initial incident stemmed from a faulty drainage system shared by a government-funded institute and a private laboratory, both of which were working with strains of the FMD virus. *See Reuters*, September 12, 2007.

Litigation

[7] Federal Court Rejects NYC Calorie-Posting Regulation for Chain Restaurants

A federal court in New York has determined that New York City’s attempt to force chain restaurants to display calorie-content information on their menu boards and menus is preempted by federal law. [N.Y. State Rest. Ass’n v. NYC Bd. of Health, No. 07-5710 \(U.S. Dist. Ct., S.D.N.Y., decided](#)



September 11, 2007). Adopted in December 2006, the regulation was scheduled to take effect on July 1, 2007. It was limited to restaurants that made public the caloric content of their menu items and would have affected about 10 percent of the restaurants in New York City, including chains such as McDonald's. The regulation was challenged in federal court by the New York State Restaurant Association, which raised constitutional- and preemption-based issues in its lawsuit.

Sidestepping any constitutional considerations, the court said that the only issue it was called on to decide was whether the labeling regulations were "within the City's province or exclusively a matter for federal regulation." The court observed that such legislation was under consideration in a number of other jurisdictions but noted a significant distinction between the differing versions, i.e., those that required all restaurants to post such information or those, like New York City's, that required only restaurants already voluntarily providing such information to post nutrition information on their menu boards. After conducting an exhaustive analysis, the court found this distinction critical under the federal Nutrition Labeling and Education Act of 1990 (NLEA), stating "[b]y making its requirements contingent on a *voluntary* claim, Regulation 81.50 directly implicates § 343(r) [of the NLEA] and its corresponding preemption provision." Essentially, the NLEA exempts restaurants from the mandatory federal labeling laws that apply to packaged food, but once they volunteer nutritional information, they are subject to Food and Drug Administration regulations that preempt state and local laws.

The court was careful to point out that the majority of regulations in other jurisdictions are not preempted under federal law because they "impose a blanket mandatory duty on all restaurants meeting

a standard definition such as operating ten or more restaurants under the same name. There is no voluntary aspect to such a disclosure requirement and no basis for arguing that the mandated disclosures are more properly considered the regulation of voluntary claims subject to § 343(r)." (citation omitted). Thus, according to the court, the city "has the power to mandate nutritional labeling by restaurants," but did so "in a manner that offends the federal statutory scheme for voluntary nutritional claims."

The decision was widely reported in the media, and while the restaurant association was apparently pleased with the decision, a spokesperson expressed caution about its implications. The city is reportedly considering whether to revise the regulation in a way that would satisfy the court. In a related development, on September 10, California became the first state in the country to require fast-food restaurants to post calorie information on their menu boards. Similar legislation is reportedly pending in 13 other states, Chicago, Philadelphia and Washington, D.C. *See CSPI Press Release*, August 30, 2007; *MSNBC.com* and *Associated Press*, September 11, 2007; *The New York Times*, September 12 and 13, 2007.

Meanwhile, the Los Angeles City Council is apparently discussing a proposed ordinance that would place a two-year moratorium on the opening of new fast-food restaurants in South Los Angeles, a tactic that has been dubbed "health zoning." According to a news source, this community has the highest concentration of fast-food eateries and higher obesity rates than in other parts of the county. If approved, the ordinance would reportedly affect more than 700,000 residents. *See The Los Angeles Times*, September 10, 2007; *MSNBC.com*, September 11, 2007.



[8] Snack Maker Responds to *Salmonella* Complaint

The maker of the Veggie Booty snack food has filed its [answer](#) to one of the [complaints](#) filed by attorney William Marler on behalf of New York residents for alleged *Salmonella* poisoning. *Scheels v. Robert's Am. Gourmet Food, Inc.*, No. 5447/07 (Supreme Court, New York, Albany County, answer filed August 23, 2007).

This case involves claims that the two Scheels children became ill with fever, diarrhea and pain after they ate the snacks. Stool samples allegedly tested positive for *Salmonella* wandsworth. While denying any wrongdoing, Robert's American Gourmet Food, Inc. raises a number of affirmative defenses including the company's compliance with local, state and federal laws, the plaintiffs' failure to mitigate damages and modification of the product after it left the manufacturer's control.

In a related development, the snacks manufacturer has apparently filed a third party complaint in the *Allen* litigation that is also being handled by Marler's law firm. Further details about that case appear in issue 222 of this Update. According to Marler, the defendants, spice and seasoning companies, are two "upstream suppliers of ingredients." See *Marlerblog.com*, September 7, 2007.

[9] Justice Department Decides to Drop Prosecutions Against Chiquita Executives

In a sentencing memorandum asking a federal judge to impose a \$25 million fine on Chiquita Brands International, Inc. for paying Colombian terror organizations to protect its operations in that country, the U.S. Justice Department has also indicated that it will not prosecute company executives. As we reported in issue 225 of this Update, a grand

jury was investigating whether to recommend charges against individual executives. According to the Justice Department, the charges will be dropped "based solely on the merits and evidence" against the executives. Chiquita had voluntarily reported the deals in April 2003 and admitted to paying \$1.7 million to the United Self-Defense Forces of Colombia, which the U.S. government designated a terrorist group in 2001. A sentencing hearing on the corporation's plea will reportedly be held September 17, 2007. The company will also serve five years' probation. See *The Wall Street Journal*, September 12, 2007.

[10] Court Approves Settlement of Tainted Spinach Claims

A federal court in Utah has approved the settlement of personal injury claims made by the mother of a child allegedly sickened during the *E. coli* outbreak that occurred in 2006 from tainted spinach. *Leafy v. Natural Selection Foods, LLC*, No. 2:06-00787 (U.S. Dist. Ct., D. Utah, order entered August 24, 2007). The plaintiff was represented by William Marler, a Washington-based attorney who specializes in food-poisoning litigation. The case settled for \$42,750.

[11] U.K. Food Executive Sentenced to Jail for *E. Coli* Outbreak

A South Wales meatpacking executive has reportedly been sentenced to one year in jail after pleading guilty to seven charges relating to an *E. coli* outbreak in September 2007 that sickened 157 and resulted in one death. William John Tudor headed the company that supplied meat to local area schools. Evidence reportedly showed that he instructed employees not to use a certain piece of equipment to pack cooked meat when food inspectors were present, but it was otherwise used for



both raw and cooked meats, allowing raw meat juices to taint cooked meats during the packaging process. See *FoodNavigator-USA.com*, September 10, 2007.

Legal Literature

[12] Products Liability Publication Revised to Include GMO Issues

A Thomson/West products liability publication on design and manufacturing defects has been revised with new sections about genetically modified organisms (GMOs) used in food production. According to author Thomas Redick, such “foods are subject to extensive regulatory review” by federal agencies. Redick also notes, “There are no recorded cases to date that are confirmed to have resulted from the use of [GMOs]. Activists opposed to the use of genetic engineering cite to the injuries sustained from a rare blood disorder ‘eosinophilia myalgia syndrome’ that was linked to consumption of the amino acid l-tryptophan tablets sold as a natural alternative to various medications during the late 1980s.” Nevertheless, “no link to the impurity traced to the bacterium [that created the food product] could be established.” Redick reports that product liability prevention programs for GMO foods are being developed by all the major GMO manufacturers. Redick also authored a GMO section related to “failure to warn of idiosyncratic reaction to GM foods.” He discusses several cases where courts have addressed idiosyncratic reactions to non-GMO products, noting that most do not impose liability. He cautions, however, “With the advent of genome mapping, which is revealing idiosyncracies at the genetic level, there will be an increasing number of genetic susceptibilities to various chemicals, radiation or food products that may trigger a duty to

warn the susceptible subgroup.” See *Product Liability: Design and Mfg. Defects* §§ 4:6 & 4:7 (September 2007).

Other Developments

[13] CFA National Food Policy Conference to Highlight Imported Food

The Consumer Federation of America (CFA) in conjunction with the Grocery Manufacturers Association/Food Products Association has announced its annual [National Food Policy Conference](#) slated for September 27-28, 2007, in Washington, D.C. The conference will cover issues related to imported food, alternative fuel policies and 30 years of U.S. food policy. Breakout sessions will address childhood obesity, food safety, food issues in the media, the Farm Bill, and agricultural sustainability. Billed as a “unique collaboration between consumer advocates, government and the food industry,” speakers will include House Agriculture Committee Chair Collin Peterson (D-Minn.) and Agriculture Secretary Mike Johanns.

Scientific/Technical Issues

[14] Study Links Food Additives to Hyperactive Behaviors in Children

A recent U.K. study has claimed that some artificial food additives can amplify hyperactive behaviors in children ages 3, 8 and 9. Donna McCann, et al., “Food additives and hyperactive behavior in 3-year-old and 8/9-year-old children in the community: a randomized, double-blinded, placebo-controlled trial,” *The Lancet*, September 6, 2007. The University of Southampton researchers followed nearly 300 children given fruit drinks containing a mixture of food colorings and the preservative



sodium benzoate. These children and a control group that received an additive-free placebo drink were then evaluated by parents, teachers and through a computer test. “A mix of additives commonly found in children’s foods increases the mean level of hyperactivity,” the researchers concluded, also noting that the effects were observed, not just in children with extreme hyperactivity, but in “the general population and across the range of severities of hyperactivity.” *See Reuters*, September 5, 2007; *The New York Times*, September 6, 2007.

Meanwhile, the British Food Standards Agency, which funded the study, has revised its advice regarding food additives and said that eliminating several artificial colorings from hyperactive children’s diets could have “some beneficial effects.” The agency recommended that concerned parents avoid the colorings and preservative implicated in the study, including: Sunset yellow (E110), Quinoline yellow (E104), Carmoisine (E122), Allure red (E129), Tartrazine (E102), and Ponceau 4R (E124); and Sodium benzoate (E211). In addition, the European Commission has asked EU food safety officials to review the research and issue a report on the impact of food additives on children’s health. “If parents are concerned about any additives they should remember that, by law, food additives must be listed on the label so they can make the choice to avoid the product if they want to,” said FSA Chief Scientist Andrew Wadge. “However, we need to remember that there are many factors associated with hyperactive behavior in children. These include genetic factors, being born prematurely, or environment and upbringing.” *See The Wall Street Journal*, September 6, 2007; *FSA Press Release*, September 7, 2007.

The British Soft Drinks Association (BSDA) has also responded that the results are not definitive enough to warrant the reformulation of products. “It should be noted that this study used a mixture of ingredients in each trial and due to the nature of the research, the effect of individual colors on the behavior of children surveyed could not be determined,” stated a BSDA press release. “In view of this, we support [the Food Standards Agency’s] decision for this study to be considered by the European Food Safety Commission.” *See FoodNavigator-USA.com*, September 6, 2007.

[15] Researchers Find Soft Drinks Not Solely Responsible for Obesity in Children

British nutrition consultants have reportedly found that children with a higher body mass index (BMI) consume 300 calories more per day than children with lower body weight, and of those extra calories, only 5 percent, or about 14 calories, can be attributed to soft drink consumption. Sigrid Gibson & Deborah Neate, “Sugar Intake, Soft Drink Consumption and Body Weight Among British Children,” *International Journal of Food Sciences and Nutrition* (Vol. 58, Issue 6). The independent researchers concluded that the study of 1,294 children between the ages of 7 and 18 did not demonstrate any “specific” role for sweetened beverages in the incidence of obesity among British youth. They reportedly suggest that overeating and physical inactivity are more significant factors in increased BMI. The study did find a correlation between increased risk of obesity and soft drinks among those higher weight subjects who consumed large quantities of soft drinks. *See FoodUSANavigator.com*, September 12, 2007.



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