Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Interagency Working Group on Import Safety

[1] Interagency Working Group Issues "Roadmap" to Achieve Import Safety

The Interagency Working Group on Import Safety this week published its "**Action Plan for Import Safety: A Roadmap for Continual Improvement**," which builds on the strategic framework first released in September 2007. Headed by HHS Secretary Mike Leavitt, the working group includes representatives from 12 federal agencies charged with studying import safety on behalf of the White House. This latest report offers 14 broad recommendations and 50 specific action steps that fall "under the organizing principles of prevention, intervention and response and expand upon the building blocks identified in the Strategic Framework." The working group specifically suggests that import safety and inspection agencies (i) focus resources on high-risk products and areas; (ii) increase the number of inspectors stationed in exporting countries; (iii) establish a certification program for high-risk products; (iv) create a publicized list of certified manufacturers and importers; (v) generate incentives to encourage importers of high-risk products to follow safety procedures; and (vi) strengthen penalties for unsafe products. The action plan also calls on Congress to grant FDA the authority to issue mandatory recalls and to give all agencies the ability to reinforce their standards. Members of the working group have agreed to meet within 30 days to assess the plan's progress and discuss possible opportunities to collaborate with the private sector. "Implementation of this Action Plan will require expanded legal authorities, improved collaboration and capacity building with our trading partners, improved collaboration with state and local governments and the private sector, increased information gathering, and the discovery and application of new science," conclude the authors of the report. "Implementation of the recommendations will require resources, including reallocation of existing sources, as well as trade-offs, to fund these priorities." *See The Wall Street Journal*, November 3, 2007; *USDA Press Release* and *Associated Press*, November 5, 2007; *The New York Times*, November 6, 2007; and *Meatingplace.com*, November 7, 2007.

Meanwhile, critics have expressed disappointment that the plan, while seeking greater FDA authority, fails to "address the absurdity of the status quo, where two separate food agencies, under two separate cabinet secretaries, each run two separate and unequal import programs," according to a press release issued by the Center for Science in the Public Interest. "Blandly calling for 'enhanced cooperation' between FDA, USDA and other agencies is unlikely to bring about the same kind of efficiency that a single strong food safety agency would,"

stated CSPI, which also derided the report as "woefully short on specifics." Agency officials, however, have dismissed such critiques as impractical. "We do not believe a single food agency would give us the efficiencies you can have from having two agencies responsible for 99 percent of the food that we eat in this country, both domestic and imported," USDA Undersecretary for Food Safety Richard Raymond was quoted as saying. *See The Washington Post*, November 5, 2007; *CSPI Press Release*, November 6, 2007.

Food and Drug Administration (FDA)

[2] FDA Unveils Food Protection Plan to Address Food Safety and Defense

FDA this week released a "**Food Protection Plan**" that aims to address "both food safety and food defense for domestic and imported products." Integrated with the action plan recently issued by the Interagency Working Group on Import Safety, the "Food Protection Plan" outlines several administrative actions designed to (i) prevent foodborne contamination, (ii) intervene at critical points in the food supply chains and (iii) respond rapidly to minimize harm. The agency specifically intends to "promote increased corporate responsibility" in foodborne illness prevention; focus inspections and sampling based on risk; and improve risk communications to the public, industry and other stakeholders. In addition, FDA has recommended several "legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illness." The plan calls on Congress to expand FDA's authority to (i) require and enforce preventative controls for high-risk food; (ii) accredit qualified third parties for voluntary food inspections; (iii) implement new import and export certification measures; and (iv) issue mandatory recalls when voluntary actions are not effective. To meet these goals, the agency has also included a proposal to enhance its information technology systems related to both domestic and imported foods. "In the United States, market forces give companies a strong motivation to be vigilant and even innovative in ensuring food safety. The laws of regulation must encourage, not disrupt, these motivations," the FDA plan concludes. "Rather than taking over responsibility from food companies, FDA wants to protect their flexibility to pursue it vigorously." *See CQ Healthbeat News*, November 6, 2007.

[3] FDA Seeks Comment on New Reference Values for Food and Food Supplement Labels

The FDA has issued an advance **notice** of proposed rulemaking (ANPR) seeking comment "on what new reference values the agency should use to calculate the percent daily value (DV) in the Nutrition Facts and Supplement Facts labels and what factors the agency should consider in establishing such new reference values." Comments must be submitted on or before January 31, 2008.

The current values are based on information available when FDA issued rules in 1993 to implement the Nutrition Labeling and Education Act of 1990. According to the FDA, "[n]ew information has since become available on nutrient values that the agency believes may impact what nutrients it should consider requiring to be listed on the food label and what nutrient values it should use as a basis for the DVs on the food label." Among the sources of new information cited are revisions to the Dietary Guidelines for Americans and the Institute of Medicine's reports on the Dietary Reference Intakes

"that update recommendations for the intake of vitamins, minerals, and macronutrients." These reports apparently spurred discussion among scientists and led the agency to seek comment on the recommendations they made.

The ANPR explains how the FDA came to require information on food labels such as calorie content, fats, sodium, sugars, protein, and vitamins and why certain vitamins were singled out for inclusion, i.e., "because of public health concerns relative to inadequate intake of these nutrients by specific portions of the population, as well as the possible association between the lack of several of these nutrients in the diet and the risk of chronic disease." According to the agency, DVs are used to determine partly "whether a food or dietary supplement is eligible to bear nutrient content or health claims." The ANPR notes that the current DV for fat is 65 grams per day, which could change to 62 g/d if the agency decides to adopt the approach recommended by the Institute of Medicine. The notice also contains lists of specific questions to which the FDA is seeking comment, and the agency advises commenters to provide scientific justification with any response. *See Federal Register*, November 2, 2007.

U.K. Food Standards Agency (FSA)

[4] FSA Reports on Meeting with Food and Drink Makers to Discuss Food Additives

The FSA has released a **report** on its recent meeting with food and drink industry representatives to discuss the removal of food colorings and sodium benzoate from foods because of their purported detrimental effect on children's behavior. A number of industry representatives reported that they had already begun to remove such substances from their products. The agency is considering setting a voluntary October 2008 deadline for retailers and manufacturers to do so and may take regulatory action if they do not comply. FSA has also issued a letter to a number of stakeholders, including trade associations, restaurateurs and retailers, seeking answers by December 14, 2007, to questions such as "What actions have you/your members already taken concerning the food colors used in the Southampton study?" "Are you/your members planning any further action?" "What is the planned timescale for those further actions?" Additional information about the Southampton study, which purportedly showed that common colorings and other additives in the foods children eat may be responsible for behavioral problems, appears in issue 215 of this Update. *See FoodNavigator-USA.com*, November 6, 2007.

State and Local Governments

[5] New Jersey AG Calls for Vigilance in Hamburger Recall

New Jersey's attorney general is apparently advising other states' consumer protection officials to step up their inspections of retail stores for hamburgers produced by the Topps Meat Co. that were recalled for potential *E. coli* contamination. Apparently, New Jersey investigators continue to find the recalled beef for sale in grocery stores. According to Attorney General Ann Milgram, "It is unacceptable that consumers can walk into a store and find these recalled contaminated products on the shelf, readily available for purchase and consumption, more than one month after the voluntary recall was announced." She called for additional public notice and outreach to retailers and consumers. *See N.J. Office of Attorney General Press Release*, November 7, 2007.

Litigation

[6] Court Interprets Insurance Policy Covering Claims of Injury from Diacetyl Exposure

A New York appeals court has ruled that the company sued by microwave popcorn factory workers must pay a deductible as to each worker injured, finding that "each of the underlying personal injury plaintiffs' claims constitutes a separate 'occurrence' under the primary insurance policies." *Int'l Flavors & Fragrances, Inc. v. Royal Ins. Co. of Am.*, No. 2007-08122 (N.Y. Appellate Div., First Dept., decided October 30, 2007). According to the court, "there was no single incident that can be identified as the event resulting in injury to the numerous claimants. The affected employees sustained injury as a consequence of repeated deliveries of IFF's flavoring compound to their workplace over a period of several years, causing them to be exposed to the hazardous chemicals at different times and for periods of unequal duration." Thus, said the court, under the policies' definition of "occurrence," "the exposure of numerous persons to a hazardous condition cannot be deemed a single 'occurrence' in the absence of any identifiable precipitating event or 'accident.'" Because the parties were "sophisticated," the court said "it would have been a simple matter to rewrite the definition" so as to aggregate individual claims.

[7] Jury Awards $3.3 Million to Nicaraguan Banana Plantation Workers

A Los Angeles, California, jury has reportedly found chemical companies and a banana plantation operator liable for injuries to six workers who alleged they became sterile after exposure to a pesticide used at the plantation. The jury, which awarded $3.3 million in compensatory damages after three weeks of deliberation, was reportedly scheduled to return to the courtroom to determine whether Dole and Standard Fruit Co. acted maliciously and, if so, to make a punitive damages determination. Defendant Dow Chemical Co. was reportedly pleased with the verdict, because the jury found no liability as to six of the 12 workers who sued the companies. The legal community has been watching the case with some interest; it raises the issue of whether international corporations can be held liable in the countries in which they are based or where they employ workers. This case was the first of five lawsuits involving thousands of workers from plantations in Ecuador, Nicaragua, Costa Rica, Guatemala, Honduras, and Panama, with similar allegations. Hundreds of former banana workers, meanwhile, are apparently camping in front of Nicaragua's National Assembly awaiting an out-of-court settlement with Dole. *See Associated Press*, November 5, 2007

Other Developments

[8] Whole Foods Amends Code of Business Conduct to Prohibit Internet Postings

The board of Whole Food Market Inc. has reportedly amended the company's code of business conduct to prohibit executives and other officials from posting messages about the natural-food chain, its stock or its competitors on third-party Web sites. The board announced its decision amid an informal Securities and Exchange Commission inquiry into 1,000 online messages boasting about Whole Foods' shares and criticize rivals. The rule, which applies to "company leadership," forbids anonymous postings by directors, executive team members and regional vice presidents and exhorts them "to avoid the

actual and perceived improper use of company information, and to avoid any impression that statements are being made on behalf of the company." The Whole Foods board has submitted the revised code of business conduct to the SEC. *See The Wall Street Journal*, November 7, 2007.

[9] French Vintners Clash with Government over Health Warning Labels

The French government this month implemented a law requiring wine labels to display a mandatory warning meant to discourage pregnant women from consuming alcoholic beverages. Described by *The Washington Post* as "the latest skirmish in a Europe-wide governmental assault on expanding waistlines, high alcohol consumption and the Continental love affair with cigarettes," the regulation has become a hot-button issue with French vintners and consumers alike who have contested the French National Health Institute's recommendation that pregnant women avoid alcohol on "all occasions, whether daily, specific or festive." Although French officials have reportedly documented at least 3,000 cases of fetal alcohol syndrome annually, many wine enthusiasts have described the barely-legible warning as unclear and potentially ineffective. "The government wanted to ease their conscience with such a logo and please anti-alcohol associations," one champagne producer was quoted as saying. "But in the end, consumers remain confused." *See The Washington Post*, October 29, 2007.

Media Coverage

[10] Michael Pollan, "Weed It and Reap," *The New York Times*, November 4, 2007

"Like the House bill passed in July, the Senate product is very much a farm bill in the traditional let-them-eat-high-fructose-corn-syrup mold," writes *New York Times* op-ed contributor Michael Pollan in this article about the current farm bill's alleged failure to address "the entire hoary contraption of direct payments, countercyclical payments and loan deficiency payments that subsidize the five big commodity crops – corn, wheat, rice, soybeans and cotton – to the tune of $42 billion over five years." Pollan argues that unless Congress confronts the bill's commodity title, the special programs added to appease "the hunger lobby," environmentalists and health advocates will remain "mere fleas on the elephant in the room." "We would not need all these nutrition programs if the commodity title didn't do such a good job of making junk food and fast food so ubiquitous and cheap," he opines. "We would not need all these conservation programs if the commodity title, by paying farmers by the bushel, didn't encourage them to maximize production with agrochemicals and plant their farms with just one crop fence row to fence row."

The American public, according to Pollan, "has begun to ask why the farm bill is subsidizing high-fructose corn syrup and hydrogenated oils at a time when rates of diabetes and obesity among children are soaring, or why the farm bill is underwriting factory farming (with subsidized grain) when feedlot wastes are polluting the countryside and, all too often, the meat supply." Pollan notes that several senators have proposed amendments to Senator Tom Harkin's (D-Iowa) version of the farm bill, which will be challenged on the floor and later in the conference committee. Senators Byron Dorgan (D-N.D.) and Chuck Grassley (R-Iowa) have reportedly introduced a measure to cap at $250,000 the payment any one farmer can receive in a year, thus

reallocating $1 billion for other purposes and slowing "the consolidation of farms in the Midwest." In addition, Senators Richard Lugar (R-Ind.) and Frank Lautenberg (D-N.J.) have argued for replacing the subsidy system with free government revenue insurance for all American farmers and using the $20 billion in savings for special programs and deficit reduction. "If the eaters and all the other 'people on the outside' make ourselves heard, we might just end up with something that looks less like a farm bill and more like the food bill a poorly fed America so badly needs," concludes Pollan, who ultimately believes that "the politics have changed, and probably for good."

[11] Andrew Bridges, "Battle Over 'Natural' Food Designation," *The Washington Post*, November 7, 2007

This article examines the latest squabble at the U.S. Department of Agriculture and Food and Drug Administration over the circumstances under which food products can properly be labeled "natural." Noting that a number of chicken producers inject their "all natural" birds with salt water and broth, a practice some call fraudulent, journalist Andrew Bridges reports that even Michael Jacobson, executive director of the Center for Science in the Public Interest, finds the issue confusing; he was quoted as saying, "It's worth bringing in the rabbis to analyze these situations because it's complicated, it's subtle. You can argue from both sides. It has fine distinctions." Petitions, comments and lawsuits have been filed over the matter involving foods ranging from poultry, beef and pork to soft drinks and other products containing high-fructose corn syrup. The final word is given to a Consumers Union scientist and policy analyst who observed, "The 'natural' thing has always been such a morass."

Scientific/Technical Items

[12] *JAMA* Study Associates BMI with Cause-Specific Excess Deaths

Based on death statistics for 2.3 million adults in the United States and cause-specific relative risks of mortality from the National Health and Nutrition Examination Survey (NHANES), government researchers reported this week that being overweight "was associated with significantly decreased mortality from . . . noncancer, non-CVD causes [other than diabetes and kidney disease]; and was not associated with mortality from cancer or cardiovascular disease." Katherine Flegal, et al., "Cause-Specific Excess Deaths Associated with Underweight, Overweight, and Obesity," *JAMA*, November 7, 2007. Underweight, on the other hand, was associated with increased mortality from noncancer, non-CVD causes, while obesity was associated with increased mortality primarily from CVD and from some cancers, diabetes and kidney disease. Accordingly, the authors conclude that "the association of BMI [body mass index] with mortality varies considerably by cause of death. These results help to clarify our earlier findings of excess overall mortality associated with underweight and obesity but not with overweight."

Reactions to the study have been mixed, with some health experts warning that the results may be misleading. An American Heart Association spokesperson observed that diabetes and heart disease often coincide and both afflict overweight people, so when diabetes is listed as a cause of death, heart disease could have contributed. Others argue that health is more than just mortality rates and that excess weight impairs the quality of life. For example, high blood pressure and cholesterol

or other conditions that can lead to heart attacks can be costly and debilitating in their own right without leading to death. A spokesperson for the American Cancer Society said this study "definitely won't be the last word," and pointed to recommendations for preventing cancer from the World Cancer Research Fund and the American Institute for Cancer Research calling for people to stay slim. Nevertheless, some researchers say that people can be fit and fat, a concept seemingly finding support in the new study. *See msnbc.com*, November 6, 2007; *The New York Times*, November 7, 2007.

[13] Researchers Study Tobacco and Obesity-Related TV Advertising

University of Illinois at Chicago researchers have published a study that compares anti-tobacco TV advertising and its effect on behavior with advertising designed to prevent obesity. Sherry Emery, et al., "Public Health Obesity-Related TV Advertising, Lessons Learned from Tobacco," *Am. J. of Preventive Med.*, October 2007. They conclude that while "evidence from tobacco control suggests that anti-obesity media campaigns could be expected to contribute to reductions in the nationwide obesity epidemic," differences between smoking and obesity-related behaviors can influence the "potential impact" of anti-obesity media messages. While those behaviors differ, the respective environments in which public health campaigns operate also differ. The researchers note, for example, that tobacco-related advertising accompanies important tobacco control policies, such as cigarette taxes and clean indoor air laws, whereas "there are currently a limited number of regulations related to obesity." In addition, tobacco-related promotions no longer occur on television, while "food advertising constitutes the single largest advertising category on children's TV, and ads for sugary children's cereals comprise a substantial proportion of these food ads." The article concludes by calling for more research.

[14] Two Studies Urge Caution on Energy Drinks

A recent study presented to the American Heart Association has claimed that energy drinks containing caffeine and the amino acid taurine may contribute to increased heart rate and blood pressure. Researchers asked a group of 15 volunteers, whose average age was 26, to abstain from all caffeine for two days preceding the study and then to consume two cans of energy drinks daily over a seven-day period. With each can reportedly containing 80 mg. of caffeine and 1,000 mg. of taurine, the participants' hearts rates rose by approximately 8 percent on the first day and 11 percent on the seventh day. In addition, the study found that maximum systolic blood pressure increased by 8 percent on the first day and 10 percent on the seventh day, while diastolic blood pressure went up by 7 percent on the first day and 8 percent on the seventh day. "While the amount of caffeine in energy drinks or coffee may cause a slight and temporary increase in blood pressure, it would have no greater effect than walking up a flight of stairs," a spokesperson for the American Beverage Association said in response to the study, which has advised people with high blood pressure or heart disease to avoid energy drinks. "So singling out energy drinks in a unique manner, particularly when compared to a more commonly consumed caffeinated beverage like coffee, does not provide a full and proper context for consumers." *See Reuters*, November 6, 2007.

Meanwhile, a Wake Forest University study has concluded that compared to young people who just

drink alcohol, those who mix energy drinks with alcohol are twice as likely to suffer injuries, require medical attention and travel with a drunk driver. The study surveyed over 4,000 U.S. students about their drinking habits, finding that those using energy drinks as mixers drank up to 36 percent more alcohol than their peers in a typical session and reported twice as many episodes of weekly drunkenness. Researchers have speculated that the caffeine and taurine in energy drinks may mask the feeling of drunkenness, but not its effects. "Students whose motor skills, visual reaction times, and judgment impaired by alcohol may not perceive that they are intoxicated as readily when they're also ingesting a stimulant. Only the symptoms of drunkenness are reduced – but not the drunkenness. They can't tell if they're drunk, they can't tell if someone else is drunk," said lead researcher Dr. Mary Claire O'Brien, who also recommended that programs focused on high-risk drinking should inform students about the dangers of mixing alcohol with energy drinks. *See BBC News*, November 5, 2007.

Food & Beverage

LITIGATION UPDATE

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