Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Federal Trade Commission (FTC)

[1] Agency Upholds Hormone-Free Milk Ads

The FTC has reportedly refused to launch an investigation into or initiate enforcement actions against dairies that advertise their products as free of synthetic hormones. Monsanto Co. requested the action, claiming the dairies were misleading consumers and charging more for their products. Additional details about Monsanto's request appear in issue 209 of this Update. According to a news source, while the agency turned aside Monsanto's request, it warned several small businesses about making unfounded claims regarding recombinant bovine somatotropin, or rBST, on their Web sites. A Washington, D.C.-based nonprofit, the Center for Food Safety, reportedly applauded the FTC's action; a spokesperson was quoted as saying, "Since more and more companies are rejecting this drug and letting consumers know it, Monsanto is getting desperate." Under current FTC regulations, milk producers are allowed to claim that they do not use rBST, if they do not "mislead consumers" to believe that hormone-free milk is safer or of better quality. *See Associated Press*, August 28, 2007.

National Toxicology Program (NTP)

[2] Advocacy Organization Challenges Industry Action Under Data Quality Act

OMB Watch, a Washington, D.C.-based nonprofit research and advocacy organization, has produced a **report**, "An Attack on Cancer Research," that contends industry interests are hindering NTP research on cancer-causing agents by filing baseless information quality challenges under the Data Quality Act (DQA). According to the report, "While most DQA challenges have not significantly weakened NTP information because the program has either rejected or only instituted temporary or minor changes, these challenges have wasted NTP resources that would have otherwise been devoted to studying cancer-causing chemicals."

The report outlines the NTP's purpose and procedures, noting that it was founded in 1978 to study and raise awareness about toxic chemicals that may pose a human health risk. NTP produces the biennial Report on Carcinogens (RoC), which lists chemicals "for which there is scientific consensus regarding carcinogenicity or genotoxicity." More than 1,700 toxic substances were listed in 2005. According to OMB Watch, the RoC "is one of the most effective tools developed by NTP to inform health professionals and guide regulatory action." OMB Watch claims that the RoC has generated more DQA challenges than any other single set of government information. The 10 challenges filed since the DQA took effect in 2000 were purportedly made by companies or industry-affiliated organizations, at

least half involved matters beyond the parameters of DQA by challenging methodology and agency policies, and one resulted in the delayed release of the latest RoC.

The report outlines specific examples of information quality challenges, including a June 2004 challenge to NTP's notice that it would study the carcinogenicity of atrazine, "an herbicide widely used on major crops like corn." The Center for Regulatory Effectiveness (CRE) apparently claimed that the notice was misleading and incomplete for failing "to clarify that a particular study on rats cited in the notice was irrelevant to human cancer." "By submitting a challenge on the notice of intent to investigate," states OMB Watch, "CRE was essentially challenging NTP's decision to gather more information on atrazine. In providing a thorough response to the challenge, NTP used valuable resources that could have been used more appropriately."

OMB Watch contends that DQA misuse leads to delay, wasted resources, reductions in certainty, duplication of existing processes, and questions of policy that are beyond DQA's scope. The report concludes by recommending (i) "dismiss DQA challenges covered by existing information quality procedures"; (ii) "only consider challenges of substantive information"; (iii) "distinguish between fact and policy"; and (iv) do not allow challenges to "delay agency action."

Department of Agriculture (USDA)

[3] APHIS Proposes Amendments to Bioterrorism Protection Act

USDA's Animal and Plant Health Inspection Service (APHIS) has issued a **proposed rule** that would amend and republish "the list of selected agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products." The Agricultural Bioterrorism Protection Act of 2002 requires APHIS to review the list on a biennial basis and submit revisions as necessary. APHIS considers the following criteria when determining the status of an agent or toxin: (i) the effect of exposure on animal or plant health and on the "production and marketability" of an animal or plant product ; (ii) the pathogenicity of the agent or toxic; (iii) the ability to treat or prevent any illness caused by the agent or toxin; and (iv) any other criteria deemed essential for the protection of animal and plant health. "Should any select agent or toxin be intentionally introduced into the United States, the consequences could be significant," warns APHIS. "Direct losses in agriculture could occur as a result of exposure, such as death or debility of affected production animals, or yield loss in plants." APHIS also notes that a bioterrorism attack could impose domestic and foreign quarantines, disrupt the food supply and damage consumer trust in U.S. agricultural products. The agency will accept public comments on the list until October 29, 2007.

Food and Drug Administration (FDA)

[4] House Democrats Questions FDA Plan to Outsource 332 Jobs

U.S. Representatives John Dingell (D-Mich.) and Bart Stupak (D-Mich.) this week sent a **letter** to FDA opening an investigation into the agency's plan to outsource 332 administrative positions to private companies. The letter, which calls the move "hasty and unwise," requests all records and documents relating to the FDA proposal on behalf of the House Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations. "It is truly incomprehensible why the Agency would again consider reducing the expertise and institutional

knowledge of the FDA at a time when the FDA's credibility with the American people is at an all-time low," opine Dingell and Stupak, also urging the agency to await the forthcoming recommendations of the President's Import Working Group. FDA last week scrapped plans to close 13 food-testing laboratories after receiving similar criticisms from Congress and public advocacy groups. *See Associated Press*, August 27, 2007.

[5] Spinach Recalled over Fears of *Salmonella* Contamination

A California-based produce company this week **recalled** 68,000 pounds of fresh spinach after routine tests detected *Salmonella* in a sample taken from a processing plant operating under contract. Although no consumers have reported illness, Metz Fresh, LLC has recalled all spinach packaged in 10- and 16-ounce bags, 4-pound cartons, and cartons containing 2.5-pound bags with the product codes 12208114, 12208214 and 12208314. The company distributed the spinach to retail and food-service customers in the United States and Canada. "Through its labeling and numbering system, Metz Fresh has already tracked, located and put 'holds' on the vast majority of the cartons of spinach affected," stated a firm press release. In addition, Metz Fresh is cooperating with state and federal officials to determine the contamination source. *See Associated Press*, August 27, 2007; *San Jose Mercury News*, August 30, 2007.

China

[6] China Defends Food Safety Standards, Prosecutes Violations

China this week issued a notice to the World Health Organization (WHO) defending its food safety record in light of recent concerns over contaminated and fraudulent exports. "The Chinese government is willing to increase information exchange and communication with international society and other countries in line with its attitude of openness and transparency," the notice reportedly stated. The announcement contained "nothing specifically new," according to a WHO representative, but showed "that China has recognized it has a challenge and is working to address it." The Chinese Health Ministry, which contended that "94 percent of vegetables meet chemical residue standards," also said it would "strike hard" against illegal behavior in the future. A court this week sentenced Zheng Shangjin, the former head of the Zhenjiang Province food-and-drug watchdog, to four years in prison for reportedly accepting 680,000 yuan ($90,000) in bribes, and an appeals court upheld the suspended death sentence for Cao Wenzhuang, former head of the State Food and Drug Administration (SFDA) drug registration department, who accepted 2.4 million yuan in bribes. Former SFDA head Zheng Xiaoyu was recently executed for similar crimes. In addition, the government has opened criminal proceedings against two companies, Xuzhou Anying Biologic Technology Development Co. and Binzhou Futian Biotechnology Co., charged with adding the industrial plasticizer melamine to proteins supplied to U.S. pet food manufacturers. *See Bloomberg.com*, August 27, 2007; *Reuters* and *Associated Press*, August 29, 2007.

WHO and Chinese officials have also scheduled a meeting for September 12-13, 2007, to address issues such as foodborne illness, improved regulations and the globalization of the food supply. WHO has been assisting China in its efforts to modernize the food system, which apparently suffers from technological hurdles and substandard infrastructure. In particular, the country lacks a "cold chain," or the

ability to refrigerate meat and produce from farm to fork. "Consulting firm A.T. Kearney estimates that more than $100 billion would have to be invested for China to have an efficient and safe food-distribution system in place," claims an article in *The Wall Street Journal*. The absence of a cold chain reportedly costs China an estimated $15 billion annually, but "they weren't willing to step up to actually do something because there was no crisis," said a senior partner at A.T. Kearney. *See Yahoo! News*, August 23, 2007; *The Wall Street Journal*, August 30, 2007.

Meanwhile, U.S. Representatives Mark Kirk (R-Ill.) and Rick Larsen (D-Wash.) met this week with officials from China's General Administration of Quality Supervision, Inspection and Quarantine to discuss the country's product safety problems. Kirk and Larsen lead the U.S.-China Working Group, which seeks to develop export opportunities for small- to medium-sized U.S. businesses. Kirk has also introduced the Import Safety Act of 2007 and advocated stiffer penalties against importers of contaminated foods. "This is a very real problem," Larsen was quoted as saying. "It's visceral. It's about your child, and it's about food on the table." *See Associated Press*, August 29, 2007.

Litigation

[7] Ninth Circuit Upholds USDA's Mad Cow Disease Rule

The Ninth Circuit Court of Appeals has upheld a U.S. Department of Agriculture (USDA) rule that classified Canada as a minimal-risk country in the context of bovine spongiform encephalopathy (BSE or mad cow disease) and allowed the import of certain beef from Canada. ***Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, No. 06-35512 (9th Cir., decided August 28, 2007)**. R-CALF USA challenged the rule on a number of fronts; this appeal involved R-CALF's contention that the rulemaking was arbitrary and capricious and violated the Administrative Procedure Act. The district court upheld the rule without analysis, deferring, as directed by the Ninth Circuit in a prior appeal of a preliminary injunction ruling, to the agency's expertise.

The Ninth Circuit determined that the district court erred in finding itself bound by the appeals court's prior determination, but decided to consider the matter on the merits. Essentially, the appeals court found that, when the USDA issued its BSE rule and classified Canada as minimal risk, it considered all relevant factors and articulated a rational connection between the facts and its decision. The court emphasized that the law does not require USDA to assume that its measures would be 100 percent effective. The fact that recent incidents of BSE occurred in cows born after the rule took effect "cast doubt on the effectiveness of the feed ban," said the court. Yet, it ruled that the agency properly relied on existing evidence and research and that R-CALF has other ways to challenge the rule, such as filing a petition to reopen the rulemaking. Upholding the district court's grant of USDA's motion for summary judgment, the court stated, "R-CALF's extra-record evidence has failed to convince us that the agency's review was unauthorized, incomplete, or otherwise improper."

[8] Monsanto Appeals Roundup Ready® Alfalfa Ban

According to a news source, Monsanto Co. has filed an appeal from a federal district court ruling that permanently enjoined the sale or planting of genetically modified alfalfa pending the U.S. Department of Agriculture's (USDA's) preparation of

an environmental impact statement (EIS). USDA had failed to prepare an EIS before it decided to deregulate Monsanto's Roundup Ready® alfalfa. The Center for Food Safety and two alfalfa seed producers who complained that conventional and organic alfalfa would be contaminated by the unrestricted planting of genetically engineered crops sought the injunctive relief. Additional information about the case appears in issues 202, 205, 206, and 208 of this Report.

The appeal reportedly seeks to correct legal standards the district court applied when it entered the injunction, which, Monsanto argues, has placed unnecessary restrictions on growers, seed dealers and the company while the USDA completes the EIS. The Ninth Circuit Court of Appeals will hear the appeal, but no date has been set for argument. Monsanto further contends that the injunction will result in irreparable financial harm to the industry, despite the fact that its genetically engineered alfalfa has been shown to pose no harm to humans and livestock; the company has previously calculated that the ban will cost the industry $250 million. The lower court's ruling reinstated USDA regulations that require labels on every bale of Roundup Ready® alfalfa sold in a commercial hay market, equipment and truck cleaning after the crop is processed or shipped, segregation of Roundup Ready® hay, and notice to buyers when they purchase the genetically modified crop. *See Truth About Trade & Technology*, August 21, 2007.

[9] *Pelman v. McDonald's Corp.*, No. 02 Civ. 7821 (S.D.N.Y., filed Sept. 30, 2002): Recent Activity

Pre-trial maneuvering continues in the *Pelman* litigation, which seeks damages on behalf of a putative class of obese and overweight teens alleging that the fast-food giant misled them with deceptive ads. In late July 2007, McDonald's Corp. filed a motion seeking an order striking the class allegations in plaintiffs' second amended complaint. Since then, plaintiffs have requested an extension of time to respond to the motion, and Judge Robert Sweet signed an order on August 27 granting the extension and scheduling a hearing for October 3. Discovery, subject to a protective order, is ongoing, and trial remains scheduled to begin in April 2008.

Other Developments

[10] Obesity Report Faults Public Policy for Lack of Exercise

Trust for America's Health (TFAH) this week released its annual report, titled "**F as in Fat: How Obesity Policies are Failing in America**," that tracks state obesity rates and advocates public policy solutions to "the obesity epidemic." The 2007 report found that Mississippi topped the list with more than 30 percent of the adult population considered obese, followed by West Virginia and Alabama. By comparison, Colorado was the "leanest state" with an adult obesity rate projected at only 17.6 percent. In addition, the report for the first time included data on childhood obesity rates, with the District of Columbia registering the highest obesity rate at 22.8 percent of children ages 10 to 17. A **supplement** to the report also summarized the states' obesity-related legislation, from physical education programs to nutritional standards for competitive foods. "If we want kids to eat healthier food, we have to invest the money for school nutrition programs so that school lunches are healthier," a TFAH spokesperson was quoted as saying. "It's one of those issues where everyone believes this is an epidemic, but it's not getting the level of political and policy-maker attention that ought to." *See Associated Press*, August 28, 2007.

[11] Iams Pet Food Ads Rejected as Unsupported

The National Advertising Division (NAD) of the Council of Better Business Bureaus has reportedly told Procter & Gamble Co. that it should change its advertising claim that "four out of five veterinarians recommend Iams to help dogs and cats live healthier longer." NAD apparently found, as part of a private, voluntary dispute-resolution process, that the company could not support its claims about health and longevity. Procter & Gamble has apparently indicated that it will take NAD's recommendations into consideration in future ad campaigns, but continues to believe its survey of veterinarians supported the "healthier longer" portion of the claims. *See Advertising Age*, August 28, 2007.

Media Coverage

[12] Andrew Schneider, "That Buttery Aroma Might be Toxic, Too," *Seattle Post-Intelligencer*, August 30, 2007

This article about diacetyl, the chemical used to add a butter flavor to foods like microwave popcorn, notes that the Environmental Protection Agency (EPA) has completed a study of the risks of consumer exposures but has yet to release it to the public. According to *Seattle Post-Intelligencer* senior correspondent Andrew Schneider, the study was released to popcorn manufacturers and led Pop Weaver, one of the largest producers, to remove the flavoring agent from its products. The article discusses workplace incidences of lung disease attributed to diacetyl exposure and lawsuits that have resulted in million-dollar jury verdicts and settlements. The EPA study is apparently the only one of its kind to explore risks to consumers.

An EPA spokesperson reportedly indicated that the popcorn industry was given the opportunity to review the study's results before publication and that the information could not be released to public health professionals because it would prevent his scientists from getting published in peer-reviewed journals. The public health community is apparently disturbed about EPA's failure to release the report. One academic was quoted as saying, "EPA cannot be permitted to play these games with matters that are important to public health. Diacetyl is a dangerous chemical, declared safe, for the most part, by the flavoring industry." He added, "With this arm-in-arm relationship between government scientists and the industry using diacetyl, how can the public feel that they are learning the truth about this chemical which is in thousands of products?"

[13] Kim Severson, "Edible Films with Superpowers," *The New York Times*, August 29, 2007

This article follows a research trend that has inspired food science labs to develop edible, antimicrobial films and powders from "natural pathogen fighters found in everyday food." *New York Times* reporter Kim Severson compares the films to an edible "plastic wrap" that dissolves in water, but which can be infused with derivatives of cloves, thyme or other foods that exhibit antimicrobial properties. A film or powder made with thyme molecules, for example, could kill *E. coli* bacteria on fresh spinach or *Salmonella* on chicken. "These natural films are really a very hot topic these days," said one food scientist with Rutgers University. "The range of applications is endless, from very delicate foods to Army rations and space missions."

Severson speculates that with recent food scares making headlines, manufacturers are looking to

meet the public demand for healthier, safer foods. "We're working on consumer-friendly antimicrobials, so people will read the package label and not freak out," said Mark Daeschel, a professor of food science at Oregon State University. Many researchers also pointed to the benefits of replacing traditional coatings like confectioner's glaze – often made using the secretions of a mite-sized beetle – with a naturally-derived product familiar to consumers. Severson notes that the all-natural films would make an attractive alternative to irradiation, a process opposed by consumer advocates. She admits, however, that researchers still face several obstacles, including technical issues such as the films' sensitivity to humidity and questions about whether milk-derived products can be used on vegan foods, for example. "And as excited as the scientists are about their new powders and films, they are quick to point out that the products are not cure-alls," she writes, citing one food scientist who warns that the new technology "is not intended to make up for sloppy growing or handling or cleaning and processing."

Scientific/Technical Items

[14] Researchers Report Finding Reactive Carbonyls in Soft Drinks

During the American Chemical Society's recent national meeting, researchers at Rutgers University reported the results of chemical tests on carbonated soft drinks containing high fructose corn syrup (HFCS). According to principal researcher Chi-Tang Ho, Ph.D., the tests found high levels of reactive carbonyls, which are also elevated in the blood of diabetics and linked to the disease's complications. According to Ho, a single can of soda contains some five times the concentration of these undesirable compounds than the concentrations found in the blood of an adult diabetic. He and his team are reportedly conducting additional tests to see what role carbonation has on raising reactive carbonyl formation in sodas with HFCS. Non-carbonated beverages with HFCS reportedly contain one-third the level of reactive carbonyls, while non-carbonated teas with HFCS have only one-sixth the levels of carbonyls in regular sodas. Nutritionists apparently contend that the study is inconclusive and does not address the risk of diabetes; according to one, "it is not a proven cause and effect." Nevertheless, scientists are concerned enough to recommend that people limit their consumption of beverages with HFCS. *See U.S. News & World Report,* August 24, 2007; *News-Medical.Net*, August 26, 2007.

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