Shook, Hardy & Bacon L.L.P.

ISSUE 347 | APRIL 30, 2010

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Court May Have Opened Door to Judicial Review of Data Quality Act Challenges

According to a news source, a think tank with links to industry interests has suggested that a recent federal appeals court ruling could give parties challenging agency rulemaking data under the Data Quality Act (DQA) the ability to obtain judicial review of the agencies' responses to their DQA petitions. The DQA required the Office of Management and Budget (OMB) to provide guidance to federal agencies "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of . . . the Paperwork Reduction Act." Each federal agency was required to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency," if that information did not comply with OMB's guidelines.

When adopted, the DQA was viewed as a way for industry interests to slow down rulemaking by giving them a process for challenging the data and research upon which agencies relied. A 2006 Fourth Circuit Court of Appeals ruling appeared to close the courts to industry challenges of federal agencies' DQA decisions, with the court determining that the DQA "creates no legal rights in any third parties."

The Center for Regulatory Effectiveness (CRE) reportedly contends that ***Prime Time International Co. v. Vilsack***, No. 09-5099 (D.C. Cir., decided March 26, 2010), by embracing a government argument that the U.S. Department of Agriculture (USDA) action at issue was an "adjudication" and thus specifically exempt from the DQA under OMB's guidelines, means that challenges to data underlying agency actions that are not adjudications could potentially be reviewed in court.

The plaintiff in *Prime Time* sought disclosure and correction under DQA of the data that USDA used to calculate assessments owed by the plaintiff under a federal tobacco support program. USDA did not respond, and Prime Time sought to challenge that non-response in court. Because the court found that the USDA's determination of Prime Time's assessments was an adjudication that could be appealed administratively and then via judicial review, it affirmed the district court's dismissal of Prime Time's claim that USDA violated the DQA.

Reaching this conclusion, the court relied on OMB's definition of information dissemination in a manner that excluded documents prepared and distributed in

the context of adjudicative proceedings. The court characterized OMB's definition as "binding," which CRE apparently claims supports its conclusion that DQA petitions involving non-adjudicatory agency actions could be reviewed in court. *See InsideEPA.com*, April 30, 2010.

USDA Organics Program Changes Course on DHA and ARA in Infant Formula

The U.S. Department of Agriculture's (USDA's) National Organic Program (NOP) has **announced** that its 2006 decision approving the fortification of organic infant formula and organic milk products with synthetic omega-3 fatty acid DHASCO (DHA) and omega-6 fatty acid ARASCO (ARA) resulted from an incorrect interpretation of nutritional guidelines and NOP board recommendations. Thus, DHA and ARA, present in 90 percent of organic infant formulas, will no longer be permitted in foods certified as organic, and NOP plans to issue draft guidance, subject to a 60-day public comment period, to "provide a transition time for businesses to reformulate products to comply with the regulations."

Organics watchdog Cornucopia Institute recently re-filed a **complaint** with the NOP contending that the use of DHA and ARA in organic infant formulas and organic dairy foods constitutes a possible violation of NOP regulatory standards. The institute claimed that a former NOP director overruled the determination of the career staff that the use of DHA and ARA was illegal and did so after contact with an industry lobbyist, who reportedly told *The Washington Post* that he communicated with the director, but that the back-and-forth was simply routine. According to institute information on the synthetic additives, DHA and ARA are nutritional oils grown and fermented from algae and soil fungus. Touted by industry as a benefit to infant cognition and eyesight, the additives, which are extracted with hexane, a neurotoxic chemical, have reportedly been linked to serious illness in some infants who purportedly experienced acute dehydration from dangerous vomiting or diarrhea.

The institute has also apparently asked the Food and Drug Administration to revoke the generally recognized as safe designation for the additives. In the meantime, the company that makes DHA and ARA has reportedly indicated that it will petition NOP to allow the fatty acids in organic food. According to a Martek Biosciences Corp. spokesperson, "Our hope is that this can be done before the additives are phased out so there are no interruptions. There is no organic alternative to these fatty acids and we firmly believe that DHA and ARA are important to health." *See The Wall Street Journal*, April 26, 2010; *USDA Press Release* and *Cornucopia News*, April 27, 2010; *The Washington Post,* April 28, 2010.

FSIS Food Safety Regulatory Initiatives Lag in Absence of Agency Head

Without a Senate-confirmed leader for the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), target dates for ongoing rulemakings have apparently slipped in recent months. In January 2010, President Barack Obama (D) nominated Elisabeth Hagen to serve as USDA's Under Secretary of Agriculture for Food Safety, but the Senate has failed to act on the nomination.

According to USDA's April 26, 2010, semiannual regulatory **agenda**, FSIS, which

SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

is responsible for the safety of meat, poultry and egg products, has completed only one rulemaking over the past six months, missing all 11 target dates set in its October 2009 agenda. Among the agency's pending rules is a pathogen-reduction performance standard for all ready-to-eat and partially heat-treated meat and poultry products to control *Listeria* monocytogenes. It was initially proposed in 2001. *See Federal Register*, April 26, 2010; *OMB Watch*, April 28, 2010.

FDA Seeks Input on Front-of-Pack Labeling

The Food and Drug Administration (FDA) has **established** a docket to obtain comments and other data related to point-of-purchase nutrition information, including front-of-pack (FOP) labeling and shelf tags. According to an April 29, 2010, press release, FDA wants to learn more about (i) "the extent to which consumers notice, use and understand nutrition symbols" on these types of labels; (ii) "research that assesses and compares the effectiveness of particular approaches to front-of-pack labeling"; (iii) "graphic design, marketing and advertising data and information that can help develop better point-of-purchase information"; and (iv) "how point-of-purchase information may affect decisions by food manufacturers to reformulate their products." The agency will use this feedback to inform its deliberations about "approaches to enhancing the usefulness to consumers of point-of-purchase nutrition information."

The docket is part of ongoing efforts to reassess FOP regulations under the Nutrition Labeling and Education Act of 1990. FDA has stated that the ideal FOP label should be grounded in the Dietary Guidelines for Americans; widely adopted by food retailers and manufacturers; presented in a standardized format; and designed to assist consumers "with a wide range of literacy, educational levels, age, and other characteristics." It has cited "the prevalence of diet-related disease in the U.S. population and the need to accommodate Americans' increasingly busy lifestyles" as impetus to "maximize the number of consumers who readily notice, understand, and use point-of-purchase information to make more nutritious choices for themselves and their families." FDA will accept comments until July 28, 2010. *See Federal Register,* April 29, 2010.

Milk Interests Petition FDA to Stop Use of Dairy Terminology on Imitation Products

The National Milk Producers Federation has filed a **petition** with the Food and Drug Administration (FDA), calling on the agency to "significantly increase enforcement efforts to prevent the misbranding of certain food items that are imitations of standardized dairy products."

The federation claims that soy-, hemp-, almond-, and rice-based products are marketed to consumers as "milk," "cheese," "ice cream," and "yogurt," but "do not meet the legal standard of identity for those standardized dairy products." The petition cites several FDA warning letters sent to producers of products advertised as milk or cheese but not containing any "milk," defined by federal law as the "lacteal secretion, practically free of colostrums, obtained by the complete milking of one or more healthy cows."

The federation contends that FDA's lack of enforcement has resulted in the "traditional retail dairy case" becoming "a chaotic center of misbranded products and false and misleading labeling," that threatens healthy dietary patterns. According to a federation press release, the petition marks the second time in a decade that the organization has called on FDA to crack down on the practice, which, it contends, has only gotten worse. The federation calls on consumers to send examples of purportedly mislabeled products to FDA or urge the agency to take action. *See National Milk Producers Federation Press Release*, April 29, 2010.

U.S. Customs and CPSC Team Up on Import Safety

The U.S. Customs and Border Protection (CBP) and the Consumer Product Safety Commission (CPSC) have apparently agreed to share safety information on imported goods, including foods and pharmaceuticals. The two agencies on April 26, 2010, signed a memorandum of understanding that grants CPSC "the capability to conduct import safety risk assessments and perform targeting work using CBP's Automated Commercial System." The new partnership aims to identify potentially dangerous imports before they enter the country, according to a concurrent CBP press release.

The alliance is the latest formed under the auspices of CBP's Import Safety Commercial Targeting and Analysis Center (CTAC). Established after President Barack Obama's (D) Food Safety Working Group urged widespread reform, CTAC is an interagency effort that draws on shared resources, analysis and expertise "to protect the American public from harm caused by unsafe imported products." The new facility is staffed with 30 personnel from CBP, CPSC and other participating agencies, including the U.S. Department of Agriculture, U.S. Immigration and Customs Enforcement, and the Food and Drug Administration.

Santa Clara County, California, Bans Toys in Restaurant Meals

The California county that helped lead the national push for menu labeling has reportedly approved an ordinance (**NS-300-820**) that would prohibit restaurants from using "incentive items" to promote meals deemed high in calories, salt or fat. The Santa Clara County Board of Supervisors apparently voted 3-2 on April 27, 2010, to set nutritional standards for restaurant food that comes with such giveaways as toys, games, trading cards, admission tickets, or any other consumer product, "whether physical or digital."

The measure declares that restaurants cannot link incentives to (i) meals that exceed 485 calories or 600 milligrams (mg) sodium; (ii) single food items that exceed 200 calories or 480 mg sodium; or (iii) beverages that contain caffeine, added non-nutritive sweeteners or more than 120 calories, or derive more than 35 percent of their total calories from fat or 10 percent from added caloric sweeteners. In addition, meals or food items offering incentives cannot contain more than 0.5 grams *trans* fat, 35 percent fat content, 10 percent saturated fat content, or 10 percent sugar content derived from added caloric sweeteners.

The ordinance applies to all establishments located in unincorporated parts of the county, including San Martin, Stanford University, and San Jose's Burbank and

Cambrian neighborhoods. It also imposes fines that could reach as high as $1,000 per violation. "This ordinance breaks the link between unhealthy foods and prizes," Supervisor Ken Yeager was quoted as saying. "Obviously, toys in and of themselves do not make children obese. But it is unfair to parents and children to use toys to capture the tastes of children when they are young and get them hooked on eating high-sugar, high-fat foods early in life."

Meanwhile, the California Restaurant Association has publicly criticized the initiative as unnecessary and difficult to enforce. "If the point is to get a dialogue going with the industry about health, that dialogue is already going," an association spokesperson told media outlets. "If the point is to solve childhood obesity, taking away a toy isn't going to help." *See Appetite for Profit, The San Francisco Chronicle,* and *San Jose Mercury News*, April 28, 2010.

LITIGATION

U.S. Supreme Court Considers GE Alfalfa Dispute

Oral **argument** in litigation over whether the U.S. Department of Agriculture (USDA) properly deregulated a genetically engineered (GE) alfalfa seed took place before the U.S. Supreme Court on April 27, 2010. *Monsanto Co. v. Geertson Seed Farms*, No. 09-475 (U.S.). The Ninth Circuit imposed a ban on use of the GE seed until the USDA completes an environmental impact statement that accounts for potential contamination of conventional alfalfa crops. While several justices questioned the appellate court's authority to fully ban the product's sale, Justice Antonin Scalia contended that GE crop planting "doesn't even destroy the current plantings of non-genetically engineered alfalfa. This is not the end of the world. It really isn't. The most it does is make it difficult for those farmers who want to cater to the European market, which will not accept genetically engineered alfalfa."

According to press reports, environmentalists and agribusiness, watching the case closely, filed numerous *amicus* briefs. Environmentalists are apparently concerned whether the Court's decision will affect a federal law requiring the government to take environmental impact into account before approving GE products, while business interests argue that cross-pollination is unlikely and that allowing the lower court's ruling to stand could stifle the development of biotech crop varieties. Organic food producers, including dairies, are also following the case, noting that alfalfa hay, which is fed to their cows, would cripple their industry if contaminated. Monsanto's counsel was quoted as saying, "This Supreme Court hearing is about farmers, fairness and choice." A decision in the case is expected in June. *See Center for Food Safety,* April 19, 2010; *The New York Times,* April 22, 2010; *DesMoinesRegister.com*, April 25, 2010; *Associated Press*, April 27, 2010; *FoodNavigatorUSA.com*, April 28, 2010.

Fourth Circuit Upholds Alcohol Ad Restrictions in Virginia's College Publications

The Fourth Circuit Court of Appeals has turned aside a First Amendment challenge to a state law restricting advertisements for alcoholic beverages in college student publications. ***Educ. Media Co. v. Swecker*, No. 08-1798 (4th Cir., corrected decision filed April 19, 2010)**.

The restrictions at issue did not allow advertisements for alcohol in any college publication distributed primarily to students younger than 21, but did allow dining establishment advertisements in those publications to refer to alcohol. The student-run newspapers challenging the restrictions claimed that they were losing tens of thousands of dollars in ad revenues annually because of the restrictions, which they contend do not advance the government's interest in combating underage drinking.

The court found sufficient evidence in the record to link decreasing demand for alcohol by college students with the advertising restrictions, citing in particular the inimitable role that student publications play on campus and "the fact that alcohol vendors *want* to advertise in college student publications." A dissenting judge disputed that finding, calling the record evidence of a link "speculative, at best." According to the dissent, "The regulation not only impermissibly infringes upon the constitutional rights of adults (with the result of limiting the adult readership to receiving only speech that the Commonwealth deems appropriate for persons under the age of twenty-one), it also infringes upon the rights of those readers who are not yet twenty-one, who nonetheless have a protected interest in receiving truthful, non-misleading information about a lawful product that they will soon have the legal right to consume. And of course the advertisers have the right to communicate such information."

The dissent also cited students' exposure to alcohol advertising in other media, such as non-student newspapers, radio and television, to explain why the restrictions will not have their intended effect. The appeals court reversed the district court's order granting the newspapers' motion for summary judgment and vacated its permanent injunction. The case was remanded for proceedings consistent with its opinion.

Deceptive Labeling Claims Against Beverage Maker Dismissed

A federal court in Illinois has dismissed claims that Coca-Cola labeling for its "classic" and "original formula" soda products violated consumer fraud laws because the products contain high fructose corn syrup (HFCS), which did not exist when the beverage was first sold in the 1880s. *Kremers v. Coca-Cola Company*, No. 09-333 (U.S. Dist. Ct., S.D. Ill., decided April 27, 2010).

One named plaintiff in this putative class action apparently testified during her deposition that she knew the products contained HFCS as early as the 1990s. The court found the litigation time-barred as to her claims. Another named plaintiff testified that he did not realize the product's label included the phrase "original formula" until counsel brought it to his attention. The court found that he failed to establish an essential element of his deception claim. Because both testified that they continued to buy the product despite knowing that its sweetener differed

from the formulation sold 100 years ago, the court determined that they failed to establish a causal link between the defendant's conduct and their damages.

The Coca-Cola Company was represented by Shook, Hardy & Bacon lawyers Zach Chaffee-McClure, Chris Cotton, Scott DuPree, Jim Eiszner, John Murphy, Laurie Novion, Antwaun Smith, Holly Pauling Smith, and Gene Williams.

Court Rules FDA Warning Letter Is Not Final Agency Action

A federal court in Colorado has dismissed as premature a medical provider's challenge to Food and Drug Administration (FDA) regulations potentially applicable to its medical procedures because the agency had issued only a warning letter against it, and warning letters are not final. *Regenerative Sciences, Inc. v. FDA*, No. 09-cv-00411 (U.S. Dist. Ct., D. Colo., decided March 26, 2010). The court's analysis of the non-final nature of FDA warning letters may have some relevance in those consumer fraud actions against food makers citing such letters to establish a fact or using them as definitive evidence of wrongdoing or a violation of the law. The agency itself acknowledged that its warning letters do not constitute a determination that a particular statute or regulation applies to the specific circumstances that led FDA to issue the letters, noting "this is a factual issue that cannot be resolved until FDA brings an action against" the letter recipient.

California Class Charges Herb Grower with Fraud

A putative class action has reportedly been filed against California's largest herb grower, shipper and marketer, alleging that the defendant "played California consumers for fools," by selling as organic, and at higher prices, conventionally grown herbs. *Quesada v. HerbThyme Farms*, No. N/A (Cal. Super. Ct., filed April 2010). According to the complaint, the company owns a large number of conventional farms and just one smaller organic farm, and, when its "profits grew at a slower rate than the company wanted, it turned to fraud." Seeking restitution, damages and injunctive relief, the plaintiff alleges that the company labeled conventionally grown herbs as "Fresh Organic" in violation of California business and consumer fraud laws. *See Courthouse News Service*, April 28, 2010.

OTHER DEVELOPMENTS

IOM Report Offers Framework for Obesity Prevention Decision Making

The Institute of Medicine (IOM) has issued a report titled "Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making" to guide the use of relevant evidence about obesity prevention policies and programs.

According to the report brief, IOM's Food and Nutrition Board reviewed "what is considered to be the relevant information base for community, environmental, and policy-based obesity prevention initiatives" and found "a clear evidence gap." In response, the board developed the L.E.A.D. framework process, short for "Locate evidence, Evaluate it, Assemble it, and Inform Decisions." The framework involves

"innovative approaches to generating, identifying, evaluating, and compiling evidence—taking a broad, transdisciplinary perspective." These approaches include (i) incorporating systems thinking; (ii) building a resource base; (iii) establishing evidence for standards quality; (iv) supporting the generation of evidence; and (v) communicating, disseminating, evaluating, and refining the L.E.A.D. framework. *See IOM Web Site*, April 23, 2010.

CSPI Urges Restaurant Chains to Stop Using Artificial *Trans* Fat

The Center for Science in the Public Interest (CSPI) has called on three national restaurant chains to follow the steps of other food establishments by no longer using artificial *trans* fat in their fare. "Bob Evans, White Castle, and Long John Silver's are now the roguish outliers among the restaurant industry," said CSPI Executive Director Michael Jacobson. "Many Americans might have thought that the era of artificial *trans* fat was over. At these chains, it lives tragically on."

Artificial *trans* fat has been dropped by chains, including McDonald's, Burger King, Wendy's, and Starbucks. The American Heart Association recommends limiting consumption of *trans* fat to no more than 2 grams per day that comes naturally from sources such as milk and beef, which "doesn't leave much room for *trans* fat from artificial sources," said CSPI. *See CSPI News Release*, April 26, 2010.

MEDIA COVERAGE

Michele Simon, "Taking on Big Soda over Taxes: Lessons Learned from Fighting Big Alcohol," *Corporations and Health Watch Newsletter,* April 2010

"Whether it's the food industry, tobacco, or alcohol, they all use the same talking points and lobbying strategies," opines the Marin Institute's Michele Simon in this April 2010 article that likens "Big Soda" to the alcohol lobby. Simon draws on her experience as a research and policy director to claim that soft drinks are more analogous to alcohol than tobacco, noting that "the message is more about cutting down." She thus offers six "lessons" for taking on industry in the fight over soft drink taxation.

In particular, Simon advises consumer advocates to resist assertions that (i) "soda doesn't cause obesity or that taxes won't work"; (ii) "a penny per ounce tax will cause massive job loss"; and (iii) companies "care about poor people and working families." She provides several strategies for refuting what she describes as industry misrepresentation and manipulation of data on these points. For example, she maintains that evidence questioning the link between soft drink consumption and obesity is "easily countered by showing those studies… tend to be funded by industry, big surprise." In addition, she urges legislators and policymakers to consider the power of opinion polling, which in the case of alcohol allegedly demonstrated the public's "overwhelming" support for taxation and provided some political cover for tax proponents.

Simon also calls on her fellow crusaders to (i) "index all excise taxes to inflation"; (ii) block "preemption at the state or federal level"; and (iii) "be prepared for the long

haul." Citing the alcohol industry's success in preempting local initiatives, her action plan emphasizes that cities and counties need "to retain the right to assess local taxes and fees as they see fit." Moreover, according to Simon, a federal soda tax that preempts state laws "would be a disaster and makes no sense from a state-rights or public health perspective."

Warning readers of such Pyrrhic victories, Simon predicts that soda taxation is likely to be incremental and ongoing. As she concludes, "Public health advocates will have to decide if the enormous resources it will take to succeed are ultimately worth spending decades fighting on taxes, or if other policies, such as reducing corn subsidies, would be more effective."

Donna Marie Owens, "Check It Out: Get Your Groceries At The Library," *National Public Radio,* April 26, 2010

This article details a new program in Baltimore that allows residents to order groceries online in two branch public libraries and pick them up there the next day. The Baltimore City Health Department launched the Virtual Supermarket Project to help combat the city's lack of healthy, fresh food in communities where major supermarkets within walking distance are scarce.

The libraries are apparently located in "food deserts" that lack access to healthy fare and where "the mortality burden from diet-related causes like diabetes, stroke and heart disease are among the highest in the city," according to one epidemiologist. Patrons pay for the groceries with cash, credit or food stamps. The orders are filled and delivered by Santoni's supermarket, a longtime Baltimore grocer.

NPR reports that approximately two dozen people have so far signed up for the program, which is funded by a $60,000 grant from the federal stimulus package, and that other cities have inquired about the possibility of replicating it. If successful, the program's goal is to partner with additional stores and possibly expand to other parts of the city.

Baltimore Mayor Stephanie Rawlings-Blake (D) was quoted as saying the project is an innovative solution until more supermarkets are built in these neighborhoods. "I think at a point when we are doing what we need to do to make our city better, safer and stronger, we'll attract that investment," she said. "But I'm so proud that we have the use of technology to fill in that gap till development catches up."

SCIENTIFIC/TECHNICAL ITEMS

Animal Study Links Dietary Phosphate to Accelerated Aging

A recent study has reportedly linked "dietary and genetic evidence for phosphate toxicity" to premature aging in genetically engineered (GE) mice. Mutsuko Ohnishi and M. Shawkat Razzaque, "Dietary and genetic evidence for phosphate toxicity accelerating mammalian aging," *FASEB Journal,* April 2010. Researchers first used "an *in vivo* genetic approach to determine the role of phosphate toxicity in mammalian aging," engineering mice that lacked the gene responsible for regulating phosphate

levels. These mice had a short life span and showed "numerous physical, biochemical and morphological features consistent with premature aging."

The study authors then genetically reduced serum phosphate levels, which ameliorated the aging-like features in a second group of mice and led to prolonged survival. But when fed "a high-phosphate diet," these GE animals again exhibited signs of accelerated aging. According to the abstract, these findings "clearly suggest[s] that phosphate toxicity is the main cause of premature aging" in mice. The study further claims to provide "*in vivo* evidence for phosphate toxicity accelerating the aging process and suggest a novel role for phosphate in mammalian aging."

Meanwhile, *FASEB Journal* jumped on these results in an April 26, 2010, press release that associates dietary phosphate toxicity with the consumption of soft drinks. "Soda is the caffeine delivery vehicle of choice for millions of people worldwide, but comes with phosphorous as a passenger," stated *FASEB* Editor-in-Chief Gerald Weissmann. "This research suggests that our phosphorous balance influences the aging process, so don't tip it."

The British Soft Drinks Association (BSDA), however, has publicly refuted this interpretation of the study, which relies on "mice with a specific genetic deformity, and does not in fact mention soft drinks at all." According to one BSDA spokesperson, "Phosphoric acid is used in some soft drinks as a flavoring, but only 3 percent of phosphorous in the overall diet comes from soft drinks." *See FoodNavigator-USA.com,* April 28, 2010.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400