

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

Legislation, Regulations and Standards

USDA Proposes Creation of U.S. Honey Producer Board	1
Federal Report Examines Consequences of "Food Deserts"	1
OEHA Advisory Board Votes Against Adding Bisphenol A to Prop. 65 List; Health Canada Clears BPA in Baby Food Packaging as Safe	2

Litigation

DOJ Seeks Injunction in Adulterated Food Case	3
Disability Benefits Ordered for Hog Slaughterhouse Worker with Brucellosis	4

Legal Literature

Richard Cupp, "Moving Beyond Animal Rights: A Legal/Contractualist Critique," <i>San Diego Law Review</i> , 2009	4
--	---

Other Developments

Whole Foods Joins Non-GMO Project Initiative to Certify Private Label Products	5
--	---

Media Coverage

Nicholas D. Kristof, "Chemicals and Our Health," <i>The New York Times</i> , July 16, 2009	5
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Conferences and Seminars

McDonough to Address Risks Related to Food Imports at Food-Borne Illness Litigation Forum	6
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LEGISLATION, REGULATIONS AND STANDARDS

USDA Proposes Creation of U.S. Honey Producer Board

The U.S. Department of Agriculture's Agricultural Marketing Service (AMS) has issued a proposed [rule](#) and referendum [procedures](#) that would establish "a new U.S. honey producer funded research and promotion program" in accordance with a U.S. Honey Producer Research, Promotion and Consumer Information Order submitted May 24, 2007, by the American Honey Producers Association (AHPA). Representing more than 550 domestic operators, AHPA has called for the implementation of a U.S. Honey Producers Board to address industry issues "such as the drastic decline in the numbers of the honeybee due to (1) natural pests and diseases that kill or weaken the honeybee; (2) record droughts in the mid-west [sic] that have destroyed the plants and flowers honeybees use to gather pollen, and (3) the overall dramatic decrease in demand for U.S. honey." To finance this initiative, AMS would require first handlers who produce more than 100,000 pounds of honey annually to collect and remit fees of \$0.02 per pound of honey.

"Without an active, vibrant domestic honey industry, many other agricultural commodities may suffer due to the loss of essential pollination services that the U.S. honey industry provides," states AMS in the proposed rule. The agency has requested comments by September 14, 2009. *See Federal Register*, July 14, 2009.

Federal Report Examines Consequences of "Food Deserts"

USDA's Economic Research Service has issued a [report](#) to Congress that assesses the effects of "food deserts," low-income rural or urban neighborhoods that frequently lack access to affordable, healthy food venues like supermarkets but instead offer convenience and small neighborhood stores that offer few, if any, healthy foods. Public health literature links such access issues to obesity and diet-related diseases.

Titled "Access to Affordable and Nutritious Food: Measuring and Understanding Food Deserts and Their Consequences," the report asserts that "a small percentage of consumers are constrained in their ability to access affordable, nutritious food because they live far from a supermarket or large grocery store and do not have easy access to transportation." USDA notes that the causes of limited food access varied between urban core areas, which were "characterized by higher levels of racial segregation and greater income inequality," and small-town and rural areas, where "lack of transportation infrastructure is the most defining characteristic."

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 311 | JULY 17, 2009

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.

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According to the report, "a large-scale, national level program may have difficulty addressing what are likely to be quite localized pockets of limited access," while "interventions that may be effective in areas with concentrated poverty are probably different than the type of interventions that may be effective if the population with limited access is more geographically dispersed." See *USDA Press Release*, June 25, 2009.

OEHHA Advisory Board Votes Against Adding Bisphenol A to Prop. 65 List; Health Canada Clears BPA in Baby Food Packaging as Safe

According to news sources, the scientific advisory committee considering whether to place bisphenol A (BPA) on California's Proposition 65 (Prop. 65) list of chemicals known to the state to cause reproductive effects has voted against the action, calling research on human health effects unclear. During the committee's July 15, 2009, [meeting](#), dozens of mothers, environmentalists and scientists reportedly provided testimony to the Developmental and Reproductive Toxicant Identification Committee of Cal/EPA's Office of Environmental and Health Hazard Assessment (OEHHA), calling on the agency to list BPA so that warning labels would be added to foods alerting consumers to its presence.

The committee's scientists apparently acknowledged the growing body of research linking BPA to fetal abnormalities in animals and noted that its decision could be revisited if future studies provide clearer evidence of human health effects. According to committee member Carl Keen, the scientists decided not to list environmental tobacco smoke (ETS) the first time it came up for a vote, but a month later the committee learned of a study with the evidence it needed to place ETS on the Prop. 65 list.

Reaction to the decision was swift; the Natural Resources Defense Council reportedly filed a petition immediately after the vote, asking OEHHA to reconsider listing BPA under Prop. 65's "authoritative body" procedure. This mechanism allows the agency to list those chemicals already identified as carcinogens or reproductive toxicants by other agencies, in this case, the National Toxicology Program's (NTP's) Center for the Evaluation of Risks to Human Reproduction. OEHHA's chief counsel was quoted as saying, "We'll have to look at the petition, and then the NTP document to see if it's sufficient for meeting our regulatory criteria for listing."

A chemistry trade group representative responded to the committee's vote by stating, "The Proposition 65 conclusion today that bisphenol A is not a reproductive or developmental toxicant is consistent with the consensus view of regulatory bodies around the world on the safety of bisphenol A." He also reportedly said that animal lab tests do not prove that BPA has the same effects on humans. See *The Los Angeles Times*, July 15, 2009; *FoodProductionDaily.com*, July 16, 2009; *Inside Cal/EPA*, July 17, 2009.

In a related development, Health Canada has [announced](#) that BPA levels in food packaging pose no risk to consumers. The agency apparently tested baby food in glass jars with metal lids from six companies and found BPA levels ranging from 0.19 part per billion to 7.22 parts per billion, levels it considers well below the migration limit set by the European Union.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 311 | JULY 17, 2009

According to Health Canada's report, "The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and young children." While noting that "[t]he nutritional benefits of baby food products far outweigh any possible risk," the agency cautioned, "[i]n view of uncertainties related to datasets on possible neurodevelopmental and behavioral effects that BPA may have in experimental animals, Health Canada's Food Directorate has recommended that precaution be exerted on products consumed by the sensitive subset of the population, i.e. infants and newborns, by applying the ALARA (as low as reasonably achievable) principle to reduce their exposure to BPA through food packaging applications."

LITIGATION

DOJ Seeks Injunction in Adulterated Food Case

Acting on behalf of an apparently energized Food and Drug Administration (FDA), the Department of Justice (DOJ) has filed a complaint for injunction against a New Jersey company and its owner seeking to halt the manufacture and sale of their dietary supplement products, in part, for failure to comply with good manufacturing practice requirements. [*U.S. v. Quality Formulation Labs., Inc., No. 09-03211 \(U.S. Dist. Ct., D.N.J., filed July 1, 2009\)*](#).

The complaint alleges that the defendants have caused their protein powders and other dietary supplements to be adulterated "in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth (as a result of rodent activity) or may have been rendered injurious to health (as a result of cross-contamination with a major food allergen)." The allergen at issue is milk.

The complaint also alleges that one of the defendants' articles of food is adulterated "in that it contains a color additive that is unsafe . . . because it is not declared on the product label." The additive at issue is FD&C Yellow No. 5. Another food item is allegedly misbranded because it contains an ingredient (whey) "whose common or usual name is not listed on the product labels." According to DOJ, other products are misbranded with a "low calorie" claim that violates the law "because the caloric intake per serving exceeds the maximum calorie limit."

The complaint details what FDA inspectors found in the plant on numerous occasions between 2007 and 2009. Evidence of a rodent infestation allegedly included live and dead rodents as well as rodent gnawing, excrement, urine staining, and tracks throughout the facility. The employees allegedly failed to clean or sanitize equipment to prevent cross-contamination of non-allergenic products with allergens.

The government seeks a permanent injunction to stop the defendants from manufacturing and distributing adulterated and misbranded food articles and seeks an order that defendants cease manufacturing any article of food until the plant is brought into compliance with the Food, Drug, and Cosmetic Act.

**FOOD & BEVERAGE
LITIGATION UPDATE**

ISSUE 311 | JULY 17, 2009

Disability Benefits Ordered for Hog Slaughterhouse Worker with Brucellosis

The Iowa Supreme Court has awarded disability benefits to a former slaughterhouse worker who allegedly contracted brucellosis from butchering hogs. [*IBP, Inc. v. Burress, No. 07-1887 \(Iowa, decided July 10, 2009\)*](#). The court determined that the disease was caused by a traumatic event and thus was a compensable injury under state law. So ruling, the court affirmed an intermediate appellate court decision rejecting a district court's determination that the claimant had an occupational disease and failed to timely file his workers' compensation petition.

The court discusses in some detail how the claimant came into contact with *Brucella* organisms through open cuts while exposed to hog blood during his 10-year tenure at IBP, Inc.'s meat-packing plant. He allegedly developed a chronic infection of the hips and bone as a result of his contact with blood products and tissue from slaughtered hogs, but was not apparently diagnosed with the disease until some six years after he left his employment.

According to the court, "the main distinction between an injury and an occupational disease is the method of contraction." Because the employer "did not present any evidence indicating [claimant] had contracted brucellosis in a manner consistent with the definition of occupational disease," and there was substantial evidence that he acquired brucellosis from contact with infected hog blood on numerous occasions, the court concluded that his claim was not barred by the statute of repose.

LEGAL LITERATURE**Richard Cupp, "Moving Beyond Animal Rights: A Legal/Contractualist Critique," *San Diego Law Review*, 2009**

Pepperdine University School of Law Professor Richard Cupp argues in this article that the better way to protect animal welfare is to focus on the human moral obligation to treat animals without cruelty. He contends that the current, rapidly expanding movement to endow animals with legal rights would be counter-productive if successful. Cupp reports that 94 law schools either now teach animal law or are planning to do so; three scholarly journals focus exclusively on animal law; and national, state and local bar associations have inaugurated sections dedicated to the subject.

Among other matters, Cupp suggests that allowing some animals to 'earn' dignity rights if sufficiently intelligent "implies that perhaps some humans should lose their dignity rights if they are sufficiently unintelligent." He envisions what would happen to our view of infants and mentally incapacitated adults if intelligent animals were accorded rights because of their intelligence. He also claims that animal "rights" activists "risk ignoring or minimizing societal costs" when they "casually use rights concepts to address animals' welfare." According to Cupp, if "killing all animals capable of suffering for food, clothing, research, or other human use were held suddenly to violate the animals' rights, our current economy would, of course, collapse."

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 311 | JULY 17, 2009

He concludes by noting that state laws against cruelty to animals have dramatically increased without the need to endow animals with legally protected “rights” and points to recent outrage over the football celebrity who raised dogs to fight. In this regard, Cupp states, “Americans appropriately focused anger toward Vick for his failure to properly care for the dogs under his control rather than on rights for the dogs. . . . None of these measures to enhance protection of animals from cruelty required an assignment of rights. All of these measures called upon participants in the social contract to exercise reasonable responsibility,” which, he argues, “is what shall ultimately determine whether animals—as well as humans—will be treated humanely.”

Cupp reports that the National Association for Biomedical Research and the Pepperdine University School of Law provided separate research grants related to his article.

OTHER DEVELOPMENTS

Whole Foods Joins Non-GMO Project Initiative to Certify Private Label Products

Whole Foods Market Inc. has reportedly announced a partnership with the Non-GMO Project to independently certify that its private label products do not contain genetically modified (GM) ingredients. A non-profit collaboration of manufacturers, retailers, processors, distributors, and consumers, the Non-GMO Project maintains a product verification program (PVP) “to scientifically test whether a product has met a set of defined standards for the presence of genetically engineered organisms,” according to a July 7, 2009, Whole Foods press release, which claims that “75 percent of processed foods in the United States may contain components from genetically modified crops.”

Whole Foods products bearing the non-GMO seal must undergo a verification process involving “on-site facility audits, document-based review and DNA testing” for “any ingredient at high risk for genetic contamination,” such as corn or soy. “Since there is no regulation regarding disclosure on products manufactured with GMO ingredients, we are committed to helping our shoppers make confident choices by knowing that what they are buying has been verified as meeting the standards of the Non-GMO Project,” a Whole Foods spokesperson was quoted as saying. See *FoodQualityNews.com*, July 9, 2009.

MEDIA COVERAGE

Nicholas D. Kristof, “Chemicals and Our Health,” *The New York Times*, July 16, 2009

“Just last month, the Endocrine Society – composed of thousands of doctors in this field – issued a powerful warning that endocrine disruptors including phthalates are ‘a significant concern to public health,’” writes *New York Times* columnist Nicholas Kristof in this op-ed article examining the chemicals’ purported role in a range of health problems such as sexual deformities, early onset puberty in girls and the “feminization” of male anatomy. According to Kristof, endocrinologists have increasingly found this “mounting evidence” persuasive enough to raise alarms despite the reassurances of the American Chemistry Council, which has pointed to research like a recent study in the *Journal of*

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 311 | JULY 17, 2009

Urology that casts doubt on the link between phthalates and hypospadias, a birth defect. "One of the conundrums for scientists and journalists alike is how to call prudent attention to murky and uncertain risks, without sensationalizing dangers that may not exist," opines Kristof, who nevertheless notes a "flurry of scientific articles questioning whether endocrine disruptors are tied to obesity, autism and allergies."

The article also cites warnings issued by individual experts associated with the Johns Hopkins Bloomberg School of Public Health, the Endocrine Disruption Exchange, and the Science and Environmental Health Network, the latter of which has criticized the current regulatory system for failing to consider phthalates in the context of a daily chemical cocktail. "If terrorists were putting phthalates in our drinking water, we would be galvanized to defend ourselves and to spend billions of dollars to ensure our safety," concludes Kristof. "But the risks are just as serious if we're poisoning ourselves, and it's time for the Obama administration and Congress to show leadership in this area."

CONFERENCES AND SEMINARS

McDonough to Address Risks Related to Food Imports at Food-Borne Illness Litigation Forum

SHB Agribusiness and Food Safety Practice Co-Chair [Madeleine McDonough](#) will serve on a panel during the American Conference Institute's "[3rd National Forum on Food-Borne Illness Litigation, Advanced Strategies for Assessing, Managing & Defending Food Contamination Claims](#)," to be held October 26-27, 2009, in Chicago. McDonough joins a faculty that includes federal regulators and in-house counsel for industry trade associations and food companies. She will discuss issues relating to "Global Food Safety: Factoring in New Threats Associated with Foreign Food Product Imports." Among the specific topics she will address are risks and threats to the food supply and managing those risks.

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

