

## FOOD & BEVERAGE LITIGATION UPDATE

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## LEGISLATION, REGULATIONS AND STANDARDS

### FDA Censures Cheerios® for Heart Health Claims

The Food and Drug Administration has issued a warning [letter](#) to General Mills, Inc., alleging that labeling for the company's Cheerios® Toasted Whole Grain Oat cereal contains "serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations (21 CFR)." FDA has specifically alleged that this Cheerios product "is promoted for conditions that cause it to be a drug because the product is intended for use in the prevention, mitigation and treatment of disease." The warning letter singles out claims suggesting that Cheerios can "lower your cholesterol 4 percent in 6 weeks" and "reduce bad cholesterol by an average of 4 percent," as well as a claim that "Cheerios is.. clinically proven to lower cholesterol. A clinical study showed that eating 1½ cups servings daily of Cheerios cereal reduced bad cholesterol when eaten as part of a diet low in saturated fat and cholesterol."

Meanwhile, General Mills has noted that "Cheerios' soluble fiber heart health claim has been FDA-approved for 12 years, and Cheerios' "lower your cholesterol 4 percent in 6 weeks' message as been featured on the box for more than two years." The company has described the disagreement with FDA as one of language, not content. "The science is not in question," the company stated. "The scientific body of evidence supporting the heart health claim was the basis for FDA's approval of the claim, and the clinical study supporting Cheerios' cholesterol-lowering benefit is very strong." See *MSNBC.com* and *Center for Science in the Public Interest Press Release*, May 12, 2009; *Advertising Age* and *FoodNavigator-USA.com*, May 13, 2009.

### EPA Revokes All U.S. Food Tolerances for Pesticide Carbofuran

The Environmental Protection Agency (EPA) has signed a [final rule](#) that will prohibit carbofuran residue in fruits and vegetables. The agency is also canceling all existing carbofuran registrations. Effective January 1, 2010, the rule will apply to both domestic and imported produce, including alfalfa, barley, beets, corn, cranberries, cucumbers, grapes, peppers, rice, soybeans, and wheat.

According to the agency, "carbofuran products pose an unreasonable risk to man and the environment which outweighs the benefits of continued use, and therefore all uses must be canceled." EPA has been investigating the insecticide, sold under the brand name Furdan®, for several years. Its granular form was banned in the

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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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mid-1990s because it was blamed for killing millions of migratory birds. EPA claims that the pesticide "can overstimulate the nervous system, causing nausea, dizziness, confusion and, at very high exposures, respiratory paralysis and death." The rule has been forwarded to the *Federal Register* for publication.

According to a spokesperson for FMC Corp., the company that manufactures the pesticide, EPA's action is not warranted by the scientific evidence; the company reportedly plans to file objections to the agency's decision. The company apparently contends that voluntary changes it made to the label "allowed the product to meet the dietary safety standard using EPA's own conservative assumptions." An industry trade association representative was quoted as saying, "the decision to revoke carbofuran's tolerances does not live up to [the Obama administration's] commitment" to "sound science, transparency, and the rule of law." See *The Associated Press*, May 12, 2009; *Southwest Farm Press*, May 14, 2009.

### Minnesota and Chicago Ban BPA in Baby Bottles

Minnesota and Chicago have reportedly become the first state and municipality to prohibit the use of bisphenol A (BPA) in plastic food and beverage containers intended for children ages 3 or younger. Minnesota Governor Tim Pawlenty (R) recently signed legislation (H.F. 326) that would prohibit the sale of these products in the state as of January 2010, although manufacturers can sell existing stock until early 2011.

Citing a failure by federal regulators to address this issue, the Chicago City Council has also approved a similar proposal that would take effect in 2010. Some research has purportedly linked BPA to developmental health problems, breast and prostate cancer in laboratory animals, but the Food and Drug Administration (FDA) previously ruled that the chemical does not pose any danger to children when consumed in minimal amounts. "The FDA continues to be very slow about taking any action on BPA," stated Chicago Alderman Manuel Flores, one of the authors of the adopted proposal. See *FoodNavigator-USA.com*, May 12, 2009; *U.S. PIRG*, May 13, 2009; *The New York Times*, May 15, 2009;

In a related development, a recent study has claimed that prenatal exposure to low doses of BPA "causes infant male monkeys to behave more like infant females," according to a May 11, 2009, synopsis published in *Environmental Health News*. A. Nakagami, et al., "Alterations in Male Infant Behaviors Towards Its Mother by Prenatal Exposure to Bisphenol A in Cynomolgus Monkeys (*Macaca Fascicularis*) During Early Suckling Period," *Psychoneuroendocrinology*, April 2009. Researchers apparently used implanted devices to deliver BPA at doses of 10 micrograms per kilogram of body weight to female monkeys throughout their pregnancies, then observed the behaviors of their male and female offspring compared to a control group's progeny. "Prenatal exposure to BPA altered the behaviors of male infants significantly," the authors concluded. "BPA-exposed male infants behaved as female infants... These results suggest that BPA exposure affects behavioral sexual differentiation in male monkeys, which promotes the understanding of risk of BPA exposure in humans."

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Meanwhile, a leading scientist with the UK Medical Research Council (MRC) has reportedly warned consumers that a cocktail of ubiquitous chemicals has led to a decline in male reproductive health. Richard Sharpe, an MRC principal investigator, has suggested that hormone disruptors found in everyday products and the environment may block the action of testosterone in the womb, resulting in a constellation of symptoms known as Testicular Dysgenesis Syndrome (TDS). Commissioned by CHEM Trust, his report apparently relies on animal studies showing that BPA, phthalates and pesticides could increase the risk of birth defects, testicular cancer and falling sperm counts. "Because it is the summation of hormone-disrupting chemicals that is critical, and the number of such chemicals that humans are exposed to is considerable, this provides the strongest possible incentive to minimize human exposure to all relevant hormone disruptors, especially women planning pregnancy, as it is obvious that the higher the exposure the greater the risk," Sharpe was quoted as saying. See *BBC News*, May 13, 2009.

### Calorie-Labeling Rule Begins in Massachusetts by November 2010

Massachusetts has adopted tough rules requiring chain restaurants with at least 20 outlets in the state to prominently display calorie information on big boards dangling from ceilings, on printed menus and at drive-through windows. The rule, unanimously adopted by the Massachusetts Public Health Council, will take effect November 1, 2010, and reportedly affects about 50 chain restaurants with nearly 5,300 locations in the state.

"This is a major step in the right direction in fighting the obesity epidemic in our state," Massachusetts Department of Public Health Commissioner John Auerbach was quoted as saying. "We know that providing this information will help our residents make more informed choices."

More than a dozen states are apparently considering similar rules. California passed a similar law in fall 2008, but its regulations do not extend to drive-through restaurants. New York City began enforcing a calorie-posting rule in July 2008 for restaurants with more than 15 outlets nationwide. See *Product Liability Law 360*, May 13, 2009, and *The Boston Globe*, May 14, 2009.

## LITIGATION

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### Tenth Circuit Refuses to Enjoin Use of Poultry Waste as Fertilizer

The Tenth Circuit Court of Appeals has affirmed a lower court's decision not to enjoin Tyson Foods, Inc. from using poultry litter as fertilizer. [\*Oklahoma v. Tyson Foods, Inc.\*, No. 08-5154 \(10th Cir., decided May 13, 2009\)](#). Oklahoma's attorney general sought a preliminary injunction to halt the practice, arguing that poultry litter contains *E. coli*, *Salmonella* and *Campylobacter* and that its use in the Illinois River Watershed in Arkansas and Oklahoma caused fecal bacterial contamination of the watershed's waterways, which are popular for water recreation and supply drinking water for local residents.

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Tyson responded that the bacteria come from multiple sources including wildlife, various farm animals and humans. The company also noted that the way its farmers treat poultry litter kills any bacteria and that the watershed's bacteria levels "do not correlate to poultry farming or litter application, but rather correspond to areas of cattle farming and human activity." The district court heard testimony for eight days and concluded that Oklahoma failed to demonstrate that "bacteria in the waters of the [watershed] are caused by the application of poultry litter rather than by other sources, including cattle manure and human septic systems." The court also found the testimony of two of Oklahoma's expert witnesses unreliable under *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

The Tenth Circuit affirmed the district court in all respects with one judge concurring in part and dissenting in part. The dissenting judge would have found that the lower court "failed to apply the correct legal standard in evaluating Oklahoma's likelihood of success on the merits" and also "failed to meet its obligation . . . of making findings of fact and conclusions of law as to all material issues at stake in its determination of that likelihood of success."

### Vermont Rejects Non-Economic Damages for Loss of Pets

The Vermont Supreme Court has refused to expand liability to allow the recovery of non-economic damages in litigation involving the death of pets. [Goodby v. Vetpharm, Inc., No. 2009 VT 52 \(Vt., decided May 8, 2009\)](#). While the issue arose in a case involving the alleged negligence of a veterinarian and pharmaceutical company, the question whether pain and suffering damages are available to pet owners also came to the fore when melamine-contaminated pet food injured or killed cats and dogs throughout the United States and Canada in 2007.

Shook, Hardy & Bacon Public Policy Partner [Victor Schwartz](#) and Associate [Phil Goldberg](#) submitted an *amicus curiae* brief to the court on behalf of the Animal Health Institute, Federation of Dog Clubs, American Kennel Club, and Pet Industry Joint Advisory Council, analyzing the legal and public policy implications of allowing such damages. The brief explained to the court how this proposed liability would depart from hundreds of years of settled law, allowing recovery for pets unavailable in comparable human situations and drastically increasing the cost of pet care, causing many pet owners to be unable or unwilling to provide their pets with necessary and proper medical treatment.

The court agreed, declining to adopt what it held would be "a dramatic alteration to the law." In the past few years, state supreme and appellate courts in nearly 30 states have reaffirmed that emotional loss in pet injury and death cases is not compensable under any legal theory. According to the court, plaintiffs requested "a judicial expansion of law to recover for loss of a pet what the law does not allow for loss of a broad variety of critically loved human beings." Stating that the changes requested "are better presented to the General Assembly," the court found no compelling public policy reason to expand the Wrongful Death Statute to allow the recovery of non-economic damages for the loss of a pet.

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### Government Moves to Dismiss Identity Theft Charges at Kosher Slaughterhouse

As anticipated, federal prosecutors have reportedly filed a motion to dismiss a number of charges of aiding and abetting aggravated identity theft against a Postville, Iowa, slaughterhouse, its former executive and a former manager. The action was taken after the U.S. Supreme Court ruled that a conviction under the identity theft law requires a showing that those presenting false identification documents to employers knew they belonged to another real person. More information about the case and its effect on charges arising from the immigration raids that occurred in Iowa in 2008 appear in issue 303 of this Update.

According to a news source, prosecutors knew they would be unable to prove that the undocumented immigrants who worked at an Agriprocessors, Inc. facility knowingly used identification papers belonging to others, and thus, they would be unable to prove that the managers and executives were guilty of aiding and abetting. After nearly 400 of the company's employees were arrested for being in the country illegally, the plant's production nearly halted, and the company filed for bankruptcy in November 2008. See *Meatingplace.com*, May 12, 2009.

### Canada Renews COOL Dispute Before World Trade Organization

Concerned that the United States does not plan to make any changes to its country-of-origin labeling (COOL) rules for meats, fresh produce and nuts, Canada has apparently decided to move forward with a complaint it originally filed in December 2008 with the World Trade Organization (WTO). According to Canada's trade minister, "Recent instructions from the U.S. Secretary of Agriculture encouraging the U.S. industry to use very strict labeling practices have removed flexibility previously envisioned in the legislation and this affects the ability of our cattle and hog exporters to compete fairly in the U.S. market."

U.S. imports of Canadian cattle reportedly dropped 32 percent in the first two months of 2009 compared with the same period in 2008, and hog imports have fallen 40 percent. The reductions are apparently blamed, in part, on COOL requirements that U.S. plants segregate and separately label imported products. Canadian producers also claim that the rules have led to a surplus in local markets, thus depressing prices. If the WTO dispute is not resolved within 60 days, Canada could, evidently, request a dispute panel to rule on the issue. If it prevails, Canada could then legally impose retaliatory measures on U.S. imports. According to a news source, Mexico is also discussing a challenge to the COOL law before the WTO. See *FoodNavigator-USA.com*, May 13, 2009.

## LEGAL LITERATURE

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### Ashley Antler, "The Role of Litigation in Combating Obesity Among Poor Urban Minority Youth: A Critical Analysis of *Pelman v. McDonald's Corp.*," *Cardozo Journal of Law & Gender*, Winter 2009

This student-authored case note discusses the obesity-related class litigation filed in 2002 against McDonald's Corp. involving named plaintiffs who are urban

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minority youths. The author contends that, while the proposed class definition includes a much broader population of New York residents, framing such litigation to connect obesity with socioeconomic status and race “could have been a valuable opportunity to reframe the obesity issue to highlight its effect on low-income urban minority youth.”

According to the article, this reframing could have garnered more positive media attention, which could have spurred the environmental changes that the author believes are needed to combat obesity in this population. The article briefly discusses how “tobacco-style” lawsuits can be part of an effective public health strategy, noting “as was the case with tobacco litigation, if the public becomes convinced that urban minority youth are being misled or manipulated by the food industry, then the politics of fast food lawsuits may change.”

### OTHER DEVELOPMENTS

#### CSPI Urges Congress to Pass Legislation Aimed At Reducing Sodium Levels in Food

The Center for Science in the Public Interest (CSPI) has launched a campaign to halve the amount of sodium in prepackaged foods and restaurant meals within 10 years. CSPI Executive Director Michael Jacobson this week presented the group’s [case](#) to the U.S. Senate Finance Committee, claiming that “Because it raises blood pressure and increases the risk of hypertension, heart attacks and kidney disease, salt is arguably the most harmful ingredient in our food supply.” According to Jacobson, “Gradually reducing sodium levels in packaged and restaurant foods by half would ultimately save an estimated 150,000 lives and billions of dollars annually.”

Jacobson’s testimony underscored a concurrent CSPI exposé on restaurant meals that contain more than 4,000 mg of sodium per plate. The consumer advocacy group apparently examined meals at 17 restaurant chains, finding that “85 out of 102 meals had more than a day’s worth of sodium, and some had more than four days’ worth,” including some plates at Red Lobster, Chili’s and Olive Garden. “A lifetime of eating much more than the recommended amounts of sodium presents an increased risk of disease in the long term,” stated a May 11, 2009, CSPI press release. “But for some, particularly the elderly, consuming 4,000 mg or more of sodium in a single meal can present an immediate risk of heart failure or other serious problems.”

Jacobson also asked the Senate Finance Committee to consider other health care reform measures, such as imposing a federal excise tax on non-diet soft drinks, certain fruit drinks, energy drinks, sports drinks, and ready-to-drink teas to help pay for the overhaul of the nation’s health care system. The Congressional Budget Office has reportedly estimated that adding a tax of 3 cents per 12-ounce serving to sweetened beverages would generate \$24 billion during the next four years. Beverage lobbies, however, have argued that such a tax would unfairly hit lower-income Americans and not deter consumption.



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In addition, Jacobson recommended that the government (i) raise the tax on distilled spirits by 50 percent and equalize the beer and wine rates; (ii) eliminate *trans* fats from the food supply; and (iii) promote intensive lifestyle counseling in the treatment of heart disease. "Americans spend north of \$15 billion to treat high blood pressure, and many billions more on expensive heart procedures, yet the government spends peanuts improving Americans' diets," he said. See *The Wall Street Journal* and *MediaPost*, May 12, 2009.

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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.

