

ISSUE 440 | MAY 18, 2012

FOOD & BEVERAGE LITIGATION UPDATE



CONTENTS

Legislatio	n, Regu	lations	and S	stand	ards
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Antibiotics in Distillers Grain Used as Livestock Feed1
Health Groups Urge White House to Require Calorie Labels for All Retail Food Establishments
EFSA Issues Call for Data on BPA in Food and Beverages2
European Commission Adopts List of Permitted Health Claims3
Cal/EPA Extends Comment Deadline for Methanol Max. Dose Level Under Prop. 65

Litigation

Consumer Fraud Claims Narrowed Against Fruit Roll-Ups® Maker3
Court Dismisses Robo-Call Litigation as to Domino's Pizza4
"Evaporated Cane Juice" at Issue in Yogurt Litigation5
JibJab Sues White Castle for Infringing Mark in Social Media Ad Campaign5

Other Developments

Report Questions International Standards for Nanoscale Materials in Food Packaging
Corporate Accountability International Targets Fast-Food Toys
"Supermoms" Lobby Washington Against Overuse of Antibiotics in Food Production
Obese Ohio Boy Released from Protective Supervision After Weight Loss

Scientific/Technical Items

Tufts Researchers Advocate Reclassifying Obesity as Addictive Disorder9
UCLA Researchers Suggest Fructose Impairs Brain Function9
Sustainable Seafood Labeling Comes Under Fire in New Study
Coffee Drinkers Have Lower Risk of Death, Claims NIH Study

LEGISLATION, REGULATIONS AND STANDARDS

Congressional Reps Ask FDA for Info on Antibiotics in Distillers Grain Used as Livestock Feed

Referring to a **report** on the presence of antibiotic residues in distillers grain, an ethanol-production byproduct used as animal feed, U.S. Representatives Edward Markey (D-Mass.) and Louise Slaughter (D-N.Y.) have requested that Food and Drug Administration (FDA) Commissioner Margaret Hamburg provide information about the agency's surveys of these residues and explain why FDA has not acted to ensure that ethanol producers are complying with federal food additives law. In their May 11, 2012, **letter**, the lawmakers contend that the misuse of antibiotics leads to the growth of antibiotic-resistant bacteria that threaten human health and results in the deaths of some 90,000 people annually.

They note, "[t]he same antibiotics that are used in animal agriculture and that are important for human medicine such as penicillin, erythromycin, virginiamycin and tylosin, are also used by ethanol producers in order to prevent bacterial growth during the corn-based ethanol fermentation process. Producers sell the byproduct of ethanol production, known as 'distillers grains with solubles' or DGS, as livestock and poultry feed." Citing the report, the lawmakers question why FDA, which has taken the position that the antimicrobial in distillers grains used as feed or feed ingredients would be considered a food additive and subject to regulation, has not taken action to enforce its rules. The report, produced by an advocacy organization known as the Institute for Agriculture and Trade Policy, suggests that industry markets the antibiotics for these uses, contending they are generally recognized as safe, or GRAS, and thus are not subject to regulation as additives.

Markey and Slaughter specifically request whether (i) a 2008 FDA survey of antibiotic residues in DGS has been published, (ii) the information collected in the survey suggests "that drug contamination may pose a risk to animals used for human consumption," (iii) the antibiotic residues are found in milk and eggs, and (iv) FDA believes that antibiotics in DGS used for animal feed "may pose a similar public health concern as the impact of directly using antibiotic



ISSUE 440 | MAY 18, 2012

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drugs to promote livestock growth."They also question why the agency chose "to ban the use of DGS contaminated with the antibiotic, virginiamycin, in laying hens, but not in other food-producing animals."

Health Groups Urge White House to Require Calorie Labels for All Retail Food Establishments

Health and consumer organizations have urged the Obama administration to provide calorie labeling in "all retail food establishments that sell restaurant-type food, including supermarkets, convenience stores, movie theaters, casinos, bowling alleys, stadium, cafes in superstores, and hotels."

In a May 16, 2012, <u>letter</u>, representatives of more than 20 organizations in the National Alliance for Nutrition & Activity (NANA) took issue with the Food and Drug Administration's (FDA's) definition of "retail food establishments" as outlined in an April 2011 proposal for nutritional menu labeling for chain restaurants and vending machines mandated under the Affordable Care Act. The proposed rule was covered in <u>Issue 389</u> of this *Update*.

NANA argued that the definition would not only exclude other venues but "significantly limit the ability of consumers to make informed choices by reducing the number of venues providing calorie labeling." In addition, the group advocates the inclusion of alcohol labeling in FDA's final rule, noting that to "exempt it out would mean that consumers would not be provided with nutrition information for the fifth-largest source of calories in adults' diets." The group also champions more explicit nutritional labeling on vending machines, asserting that FDA's draft rules that allow labeling signs next to, above or below a vending machine make the signs "unlikely to be in a person's field of vision when making a selection."

EFSA Issues Call for Data on BPA in Food and Beverages

The European Food Safety Authority (EFSA) has issued a <u>call for data</u> as part of its ongoing risk assessment of bisphenol A (BPA) that includes an exposure assessment from both dietary and non-dietary sources. Spurred in part by a September 2011 report published by the French Agency for Food, Environmental and Occupational Health and Safety, EFSA has asked member states, researchers and other stakeholders to submit (i) "occurrence data in food and beverages intended for human consumption"; (ii) "migration data from food contact materials"; and (iii) "occurrence data in food contact materials."

According to EFSA, its latest BPA assessment will consider the "most vulnerable groups of the population (e.g. pregnant women, infants and children, etc.)" and rely on occurrence data "available in the public domain and from scientific literature" as well as any available biomonitoring data. The agency will accept data submissions until July 31, 2012.



ISSUE 440 | MAY 18, 2012

European Commission Adopts List of Permitted Health Claims

The European Commission has approved a list of 222 health claims—"for example on the role of calcium and bone health or vitamin C and the immune system"—that are permitted for use on food labeling and advertising. According to a May 16, 2012, press release, food manufacturers must adapt their practices to the new requirements by the beginning of December 2012, at which point "all claims that are not authorized and not on hold/under consideration shall be prohibited."

"Today's decision is the culmination of years of work and marks a major milestone in regulating health claims on food," said Health and Consumer Policy Commissioner John Dalli. "The EU-wide list of permitted health claims will be available on-line and will allow consumers everywhere in the EU to make an informed choice. Non-scientifically backed claims will have to be removed from the market after a short transition period."

Cal/EPA Extends Comment Deadline for Methanol Max. Dose Level Under Prop. 65

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has extended the **comment deadline** on its proposal to establish a maximum allowable dose level for methanol, a substance the forms naturally in fruits and vegetables when they are prepared for consumption by methods including slicing, chopping, pureeing, and juicing. At the request of the Technology Sciences Group, OEHHA has extended the deadline to June 25, 2012. OEHHA added methanol to the list of chemicals known to the state to cause reproductive toxicity (Prop. 65) in March. Additional details about the listing and proposed dose level appear in <u>Issue 431</u> of this *Update. See OEHHA News Release*, May 17, 2012.

LITIGATION

Consumer Fraud Claims Narrowed Against Fruit Roll-Ups® Maker

A federal court in California has dismissed several of the claims brought in a putative class action against General Mills, alleging that the company misleads consumers with the package labeling for its Fruit Roll-Ups® and Fruit by the Foot® products. *Lam v. General Mills, Inc.*, No. 11-5056-SC (U.S. Dist. Ct., N.D. Cal., order entered May 10, 2012). Additional details about the litigation, in which the Center for Science in the Public Interest is representing the plaintiffs, appear in <u>Issue 414</u> of this *Update*.

The court agreed with General Mills that label statements about the products' flavorings, i.e., "naturally flavored" and "fruit flavored," conform to federal law, and thus state-law claims alleging that these statements are misleading or



ISSUE 440 | MAY 18, 2012

deceptive are preempted. In this regard, the court noted, "the regulation allows a producer to label a product as 'natural strawberry flavored,' even if that product contains no strawberries. While the regulation's logic is troubling, the Court is bound to apply it." All claims based on these statements were dismissed with prejudice. The court also agreed with General Mills that labeling its products as "gluten free" is not misleading, rather "[t]he statement is objectively true and communicates nothing more than the absence of gluten in the product—a message used to convey the suitability of the Fruit Snacks to consumers with celiac disease and others who may wish to avoid gluten."

As for the company's use of the statement "made with real fruit," the court agreed with the plaintiff that, in conjunction with the word "strawberry" in large type on nearly every package surface and the "fanciful depiction of the products" as a type of fruit leather, "might lead a reasonable consumer to believe that product is made with real strawberries, not pears from concentrate." And while General Mills may list the actual ingredients in "small print on the bottom of the side panel," the court could not conclude at the pleading stage "that a consumer should be expected to look beyond 'made with real fruit' in order to discover the truth in small print." The court cited Williams v. Gerber Products Co., 552 F.3d 934 (9th Cir. 2008), as support for this assertion, stating, "Likewise, here, the Fruit Snacks' ingredients list cannot be used to correct the message that reasonable consumers may take from the rest of the packaging: that the Fruit Snacks are made with a particular type and quantity of fruit."

The court dismissed with prejudice the plaintiff's express and implied warranty claims which were based on allegations that the company warranted its products as healthful. She failed to point to any statement indicating that the products are healthful and neither challenged the truth of any of the packaging statements nor alleged that the products "are not proper or safe for consumption as food." The plaintiff was given 30 days to amend her complaint to more specifically plead her claims in relation to the company's "other similar products."

Court Dismisses Robo-Call Litigation as to Domino's Pizza

A federal court in Washington has dismissed franchisor Domino's Pizza from litigation alleging that a franchisee's use of automatic calls with a prerecorded message to numbers stored from previous orders violated state and federal laws prohibiting "robo-calls." *Anderson v. Domino's Pizza, Inc.*, No. 11-cv-902 RBL (U.S. Dist. Ct., W.D. Wash., Tacoma, decided May 15, 2012). While the claims against the franchisee and the telemarketing company that placed the calls remains intact, the court refused to certify a class because the plaintiff's motion was untimely, the statutory damages alone would be significant, and the "burden of any award [which would be grossly disproportionate given the actual damages] would fall on a small business."



ISSUE 440 | MAY 18, 2012

According to the court, Domino's requires franchisees to use a phone system that can store customer numbers and introduced its franchisees to the telemarketer during a national convention in 2009. Domino's also requires its franchisees to participate in advertising and promotions campaigns. Still, the court found this insufficient to "compel the conclusion that Domino's was complicit in the allegedly illegal calling here." And, while Domino's likely benefited from the calls, allowing this as a basis for liability "would dramatically expand the scope of [the Washington statute governing 'automatic dialing and announcing devices'], a task this court is unwilling to perform."

"Evaporated Cane Juice" at Issue in Yogurt Litigation

A California resident has filed a putative class action against a company that sells Greek-style yogurt products labeled with the terms "evaporated cane juice," "All Natural Ingredients" or "Only Natural Ingredients," claiming that they are false and misleading. *Kane v. Chobani, Inc.*, No CV12-02425 (U.S. Dist. Ct., N.D. Cal., San Jose Div., filed May 14, 2012). According to plaintiff Katie Kane, the company includes on the ingredients list for some of its yogurt products the term "evaporated cane juice," which the Food and Drug Administration (FDA) has warned other companies is false and misleading, and uses phrases containing the word "natural" despite making the yogurt with artificial ingredients, flavorings and colorings, such as "fruit or vegetable juice concentrate." She contends that these product representations "mislead consumers into paying a premium price for inferior or undesirable ingredients" and "render products misbranded under federal and California law."

Seeking to certify a statewide class of consumer, the plaintiff alleges unlawful, unfair and fraudulent business acts and practices; misleading, deceptive and untrue advertising; unjust enrichment; and violations of the Consumers Legal Remedies Act (CLRA), Beverly-Song Act and Magnuson-Moss Act. She requests an award of damages, restitution or disgorgement "for all causes of action other than the CLRA, as Plaintiff does not seek monetary relief under the CLRA, but intends to amend her Compliant to seek such relief"; injunctive relief; punitive damages; attorney's fees; costs; and interest.

JibJab Sues White Castle for Infringing Mark in Social Media Ad Campaign

JibJab Media Inc., a digital media company known for its photo cut-out animated videos sometimes used as political satire, has filed a trademark infringement suit against White Castle, alleging that the fast-food chain has infringed its trademarks by launching a social media ad campaign called "Jib Jab Chicken Ring" to promote its "chicken rings" menu item. *JibJab Media Inc. v. White Castle Mgmt. Co.*, No. CV12-04178 (U.S. Dist. Ct., C.D. Cal., filed May 14, 2012).



ISSUE 440 | MAY 18, 2012

According to the complaint, JibJab allows paid subscribers "to personalize videos and images by uploading digital photos and inserting images of faces into JIBJAB® content." White Castle allegedly named its promotion with the JIBJAB mark, and its online application "copies the look and feel of JibJab's cut-out animation style and further mimics JibJab's personalized content by offering users the ability to upload digital photos and insert faces into these video templates." White Castle also allegedly "explicitly announced that the videos will be 'jib jab' style." Such use, according to JibJab, was willful, done without authorization or compensation and caused confusion among members of the public.

Alleging trademark infringement and unfair competition in violation of the Lanham Act, the plaintiff seeks an injunction requiring White Castle to cease using JIBJAB marks and remove any infringing content from social media pages under its control. The plaintiff also seeks damages of \$2 million per counterfeit mark, an accounting of profits, compensation for losses sustained, treble damages, attorney's fees, and costs.

OTHER DEVELOPMENTS

Report Questions International Standards for Nanoscale Materials in Food Packaging

The Institute for Agriculture and Trade Policy (IATP) recently issued a report questioning the ability of international governing bodies to adequately address the use of engineered nanoscale materials (ENMs) in food contact and packaging materials. Noting that the Codex Alimentarius Commission, operating under the auspices of the U.N. Food and Agriculture Organization (FAO) and the World Health Organization (WHO), "has yet to agree on any agrinanotechnology standards, nor indeed, even to begin work on such standards to protect consumer health," the IATP report calls for a renewed effort to assess and regulate ENMs as a whole before specific applications are released on the market.

To this end, IATP policy analyst Steven Suppan provides an overview of Codex's regulatory mechanisms in addition to outlining challenges unique to ENMs in food packaging, such as a dearth of scientific data and confusion over the definition of "nanomaterials." In particular, Suppan urges Codex to avoid duplicative work by taking a comprehensive, health-based approach to agri-nanotechnology as opposed to a piecemeal one focused on legalizing the "commercialization of this or that product." According to Suppan, such a process would be supported "by the establishment of adequately funded FAO/WHO expert panels to assess the risks of food additives, pesticides or veterinary medicines that incorporate ENMs."



ISSUE 440 | MAY 18, 2012

"Sometimes a political gesture is important, even from resource-deprived entities such as FAO, WHO and Codex," concludes Suppan. "Committing Codex to work on agri-nanotechnology standards would be a politically and technically significant first step to put pressure on 'other entities' to complete enough of their work to help enable Codex to face the many challenges of standard setting for agricultural and food applications of nanotechnologies."

Meanwhile, researchers with the Indian Institute of Technology Guwahati have apparently **identified** the presence of amorphous carbon nanoparticles (CNPs) in carbohydrate-based food caramels such as bread, sugar caramel, corn flakes, and biscuits. Md Palashuddin Sk, et al., "Presence of Amorphous Carbon Nanoparticles in Food Caramels," Scientific Reports, April 2012. After analyzing bread buns, jaggery and other items purchased at local markets, the study's authors reported that nanoparticles were present in samples "where the preparation of the food mainly involves heating of the starting ingredients in the absence of water, leading to formation of caramels." In these instances, they noted, CNPs formed at higher temperatures were smaller than those formed at lower temperatures.

Based on these findings, the researchers speculated that the public might better accept nanoparticles in consumer products if they were derived from naturally occurring food sources, "some of which have been consumed for centuries, and thus [] considered as safe." As the study concluded, "Arguably[,] this discovery revealed that human consumption of nanomaterials in the form of food caramels has its history possibly from the period when humans for the first time started eating bread... Our findings of the presence of fluorescent CNPs in food caramels may also help their use in tracking and imaging conjugated biomolecules and drugs in vivo, without being imperiled."

Corporate Accountability International Targets Fast-Food Toys

Corporate Accountability International (CAI) has issued a May 2012 report that purportedly aims "to help parents, community residents, health professionals, activists, youth and others take action to safeguard their communities' health against the abuses of global fast food corporations." Outlining four policy approaches intended to reduce the "harmful influence of fast food corporations," the report advocates (i) school policies that would curb fast food marketing to children, (ii) zoning laws that would reduce industry influence "in communities, hospitals and other institutions," (iii) limits on "fast food promotions that target children," and (iv) a reduction in public subsidies "for fast food corporations... as a means of leveling the playing field for businesses that sell healthier food."

To these ends, the report supplies 20 specific action items that call for, among other things, prohibiting toy giveaways in children's meals and encouraging the Federal Trade Commission and state attorneys general to crack down



ISSUE 440 | MAY 18, 2012

on "unfair and deceptive advertising campaigns." In addition, CAI provides instructions for drafting local ordinances and building support among community opinion leaders. "Fast food corporations are always ready to strike back. Corporations are already seeking to preempt legislation restricting give-aways," claims the policy guide, which offers strategies for anticipating and defeating preemption efforts. "Each year, fast food corporations spend more than a half billion dollars advertising fast food meals to children. Marketing, especially to children, has proven to be a hugely successful tactic for the industry, which will continue to lobby for the right to bypass parents to reach children directly."

"Supermoms" Lobby Washington Against Overuse of Antibiotics in Food Production

A group calling itself "Supermoms Against Superbugs" reportedly gathered in Washington, D.C. recently to lobby for greater limits on antibiotics used in U.S. food production. Organized by the Pew Campaign on Human Health and Industrial Farming and the American Academy of Pediatrics, the coalition included chefs, farmers, pediatricians, and consumers who participated in meetings with congressional staff, the Food and Drug Administration, and the White House Domestic Policy Council. See Pew Campaign on Human Health and Industrial Farming Press Release, May 15, 2012.

Obese Ohio Boy Released from Protective Supervision After Weight Loss

An Ohio court has apparently released a 9-year-old boy from the supervision of Cuyahoga County Children & Family Services after he lost more than 50 pounds while in foster care and while living with an uncle in Columbus. Additional information about the case appears in Issue 421 of this *Update*.

The boy, who came to the attention of authorities in March 2010 when he was taken to a hospital with breathing problems, was released to his mother's custody under protective supervision in March 2012. He has gained a few pounds, but because he continues to work out regularly at a YMCA and has been monitored by a Big Brother, and because his mother will evidently be able to access agency assistance for 90 days, the court determined that the child's interest had been sufficiently protected.

During the most recent court proceedings, the prosecuting attorney reportedly recommended that the child's mother consider hiring a personal chef to serve healthy meals. She has apparently secured a job, but an American Civil Liberties Union attorney involved in the case indicated that a personal chef would not fit in her budget even if the county picked up half the tab. According to a family services spokesperson, other counseling options are available to the mother, and if she continues to properly care for the boy, the case will not be returned to court. See The Plain Dealer, May 10, 2012.



ISSUE 440 | MAY 18, 2012

SCIENTIFIC/TECHNICAL ITEMS

Tufts Researchers Advocate Reclassifying Obesity as Addictive Disorder

A recent analysis of scientific literature has argued in favor of reclassifying obesity as an addictive disorder based on criteria described in the Diagnostic and Statistical Manual (DSM-IV) of Mental Disorders of the American Psychiatric Association, version IV, in part because such a reclassification would help initiate policy changes aimed at curbing "the obesity epidemic." Patricia Allen, et al., "Rationale and Consequences of Reclassifying Obesity as an Addictive Disorder: Neurobiology, Food Environment and Social Policy Perspectives," Physiology & Behavior, May 2012. Concluding that previous research supports its contention that "common dietary obesity satisfy [sic] all DSM criteria for an addictive disorder," the article draws parallels between "Big Tobacco" and "Big Food" to suggest that strategies used to reduce smoking rates, such as increased taxation and limits on advertising, could be valid policy models for addressing "food addiction/food dependence." In particular, the study urges lawmakers and other policy makers to view obesity not as a personal problem but "as a multi-factorial complex disease" with environmental, neurobiological and physiological causes.

"The current food environment encourages these addictive-like behaviors where increased exposure through advertisements, proximity and increased portion sizes are routine," conclude the study authors. "Taking lessons from the tobacco experience, it is clear that reclassifying common dietary obesity as an addictive disorder would necessitate policy changes (e.g., regulatory efforts, economic strategies, and educational approaches). These policies would be instrumental in addressing the obesity epidemic, by encouraging the food industry and the political leadership to collaborate with the scientific and medical community in establishing new and more effective therapeutic approaches."

Additional details about opposition to the reclassification of obesity as an addictive disorder appear in Issue 432 of this *Update*.

UCLA Researchers Suggest Fructose Impairs Brain Function

A recent study has claimed that rats fed a diet high in fructose had more difficulty navigating a maze than those that also consumed omega-3 fatty acids, thereby raising questions about the impact of sugar consumption on cognition. Rahul Agrawal and Fernando Gomez-Pinilla, "'Metabolic Syndrome' in the brain: deficiency in omega-3 fatty acid exacerbates dysfunctions in insulin receptor signaling and cognition," *The Journal of Physiology*, May 2012. University of California, Los Angeles (UCLA), researchers for six weeks supplied two groups of rats with a fructose solution instead of drinking water while supplementing one group's rat chow with flaxseed oil and docosahexaenoic

9



ISSUE 440 | MAY 18, 2012

acid (DHA). According to the results, the rats in the fructose-only group were not only slower than their counterparts during the maze task, but their brain tissues exhibited an increased resistance to insulin.

"The second group of rats navigated the maze much faster than the rats that did not receive omega-3 fatty acids," said study co-author Fernando Gomez-Pinilla in a May 15, 2012, UCLA press release. "The DHA-deprived animals were slower, and their brains showed a decline in synaptic activity. Their brain cells had trouble signaling each other, disrupting the rats' ability to think clearly and recall the route they'd learned six weeks earlier."

In addition to speculating that fructose blocks insulin's ability "to regulate how cells use and store sugar for the energy required for processing thoughts and emotions," the researchers noted that DHA intake "seemed to restore metabolic homeostasis" and protect against the alleged cognitive effects of sugar. "It's like saving money in the bank. You want to build a reserve for your brain to tap when it requires extra fuel to fight off future diseases," explained Gomez-Pinilla, who hailed the findings as evidence that diet influences the brain as well as the body. "We're less concerned about naturally occurring fructose in fruits, which also contain important antioxidants. We're more concerned about the fructose in high-fructose corn syrup, which is added to manufactured food products as a sweetener and preservative."

Sustainable Seafood Labeling Comes Under Fire in New Study

A study published in Marine Policy has claimed that many fish stocks certified as sustainable by the Marine Stewardship Council (MSC) and Friends of the Sea (FOS) are nevertheless overfished or subject to overfishing as defined by the international standards accepted by both certifying organizations. Rainer Froese and Alexander Proelss, "Evaluation and legal assessment of certified seafood," Marine Policy, May 2012. The two researchers apparently examined data from 71 MSC-certified stocks and 76 FOS-certified stocks to determine how many fish were present in each stock and how many were being removed. They ultimately found that, of the fishing stocks with available status information, 19 percent of those certified by FOS and 31 percent certified by MSC were overfished or subject to ongoing overfishing.

According to the study, a stock is deemed "overfished" if its biomass falls below "the level that can produce the maximum sustainable yield" or "subject to overfishing""if removals... from the stock are higher than those that would allow the stock to grow to and maintain a size that can produce the maximum sustainable yield." The authors urge MSC and FOS to revisit their certification criteria by giving more weight "to the status of stock," closing any loopholes and engaging independent reviews of stock assessments. They also call on the certifying agents to revise their labeling to show consumers and retailers which products are from stocks "that still need to rebuild biomass."



ISSUE 440 | MAY 18, 2012

"States may ban the import of seafood products from overfished stocks, but only in very specific cases," notes the report, which nevertheless concludes that certified seafood is still worth purchasing "because the percentage of moderately exploited, healthy stocks is 3-4 times higher than in non-certified seafood."

Coffee Drinkers Have Lower Risk of Death, Claims NIH Study

A study conducted by the National Institutes of Health (NIH) and AARP has reportedly found that older adults who drank either caffeinated or decaffeinated coffee "had a lower risk of death overall than others who did not drink coffee," according to a May 16, 2012, NIH press release. Neal Freedman, et al., "Association of Coffee Drinking with Total and Cause-Specific Mortality," New England Journal of Medicine, May 2012. After analyzing data from 400,000 men and women ages 50 to 71 who participated in the NIH-AARP Diet and Health Study, researchers evidently concluded that coffee drinkers "were less likely to die from heart disease, respiratory disease, stroke, injuries and accidents, diabetes, and infections, although the association was not seen for cancer." In particular, the study's authors noted that the "association between coffee and reduction in risk of death increased with the amount of coffee consumed," as subjects who reported consuming three or more cups per day had an approximately 10 percent lower risk of death compared to those who did not drink coffee at all.

"Coffee is one of the most widely consumed beverages in America, but the association between coffee consumption and risk of death has been unclear. We found coffee consumption to be associated with lower risk of death overall, and of death from a number of different causes," one author was quoted as saying. "Although we cannot infer a causal relationship between coffee drinking and lower risk of death, we believe these results do provide some reassurance that coffee drinking does not adversely affect health."

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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.



