

FOOD & BEVERAGE LITIGATION UPDATE



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LEGISLATION, REGULATIONS AND STANDARDS

FDA Finalizes Manufacturing Practices for Infant Formula

The U.S. Food and Drug Administration (FDA) has announced a final rule setting standards for manufacturers of infant formula. With a compliance date of September 8, 2014, the final rule includes (i) "current good manufacturing practices specifically designed for infant formula, including required testing for the harmful pathogens (disease-causing bacteria) *Salmonella* and *Cronobacter*"; (ii) "a requirement that manufacturers demonstrate that the infant formulas they produce support normal physical growth"; and (iii) "a requirement that infant formulas be tested for nutrient content in the final product stage, before entering the market, and at the end of the products' shelf life."

Although many companies have already adopted these standards on a voluntary basis, the final rule creates federally enforceable requirements for powdered, liquid concentrate and ready-to-feed formulas. "FDA does not approve infant formulas before they can be marketed," notes the agency in a June 9, 2014, press release. "However, all formulas marketed in the United States must meet federal nutrient requirements, which are not changed by the new rule. Infant formula manufacturers are required to register with FDA and provide the agency with notification prior to marketing a new formula."

FDA Clarifies Position on Use of Wood Shelving in Artisanal Cheesemaking

The U.S. Food and Drug Administration (FDA) has issued a clarification of its position on artisanal cheesemakers' use of wood shelving, which can aid in aging cheese by controlling moisture to form rinds and hosting microbes that add character and flavor. FDA's *Constituent Update* called reports that the agency established a new rule banning wood shelving "not accurate," instead noting that its regulations merely require that "utensils and other surfaces that contact food must be 'adequately cleanable' and 'properly maintained.'" The confusion comes from a letter sent by FDA's Center for Food Safety and Applied Nutrition to the New York State Department of Agriculture and Markets indicating that wooden surfaces could not be adequately cleaned, thus violating the standards of the Food Safety Modernization Act. The *Constituent Update* noted that the letter was intended as a background of wood shelving use for aging cheeses and an analysis of relevant scientific publications, and upon later inspection FDA recognized that "the language

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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.

used in this communication may have appeared more definitive than it should have, in light of the agency's actual practices on this issue."

FDA Issues Draft Guidance on Fish and Mercury Intake for Children and Pregnant Women

The U.S. Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have joined to issue [draft guidance](#) on mercury levels and fish consumption, directed at pregnant women and guardians of young children. Recommendations include eating 8 to 12 ounces (two to three servings) of low-mercury fish like tilapia, catfish, cod, salmon, and shrimp as well as avoiding four fish high in mercury (shark, swordfish, king mackerel, and tilefish from the Gulf of Mexico) and limiting albacore tuna intake to less than 6 ounces per week. The conclusion of the comment period has not yet been announced. More information on FDA's updated guidance appears in [Issue 525](#) of this *Update*.

USDA Formalizes Swine Virus Reporting Requirement

The U.S. Department of Agriculture (USDA) has issued an order requiring pork producers, veterinarians and diagnostic laboratories to report new incidents of porcine epidemic diarrhea virus (PEDv) and porcine deltacoronavirus to state health officials or USDA's Animal and Plant Health Inspection Service. The order formalizes measures announced in April to combat the spread of PEDv, which has killed some seven million piglets since it was identified in early 2013. USDA also announced \$26.2 million to fund a variety of activities to combat the diseases and support affected producers, including vaccine development, state management and diagnostic testing. More information on the April announcement appears in [Issue 521](#) of this *Update*.

ASA Upholds Complaints Against "Superfood" Claims of Chia and Flax Seeds

The U.K. Advertising Standards Authority (ASA), has [upheld](#) four complaints challenging whether a TV ad for Bioglan "superfood" chia and flax seeds complied with the European Register of Nutrition and Health claims with its use of the word "superfood" and comparisons demonstrating the seeds' protein, calcium and fiber content.

At issue specifically was food manufacturer PharmaCare's claim that adding its chia and flax seeds to breakfast provides "as much protein as a small egg; more calcium than 100ml of milk; as much fiber as a cup of oats; and a high source of the Omega 3 fatty acid ALA." Concluding that although PharmaCare was within its rights to present the seeds as sources of the specific nutrients, the multiple references to "superfood" to reference "a general, non-specific benefit of the food for overall health," needed to be accompanied by a specific authorized health claim.

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“We noted that the Regulation [Article 10(3) of the EU Regulation 1924/2006 on Nutrition and Health Claims Made on Foods] required that only comparative nutrition claims listed in the Annex to the Regulation could be used, and that they must compare the nutrients in the advertised product to a range of foods of the same category (which did not have a composition that allowed them to have nutrition claims),” said ASA. “We therefore considered that PharmaCare would need to demonstrate that the claims ‘as much [named nutrient] as ...’ and ‘more [named nutrient] than ...’ were approved comparative nutrition claims and that the product (chia and flax seeds) was in the same food category as eggs, milk and oats, against which the comparative nutrition claims were made.”

New York Senate Passes Bill Banning Powdered Alcohol

The New York State Senate has passed legislation ([S7217A](#)) that would ban the sale of powdered alcohol, a concentrated alcoholic beverage deemed “unnecessary” and “dangerous” by the bill’s sponsor, Sen. Joseph Griffo (R-Rome). One such product, Lipsmark, LLC’s Palcohol[®], was approved in April by the Alcohol and Tobacco Tax and Trade Bureau (TTB), but the agency later reversed its approval, stating that it had been made in “error.” Lipsmark has reportedly resubmitted its application for approval.

If the bill is passed by the New York State Assembly, powdered alcohol would be banned in the state even if TTB approves it to be marketed in the United States. “Should the [Food and Drug Administration] reverse its decision again and approve it, we should have a law in place to prohibit the sale of this product in New York. I hope the Assembly will join us in passing this legislation,” said Griffo.

Powdered alcohol has been banned in Alaska, and legislation to prohibit it was approved recently in South Carolina and Vermont. Additional details about Palcohol[®] appear in Issue [523](#) of this *Update*. See *New York State Senate News Release*, June 11, 2014.

LITIGATION

Claims About Pesticides in “100% Natural” Teas to Proceed

A federal court in California has denied the motion to dismiss filed by The Hain Celestial Group in four consolidated putative class actions alleging that the company deceives consumers by labeling and promoting 10 of its Celestial Seasonings[®] teas as “100% Natural” when they contain chemical insecticides, fungicides and herbicides. *Von Slomski v. The Hain Celestial Group, Inc.*, No. 13-1757 (U.S. Dist. Ct., C.D. Cal., order entered June 10, 2014). So ruling, the court disagreed that the plaintiffs failed to state a claim or lacked standing, or that the litigation should be dismissed under the primary jurisdiction doctrine.

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The company challenged the Eurofins test on which the plaintiffs rely to support their claim that the teas contain “significant levels” of man-made, chemical pesticides. According to the defendant, the plaintiffs failed to provide details about the testing, and the study “was published by ‘an admittedly biased short-seller that admits that it issued the report in hopes of driving down Hain Celestial’s stock price.’” Stating that neither the strength of the evidence nor its alleged bias is proper to consider at this stage of the proceedings, the court concluded “that it is plausible that the teas contain pesticides.”

The court also rejected the company’s argument that the plaintiffs have not plausibly alleged that a reasonable consumer would likely be deceived by the “100% Natural” label. In the court’s view, this was not one of the rare cases where it could find, based on the pleadings, that the labeling was unlikely to deceive a reasonable consumer. The court also ruled that the plaintiffs are not required to allege a specific definition of “natural.” The court was unpersuaded that “unless a product is labeled ‘organic,’ reasonable consumers would understand that the product may contain traces of pesticides,” noting that the evidence may support that theory, but that “based on the allegations, it strikes the Court as plausible that the evidence will favor Plaintiffs.” The court further refused to conclude that “100% Natural” is non-actionable puffery.

Acknowledging that courts have split over whether named plaintiffs have standing as to products they have not purchased, the court decided that the issue was “better dealt with at the class certification stage.” It also declined to rule that they lacked standing to pursue claims based on representations made on the company Website. While it agreed that the plaintiffs had not alleged “that they relied on the representations, . . . that doesn’t result in the dismissal of any claims. Plaintiffs adequately allege reliance on the representations on the product label and have standing to pursue their claims based on those representations.”

As for primary jurisdiction, the court noted the U.S. Food and Drug Administration’s “lack of interest in providing further guidance on the use of the word ‘natural’ in food labeling” made staying or dismissing the case for the agency to do so futile.

Vermont GE Labeling Law Challenged as Constitutionally Infirm

Four food, beverage and business trade organizations have filed a constitutionally based challenge to Vermont’s recently enacted law that would require food and beverage manufacturers to disclose on product labels that their products are “produced with genetic engineering” (GE), or “may be” or are “partially” so produced and to prohibit the use of terms such as “natural” in the labeling, signage and advertising of GE products. *Grocery Mfrs. Ass’n v. Sorrell*, No. 14-0117 (U.S. Dist. Ct., D. Vt., filed June 12, 2014).

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According to the complaint, it will be difficult or impossible to comply with the law's July 1, 2016, effective date, because members must "revise hundreds of thousands of product packages," "establish Vermont-only distribution channels" or "revise the labels for all of their products, no matter where they might be sold in the United States." The plaintiffs claim that the law's proscriptions "are beyond Vermont's power to enact" by "compelling manufacturers to convey messages they do not want to convey, and prohibiting manufacturers from describing their products in terms of their own choosing, without anything close to a sufficient justification." They also contend that federal labeling laws preempt the state requirements.

Alleging First and Fifth Amendment violations, including free speech restrictions and arbitrary enforcement, as well as violations of the Commerce and Supremacy Clauses, the plaintiffs allege that the law unjustifiably singles out processed foods while protecting in-state interests such as dairy and tourism, because it exempts food derived entirely from an animal which has not itself been produced with genetic engineering, foods sold in restaurants, alcoholic beverages, and processing aids and enzymes. They also claim that the state government apparently has a weak interest in the law and simply served "as a pass-through for advocates of controversial views that the State did not purport to endorse, and that are based on conjecture about 'unintended consequences' that the State did not bother to substantiate, or even investigate." They further contend that concerned consumers can avoid GE foods by other means, such as buying certified organic or voluntarily labeled products, or consulting informative Websites.

Olive Oil Purity Claims Target Company Owners

After Kangadis Food Inc. filed for bankruptcy claiming that putative class litigation challenging its alleged misleading olive oil representations has cost the company, which does business as The Gourmet Factory, more than \$1.4 million in attorney's fees and could cost an additional \$750,000 if the claims go to trial, the named plaintiffs filed class claims against its owners in a New York federal court. *Ebin v. Kangadis Family Mgmt. LLC*, No. 14-1324 (U.S. Dist. Ct., S.D.N.Y., filed June 11, 2014).

The heavily redacted complaint alleges that these individuals were directly involved in trying to pass off pomace oil, processed from olive oil residue, as "100% Pure Olive Oil" under the Capatriti brand. Details about the litigation appear in Issue [515](#) of this *Update*.

One of the individuals named as a defendant in the new lawsuit—identified as Aristidis Kangadis—apparently evaded deposition when the company's counsel argued to the court that he "is a 73 year old gentleman who is not identified in the Defendants' Disclosures or other discovery responses as having knowledge of the relevant facts. He is ... uninvolved with the business.

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He has no official role in the company.” The plaintiffs do not apparently agree, alleging “In fact, Aristidis Kangadis...” with the following 10 pages redacted. Additional allegations regarding piercing the corporate veil and alter ego are also redacted.

Alleging breach of express warranty, breach of implied warranty of merchantability, deceptive acts or practices under New York law, violation of New Jersey’s consumer fraud law, negligent misrepresentation, and fraud, the plaintiffs seek the certification of a nationwide class of purchasers.

OTHER DEVELOPMENTS

CSPI Threatens Campbell Soup with Litigation over V8 Beverages

The Center for Science in the Public Interest (CSPI) has informed the CEO of Campbell Soup Co. that it will seek injunctive and monetary relief if the company continues to (i) “mislead[] consumers about the juice content, nutritional value, and healthfulness of its Products”; (ii) “represent[] that its V8 V-Fusion Refreshers contain no added sugars”; and (iii) mak[e] deceptive nutrient content claims on its V8 Splash Products in violation of United States Food and Drug Administration’s (‘FDA’) Fortification rule.”

At issue are products from the V8 V-Fusion Refreshers (20-25% juice) variety of the V8 V-Fusion product line and the entire line of V8 Splash juice drink products, including V8 Splash (5-10% juice), Diet V8 Splash (8% juice) and V8 Splash Smoothies (10% juice). CSPI characterizes these products as “sugary juice cocktails.”

According to CSPI, the marketing and labeling for these products are confusingly similar to V8 100-percent juice products for which Campbell “has built a trusted reputation and nutritious ‘health halo’” despite their high sodium content and the lack of equivalence between consuming vegetable juice and “real vegetables.” The food advocacy group claims that Campbell implies that the V8 V-Fusion and V8 Splash products, with prominent nutrient-content claims and fruit and vegetable depictions on product labels, are equally healthy when they are actually fruit/vegetable juice cocktails that contain mostly water, artificial food dyes, high-fructose corn syrup or artificial sweeteners, added sugars, and/or a low percentage of juice. Any vitamins are added, according to CSPI, and their low levels “are unlikely to provide any of Campbell’s claimed health benefits.”

CSPI claims that Campbell falsely represents that its V8 V-Fusion line of products has no added sugar, because the V8 V-Fusion Refreshers do have added sugar. It claims that this representation violates federal law. 21 C.F.R. 101.60(c)(iii)(B)(2)(1). The group also claims that the fortification of V8 Splash products violates FDA’s Fortification rule, which “bans the addition of nutrients to

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nutritionally void or harmful beverages.” CSPI contends that the V8 Splash products consist mostly of water and high-fructose corn syrup, and thus the company cannot fortify them by adding vitamins and then claiming they are “an excellent source of vitamins A and C.”

In closing, CSPI claims that a consumer injury occurs “each time a consumer sees marketing for, or purchases, one of these Products.” It warns that litigation for permanent injunctive relief and disgorgement will ensue if Campbell chooses not to respond to CSPI’s findings. The letter specifically refers to the laws of California, Massachusetts, New Jersey, and Texas, implying that litigation could be filed in these jurisdictions or jurisdictions with similar consumer-protection laws.

Rudd Center Faults CFBAI in Report on TV Food Advertising to Young People

The Yale Rudd Center for Food Policy and Obesity has released a new brief updating its annual report on trends in TV food advertising to young people. Documenting changes “in the total number of food-related TV ads viewed by children and adolescents from 2002 to 2013,” the brief concludes that despite the Children’s Food and Beverage Advertising Initiative (CFBAI), “the total number of food and beverage ads viewed by children has increased by 8% and advertising to adolescents increased 25% since 2007.”

Although youth exposure to food-related TV ads apparently peaked in 2004, Rudd Center alleges that the number of food- and beverage-related TV ads viewed by children younger than age 12 has only increased since companies adopted CFBAI in 2007. According to the brief, TV ads for fast-food restaurants represented 23 percent of food-related ads viewed by children and 28 percent of ads viewed by adolescents in 2013. In addition to fast food-related ads, children and adolescents purportedly viewed the most TV commercials for cereals, candy, other types of restaurants, prepared meals, and beverages. Among other trends, Rudd Center noted that exposure to ads for crackers and savory snacks “increased by over 50% for children and adolescents from 2011 to 2014, continuing increases in advertising to children from 2004.”

“[Y]ouths saw more ads for candy, carbonated beverages and fast food in 2013 than 2007, while ads for healthy product categories represented less than 5% of food ads viewed,” opines the brief. “These findings demonstrate that industry self-regulation has not resulted in meaningful improvements in TV food advertising to youth.”

PCRM Dietitian Claims “Big Food” Follows “Big Tobacco” Playbook

A dietitian and nutrition educator associated with the Physicians Committee for Responsible Medicine (PCRM), which promotes a vegan lifestyle and has apparently been associated with the animal rights organization People for

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the Ethical Treatment of Animals, draws parallels between the tobacco and food industries in an article titled “Why Big Food is the Big Tobacco of the 21st Century.” Susan Levin notes that in 1962, the Royal College of Physicians called for restricting tobacco advertising and sales to children and increasing the cigarette tax, and that within the last week the United Nations “made almost the exact same recommendations about unhealthy foods, which it says are now a bigger threat to global health than tobacco.”

Levin implies that the food industry distorts science to market a dangerous product, just like tobacco, and cites as an example how cigarette manufacturers reformulated their products to low-tar and filtered when sales declined “after early reports uncovered . . . health risks.” According to Levin, “Big Food” continues to sell meat and dairy products, albeit reformulated as low fat and low sodium to address public concerns about diets high in fat and salt, despite “[a] mountain of evidence link[ing] meat and dairy-heavy diets to cancer, type 2 diabetes, obesity, and heart disease.” She claims that the meat and dairy industry have an even deeper relationship with government than tobacco does and contends, “The battle currently raging on Capitol Hill to gut healthy school lunch standards is a perfect example of the food industry’s powerful sway over Congress.”

While she admits that Congress is unlikely in the near term to tax “Big Food,” crack down on “junk food” advertising to children and overhaul government subsidies as recommended by the United Nations, she concludes, “the sooner we start treating Big Food like Big Tobacco, the better off we’ll be.” See *AL.com*, June 9, 2014.

Action on Sugar Campaign Targets Ginger Beer

The U.K.-based Action on Sugar campaign has issued a new survey allegedly revealing “the shockingly high and unnecessary levels of sugar in carbonated sugar-sweetened soft drinks,” according to a June 12, 2014, press release. After analyzing 232 sugar-sweetened drinks sold in grocery stores, Action on Sugar researchers reported that 79 percent of surveyed beverages contain six or more teaspoons of sugar per can. In particular, the campaign singled out ginger beer as one category of sugar-sweetened beverage with higher sugar levels than expected, recommending that these drinks contain only 9 grams of sugar per 100 milliliters.

“Added sugars are completely unnecessary in our diets and are strongly linked to obesity and Type II Diabetes, as well as to dental caries; which remains a major problem for children and adults,” said Action on Sugar Chair Graham MacGregor. “Replacing sugar with sweeteners is not the answer: we need to reduce overall sweetness so people’s tastes can adjust to having less sweet drinks... A similar approach has successfully reduced salt intake; people are consuming 15% less salt than they were 10 years ago, and now prefer less salty foods... It is NOW time to do the same for sugar.”

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Must Cheese Be Labeled GMO?

According to a Harvard microbiologist, 80 to 90 percent of the hard cheese produced in the United States uses, as part of the curd-separation process, rennet made with a genetically modified (GMO) ingredient—chymosin. Noting that “chymosin produced by *E. coli* was the first enzyme made with recombinant DNA technology approved for use in food. . . all the way back in 1991,” Kevin Bonham asks whether GMO technology opponents would object to eating cheese made with this type of chymosin, which is also naturally occurring in calf stomachs and chemically indistinguishable from its animal-derived counterpart, and whether companies, such as Whole Foods, promising to label their GMO products will use the label on cheese products. Apparently, “[m]ost regulatory agencies don’t consider chymosin an ingredient.” Bonham also reports that “the problem goes way beyond cheese,” because the U.S. Food and Drug Administration “has approved over 30 recombinant enzymes for use in food production, including α -amylase, which is used in the production of almost all glucose or fructose syrups.” See *Scientific American*, June 9, 2014.

Possible Data Breach at P.F. Chang’s

P.F. Chang’s China Bistro Inc. is investigating a potential data breach that may have exposed thousands of customers’ credit and debit card data. After contacting banks to determine commonly visited locations, a cybersecurity blogger reported that the data of customers who visited P.F. Chang’s between March 2014 and May 19, 2014, has been offered for sale on an underground Website known for selling data resulting from the Target breach in late 2013. While the source of the potential breach remains unknown, experts suggest that thieves planted malware onto the point-of-sale systems that employees use to run customer’s credit cards because similar malware was used to steal credit and debit card information from other retailers. See *USA Today*, June 11, 2014.

Camel Milk Gains Support as Next Popular “Super Food”

Camel’s milk and its associated products may be the next “super food” category, according to *USA Today*. Several U.S. farms with breeding camels have reportedly adopted camel milking programs in seven states, with new programs set to open soon in seven more. Scientific studies show that camel milk has higher levels of several nutrients—including protein, potassium, magnesium, B vitamins, iron, copper, manganese, vitamin C, and zinc—as well as lower cholesterol than cow’s milk. The process of milking the camels is apparently easier than milking cows, as dromedary (single-humped) and Bactrian (double-humped) camels are taller and do not require seating or crouching while milking them, but they produce less milk than cows. One camel farmer uses a 15-second flash pasteurization process that reportedly

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retains nutrients more efficiently, but the pasteurization for camel milk has yet to be standardized. See *USA Today*, June 8, 2014.

MEDIA COVERAGE

***The Atlantic* Tackles Fructose and Sugar Confusion**

A recent article in *The Atlantic* illustrated the confusion surrounding fructose, glucose, sugar, and other sweeteners by interviewing several researchers whose conclusions on nutrition and sugar contradict each other to varying degrees. James Hamblin points to Mehmet Oz's unqualified support—and later retraction—of agave syrup as a natural and healthy sweetener alternative to sugar or high-fructose corn syrup as an example of how the current scientific understanding of fructose and glucose is incomplete and difficult to draw conclusions from. Agave is composed of 90 percent fructose and 10 percent glucose, compared to an even split for table sugar and 55 percent fructose in high-fructose corn syrup. Because of its low glucose content, agave has a low glycemic index, which led many nutritionists to believe that it was a healthy alternative. Fructose has since been blamed for, among other diseases, liver damage and atherosclerosis, and described as “toxic,” a label that one researcher dismisses: “If you have too much oxygen, it is toxic. If you get too much water, you have water intoxication. That doesn't mean we say oxygen is toxic.” Hamblin criticizes prematurely conclusive recommendations on nutrient-based eating, whether nutritionists advise low-fat diets as they did a decade ago or low-sugar diets as they do now. “If there is a problem in all of this,” he writes, “it's that speaking definitively before definitiveness is due can spread more confusion.” See *The Atlantic*, June 5, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Red Meat Intake in Early Adulthood Allegedly Linked to Breast Cancer Risk

A recent study has allegedly linked higher red meat intake in early adulthood to an increased breast cancer risk, raising questions about how dietary habits adopted before midlife can affect health outcomes. Maryam Farvid, et al., “Dietary protein sources in early adulthood and breast cancer incidence: prospective cohort study,” *BMJ*, June 2014. In addition to analyzing food questionnaire data from 88,803 premenopausal women ages 26-25 who were enrolled in the Nurses' Health Study II, researchers with the Harvard School of Public Health documented 2,830 cases of breast cancer during 20 years of follow-up. Based on this data, they concluded that not only were higher intakes of total red meat associated with an increased risk of breast cancer

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overall, but that “higher intakes of poultry, fish, eggs, legumes, and nuts were not related to breast cancer overall.”

“So far, studies have suggested no significant association between red meat intake and breast cancer,” explains a concurrent *BMJ* press release. “However, most have been based on diet during midlife and later, and many lines of evidence suggest that some exposures, potentially including dietary factors, may have greater effects on the development of breast cancer during early adulthood.”

To this end, the study’s authors reported that the “each serving per day increase in red meat was associated with a 13% increase in risk of breast cancer,” noting that although “this is relatively small risk” when applied to breast cancer, “the absolute number of excess cases attributable to red meat intake would be substantial, and thus a public health concern.” As a result, the authors suggested that replacing red meat with legumes and poultry during early adulthood per American Cancer Society dietary guidelines could reduce breast cancer risk later in life.

OFFICE LOCATIONS

Denver, Colorado
+1-303-285-5300

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

Philadelphia, Pennsylvania
+1-215-278-2555

San Francisco, California
+1-415-544-1900

Seattle, Washington
+1-206-344-7600

Tampa, Florida
+1-813-202-7100

Washington, D.C.
+1-202-783-8400

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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.

