

## FOOD & BEVERAGE LITIGATION UPDATE

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### LEGISLATION, REGULATIONS AND STANDARDS

#### U.S. Lawmakers Issue Report on Energy Drinks

U.S. Rep. Edward Markey (D-Mass.) and Sens. Richard Durbin (D-Ill.) and Richard Blumenthal (D-Conn.) have [issued](#) a joint report presenting the results of their investigation into the energy drink industry. Titled "What's all the Buzz About?," the report is based on survey responses from 14 energy drink companies asked to outline their current marketing, labeling and manufacturing practices. According to the lawmakers, the responses highlight various inconsistencies in how these companies market and label their products under current regulations, "leading to consumer confusion and a lack of transparency."

In particular, the report alleges that (i) "four out of the 14 companies surveyed classify and market one or more of its products as dietary supplements, as opposed to conventional beverages"; (ii) "concentrations of caffeine are not uniformly represented on the label of the brands evaluated," with some concentrations exceeding safety levels set by the Food and Drug Administration (FDA) for soda; (iii) "energy drink companies make a range of advertising claims related to the functional benefits of their products that are not generally evaluated or substantiated by FDA"; and (iv) "energy drinks contain a myriad of specialty ingredients whose combinations and additive impacts are not thoroughly evaluated or well understood." The report also claims that despite pledges to the contrary, companies frequently target adolescent consumers with unconventional marketing practices as well as product design and placement on store shelves.

To address these concerns, the report ultimately urges energy drink manufacturers to label the caffeine content of their products; warn consumers when the caffeine content exceeds 200 parts per million, the amount that FDA generally recognizes as safe; and cease marketing their products to youth younger than age 18. The legislators have also asked companies to submit to FDA "any serious adverse events associated with energy drink use."

"It's time for energy drink makers to stop masking their ingredients, stop marketing to kids, and start being more transparent with their products," said

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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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Markey in an April 10, 2013, press release. "It's time for the FDA to crack down on these drink makers and for the FTC [Federal Trade Commission] to investigate advertising practices of these companies to ensure that kids and parents are not being subjected to deceptive marketing practices."

### DOJ Charges Kentucky Cattle Company for Falsifying Records

The U.S. Department of Justice (DOJ) has reportedly indicted a London, Kentucky-based cattle company and its treasurer for falsifying records related to a federal investigation and creating false documents. The charges apparently arise out of a Food and Drug Administration (FDA) investigation to determine whether the company was violating a 2006 court-ordered injunction requiring it to notify buyers if the company sells them animals with medical drugs in their systems. The order also requires the company to "identify the potential cause for the medical drugs in the animals and to refrain from purchasing animals from sellers who supply cattle that contain medical drugs."

Williams Cattle Co. treasurer Pamela Collette allegedly "falsified weekly reports that were supposed to be sent to buyers verifying that the animals sold were drug free, in an attempt to influence the outcome of the investigation. She is also alleged to have created false documents that appeared to be prepared by a company that sold animals to Williams Cattle, when in fact the company had not generated the documents."

Collette will be arraigned in federal court April 24, 2013. If convicted, she could be sentenced to five years in prison on each charge and a \$250,000 fine. The company faces the same fine for each count. *See U.S. DOJ Press Release*, April 9, 2013.

### OSHA Cites Flavoring Company over Diacetyl Exposure

The U.S. Occupational Safety and Health Administration (OSHA) has reportedly cited Natural Flavors Inc. for 12 alleged workplace safety and health violations at its Newark, New Jersey, facility and proposed penalties in excess of \$60,000. According to OSHA, an inspection confirmed that company employees were "overexposed to diacetyl," a butter flavoring purportedly associated with bronchiolitis obliterans, a debilitating lung disease.

An agency regional administrator said, "As early as 2004, the flavoring manufacturing industry has been aware that its workers who are overexposed to diacetyl on the job have developed severe, life-threatening lung disease. It is outrageous that Natural Flavors would expose workers to this debilitating chemical without taking the necessary steps to properly assess exposure and protect its employees." OSHA included a willful violation in the citation for the company's alleged failure "to adequately identify and evaluate respiratory hazards." *See OSHA Regional News Release*, April 8, 2013.

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### FDA Proposes Fees to Finance FSMA Implementation

The U.S. Food and Drug Administration (FDA) has [proposed](#) two new fees—a food import user fee and a food facility and inspection fee—that the agency says will “enhance the safety protections for imported food and feed” as well as support “new and improved activities required by the Food Safety Modernization Act (FSMA) to modernize FDA’s inspection system.” According to FDA, programs to support FSMA are scheduled to cost \$295 million next year and will apparently be 94-percent funded by user fees.

“These investments will provide industry with consistent and transparent food and feed safety guidance to assure the safety of America’s food and feed supply,” the agency asserts in its budget proposal. FDA has also proposed new user fees to support its cosmetic and food contact substance notification programs.

In a statement releasing the budget, FDA Commissioner Margaret Hamburg said, “These are tight budget times, and the FDA budget request reflects this reality. Our budget increases are targeted to strategic areas that will benefit patients and consumers and overall strengthen our economy. Through the good work of the FDA, Americans will receive life-saving medicines approved as fast as or faster than anywhere in the world, confidence in the medical products they rely on daily, and a food supply that is among the safest in the world.” See *FDA News Release*, April 10, 2013.

### BPA and Obesity Case Study to Illustrate NTP’s Literature Review Approach

The National Toxicology Program (NTP) will host an April 23, 2013, Webinar to discuss case studies on the alleged health effects of [bisphenol A](#) (BPA) and the chemicals perfluorooctanoic acid and perfluorooctane sulfonate. The studies are intended to illustrate how the NTP Office of Health Assessment and Translation will implement its draft systematic literature-based review methodology in carrying out potential human health hazard assessments. Comments on the draft approach and case studies are requested by June 11.

The BPA case study provides a draft protocol to evaluate the evidence for an association between obesity and exposure to the chemical, used in food contact materials, including plastic and metal cans; cash register receipts; sports equipment; and CDs and DVDs. It does not reach any final risk conclusions, but shows how relevant literature will be identified and rated in developing hazard identification conclusions.

### NTP Seeks Information on Folic Acid Safety

The National Toxicology Program (NTP) and the Office of Dietary Supplements are seeking information and comments on an [approach document](#) titled “Identifying Research Needs for Assessing Safe Use of High Intakes of Folic

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Acid.” According to NTP, the information gathered through the request will be used to prioritize topics for a workshop the agency is planning “to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid.”

Although “[t]he benefit of supplemental folic acid for pregnant women to prevent neural tube defects in their children is well established,” NTP stated, “at the same time, there is interest in understanding potential adverse health impacts from high intakes of folic acid.” The agency is specifically seeking information on the following topics: (i) “health effects of most concern for high folate intake”; (ii) “assessments of folic acid intake and folate levels that are relevant and validated for high exposure”; (iii) “critical co-factors for the evaluation of potential health impacts of folic acid”; and (iv) “experts in the field who should be considered for inclusion in the workshop.” NTP will accept information and comments through May 28, 2013. *See Federal Register*, April 5, 2013.

### WHO Issues Global Alert on New Strain of Avian Influenza (H7N9)

The World Health Organization (WHO) has [issued](#) a global alert and response update on a new strain of novel avian influenza A (H7N9) virus identified by Chinese health officials, who have apparently confirmed 38 cases resulting in 10 fatalities. According to WHO, which has not yet recommended any trade or travel restrictions, there is no evidence to date of “of ongoing human-to-human transmission,” although the agency is working with Chinese authorities to monitor those with close contacts to infected patients and to determine potential disease reservoirs in domestic and wild poultry.

Meanwhile, the U.S. Centers for Disease Control and Prevention (CDC) has reportedly activated its Emergency Operations Center in Atlanta, Georgia, in response to the outbreak, in addition to publishing [interim guidance](#) for U.S. clinicians, public health departments and health care workers outlining virus testing and control methods. “Ongoing (sustained) person-to-person spread is necessary for a pandemic to occur,” states a recent CDC press release. “This is a ‘novel’ (non-human) virus and therefore has the potential to cause a pandemic if it were to change to become easily and sustainably spread from person-to-person . . . CDC takes routine preparedness actions whenever a new virus with pandemic potential is identified, including developing a candidate vaccine virus to make a vaccine if it were to be needed.” *See CIDRAP News*, April 9, 2013; *CDC Press Release*, April 11, 2013.

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### FSA to Consolidate Food Safety Rules

The U.K. Food Standards Agency (FSA) has launched public consultations on two sets of proposed legislation, "[The Contaminants in Food \(England\) Regulations 2013](#)" and "[The Food Additives, Flavourings, Enzymes, and Extraction Solvents \(England\) Regulations 2013](#)." The first set of regulations related to food contaminants will revoke the 2010 version and take into account new European Commission regulations regarding (i) "maximum levels for nitrate in foodstuffs"; (ii) "maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed"; and (iii) under-enforcement of EU provisions providing for "the labeling of groundnuts, other oilseeds, derived products thereof and cereals." The Contaminants in Food Regulations will also revoke "national legislation on mineral hydrocarbons in food and revoke and remake[] the provisions of the Erucic Acid in Food Regulations 1977."

The second set of regulations will consolidate "all legislation within [FSA's] remit covering food additives, flavourings, enzymes, and extraction solvents into a single consolidated statutory instrument." Part of the agency's effort to simplify food safety legislation in response to the government's Red Tape Challenge Initiative, the proposed legislation will (i) "introduce the use of compliance notices for non-safety related offences for enforcement purposes"; (ii) "update the food additive legislation to reflect the establishment of Annexes II and III to the Additive Regulation (EC) No. 1333/2008 and the removal of the transitional measure for the additive Directives"; (iii) "amend the flavouring legislation to refer to the revised transitional measures"; and (iv) "revoke The Food (Suspension of the Use of E128 Red 2G as Food Colour) (England) Regulations 2007 No. 2266."

The agency will accept comments from food manufacturers, suppliers and distributors, consumers, and other stakeholders on both sets of regulations until June 5, 2013.

### California Lists BPA as Reproductive Toxicant Under Prop. 65

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has added bisphenol A (BPA) to the "list of chemicals known to the State to cause reproductive toxicity for purposes of Proposition 65" (Prop. 65). The [listing](#), which will require warnings to consumers, took effect April 11, 2013. Failure to provide the warnings can result in significant financial penalties, and alleged violations can be enforced by private citizens.

OEHHA based its determination on a National Toxicology Program report which concluded that the chemical "causes reproductive toxicity (developmental endpoint) at high doses." BPA is commonly found in cash register receipts, CDs and DVDs, and food packaging material, including plastic containers and bottles, and metal cans and lids.

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When OEHHA proposed listing the chemical, it also proposed adopting a maximum allowable dose level (MADL) of 290 micrograms per day. Additional information about the MADL proposal appears in Issue [468](#) of this *Update*.

When this *Update* was prepared, the agency had not yet indicated whether or when it would finalize the MADL. Details about the history of BPA's use in the United States and the Food and Drug Administration's refusal to prohibit the use of BPA in food packaging are addressed in Issue [433](#) of this *Update*. See *OEHHA News Release*, April 11, 2013.

### LITIGATION

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#### SHB Public Policy Group Spearheads Victory in Texas Supreme Court on Damages in Pet Injury Cases

SHB's Public Policy Group recently contributed to a favorable outcome for animal medicine manufacturers in the Supreme Court of Texas, which ruled in *Strickland v. Medlen* that emotion-based damages, including loss of companionship and sentimental damages, are not permitted in pet injury claims in Texas. Presenting on behalf of amici during oral argument, SHB Partner [Victor Schwartz](#) highlighted the public policy issues at stake after a lower appellate court in Texas broke with the majority of courts nationally by allowing broad, new emotion-based damages for pet deaths in a November 2011 ruling. SHB Partner [Phil Goldberg](#) authored the [amici brief](#) on behalf of the Animal Health Institute and several animal health organizations, developed other amici and helped prepare defense counsel on key issues, while Partner [Manuel Lopez](#) served as local counsel on the SHB amici brief and provided expertise on the appellate process.

In its ruling, the court ultimately recognized that finding for additional liability for the loss of a pet could have significant downsides for pets themselves. "For example, the American Kennel Club, joined by the Cat Fanciers' Association and other pro-animal nonprofits, worry that 'pet litigation will become a cottage industry,' exposing veterinarians, shelter and kennel workers, animal-rescue workers, even dog sitters, to increased liability: 'Litigation would arise when pets are injured in car accidents, police actions, veterinary visits, shelter incidents, protection of livestock and pet-on-pet aggression, to name a few,'" states the court, citing the amici brief authored by Goldberg. "As risks and costs rise, there would be fewer free clinics for spaying and neutering, fewer shelters taking in animals, fewer services like walking and boarding, and fewer people adopting pets, leaving more animals abandoned and ultimately put down."



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### Court Dismisses Consumer-Fraud Claims for Chocolate Products Not Purchased

A federal court in California has dismissed consumer-fraud putative-class claims filed in a first amended complaint against the Ghirardelli Chocolate Co., alleging violations pertaining to white chocolate products that the named plaintiff did not purchase. *Miller v. Ghirardelli Chocolate Co.*, No. 12-4936 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., order entered April 5, 2013). Details about a similar order entered as to the original complaint appear in Issue [465](#) of this *Update*.

While the court disagreed with the defendant that the products were dissimilar because its label description—"Ghirardelli® Chocolate"—is like a Dunkin' Donuts logo used on products, such as coffee, that are clearly not donuts, the court found that "an 'unlawful' claim based on 'chocolate' necessarily reaches back to the FDA definition. Identity labeling of food requires—under the plain language of the regulation—that the statement of identity of the commodity on the principal display panel of a food in package form be 'the name . . . required by any applicable Federal law or regulation.' That identity of the commodity here under FDA regulations is 'white chocolate,' not 'chocolate.' That in turn means that a determination of standing is back to an examination of the entire label, and the court previously found—even with the juxtaposition of 'Ghirardelli®' to 'Chocolate' and the resulting implication of a connection to chocolate—the five products and the alleged misrepresentations were not sufficiently similar."

The court denied the defendant's motion to dismiss the unfair competition law claim, finding that (i) the state's Sherman Law, which incorporates federal law and regulations adopted after its effective date, is not unconstitutional because it provides a mechanism for delay and public input on any proposed incorporation before a federal regulation takes effect in California; and (ii) purported pleading deficiencies as to the company's failure to disclose that the products are "imitation," "artificial" or "artificially flavored" are premature at the pleading stage—according to the court, "Ghirardelli has enough information to answer the complaint."

### New "Misbranded Food" Lawsuit Filed by Repeat Plaintiffs

Two California residents who recently sued Trader Joe's for allegedly misbranding certain foods by using "organic evaporated cane juice" on its product labels have filed a putative nationwide class action against a yogurt company with similar allegations. *Gitson v. Clover-Stornetta Farms, Inc.*, No. 13-1517 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed April 4, 2013). Details about the Trader Joe's lawsuit appear in Issue [477](#) of this *Update*.

The named plaintiffs contend that the defendant markets some 14 different flavors of its yogurt products, all of which list "organic evaporated cane juice" as an ingredient on their labels "in violation of a number of labeling regula-

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tions.” They cite Food and Drug Administration (FDA) guidance, warning letters and an open letter to demonstrate that use of this term for a yogurt sweetener is “illegal.”

The plaintiffs also target the company’s Websites for their alleged use of “illegal claims.” According to the complaint, they relied on “Defendant’s unlawful and deceptive misrepresentations on Defendant’s website before purchasing Defendant’s products.” Citing an FDA letter to the Washington Legal Foundation, the plaintiffs claim that “Defendant’s web address is printed on its package labels, and by law Defendant’s website misrepresentations are incorporated in its labels.” They also challenge “all natural” claims on the products, asserting that “locust bean gum, tapioca starch, elderberry juice (for color), and beet juice concentrate (for color)” are not natural ingredients. Calling the products “legally worthless,” the plaintiffs claim that they “paid a premium price for the misbranded food products.”

Seeking to certify a nationwide class of product purchasers or an alternative subclass of California consumers, the plaintiffs allege unlawful, unfair and fraudulent business acts and practices; misleading, deceptive and untrue advertising; violation of the Consumers Legal Remedies Act; and restitution based on unjust enrichment/quasi-contract. They request an order requiring the defendant to cease from selling these products and to engage in corrective action, damages, restitution, disgorgement, punitive damages, attorney’s fees, costs, and interest.

### Firearms Maker Sues Vodka Co. for Using Tommy Gun Shape as Bottle

A firearms company that holds the Tommy Gun™ trademark has brought an infringement action against a company selling its vodka products in 19-inch bottles shaped like Tommy guns. *Saeilo Enters., Inc. v. Alphonse Capone Enters., Inc.*, No. 13-2306 (U.S. Dist. Ct., N.D. Ill., E. Div., filed March 27, 2013). The plaintiff seeks damages, treble damages, profits, attorney’s fees, and costs under state and federal law, as well as a permanent injunction, cancellation of the vodka maker’s trademark registrations and the destruction of remaining stock. According to a news source, the plaintiff has been aggressive in protecting its brand and, in 2008, sued a company making Tommy gun replicas. It has also apparently trademarked the term “Chicago Typewriter,” a slang expression for the submachine gun. See *ABA Journal*, April 5, 2013.

### Ohio Appeals Court Strikes State Bill Preempting City *Trans* Fat Ban

An Ohio appeals court has determined that Ohio legislators improperly enacted an appropriations bill rider that was intended to preempt a Cleveland ordinance prohibiting the use of “industrially produced *trans* fat” in foods prepared by retail food establishments and food service operations, such as fast-food restaurants, unless the foods were served “in a manufacturer’s



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original sealed package.” *City of Cleveland v. Ohio*, No. 98616 (Ohio Ct. App., 8<sup>th</sup> App. Dist., Cuyahoga Cnty., decided March 28, 2013). Additional information about Cleveland’s lawsuit challenging the state law appears in Issue [422](#) of this *Update*.

The court agreed with the city that the state law was an unconstitutional attempt to preempt the city from exercising its home rule powers under the state constitution and that the provisions, enacted as amendments to a state appropriations bill, violated the constitution’s one-subject rule. In determining that the appropriations bill amendment was not a “general law,” the court found that it (i) was “largely devoid of specific food content regulation” such as the prohibition found in the city ordinance and thus that the state law “is not part of a statewide and comprehensive legislative enactment”; (ii) failed to address retail food establishments, because by its terms it “applies only to food service operations,” and thus did not have “a uniform application throughout the state”; (iii) did not set forth any regulation on food content while preempting municipal legislative action on food content, thus serving only to curtail Cleveland’s police powers; and (iv) “fails to prescribe any rule of conduct upon the citizens of Ohio in regard to the broader topics of food nutrition information and food content that it purports to regulate.”

As for the one-subject rule violation, the court addressed the process of its enactment and concluded, “[T]he amendments were drafted on behalf of a special interest group with the specific purpose of snuffing out the Ordinance.” The preemption provisions were “tucked away” in a two-year Senate appropriations bill and “were not vetted by the usual committee process.” The House did not vote on the provisions, nor were there any hearings on them. They were unsupported by nutritionist, dietician or other health care professional testimony. And they took “up less than two pages of an appropriations bill in excess of 3,000 pages.” According to the court, these facts “create a strong suggestion that the provisions were combined for tactical reasons. The amendments in this case present us with a classic instance of impermissible logrolling.” The court affirmed the trial court’s grant of the city’s motion for summary judgment.

## OTHER DEVELOPMENTS

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### Advocacy Groups Urge Retailers to Consider Placement and Advertising of “Sugar” Drinks

The Center for Science in the Public Interest (CSPI), other advocacy groups and local public health officials have sent letters to the CEOs of [supermarkets](#) and [pharmacies](#) urging them to “encourage customers to purchase healthier, no- and low-calorie drinks in place of higher calorie sugar drinks to improve customers’ health, as well as boost [their] company’s reputation for social responsibility and caring for the health of its customers.”

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The letters cite scientific studies purportedly demonstrating that “sugar drinks (carbonated or not) are a major contributor to the obesity epidemic,” “the single largest source of calories in many Americans’ diets,” and “the only food or beverage that has been directly linked to obesity.”

“With supermarkets [and pharmacies] selling the lion’s share of sugar drinks, your company and others clearly have an opportunity to promote your customers’ health by encouraging customers to switch from high-calorie to low-calorie drinks,” the letters assert. “Possibilities include limiting sugar drinks in check-out aisles, posting signs in the soft-drink aisle to encourage people to switch to drinks with few or no calories, featuring primarily non- and low-sugar soft drinks at end caps and in ‘spectacular’ displays, giving greater prominence to lower-calorie drinks in...advertising, and adjusting prices to encourage the purchase of non-and low-caloric drinks.” *See CSPI News Release*, April 10, 2013.

### Researchers Claim Filtering Process Adds Arsenic to Beer

Scientists presenting at the National Meeting & Exposition of the American Chemical Society have reportedly identified elevated levels of arsenic in some beers sold in Germany. According to Mehmet Coelhan, who conducted the study of 140 beers as part of a monitoring program, “the discovery could be of importance for breweries and other food processors elsewhere that use the same filtering technology implicated in the elevated arsenic levels in some German beers.”

The team concluded that arsenic was released into the beer from a filtering material called “kieselguhr, or diatomaceous earth, that’s used to remove yeast, hops and other particles and give the beer a crystal clear appearance.” According to Coelhan, “The resulting arsenic levels were only slightly elevated, and it is not likely that people would get sick from drinking beers made with this filtration method because of the arsenic. The arsenic is still at low levels—the risk of alcohol poisoning is a far more realistic concern, as stated in previous studies on the topic.” *See American Chemical Society News Release*, April 7, 2013.

## SCIENTIFIC/TECHNICAL ITEMS

### Energy Drink Additive Allegedly Linked to Heart Disease

A recent study has allegedly linked L-carnitine, a nutrient found in red meat and commonly used as an additive in energy drinks, to an increased risk of cardiovascular disease (CVD). Robert Koeth, “Intestinal microbiota metabolism of L-carnitine, a nutrient in red meat, promotes atherosclerosis,” *Nature Medicine*, April 2013. According to the study, L-carnitine, like the trimeth-

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ylamine-containing compound choline, forms a proatherogenic compound known as trimethylamine-*N*-oxide (TMAO) when metabolized by intestinal microbiota. Given the “markedly” increased ingestion of L-carnitine in industrial societies, researchers apparently set out to examine the effects of the nutrient on CVD risk using isotope tracer studies in humans as well as animal models.

In particular, the study’s authors reportedly “tested the carnitine and TMAO levels of omnivores, vegans and vegetarians, and examined the clinical data of 2,595 patients undergoing elective cardiac evaluations,” in addition to examining “the cardiac effects of a carnitine-enhanced diet in normal mice compared to mice with suppressed levels of gut microbes.” The results evidently showed that not only did increased TMAO levels predict CVD risk in humans who also exhibited high carnitine levels, but that the metabolite caused CVD in mice by altering “cholesterol metabolism on many levels.” The findings also suggested that a diet high in carnitine primes intestinal microbiota to produce TMAO, whereas vegans and vegetarians included in the study apparently lacked the microbiota to produce much TMAO even after consuming red meat.

“The bacteria living in our digestive tracts are dictated by our long-term dietary patterns,” said the study’s lead author, Stanley Hazen, in an April 7, 2013, Cleveland Clinic press release. “A diet high in carnitine actually shifts our gut microbe composition to those that like carnitine, making meat eaters even more susceptible to forming TMAO and its artery-clogging effects. Meanwhile, vegans and vegetarians have a significantly reduced capacity to synthesize TMAO from carnitine, which may explain the cardiovascular health benefits of these diets.”

Hazen also warned about the potential danger of supplementing the diet with additional carnitine. “Carnitine is not an essential nutrient; our body naturally produces all we need,” he noted. “We need to examine the safety of chronically consuming carnitine supplements as we’ve shown that, under some conditions, it can foster the growth of bacteria that produce TMAO and potentially clog arteries.”

### **BMJ Studies Examine Global Health Impact of Salt Reduction**

Three research articles recently published in *BMJ* have reportedly concluded that reducing dietary salt consumption and increasing potassium intake “will have major health and cost benefits across the world,” according to an April 4, 2013, summary in *BMJ Case Reports*. The first study involved a systematic review and meta-analysis focusing on “the effect of longer term modest salt reduction on blood pressure.” Feng He, et al., “Effect of longer term modest salt reduction on blood pressure: Cochrane systematic review and meta-analysis of randomized trials,” *BMJ*, April 2013. Using data from 34 trials with 3,320 participants, the study’s authors determined that “a modest reduction in salt intake for four or more weeks cause significant and, from a population viewpoint, important falls in blood pressure in both hypertensive and normotensive individuals.” In

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particular, they argued that reducing salt intake to 3 grams per day “will have a greater effect” than current recommendations “and should become the long term target for population salt intake.”

The second research article also conducted a systematic review and meta-analyses using data from 14 cohort studies and 52 randomized controlled trials focused on adults, as well as nine controlled trials and one cohort study focused on children. Nancy Aburto, et al., “Effect of lower sodium intake on health: systematic review and meta-analyses,” *BMJ*, April 2013. Based on their analyses, the authors evidently concluded that decreased sodium intake in both children and adults reduces blood pressure, while decreased intake in adults is also associated with a lower risk of stroke and fatal cardiovascular disease, with “no adverse effect on blood lipids, catecholamine levels, or renal function.”

The third systematic review and meta-analyses examined the “effect of increased potassium intake on cardiovascular risk factors and disease,” using data from 22 randomized controlled trials and 11 cohort studies. Nancy Aburto, et al., “Effect of increased potassium intake on cardiovascular risk factors and disease: systematic review and meta-analyses,” *BMJ*, April 2013. The results apparently showed that increased potassium intake not only “reduces blood pressure in people with hypertension” but is also associated “with a 24% lower risk of stroke,” thus suggesting that “increased potassium intake is potentially beneficial to most people without impaired renal handling of potassium for the prevention and control of elevated blood pressure and stroke.”

“The World Health Organization... recommends to reduce dietary salt intake to less than 5 g (about one teaspoon) per person per day and set a global goal of 30% relative reduction in mean adult population intake of salt by 2025,” notes *BMJ Case Reports*. “Much evidence shows that reducing salt intake lowers blood pressure and thereby reduces the risk of stroke and heart disease. Less is known about the potential benefits of increasing potassium intake, but lower potassium consumption has been linked with elevated blood pressure.”

### GMO Panel Member Calls for Transparency of Biosafety Data

In a recent [paper](#), a member of European Food Safety Authority and Norwegian Scientific Committee for Food Safety genetically modified organism (GMO) panels has explored whether biosafety data provided to regulatory authorities by companies developing GMOs should be protected from disclosure. K.M. Nielsen, “Biosafety Data as Confidential Business Information,” *PLOS Biology*, 2013. Noting that standards or criteria as to what constitutes “legitimate” confidential business information (CBI) in GM product applications are lacking, the author argues that CBI claims are used indiscriminately

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and prevent independent research and monitoring. The article concludes with the author's suggested criteria for "warranted CBI claims." Among other things, the criteria would exclude from protection "information present in patent documents or for information not considered to be or not under confidentiality agreements in other companies/locations/countries."

### OFFICE LOCATIONS

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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.

