

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

USDA Sets Standards for Olive Oil

According to an agricultural and food law blog, the U.S. Department of Agriculture (USDA) has published the U.S. Standards for Grades of Olive Oil and Olive-Pomace Oil, effective October 25, 2010. They supersede standards that were in effect since 1948. According to the agency, the standards "are designed to facilitate orderly marketing by providing a convenient basis for buying and selling, for establishing quality control programs, and for determining loan values. The standards also serve as a basis for the inspection and grading of commodities by the Federal inspection service." The USDA Website contains only a cached version of this document; it is unclear whether the material is undergoing some further change. See U.S. Agricultural & Food Law and Policy Blog, October 20, 2010.

FSIS Issues In-Plant Video Monitoring Draft Guidelines

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has issued draft guidelines for video monitoring at federally inspected meat and poultry plants. Although the guidelines do not require in-plant video monitoring, such practices can be used to help strengthen food safety and humane animal-handling practices, and to monitor product inventory and building security, according to an October 14, 2010, FSIS news release. "Records from video or other electronic monitoring or recording equipment may also be used to meet FSIS' record-keeping requirements," the agency stated.

The guidelines stem from a 2008 USDA Office of Inspector General (OIG) recommendation that called for FSIS to "determine whether video monitoring would be beneficial in slaughterhouse establishments," FSIS Administrator Al Almanza was quoted as saying. "In agreeing to that OIG recommendation, FSIS committed to issuing compliance guidelines for using video records and a directive clarifying FSIS' authority to access establishment video records. FSIS recognizes the importance of this resource." FSIS has requested comments by December 14, 2010.



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Bitter Battle over Organic Hops Comes to a Head

The American Organic Hop Grower Association (AOHGA) has reportedly persuaded a National Organic Standards Board (NOSB) subcommittee to reverse a recommendation that aimed to keep hops on the National List of Allowed and Prohibited Substances, which governs the use of synthetic and non-synthetic materials in organic production and handling. In advance of an October 25-28, 2010, public meeting in Madison, Wisconsin, NOSB had requested feedback on a number of National List exemptions, including one that currently permits the use of non-organic hops in organic beer. Although the NOSB Handling Committee initially backed a continuation of this policy due to the limited availability of organic hops, AOHGA faulted NOSB for holding hops "to a higher standing than virtually any other agricultural product" by allegedly insisting that all 150 varietals become available in organic form before removal from the list.

AOHGA thus urged organic beer brewers and other supporters to petition the board, claiming in part that the National List exemption would continue to undercut the economic feasibility of producing organic hops "for a market that can be supplied by non-organic hops." Noting recent increases in the quantity of commercially available organic hop varieties, the group also argued that "every type or style of beer can be made with the existing commercially available organic hop varieties." As AOHGA Executive Director Meghann Quinn reiterated in a October 12, 2010, final <u>comment</u>, "Again, the quantities and varieties available will certainly increase once brewers source organic hops using forward contracts."

In response to the petition, the NOSB Handling Committee has voted unanimously to reverse its previous ruling, proposing that the board remove organic hops from the National List by January 1, 2013. "This time interval formally recognizes the growth of organic hops' availability and yet allows brewers two growing seasons to secure their organic hops through forward contracting, making adjustments to future product formulations and specifications, and preparing their customers and consumers for the product changes anticipated, if any," states the committee's discussion document.

The committee has also left room for brewers to petition NOSB to include individual hop cultivars on the National List, thereby continuing the exemption for those varietals felt "to be inadequately available in organic form." In striking this compromise, the committee has expressed its intention to "facilitate the growth and development of the organic hop market without the potentially catastrophic effects that immediate removal of hops from [the National List] would cause." Additional details about the upcoming NOSB meeting appear in <u>Issue 365</u> of this *Update. See OregonLive.com*, October 17, 2010.



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NOP Issues Draft Guidance for Certifying Agents and Certified Operations

The U.S. Department of Agriculture's Agricultural Marketing Service has announced the availability of five draft guidance documents for National Organic Program (NOP) certifying agents and certified operations. The documents cover the following topics: (i) Compost and Vermicompost in Organic Crop Production (NOP 5021); (ii) Wild Crop Harvesting (NOP 5022); (iii) Outdoor Access for Organic Poultry (NOP 5024); (iv) Commingling and Contamination Prevention in Organic Production and Handling (NOP 5025); and (v) The Use of Chlorine Materials in Organic Production and Handling (NOP 5026). Once finalized, the guidance will become available through "The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Agents," which provides "those who own, manage, or certify organic operations with guidance and instructions that can assist them with complying with the [NOP] regulations." To this end, NOP will accept written comments on the drafts until December 13, 2010. *See The Federal Register*, October 13, 2010.

EC Proposes Limited Ban on Food from Cloned Livestock

The European Commission has reportedly proposed a five-year ban on animal cloning for food production in the European Union (EU), but stopped short of prohibiting meat and milk from clone offspring. According to an October 19, 2010, *Europa* press release, the plan would also suspend "the use of cloned farm animals and the marketing of food from clones," while envisaging "the establishment of a traceability system for imports of reproductive materials for clones, such as semen and embryos of clones."

In issuing its decision, the Commission stressed animal welfare concerns but also noted that "there is no scientific evidence confirming food safety concerns regarding foods obtained from cloned animals or their offspring." It emphasized that the proposal would not suspend cloning "for uses other than food, such as research, conservation of endangered species or use of animals for the production of pharmaceuticals." As Health and Consumer Policy Commissioner John Dalli stated, "The Communication adopted today is a response to calls from the European Parliament and Member States to launch a specific EU policy on this sensitive issue. I believe that the temporary suspension constitutes a realistic and feasible solution to respond to the present welfare concerns."

Meanwhile, the Commission's failure to include clone offspring in the ban has already drawn criticism from European Parliament Vice President Gianni Pitella, who called for "a moratorium—as soon as possible—to guarantee consumer protection in this sector." Dalli, however, expressed hopes that the compromise would resolve a deadlock among the European Council, Commission and Parliament on the issue of novel food regulations, which



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govern the use of food and food ingredients that were not "significantly used for human consumption within the EU" before May 15, 1997. He also confirmed that a report on cloned livestock will be delivered to the European Council by the end of 2010. *See the Daily Mail, EurActiv, Law360,* and *Telegraph,* October 19, 2010; *Meatingplace* and *The Wall Street Journal,* October 20, 2010.

EFSA Issues Additional Opinions on "Functional Food" Health Claims

In its ongoing review of food product health claims, the European Food Safety Authority (EFSA) has <u>adopted</u> 75 new opinions addressing 808 claims. EFSA's independent scientists <u>opined</u> that claimed functional-food effects, such as improves the "immune system" or "immune function," "supports immune defences," "reduces inflammation," or "decreases potentially pathogenic gastro-intestinal microorganisms," were either insufficiently defined or unsupported by scientific data. The authority also turned aside claims that the probiotic bacteria in a specific brand of yogurt maintain immune defenses against the common cold.

According to a news source, the scientific studies that yogurt-maker Yakult submitted to justify such claims were inadequate. Some suggest that this week's rulings by EFSA have seriously compromised industry efforts to promote functional foods, in which companies have made significant investment. Industry is reportedly challenging the determinations, complaining that the authority is applying excessively rigorous standards, and has asked for meetings to discuss the criteria used.

According to EFSA, "many" general function claims in this series were subject to unfavorable opinions "due to the poor quality of the information provided to EFSA." Information gaps the authority identified include (i) "inability to identify the specific substance on which the claim is based (e.g. claims on 'dietary fibre' without specifying the particular fibre)"; (ii) "lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of body functions (e.g. claims on renal 'water elimination')"; (iii) "lack of precision regarding the health claim being made (e.g. claims referring to terms such as 'energy' and 'vitality')"; (iv) "or lack of human studies with reliable measures of the claimed health benefit."

Overall, the opinions were favorable only where sufficient scientific evidence supported the claims and generally "related mainly to vitamins and minerals but also included claims on specific dietary fibres related to blood glucose control, bowel function or weight management; fatty acid claims related to brain function, vision or heart health; or claims related to live yoghurt cultures and lactose digestion."



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The opinions have been forwarded to the European Commission (EC) and EU member states which are responsible for authorizing product claims. EFSA plans to finalize all "general function" health claims, other than for botanicals, by the end of June 2011. This is EFSA's third series of opinions; to date, the authority has assessed 1,745 claims from a list of more than 4,500 submitted by the EC and member states. *See The Guardian*, October 19, 2010.

Texas Officials Investigate Deaths Linked to Listeria-Tainted Celery

The Texas Department of State Health Services (DSHS) has ordered a San Antonio produce plant to stop processing food and recall all products shipped since January 2010 because "laboratory tests of chopped celery from the plant indicated the presence of *Listeria monocytogenes*." DSHS has prohibited Sangar Fresh Cut Produce from reopening without approval from the department, which issues such orders when conditions pose "an immediate and serious threat to human life or health," according to an October 20, 2010, DSHS press release.

After an eight-month investigation into a *Listeriosis* outbreak that included five deaths, DSHS allegedly linked Sangar's chopped celery to six illnesses in people "with serious underlying health problems." State inspectors also reportedly "found sanitation issues at the plant and believe the *Listeria* found in the chopped celery may have contaminated other food product there." The recall primarily affects fresh produce sealed in packages and distributed "to restaurants and institutional entities, such as hospitals and schools."

Meanwhile, Sangar President Kenneth Sanquist has publicly disputed the state's findings, saying that independent testing "shows our produce to be absolutely safe, and we are aggressively fighting the state's erroneous findings." Plaintiffs' lawyer Bill Marler, however, has since issued Freedom of Information Act requests to the state of Texas to examine the viability of the DSHS testing. "Sangar Fresh Cut Produce's listeria [sic] outbreak will surely result in lawsuits," according to an October 20, 2010, post on Marler's *Food Poison Journal. See Food Poison Journal*, October 20 and 21, 2010; *CNN.com*, October 21, 2010.

LITIGATION

Texas Bellwether Claims Settled in GM Rice Contamination MDL

According to a news source, three days after trial began in a lawsuit brought by Texas rice farmers over losses they allegedly sustained when the price for U.S. long-grain rice plunged on global markets after it was discovered that conventional crops were contaminated with a genetically modified (GM) seed, the parties settled the case. *In re Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., settled October 15, 2010). While continuing to main-



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tain that it was not negligent, defendant Bayer CropScience has apparently indicated that it has been willing to settle the claims "on reasonable terms" and was "pleased to be able to do so in this instance."

The Texas bellwether cases, consolidated with thousands of others before a multidistrict litigation court (MDL), reportedly involved three growers claiming some \$430,000 in damages and unspecified punitive damages. The growers settled for \$290,000, according to CropScience CEO Bill Buckner. The company has lost three trials in federal court and three in state court, all involving similar claims and all on appeal or undergoing review by post-trial motion. The total damages awarded to date exceed \$50 million, including \$42.5 in punitive damages. The settlement will not affect the remaining 6,000 claims. *See Bloomberg*, October 18, 2010.

Claims Narrowed in Chewy Bars® Trans Fat Class Action

A federal court in California has dismissed on preemption and standing grounds a number of state-law claims against The Quaker Oats Co. in a lawsuit alleging that the company falsely advertises its Chewy Bars® as containing "0 grams trans fat" when the ingredient list labeling includes hydrogenated vegetable oil. *Chacanaca v. The Quaker Oats Co.*, No. 10-0502 (U.S. Dist. Ct., N.D. Cal., San Jose Div., decided October 14, 2010). So ruling, the court lifted a discovery stay order and scheduled a case management conference for December 16, 2010.

The defendant sought judgment on the pleadings at the outset of the action, arguing that "the doctrines of express preemption, primary jurisdiction, and Article III standing warrant immediate dismissal of the entire case." The court agreed to dismiss all state-law deception claims involving the "0 grams trans fat" statement, the "good source" of calcium and fiber statements and a statement that the product contains whole grain oats but lacks high-fructose corn syrup. According to the court, as pleaded, these claims "seek to impose a requirement in *addition* to what is mandated by federal statutes and regulations and therefore fail on preemption grounds." Because the plaintiffs had not pleaded they were competitors of Quaker Oats, the court also found that they lacked standing to bring an unfair competition claim under the Lanham Act.

The court will allow the plaintiffs to pursue claims pertaining to "the term 'wholesome,' the 'smart choices made easy' declaration [appearing on a decal], and depictions of oats, nuts, and children." The court determined that "[n]either the decal nor the children are appropriately categorized as nutrient content claims, and defendant's contention that the [Nutrition Labeling and Education Act] preempts the charge that they are misleading is without support. The NLEA does not regulate 'front of the box' symbols such as the smart choices decal or the photographs." Because the Food and Drug



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Administration had not "developed even an informal policy governing or defining the word 'wholesome," the court also found that plaintiffs were not preempted from litigating whether this statement was misleading.

The court rejected the defendant's contention that the decal, "wholesome" language and depictions should be left to agency consideration under the primary jurisdiction doctrine, finding that "whether or not the 'smart choices made easy' decal, the photographs of oats, nuts, and children in soccer uniforms, or the term 'wholesome' are misleading—do not entail technical questions or require agency expertise." Also rejected were defendant's arguments that the plaintiffs did not establish injury in fact because they had not alleged any health-related ailment from their consumption of snacks with *trans* fats, the product statements were non-actionable puffery, or that the plaintiffs failed to plead their claims with sufficient particularity.

Among the claims that survived the motion for judgment on the pleadings is that the "smart choices program itself is 'deceitful,' and is a product of an 'industry-funded initiative created by a coalition of market giants." The plaintiffs allege that the decal is "nutritionally suspect' and is designed to make 'highly processed foods appear as healthful as unprocessed foods."

Stay in Snapple "Natural" Beverage Lawsuit Extinguished

A federal court in New Jersey has granted the defendant's unopposed motion to extinguish the stay in a lawsuit contending that Snapple beverage products are falsely advertised as "natural" because they contain high-fructose corn syrup, a purportedly non-natural ingredient. *Holk v. Snapple Beverage Corp.*, No. 07-3018 (U.S. Dist. Ct., D.N.J., decided October 15, 2010) (unpublished). The court had stayed the litigation pending the Food and Drug Administration (FDA) reaching a decision about the definition of "natural." According to the court's order, "The FDA in response has declined to address that issue."

Noting that another district court in New Jersey has lifted a stay imposed for the same reason in similar litigation (*Coyle v. Hornell Brewing Co.*), the court agreed to reopen the case, but refused to reinstate the motions that were pending when the case was "administratively terminated." The court ordered the parties "to move again, upon new notices of motion and in accordance with the Federal Rules of Civil Procedure and the Local Civil Rules, for any relief sought in the Previous Motions." Additional information about *Coyle* appears in <u>Issue 356</u> of this *Update*; additional information about *Holk* appears in <u>Issue 360</u> of this *Update*.



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Court Excludes Experts Linking Personal Injury to Antibiotic in Horse Feed

An appeals court in New Mexico has affirmed a trial court's decision to dismiss claims that a horse rancher's family became ill as a result of exposure to horse feed containing an antibiotic toxic to horses. *Parkhill v. Alderman-Cave Milling & Grain Co.*, No. 29,120 (N. M. Ct. App., decided October 6, 2010). The parties settled claims that the feed sickened or killed horses from several of the plaintiffs' horse ranches, and the trial court dismissed claims, as a sanction for discovery abuse, that the family's personal health was affected by exposure to the feed. The appeals court did not reach the sanctions issue, finding that the lower court properly excluded the testimony of the plaintiffs' experts.

The toxin involved was monensin, an antibiotic that is a common additive to feed for livestock, but prohibited in horse feed. The plaintiffs alleged that immediately after contact with the feed they developed skin rashes, irritated eyes, brittle nails, and diarrhea. While they did not seek treatment then, some eight weeks after the feed was no longer used on their ranches, Joey Parkhill sought treatment from his family physician for shoulder pain, and then he and the rest of the family consulted with the physician for "generalized health complaints, including dizziness and light-headedness, breathing difficulties, insomnia, decreased energy, irritability, elevated blood pressure, and weight gain." They sought to have this physician and another testify that their health problems were caused by monensin exposure.

The appeals court agreed with the trial court that the experts were not qualified to testify that monensin exposure caused the family's health problems. Regarding the treating physician, a majority of the court concluded that "testimony as to external causation, or etiology, was beyond the expertise of the average treating physician and beyond the scope of a differential diagnosis conducted for the purposes of diagnosis and treatment." A concurring judge would have held that the majority went too far "by excluding differential diagnosis testimony to establish cause in all toxic tort cases."

According to the court, the physician who was hired for the litigation and proffered as an expert in environmental medicine and toxicology could not testify that the illnesses were caused by the family's exposure to monensin because he had no experience with the antibiotic, did not quantify the dose they received and did not know that monensin is handled at much greater concentrations in the livestock industry with no adverse health consequences for workers. In this case, the ranch hands who worked for the family apparently experienced no ill effects from the contaminated horse feed.



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OTHER DEVELOPMENT

Corporate Watchdog Targets Fast Food Industry

Corporate Accountability International Deputy Director Leslie Samuelrich contends in a recent *AlterNet* article that fast food companies "spend hundreds of millions of dollars each year marketing a dangerous product to America's children." She claims the companies deny putting children at risk and, instead, blame parents for their children's obesity problems. According to Samuelrich, nonprofits and government agencies that promote healthy eating habits are not engaged in a "fair fight" with the industry, noting for example that the Robert Woods Johnson Foundation spends \$100 million annually to address childhood obesity, while "major food and beverage corporations spend at least \$1.6 billion in the United States every year—16 times more—to convince kids to eat unhealthy food."

Corporate Accountability International, describing itself as a corporate watchdog, says that it has been "waging winning campaigns to challenge corporate abuse for more than 30 years." It has conducted campaigns against the tobacco industry, publishing materials and handbooks and organizing boycotts against specific companies, and has taken on issues such as green-washing, purported human rights violations abroad and "corporate control of water." The organization's summer 2010 newsletter claims that companies such as fast food corporations have taken "a lesson from Big Tobacco's playbook," and shield themselves from public accountability by recruiting medical experts to serve on advisory councils to "create[] the appearance the corporation is committed to children's health." *See AlterNet.org*, October 20, 2010.

New Report Tracks BPA Use by Packaged Food Companies

Green Century Capital Management, an investment advisory firm focused on environmentally responsible companies, and As You Sow, an advocacy group that promotes corporate accountability, have issued a 2010 **report** that ranks packaged food companies on their efforts to address bisphenol A (BPA). Building on a previous effort published in April 2009, *Seeking Safer Packaging 2010* seeks to analyze "how companies are responding to this critical issue by disclosing information, exploring substitutes and committing to phase out BPA."

The findings apparently indicate "that notable progress has been made toward commercializing substitutes to BPA epoxy can linings," with the "overwhelming majority" of the 26 survey respondents acknowledging "some efforts" to mitigate potential risks. The report notes, however, that outside some industry leaders, "some of the largest companies are the biggest laggards in seeking substitutes to and phasing out BPA."



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According to the authors, "New scientific and investigative reports on the potential health impacts have been published, more states and cities are adopting restrictions, and consumer concern is rising." They ultimately urge all companies to "make significant investments in phasing out BPA from products and take aggressive action to remove it where feasible and safe substitutes exist." As the report concludes, "Companies should also increase transparency on how they are responding to consumer concerns and possible risks to shareholder value associated with the chemical." Additional information about the April 2009 report appears in Issue 301 of this Update. See As You Sow Press Release, October 21, 2010.

MEDIA COVERAGE

Andrew Korfhage, "The Chocolate You Eat Is Likely Made by Enslaved Children," *AlterNet*, October 18, 2010

"Sorry to scare you, but on Halloween much of the chocolate Americans will hand out to trick-or-treaters will be tainted by the labor of enslaved children," writes Andrew Korfhage in this October 18, 2010, *AlterNet* article alleging that chocolate manufacturers have failed to eradicate child labor practices as promised. According to the author, Hershey's and other companies pledged "nearly a decade ago to set up a system to certify that no producers in their supply chains use child labor," but have yet to take any "meaningful action."

Korfhage credits a 2001 exposé with documenting the "scandalous conditions under which most U.S. chocolate is made," noting that the effort spurred Representative Eliot Engel (D-N.Y.) and Senator Tom Harkin (D-Iowa) to introduce legislation seeking "slave-free" certification for all U.S. chocolate. "[B]ut before Harkin's bill could pass the Senate, the chocolate industry had announced a voluntary four-year plan to clean up its own supply chains, without legislation," claims Korfhage, who cites a recent Tulane University report finding that "the majority of children exposed to the worst forms of child labor remain unreached."

The article concludes by urging consumers to source their chocolate from companies that "certify their supply chains, via labels such as the Fair Trade label and the IMO Fair for Life label." It also calls on the public to contact lawmakers and "demand by law that slave-produced chocolate doesn't belong on the shelves of stores in the USA."



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SCIENTIFIC/TECHNICAL ITEMS

Studies Examine U.S. Salt Intake over 50 Years, Iodine Deficiency

A recent study has reportedly claimed that dietary salt intake has remained constant in the U.S. population for the past five decades, raising questions about government efforts to restrict sodium consumption. Adam Bernstein and Walter Willett, "Trends in 24-h urinary sodium excretion in the United States, 1957–2003: a systematic review," *American Journal of Clinical Nutrition*, November 2010. Researchers examined data on urine sodium excretions collected from 26,271 individuals by 38 MEDLINE studies published between 1957 and 2003. "In a multivariate random-effects model with study year, sex, age, and race, the study year was not associated with any significant change in sodium excretions," states the abstract, which concludes that "[s]odium intake in the US adult population appears to be well above current guidelines and does not appear to have decreased with time."

The study was accompanied by an editorial questioning the effectiveness of a U.S. sodium reduction policy that targets, not just at-risk individuals, but "the population at large." Titled "Science Trumps Politics: Urinary Sodium Data Challenge US Dietary Sodium Guidelines," the editorial resists the tendency to blame the government's failure on "the food industry's excessive use of sodium in their products." As the article claims, "Both the application of such a government policy to the entire population and the simplistic assessment that its failure to date can be attributed to the food industry's reluctance to provide lower sodium foods belie the scientific complexity of the issues, including sodium's role in health and disease."

Citing their own previous research, the editorial's authors support the latest findings and suggest that salt consumption "is not a readily modifiable nutritional parameter for the population at large." They also note that although a reduction in food sodium content might theoretically reduce individual salt consumption, "the reality [is] that, over the millennia, before the introduction of processed foods, sodium was added to foods at the time of preservation, cooking, or consumption. An individual in our society has the identical options today as the food industry moves to offering more products whose ratio of calories to sodium is increased (ie, lower sodium content per serving). This individual choice could abrogate any effect on average sodium intake in society as these data indicate has happened."

In a related development, a second study has evaluated "the association between dietary salt restriction and iodine deficiency among adults in the United States," finding that women who restricted dietary salt intake were more likely to be iodine deficient. Francis Tayie and Katie Jourdan, "Hypertension, Dietary Salt Restriction, and Iodine Deficiency Among Adults," *American Journal of Hypertension*, October 2010. Researchers apparently used multiple



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regression models to assess "the association between hypertension conditions, salt restriction and iodine deficiency among 996 men and 960 women" enrolled in the 2001-2004 waves of the National Health and Nutrition Examination Surveys (NHANES).

The study sample reportedly indicated that approximately 25 percent of men and 40 percent of women were iodine deficient, but that "salt restriction did not associate significantly with iodine deficiency among men." Among women, however, those who restricted their dietary salt intake had "significantly lower urinary iodine concentration" than women who did not avoid salt. "Salt restriction associated with iodine deficiency among women but not men," concluded the study authors, who recommended that physicians suggest alternative sources of iodine to women in particular.

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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.



