

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Final Rule on Nutrient Content Claims for Omega-3 Fatty Acids

The U.S. Food and Drug Administration (FDA) has [announced](#) a final rule prohibiting statements on food product labels, including dietary supplements, that claim products are “high in,” “rich in,” or an “excellent source of” docosahexaenoic acid (DHA) or eicosapentaenoic acid (EPA) as well as similar claims for alpha-linolenic acid (ALA). The rule finalizes a proposed rule the agency published in 2007 without any substantive changes.

Under the U.S. Federal Food, Drug, and Cosmetic Act (the Act), nutrient-content claims such as “high in” are allowed only for nutrients for which a reference level for the claim has been set, or, in some situations, if the requirements of the Act have been met, such nutrient levels can be based on authoritative statements published by certain types of scientific bodies, such as the Institute of Medicine of the National Academies (IOM).

FDA apparently received notifications in 2004 and 2005 asserting that IOM had issued authoritative statements that identified such nutrient levels for DHA, EPA and ALA. The agency reports, however, that multiple notifications identified multiple, and sometimes conflicting, nutrient levels for the omega-3 fatty acids, leading FDA to determine that none of the claims met the Act’s requirements.

Stakeholder comments on the agency’s analysis of the proposed rule’s impact suggested that hundreds of product categories, including seafood, yogurt, cheese, meat, eggs, milk, juice, bread, and baby food would be affected by the rule and labeling changes would be costly and place an unfair burden on small businesses. Allowing for a transition period, FDA noted that the rule will take effect January 1, 2016, and manufacturers will have up to one year to comply and change food and supplement labels accordingly. See *CFSAN Constituent Update*, April 25, 2014.

FDA Backs Down on Controversial Spent Grain Proposal

In a blog post, U.S. Food and Drug Administration (FDA) Chief Food Safety Inspector Michael Taylor said that the agency will not disrupt the current practice of breweries and food manufacturers selling or donating spent grains to farmers for use as animal feed. The proposed rule would have required

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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.

breweries to dry, package and inspect spent grain before it could be given to cattle, which could have cost the brewing industry an estimated \$50 million per year, according to Sen. Charles Schumer (D-N.Y.). Additional details appear in Issue [519](#) of this *Update*.

FDA will still issue revised proposals on spent grains this summer, but Taylor said they will not include requirements that human food manufacturers establish separate animal feed safety plans and controls to cover their by-products. "The recycling of human food by-products to animal feed contributes substantially to the efficiency and sustainability of our food system and thus is a good thing," Taylor wrote. "We have no intention to discourage or disrupt it." See *The Hill*, April 25, 2014.

NOP Issues Final Guidance on "Made with Organic" Labeling

The U.S. Department of Agriculture's (USDA's) National Organic Program (NOP) has [issued](#) final guidance on the use of "Made with Organic ***" claims on product labeling. According to NOP, the guidance seeks to clarify "the following aspects of products in this labeling category": (i) "composition"; (ii) "compliant organic labeling claims"; (iii) "organic and nonorganic forms of the same ingredient"; (iv) "percentage of organic ingredients statements"; and (v) "ingredients or food groups in the 'made with organic * * *' claim."

Available through "The Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations," the [new policies](#) reflect NOP's current thinking on organic product labeling. In particular, "Made with Organic ***" products "must contain at least 70 percent organic ingredients, excluding salt and water"; "may contain up to 30 percent nonorganic ingredients," provided any nonagricultural ingredient is allowed by the National List of Allowed and Prohibited Substances; and "must not contain any ingredient that was produced using excluded methods, such as genetic engineering, sewage sludge, or ionizing radiation." If a product meets these requirements, then it can use a "Made with Organic" statement for up to three ingredients, food groups or a combination of ingredients and food groups. In addition, the agency has barred the use of generic organic ingredient claims (e.g., "Made with Organic Ingredients") and now requires that product ingredient lists include both the organic and nonorganic forms of the same ingredient (e.g., "organic flour, organic sugar, organic butter, nonorganic butter"). See *Federal Register*, May 1, 2014.

Codex Alimentarius Commission Schedules Mid-June Meeting

The U.S. Department of Agriculture's Food Safety and Inspection Service and the Food and Drug Administration have [announced](#) a June 18, 2014, public meeting in Washington, D.C., to provide information and receive comments

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on agenda items and draft U.S. positions for discussion during the 37th Session of the Codex Alimentarius Commission in Geneva, Switzerland, July 14-18, 2014.

Agenda items include (i) proposed amendments to the procedural manual; (ii) amendments to Codex standards and related texts; (iii) proposals for the elaboration of new standards and related texts and for the discontinuation of work; (iv) matters referred to the Commission by Codex committees and task forces; (v) the Commission's 2014-2019 strategic plan; and (vi) relations between the Commission and other international organizations. See *Federal Register*, April 30, 2014.

California SSB Label Shelved

A California Senate bill ([S.B. 1000](#)) that would require warning labels on sodas and other sugar-sweetened beverages (SSBs) was put on hold April 28, 2014, over concerns about enforcement costs of the legislation. In a 6-0 vote, the Senate Appropriations Committee referred the bill to its suspense file, which means it will be reconsidered after the state budget has been prepared.

Introduced in February by Sen. Bill Monning (D-Carmel), the bill would require labels warning of obesity and diabetes risks on all beverages with added sweeteners, including soda, tea, juice, and almond/rice/soy milk products, that have 75 or more calories per 12 ounces. Labels would also be required on self-serve soda dispensers and restaurant menus.

According to news sources, the California Department of Public Health expects to incur between \$150,000 and \$300,000 in costs to adopt regulations to implement the bill and to allow local agencies to enforce its provisions. Further, the department anticipates ongoing costs of \$400,000 annually to enforce the bill's labeling and notice requirements because it lacks inspection or food-safety enforcement authority at retail sites.

While Monning apparently said that the committee's decision to move the bill to the suspense file is "common procedure," the *Los Angeles Times* reported that he intends to rework the bill to reduce those costs before reintroducing it for another vote later this spring. See *Los Angeles Times*, April 28, 2014; *Law360*, April 30, 2014.

Financial Disclosure Requirements for OEHHA Committee Experts Finalized

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has [reported](#) that the Office of Administrative Law approved regulatory amendments that "clarify the qualifications for appointment to the Carcinogen Identification Committee and Developmental and Reproductive Toxicant Identification Committee, and remove redundant language regarding required financial disclosures." These committees review chemicals

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for potential listing as known to the state to cause cancer or reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986. Additional information about the amendments, which take effect July 1, 2014, appears in Issue [501](#) of this *Update*. See *OEHHA News Release*, April 29, 2014.

OEHHA Updates Table of Hazard ID Documents

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has [issued](#) an updated table of available hazard identification documents or materials for chemicals considered or reconsidered for listing by the state's qualified experts—that is, the Carcinogen Identification Committee and Developmental and Reproductive Toxicant Identification Committee—from 1996 to April 2014. The table contains links to materials on chemicals such as Bisphenol A, phthalates, MTBE, and sodium saccharin, and indicates when they were listed or de-listed.

Chicago Prohibits Plastic Bags at Retail Chains

The Chicago City Council has reportedly passed, 36-10, a ban on plastic bags at chain stores (i.e., at least three locations with the same owner) beginning in August 2015 for those larger than 10,000 square feet and August 2016 for smaller establishments. The prohibition follows several months of debate on the measure, with environmental advocates contending that the ban will reduce the number of bags littering the city and store owners arguing that more expensive paper bags will lead to higher prices. See *Chicago Tribune*, April 30, 2014.

LITIGATION

MDL Magistrate Excludes Plaintiffs' Expert in DHA Omega-3 Fortified Milk Suits

A federal magistrate in Florida has decided that the opinion proffered by the plaintiffs' expert in litigation challenging "brain health" marketing claims for algal-derived DHA Omega-3 fortified milk products is unreliable, thus granting the defendant's motion to exclude it. *In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practices Litig.*, MDL No. 12-2324 (U.S. Dist. Ct., S.D. Fla., order entered April 28, 2014). The ruling affects claims brought by consumers in six states alleging that the defendant violated state laws by falsely claiming that the DHA in its products "Supports Brain Health" and "Supports a Healthy Brain," and that "competent, scientific evidence shows that these claims are false."

While the court found that most of the defendant's arguments in support of exclusion went to the weight of the testimony rather than its admissibility, it agreed that the expert failed to show how small studies involving 49 women

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and 658 children in the United Kingdom could be extrapolated to the putative class of consumers of the defendant's milk products in the United States and for that reason was unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The court disagreed that (i) the studies did not fit the case, (ii) the expert cherry-picked the studies to support his conclusion, and (iii) the five studies on which the expert relied contained contradictory conclusions.

UC Davis Seeks Dismissal of California Strawberry Commission's Breach of Contract Suit

The University of California, Davis, has reportedly filed a motion in California state court to dismiss the breach of contract suit that the California Strawberry Commission filed in October after it learned that the university may stop breeding and selling strawberry germplasm to farmers. UC Davis has developed and sold its strawberry germplasm at low royalty rates to the commission for several decades through a research program headed by two professors. According to the commission's complaint, the professors announced their intention to resign in 2012 and take their research to a private company, raising the cost of royalties and limiting the sales to select strawberry growers, and as a result, the university notified the commission of its intention to shutter the program.

In its complaint, the commission argued that its growers have directly funded the university program, so they are entitled to receive the new strawberry varieties that the professors intended to take to the private companies to further cultivate. The university sought "to take the fruits—both literally and figuratively—of decades-long research that the commission funded for the benefit of the California strawberry industry and hand them over to private financial interests," the commission argued. In a blog post announcing its motion to dismiss the suit, UC Davis rejected the contention that the program will end. "The strawberry breeding program at UC Davis is the pre-eminent public breeding program in the world today and the only public breeding program in the state," said Chancellor Linda P.B. Katehi. "We are committed to maintaining that status for years to come." See *UC Davis News*, April 23, 2014; *Sacramento Bee*, April 27, 2014.

OTHER DEVELOPMENTS

WHO Issues Antimicrobial Resistance Report

The World Health Organization (WHO) has [published](#) its first global report on antimicrobial resistance, warning that the threat has spread to every region in the world and is attributable, in part, to inappropriate use of antibiotics in animal husbandry.

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Among the report's key findings are (i) "standard treatments no longer work"; (ii) "infections are harder or impossible to control"; (iii) "the risk of the spread of infection to others is increased"; (iv) "illness and hospital stays are prolonged, with added economic and social costs"; and (v) "the risk of death is greater—in some cases, twice that of patients who have infections caused by non-resistant bacteria." According to the report, even "last resort" antibiotics have become ineffective in certain populations.

The report also discusses information gaps, noting that surveillance of antimicrobial resistance "is neither coordinated nor harmonized." To address the issues identified, WHO is developing a global action plan that will include the development of tools and standards to harmonize surveillance of antimicrobial resistance in humans and food-producing animals, "elaboration of strategies for population-based surveillance of [antimicrobial resistance] and its health and economic impact," and collaboration among surveillance networks "to create or strengthen coordinated regional and global surveillance."

WHO Assistant Director-General for Health Security Keiji Fukuda said, "Without urgent, coordinated action by many stakeholders, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill. Unless we take significant actions to improve efforts to prevent infections and also change how we produce, prescribe and use antibiotics, the world will lose more and more of these global public health goods and the implications will be devastating." See *WHO News Release*, April 30, 2014.

Meanwhile, a Dutch company has reportedly constructed an experimental facility outside the town of Eersel to improve the health of meat chickens. According to animal welfare expert Peter Vingerling of Vencomatic, "We didn't design this in order to raise chickens without antibiotics. We did it to be sustainable and serve animal welfare. But then we noticed that, over a couple of years, we hadn't had to use any drugs at all." Since 2008, Vencomatic has apparently raised 1.26 million meat chickens in a specially constructed warehouse, and the birds, which did not receive the routinely administered antibiotics that have become a matter of contention in Europe and the United States, achieved growth and weight outpacing the industry average, in a healthier condition. See *Slate*, April 30, 2014.

Apples Top EWG List of Most Contaminated Produce for Fourth Year

The Environmental Working Group (EWG) has [issued](#) its *2014 Shopper's Guide to Pesticides in Produce*, which ranks pesticide contamination in "48 popular fruits and vegetables based on an analysis of more than 32,000 samples tested by the U.S. Department of Agriculture [USDA] and the federal Food and Drug Administration [FDA]."

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Apples topped this year's annual "Dirty Dozen™" list of most pesticide-contaminated produce for the fourth year. Other fruits and vegetables in the Dirty Dozen include strawberries, grapes, celery, peaches, spinach, sweet bell peppers, imported nectarines, cucumbers, cherry tomatoes, potatoes, and imported snap peas. Kale, collard greens and hot peppers were highlighted in a section called "Dirty Dozen-Plus™," as items "frequently contaminated with insecticides that are particularly toxic to human health."

Avocados topped this year's "Clean Fifteen™" list—fruits and vegetables with the least amount of residues, with only 1 percent showing any detectable pesticides. Other items on that list include corn, pineapples, cabbage, frozen sweet peas, onions, asparagus, mangoes, papayas, kiwi, eggplant, grapefruit, cantaloupe, cauliflower, and sweet potatoes. *See Environmental Working Group News Release*, April 29, 2014.

CCFC and CAI Criticize USDA Proposal on Food Marketing in Schools

The Campaign for a Commercial-Free Childhood (CCFC) and Corporate Accountability International (CAI) published an April 25, 2014, letter to U.S. Department of Agriculture (USDA) School Programs Branch Chief Julie Brewer, criticizing a proposed rule that would require schools "to implement policies for the marketing of foods and beverages on the school campus during the school day consistent with nutrition standards for Smart Snacks." According to the letter, the proposal not only gives a "green light" to food marketing in schools, but "opens the floodgates for many other types of marketing in schools."

Claiming that "the commercialization of childhood is linked to a host of problems facing children today that extend well beyond the consumption of unhealthy foods," CCFC and CAI have asked USDA to acknowledge that "commercial-free school environments are preferable to those that allow marketing." The letter also takes issue with the agency's "Smart Snacks" program, alleging that the nutrition standards "do not go far enough to protect children's health."

"For leading corporate brands..., the main goal of being in school is less about the foods being sold and more about inculcating brand loyalty in a captive audience of children," opine CCFC and CAI. "Therefore it's important for USDA not to encourage more marketing by saying it's OK to advertise the still highly processed foods and beverages." *See CCFC Press Release*, April 25, 2014.

Scientists Develop Magnetic DNA Tag to Protect Olive Oil from Counterfeiters

Researchers from Switzerland's technology and natural sciences university, ETH Zurich, have reportedly developed a method of tagging olive oil that

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can determine the product's origin and whether it has been adulterated. Consisting of tiny, magnetic DNA particles encapsulated in a silica casing that are mixed with the oil, a few grams of the material are enough to tag the entire olive oil production of Italy. According to the researchers, if counterfeiting is suspected, the particles added at the place of origin can be extracted from the oil and analyzed, revealing the original producer. "The method is equivalent to a label that cannot be removed," said researcher Robert Grass.

Lab experiments evidently revealed that the tags dispersed well in the oil, did not affect clarity or taste, remained stable when heated, and passed a two-year aging trial. Research also showed that the analysis and testing method "can be carried out today by any medical lab at minimal expense." Grass observes that the potential for use of invisible labels in the food industry, where adulterated and counterfeit products generate vast profits for criminals, is substantial. The researchers also suggested that the tagging method could be used for gasoline and cosmetics. See *ETH Zurich News Release*, April 24, 2014.

MEDIA COVERAGE

CNNMoney Reports on Alleged Wage Violations in Fast Food Industry

CNNMoney has published a May 1, 2014, article claiming that the Department of Labor (DOL) has difficulty cracking down on labor and wage violations in the fast food industry due to the franchise model. Based on data collected by DOL's Wage and Hour Division that reportedly found individual Subway franchisees "in violation of pay and hour rules in more than 1,100 investigations spanning from 2000 to 2013," the article claims that these cases amounted to "17,000 Fair Labor Standards Act violations and resulted in franchisees having to reimburse Subway workers more than \$3.8 million over the years."

"Even though fast food locations may look the same and restaurants abide by similar branding and business guidelines, each franchise owner is treated essentially as a small business," opines *CNNMoney's* Annalyn Kurtz. "Meanwhile, the corporate parents can distance themselves from being found liable of labor violations."

In addition to DOL's renewed focus on "fissured workplaces" "in which there's an indirect relationship between the worker and the parent company that ultimately benefits from their labor," the article notes the rise in private lawsuits related to wage and hour complaints. Backed by unions, these actions increasingly seek to hold corporations liable along with individual franchises. "In cases like these, the corporate parents like to draw a distinction between themselves and their independently operated stores," Kurtz concludes. "Restaurants and hotels in particular, are a major focus [of DOL's

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investigation into fissured workplaces], not only because they fall into this category, but because they employ a large share of low-wage workers.”

SCIENTIFIC/TECHNICAL ITEMS

Study Examines Alternative Hormonal Receptor Affected by BPA

A recent study has reportedly identified an alternative hormonal receptor that mediates bisphenol A (BPA), raising questions about the purported link between BPA exposure, diabetes and obesity. Marie Tohmé, et al., “Estrogen-related receptor γ is an in vivo receptor of bisphenol A,” *The Journal of the Federation of American Societies for Experimental Biology*, April 2014. Researchers with the Institute of Functional Genomics of Lyon (ENS de Lyon) and Deakin University apparently used a zebrafish model to demonstrate that “the in vivo action of [BPA] was mediated by the orphan nuclear receptor, ERR γ (estrogen-related receptor),” which previous studies have implicated in metabolism regulation, insulin secretion, newborn obesity, and inner ear development.

“We found that the way the BPA binds to and activates ERR γ is 1000 times better than with the estrogen receptor. This means that ERR γ is 1000 times more potent; a tiny amount of BPA will result in a huge activation of ERR γ but only a mild activation of estrogen receptors,” explained one study author in an April 29, 2014, Deakin University Press release. “As the current guidelines are based on the activation of estrogen receptors, we need to rethink the tolerable daily intake as BPA will induce effects at a lower dose than currently acknowledged. In Europe this is already happening with the intake soon to be dropped to 5 micrograms per kilo per day.” See *ENS de Lyon Press Release*, April 22, 2014.

Mother’s Diet Before Conception Can Allegedly Modify Child’s DNA

Researchers have reportedly found that nutrient levels in a pregnant woman’s diet before conception can permanently affect how the child’s genes function. Paula Dominguez-Salas et al., “Maternal nutrition at conception modulates DNA methylation of human metastable epialleles,” *Nature Communications*, April 2014. The London School of Hygiene & Tropical Medicine (LSHTM) researchers selected 167 pregnant women from a group of 2,000 in the Gambia based on when their fetuses were conceived—some at the peak of rainy season, when the Gambian diet includes fewer calories but more nutrient-rich vegetables, and some at the peak of dry season, when the diet includes more calories but fewer vitamins.

The study evidently found that the infants born from the rainy season conceptions had significantly higher rates of the chemical compounds that

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activate genes than the infants born from the dry season conceptions. These compounds—methyl groups—can determine whether a gene is activated or silenced in the child through a process called methylation, and higher rates of methyl groups lead to more activated genes. The team also found a link between the amount of methyl groups and the Body Mass Index of the mothers, with heavier mothers' infants showing lower levels of methylation—despite that none of the women was overweight and all had levels of nutrients in their blood that doctors would label normal. "Our ultimate goal is to define an optimal diet for mothers-to-be that would prevent defects in the methylation process," said Andrew Prentice, a professor of international nutrition and co-author of the study. "Our research is pointing towards the need for a cocktail of nutrients, which could come from the diet or from supplements." See *LSHTM Press Release*, April 29, 2014.

USDA Researchers Claim Low Seafood Intake Linked to Cognitive Decline

Research presented at the Experimental Biology 2014 meeting has apparently confirmed the importance of dietary long-chain polyunsaturated fatty acids (PUFAs), concluding that lower intakes of eicosapentaenoic acid (EPA) and docosahexanoic acid (DHA) were predictive of cognitive decline. According to an April 27, 2014, press release, scientists with the U.S. Department of Agriculture's Human Nutrition Research Center on Aging at Tufts University used food-frequency questionnaires to assess the consumption of omega-3 PUFAs among 895 study participants, who also completed cognitive testing over a two-year follow-up period. The results evidently showed that participants in the lowest four quintiles of EPA and DHA consumption showed more signs of cognitive decline than those in the highest quintile.

"While more research is needed to determine whether intake of fatty fish such as salmon, tuna and trout can help prevent against cognitive decline, our preliminary data support previous research showing that intake of these types of fish have health benefits," one of the researchers was quoted as saying.

Extra Cup of Coffee May Reduce Type 2 Diabetes Risk

A recent study from the Harvard School of Public Health (HSPH) has reportedly found that "[p]eople who increased the amount of coffee they drank each day by more than one cup over a four-year period had an 11% lower risk for type 2 diabetes than those who made no changes to their coffee consumption." Shilpa Bhupathiraju et al., "Changes in coffee intake and subsequent risk of type 2 diabetes: three large cohorts of US men and women," *Diabetologia*, April 2014. Researchers examined data from the Nurses' Health Study from the Brigham and Women's Hospital, which evaluated participants' diets every four years from 1986 to 2006 with a questionnaire. Their analysis showed that subjects who increased their coffee intake—the median increase was about a cup and a half each day—during the four-year period between question-

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naires had an 11 percent lower risk of developing type 2 diabetes in the next four-year period. The researchers also found that subjects who decreased their consumption of coffee by more than a cup—with a median drop of two cups per day—had a 17 percent higher risk for diabetes. The study was supported by grants from the National Institutes of Health and the American Heart Association. *See HSPH Press Release, April 24, 2014.*

Tuna Caught Off U.S. Coasts Contain Trace Levels of Fukushima Radiation

Researchers have apparently found levels of radiation “too small to be of realistic concern” from the Fukushima Daiichi nuclear meltdown in albacore tuna caught off the coasts of Washington and Oregon. Neville et al., “Trace Levels of Fukushima Disaster Radionuclides in East Pacific Albacore,” *Environmental Science & Technology*, April 2014. The study examined 26 Pacific albacore caught between 2008 and 2012 to compare radiation levels before and after the power station’s destruction in 2011. The researchers reported that levels of specific radioactive isotopes tripled in some of the fish caught after the disaster, but the levels present were still too small to have any noticeable effect on humans. “A year of eating albacore with these cesium traces is about the same dose of radiation as you get from spending 23 seconds in a stuffy basement from radon gas, or sleeping next to your spouse for 40 nights from the natural potassium-40 in their body,” said lead author Delvan Neville of Oregon State University. The trace amounts of Fukushima radiation provide some information about the young albacore’s migration patterns, which is largely unknown before they enter U.S. fisheries at about three years of age. *See Oregon State University News & Research Communications, April 28, 2014.*

OFFICE LOCATIONS

Geneva, Switzerland
+41 (0) 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 (0) 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
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+1-202-783-8400

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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.

