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LEGISLATION, REGULATIONS AND STANDARDS

Republican Lawmakers Issue Report Critical of Some Stimulus Funding Projects

Senators Tom Coburn (R-Okla.) and John McCain (R-Ariz.) have issued a report, "Summertime Blues," in which they provide information about "100 stimulus projects that give taxpayers the blues." Among the projects is a \$521,000 grant to the University of Illinois to study whether taxes on soft drinks and other sugarsweetened beverages can affect the incidence of obesity. According to the senators, "While it is hard to disagree that soda and other sugary drinks are contributing factors to the national obesity epidemic, it is easy to disagree whether federal dollars should be used to study the relationship between taxes and obesity."

In a related development, the CEO of a nonprofit foundation writing in *The Hill's* "Pundits Blog," called the District of Columbia's decision to take a "soda tax" off the table "an unfortunate mistake." Kathy Kemper opines that the proposal "would take our capital city far in reducing sugar consumption among the city's adults and our children, who are suffering from a high obesity rate that's caused by poor eating, drinking and no exercise habits." Kemper contends that sugary drinks "should not be a staple in any grocery cart" and that the city's "epidemic of diet-related disease needs to be penalized."

She reminds readers of a "recent history lesson" involving the tobacco industry, which she claims "fought like crazy," when federal agencies sought to reduce tobacco use with public education campaigns. According to Kemper, "The beverage industry should learn from Big Tobacco's experience and save themselves a lot of money, anguish and time. That industry—and every resident of the District—should get on board and support not only a small tax on soda but also increased labeling and education about healthy drinking habits."

Meeting to Consider U.S. Positions for Codex Session on Veterinary Drug Residues in Foods

In advance of the August 30-September 3, 2010, session of the Codex Committee on Residues of Veterinary Drugs in Foods, draft U.S. positions will be considered during a <u>public meeting</u> scheduled for August 16. Written comments may be presented during the meeting or forwarded to the U.S. delegate to the Codex session, Dr. Kevin Greenlees, who works in the Office of New Animal Drug Evaluation at the Food and Drug Administration (FDA).



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> Mark Anstoetter 816-474-6550 manstoetter@shb.com

> > or



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 Among other issues on the upcoming Codex agenda are (i) draft maximum residue limits for veterinary drugs (at step seven of an eight-step Codex process), (ii) a discussion paper on methods of analysis for these residues in foods, (iii) a draft priority list of veterinary drugs requiring evaluation by a joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) expert committee on food additives, (iv) a discussion paper on veterinary drugs in honey production, and (v) a discussion paper on a sampling plan for residue control for aquatic animal products.

Created by the FAO and WHO in 1963, the Codex Alimentarius Commission adopts international food standards, codes of practice and other guidelines and promotes their adoption and implementation by governments with the goal of protecting consumer health and ensuring fair practices in the food trade. The U.S. Code of Federal Regulations requires the FDA to review all food standards adopted by the commission and accept or reject them for application in the United States. U.S. positions on Codex proposals are open to input by interested parties and stakeholders. *See Federal Register*, August 12, 2010.

Chinese Health Officials Investigate Infant Formula Linked to Early Onset Puberty

The Chinese Ministry of Health has apparently announced an investigation into claims linking infant formula manufactured by Synutra International, Inc., to early onset puberty. According to state-run media, the ministry has assembled a panel of nine experts to examine whether the formula caused three infants ages 4 to 15 months to develop prematurely. The group will work with local authorities in Hubei Province to test milk powder samples taken from the homes of the infants in question. *See Xinhau News Agency*, August 12, 2010.

The decision came after *China Daily* reported that doctors identified excessive levels of two hormones, estradiol and prolactin, in the children, thus sparking public speculation about tainted formula. Synutra, however, has since joined its milk powder supplier, New Zealand-based Fonterra Cooperative Group Ltd., in denying the rumors, which have noted that both companies were caught up in a 2008 scandal over melamine-tainted dairy products. As Synutra stated in an August 11, 2010, press release, "The recent press conference by the Ministry of Health communicated that a definitive cause for premature development in the infant cases submitted could not be determined and that there are many possible contributing factors, which may cause premature development." *See China Daily,* August 11, 2010; *Synutra Press Release* and *Time,* August 12, 2010.

San Francisco Considers Restricting Restaurant Toy Giveaways; Advocacy Group Calls for End to Action-Figure Happy Meal Promotion

Three elected San Francisco officials recently introduced legislation to amend the city's health code by restricting restaurant toy giveaways to only those meals that meet stringent nutritional guidelines. The Healthy Food Incentives Ordinance (10196) would apply to all San Francisco restaurants, but mostly affect fast-food establishments that offer toys linked to the purchase of meals targeted to children and high in calories, salt or fat. In April 2010, Santa Clara County, California, became the first local government to enact a similar measure, highlighted in Issue 347 of this Update.



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The proposed San Francisco measure would prohibit restaurants from offering an "incentive item" such as toys, trading cards or admission tickets with a single menu item containing more than 200 calories or 480 milligrams of sodium or an entire meal containing more than 600 calories or 640 milligrams of sodium. Another stipulation calls for toy giveaway meals to provide no more than 35 percent of total calories from fat, "except for fat contained in nuts, seeds, peanut butter or other nut butters, or an individually served or packaged egg, or individually served or packaged low-fat or reduced fat cheese." The plan also requires the meals to include at least half a cup of fruits and three-quarters of a cup of vegetables.

"Our legislation will encourage restaurants that offer unhealthy meals marketed toward children and youth to offer healthier food options with incentive items or toys," co-sponsor District 1 Supervisor Eric Mar (D) told a news source. "It will help protect the public's health, reduce costs to our health care system and promote healthier eating habits." A San Francisco Health Department official reportedly agreed, claiming restaurants could meet the proposed standards by reducing portion sizes or altering ingredients. "This is not an anti-toy ordinance; this is a prohealthy-meal ordinance," he said.

The California Restaurant Association has publicly criticized the plan. "Toy bans are only proven to disappoint kids, frustrate parents and generate headlines for ambitious politicians," an association spokesman said. *See San Francisco Chronicle,* August 11, 2010.

In a related development, the Campaign for a Commercial-Free Childhood (CCFC) has urged parents to write letters to McDonald's demanding that the fast-food chain withdraw its current Happy Meal promotion featuring eight Marvel comic action figures. One figure, The Human Torch, depicts a man engulfed in flames while another, The Thing, menacingly roars "It's Clobberin'Time!" when a button is pressed.

"It's bad enough to use junk toys to sell children on junk food," CCFC Director Susan Linn said in a press statement. "But now, for preschool boys, a so-called happy meal at McDonald's features the horrifying spectacle of a man engulfed in flames and a menacing figure that explicitly spurs them to violence." *See CCFC Press Release*, August 4, 2010.

LITIGATION

Federal Appeals Court Finds Farmers' Claims Against Pesticide Maker Not Preempted

The Third Circuit Court of Appeals has allowed claims filed by New Jersey blueberry farmers to proceed against the company that makes a pesticide which allegedly damaged their crops, finding that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt their lawsuit. *Indian Brand Farms, Inc. v. Novartis*. *Crop Protection, Inc.*, No. 08-4484 (3d Cir., decided August 10, 2010).

The company changed its pesticide in 1997, and plaintiffs used it the same way they had successfully used prior products, mixing it with fungicides before applying it to



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their crops. The company's marketing brochure for the reformulated product said it was safer and more effective and had the same powerful product performance. The brochure contained no instructions for the product's use, and the product label did not indicate that one of its inert ingredients was an ionic surfactant nor that it should not be mixed with fungicides. The product containing the surfactant, when mixed with fungicides, allegedly injured or killed the plaintiffs' blueberry plants.

The district court ruled that FIFRA preempted plaintiffs' negligent misrepresentation and failure-to-warn claims, because it concluded that marketing brochures qualified as "labeling" under the law. The court also concluded that their design defect claim must be dismissed because the farmers' practice of mixing the pesticide with a fungicide was not reasonably foreseeable and would have required the company to test its product "in combination with every fungicide for use on all plants."

The Third Circuit noted that a brochure could constitute "labeling" under FIFRA if it was a written material "accompanying" the product and turned to case law under the Federal Food, Drug, and Cosmetic Act to interpret the term. The court concluded that Congress would not have intended for a marketing brochure to be included within the scope of the term "labeling," otherwise "all sales and marketing materials would necessarily be included within the scope." Because all but the first-named plaintiff had proffered *prima facie* evidence of their reliance on the company's alleged written misrepresentations in the brochure, their negligent misrepresentation claims were not dismissed.

As to plaintiffs' failure-to-warn claim, the court stated, "Given that Congress in FIFRA imposed a generalized duty to include in one's labeling any warning statement necessary to protect plant life and the fact that the EPA has not seen fit to narrow that duty, we find no basis for concluding that New Jersey law imposes a duty to warn different than or in addition to the scope of the requirement imposed by FIFRA." Thus, the court allowed all plaintiffs to proceed in prosecuting their failure-to-warn claim.

The court found that the record evidence "raised a genuine issue of material fact as to whether the risk of harm to Plaintiffs' crops was foreseeable, and whether such risk of harm could have been reduced or avoided by a reasonable alternative design, *i.e.*, a pesticide not containing an ionic surfactant." Accordingly, the court reversed the grant of summary judgment as to the plaintiffs' design defect claim. A dissenting judge, would have affirmed this part of the district court's ruling, finding that the plaintiffs did not "carry their burden of demonstrating that their misuse of AG600 was reasonably foreseeable to Novartis."

Expert Witness in Popcorn Lung Litigation Files Non-Party Appeal of Decision to Exclude His Testimony

Dr. David Egilman, who was excluded from testifying as an expert witness in the case of a person who claimed the fumes from microwave popcorn caused his lung disease, has reportedly filed a non-party appeal from the decision finding his testimony unreliable. More details about the case and the court ruling appear in <u>Issue 356</u> of this *Update*.



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A federal district court determined in *Newkirk v. ConAgra Foods, Inc.* that Egilman lacked any scientifically sound basis for attempting to extrapolate workplace exposures to the diacetyl used in popcorn and other baked goods to exposures in the home. Workplace exposures, which have been extensively studied, have linked exposure to the butter-flavoring chemical to bronchiolitis obliterans, a debilitating lung condition often referred to as "popcorn lung."

Egilman, according to a news source, purportedly testified in 2005 in pharmaceutical litigation that he had earned between \$2 million and \$2.5 million over the previous 25 years testifying as an expert witness in personal injury cases. While non-parties are apparently entitled to appeal federal court rulings, they must have a direct financial interest in the outcome of the litigation. At least one commentator has questioned whether expert witnesses should be allowed to file appeals when their testimony has been excluded, speculating that the courts could be overwhelmed by challenges to these rulings. According to a news source, Egilman once successfully demonstrated that he had standing to file a non-party appeal in a case in which the trial judge apparently excluded him from ever testifying again in his courtroom after finding that Egilman was "hostile, biased and vindictive."

A Colorado Appeals Court in 2002 reportedly overturned a sanctions order against Egilman in that case indicating that the judge's aspersions could jeopardize his ability to obtain future employment as an expert witness. The court in *Newkirk* did not attack Egilman on a personal level and simply precluded him from testifying in that case.

Meanwhile, a Missouri jury has reportedly rejected the claims of a woman who sought to hold ConAgra liable for her lung injury, which she alleged was caused by exposure to microwave popcorn that she prepared when she worked in video stores and at home. Egilman apparently testified on Elaine Khoury's behalf. Both Khoury and Newkirk have indicated their intention to appeal the decisions in their respective cases. *See The* (Kansas City) *Pitch*, August 3, 2010; *onpointnews.com*, August 9 and 13, 2010.

Another Court Stays Litigation over Whether HFCS Is "Natural"

A U.S. magistrate judge in New Jersey has issued an order staying a case that alleges "natural" labeling for Snapple beverages is misleading because the product contains high-fructose corn syrup (HFCS), which plaintiffs contend is not an all-natural ingredient. *Holk v. Snapple Beverage Corp.*, No. 07-3018 (U.S. Dist. Ct., D.N.J., order entered August 10, 2010). The parties drew the court's attention to a stay issued in similar litigation involving Arizona lced Tea[®] beverages. Additional information about that case appears in <u>Issue 356</u> of this *Update*.

The stay will remain in effect for six months, pending a Food and Drug Administration (FDA) review of the matter. "That time period may be extended for good cause shown, in the event the FDA shows a willingness to consider this issue but needs more time to do so. If, on the other hand, the FDA declines to consider the issue, counsel are directed to notify the Court promptly so that the case can be returned to active status." The court also denied plaintiff's motion for class certification and the parties' motions to disqualify experts without prejudice to their rights to refile when and if the stay is lifted.



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The magistrate determined that under the primary jurisdiction doctrine the agency was in a better position to address whether HFCS is a natural ingredient and that a stay would not prejudice either party. While the matter was ripe for decision, because various motions had been filed and fully briefed, the magistrate sided with those courts that had issued stays rather than those that had decided to move ahead. The magistrate was concerned that to move forward would "leave open the possibility of inconsistent judicial constructions of 'natural' and as to whether HFCS and citric acid are natural ingredients." (citing *Ries v. Hornell Brewing Co.*, No. 10-1139 (U.S. Dist. Ct., N.D. Cal., stay entered July 28, 2010)).

California Resident Targets Chewing Gum Maker in Purported Class Action

Alleging that no scientific evidence supports Wm. Wrigley Jr. Co's claim that the cardamom in its Eclipse[®] Breeze chewing gum "neutralize[s] the toughest breath odors," a California resident has filed consumer fraud claims against the company in a federal court on behalf of a nationwide class of consumers. *Sityar v. Wm. Wrigley Jr. Co.*, No. 10-5965 (U.S. Dist. Ct., C.D. Cal., filed August 10, 2010). The complaint alleges that he was misled by the company's claims and "has spent money purchasing the Product at a price premium when the Product actually had less value than was reflected in that price he paid for the Product."

Seeking restitution, disgorgement, declaratory and injunctive relief, a corrective advertising campaign, costs, and attorney's fees, the plaintiff alleges violations of California unfair competition and false advertising laws, breach of express warranty and violation of California's Consumer Legal Remedies Act. The plaintiff alleges that the only evidence of "medicinal properties" attributed to cardamom appears in the *Encyclopedia of Spices* and is based on traditional lore. He also alleges that a company spokesperson responded to his request for scientific support by stating, "Unfortunately, we do not have a copy of the scientific study that you have requested available to send."

California Court Allows Grilled Chicken Prop. 65 Labeling Suit to Proceed

A California appellate court has reversed a summary judgment order that terminated litigation involving claims that chain restaurants violated Proposition 65 (Prop. 65) by selling grilled chicken products to consumers without appropriate warnings about carcinogens created by the cooking process. *Physicians Comm. for Responsible Med. v. McDonald's Corp.*, No. B218089 (Cal. Ct. App., 2d App. Dist., Div. One, decided August 12, 2010). The carcinogens at issue are polycyclic aromatic hydrocarbons and PhIP (2-amino-1-methyl-6-phenylimidazol[4,5-b]pyridine).

The trial court had dismissed the claims in late 2008 finding that the proposed warnings, which mentioned "well cooked,""thoroughly cooked" and "grilled" chicken, were barred by conflict preemption because they would frustrate the U.S. Department of Agriculture's (USDA's) "longstanding policy of promoting the safe cooking of chicken" under the federal Poultry Products Inspection Act (PPIA). The court agreed with the defendants that the warnings would have frightened consumers from properly cooking chicken.



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The trial court dismissed the claims again in June 2009 after the plaintiff identified two additional proposed warnings—one stating that "certain chicken products" contain a carcinogen and the other including Prop. 65's "safe harbor" warning. The latter provides simply: "WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold here." According to the trial court, while some defendants were posting the Safe Harbor warnings in their restaurants, they had not done so as a result of the litigation, and these too were preempted by federal law.

The appeals court determined that the safe harbor warning does not create a conflict between Prop. 65 and the PPIA because the warning "*does not even mention chicken*. The Safe Harbor Warning therefore does not communicate any message about chicken of any description, whether well cooked, thoroughly cooked, or grilled." Even if the plaintiff were to engage in adverse publicity, linking the safe harbor warning to PhIP in chicken, the court said, "[u]ndesirable publicity by a nonprofit organization does not create a conflict between state and federal law or policy."

The court also noted, "there was no showing in the trial court that Proposition 65 warnings are required." Apparently, no evidence had been proffered showing that PhIP levels are high enough to justify the warnings, and the parties had failed to address an issue raised by California's attorney general in an amicus brief. A Prop. 65 "cooking provision" allows higher than no significant risk levels where the carcinogenic chemicals in food are produced by cooking required to avoid microbiological contamination. The attorney general argued that the cooking provision prevents any facial conflict between Prop. 65 and any federal policy under the PPIA. Because the "factual and statistical record regarding the actual level of PhIP in the Restaurants' grilled chicken is undeveloped," the court said, "the Cooking Provision does not eliminate the possibility that a warning would be required." The court left these matters for further development by the trial court.

Non-Profit Sues Nestlé Alleging Deceptive Advertising of Children's Nutrition Drink

The National Consumers League has filed a consumer fraud action in a Washington, D.C. court against Nestlé HealthCare Nutrition, Inc., alleging that the company falsely advertises its BOOST Kid Essentials[®] drinks as products that can strengthen children's immune systems and aid their digestive systems. *The Nat'l Consumers League v. Nestlé HealthCare Nutrition, Inc.*, No. 5772-10 (D.C. Super. Ct., filed July 30, 2010).

Bringing the action on behalf of the D.C. general public, the non-profit organization alleges one count of violating the D.C. Consumer Protection Procedures Act and seeks declaratory and injunctive relief, as well as "treble damages or statutory damages in the amount of \$1,500 per violation, whichever is greater," costs and attorney's fees. The league relies on the Federal Trade Commission's (FTC's) complaint against the company to assert that clinical studies do not support the promotional health-related representations. Additional details about the FTC's settlement of its complaint and Nestlé's agreement to refrain from making healthrelated claims without reliable scientific evidence appear in <u>Issue 356</u> of this *Update*.



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Russian Court Favors Development Fund in Land Dispute, Rare Fruits and Berries May Be Destroyed

A Russian court has reportedly given the green light to a housing development agency to build houses on a field where thousands of rare berries and other fruits have been preserved since the 1920s. The Pavlovsk Experimental Station, located near St. Petersburg, was apparently developed to serve as an historic gene bank. Scientists over the years have deemed the facility so important that 12 reportedly starved to death during the World War II siege of Leningrad rather than eat the plants they were saving. Some 90 percent of the station's more than 5,000 plant varieties exist nowhere else and many cannot be grown from seed. The research institute that operates the station reportedly plans to appeal the ruling to the Russian Supreme Arbitration Court. *See The Los Angeles Times*, August 10, 2010; *TheAwl.com*, August 11, 2010.

OTHER DEVELOPMENTS

CSPI Screams over Ben & Jerry's Ice Cream

The Center for Science in the Public Interest (CSPI) has issued an August 12, 2010, statement and <u>letter</u> lambasting Ben & Jerry's "All Natural" ice cream and frozen yogurt for allegedly containing "alkalized cocoa, corn syrup, partially hydrogenated soybean oil, or other ingredients that either don't exist in nature or that have been chemically modified." The watchdog has threatened to take its concerns to the Food and Drug Administration (FDA) and state attorneys general if Unilever fails to drop the products' marketing claim.

The group singles out cocoa processed with alkali as "the most frequently used unnatural ingredient," followed by corn syrup, dextrose, invert sugar, brown rice syrup, partially hydrogenated soybean oil, and maltodextrin. Moreover, CSPI maintains that alkalizing cocoa changes its chemical structure and reduces acidity and flavonol content. "Indeed," states the CSPI press release, "Unilever recently sponsored research to investigate an association between flavonol intake and incidence of stroke."

CSPI purports that 48 flavors include such "non-natural" ingredients, adding that FDA has not issued a formal definition but evidently considers the term natural to mean "that nothing artificial or synthetic…has been included in, or has been added to, a food that would not normally be expected in the food." CSPI thus concludes that these products are misbranded under section 403(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 434(a).

CAMY Reports Decline in Youth Magazine Alcohol Ads

The Johns Hopkins Bloomberg School of Public Health's Center on Alcohol Marketing and Youth (CAMY) has issued a <u>report</u> showing that alcohol companies "have largely met the industry's voluntary standards of not placing ads in magazines with 30 percent or more youth readership."



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Nevertheless, the report singled out 16 brands allegedly responsible "for half of the advertising placed in publications more likely to be seen per capita by youth than adults."

Researchers apparently used gross rating points, as opposed to gross impressions alone, to measure "how much an audience segment is exposed to advertising per capita." In addition to tracking youth exposure to alcohol advertising, the report focused on the prevalence of youth exposure coming from overexposure. According to CAMY, "Advertising in media in which youth ages 12 to 20 make up more than 15 percent of the audience generally results in these youth being 'overexposed,' that is, they are receiving advertising exposure that is out of proportion with their presence in the population." The results evidently showed that while youth exposure in magazines "with youth age 12-to-20 audience composition above 15 percent declined by 48.4 percent[,]...the percentage of youth exposure coming from this advertising increased from 69 percent to 78 percent."

Moreover, CAMY noted in an August 10, 2010, press release that as youth exposure to distilled spirit magazine ads declined by 62 percent, exposure to beer advertising in magazines rose by 57 percent between 2001 and 2008. "Beer advertisers appear to be filling the gap left by distillers in youth-oriented magazines," stated CAMY Director David Jernigan. "If the entire industry is serious about underage drinking, it should adopt stricter standards to protect against youth exposure to its advertising."

SCIENTIFIC/TECHNICAL ITEMS

Feral GM Canola Found in North Dakota

Researchers from the Environmental Protection Agency, University of Arkansas and University of California, Fresno, have reportedly identified populations of genetically modified (GM) canola growing wild in North Dakota. According to results presented at the Ecological Society of America's (ESA's) 95th Annual Meeting, scientists found that 347 of the 406 plants collected from roadsides contained either CP4 EPSPS protein, which confers tolerance to glyphosate herbicide, or PAT protein, which confers tolerance to glufosinate herbicide. "There were also two instances of multiple transgenes in single individuals," University of Arkansas ecologist Cynthia Sagers was quoted as saying. "Varieties with multiple transgenic traits have not yet been released commercially, so this finding suggests that feral populations are reproducing and have become established outside of cultivation." *See ESA Press Release*, August 6, 2010.

Sagers has reportedly called for further research, suggesting that GM canola has been "part of the landscape for several generations." She has conceded, however, that roadside sampling could be biased if cultivated GM seeds were spread, not by distant farms, but during transport via truck. As Sagers told one media source, "The regulatory protocols designed to reduce or prevent escape and proliferation of feral transgenic crops are ineffective. Current tracking and monitoring of GM organisms are insufficient." *See Nature.com*, August 6, 2010.



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BPA Linked to Lobster "Shell Disease"

A molecular biologist has allegedly found that waterborne chemicals such as bisphenol A (BPA) are a contributing factor to lobster shell disease, a bacterial infection linked to population die-offs in the Long Island Sound. Undertaken on behalf of the New England Lobster Research Initiative and presented during the 9th Annual Ronald C. Baird Sea Grant Science Symposium, the study reportedly suggests that alkylphenols from plastics, paint and detergents can delay new shell growth, making lobsters more susceptible to pathogens during the molting process. These substances also apparently prolong maturation in juveniles, while mothers who contract shell disease are often forced to molt midway through the reproductive cycle and thus lose their offspring.

As University of Connecticut Research Professor Hans Laufer explained in an August 10, 2010, press release, "[a]lkylphenols have phenomenal juvenile hormone activity," which affects "growth, reproduction, metamorphosis, and development." He further noted that 90 percent of the U.S. population is also contaminated with BPA and similar chemicals. "This is as big a threat to human health as tobacco," Laufer was quoted as saying. "Many companies are saying that they're safe, but they're not."

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Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500 Kansas City, Missouri +1-816-474-6550 London, England +44-207-332-4500 Miami, Florida +1-305-358-5171 San Francisco, California +1-415-544-1900 Tampa, Florida +1-813-202-7100 Washington, D.C. +1-202-783-8400

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FOOD & BEVERAGE LITIGATION UPDATE

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.



