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### LEGISLATION, REGULATIONS AND STANDARDS

#### FDA Holds Meeting on Economically Motivated Adulteration

The Food and Drug Administration (FDA) held a public meeting May 1, 2009, designed to find ways to prevent, detect and address the adulteration of food, pet food, dietary supplements, medical devices, and cosmetics for economic reasons that pose the greatest public health risk. FDA invited testimony on Economically Motivated Adulteration (EMA) from industry representatives, organizations and stakeholders. The agency requests comments on EMA by August 1, 2009. *See Federal Register*, April 6, 2009.

#### FDA Fails to Reach Food-Safety Inspection Audit Goals

The Food and Drug Administration (FDA) apparently failed to meet its 2007-08 goals for auditing food-safety inspections that states did on its behalf, according to a news source. State agencies apparently do half of FDA's food inspections, and FDA aims to audit 7 percent to make sure states reach a satisfactory standard. But FDA fell short of its goal in 17 of 39 states, according to FDA data. In five states, including Kansas, FDA did no audits.

But data show that FDA's performance has apparently improved. For example, data for the 2006-07 contract year show its audit goal was unmet in 21 of 37 states, with no audits performed in eight states. In 1998, the FDA reportedly did no audits in 21 of 38 states.

"We don't meet our target ever year, but ... we're looking at continuous improvement," Richard Barnes, FDA director of federal-state relations, was quoted as saying. *See USA Today*, May 7, 2009.

#### California Posts Bisphenol A Assessment Online in Prop. 65 Proceeding

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **published** hazard identification materials for bisphenol A in advance of a July 15, 2009, meeting at which the agency will consider whether to list the substance under Proposition 65 (Prop. 65) as a chemical known to the state to cause reproductive harm. Written comments are requested by June 30, 2009. If bisphenol A is listed, manufacturers of products sold in the state containing the chemical will have to provide consumers appropriate warnings.



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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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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. The May 2009 draft of "Evidence on the Developmental and Reproductive Toxicity of Bisphenol A" observes that the substance "is produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins . . . used in certain food and drink packaging." According to the draft, detectable levels of the chemical "have been found in the general population."

While human studies are apparently "of limited usefulness for evaluating causal relationships" and numerous animal studies are difficult to interpret due to "the variety of species, strains, dosing regimens, endpoints evaluated and techniques used for their evaluation, and analytical methodologies used," OEHHA concludes, "Overall, studies that used sensitive methodologies to assess appropriate endpoints consistently reported developmental, female-reproductive and male-reproductive effects."

### Kansas Senate Will Not Override Veto of Milk Hormone Bill

The Kansas Senate will apparently not try to override former Kansas Governor Kathleen Sebelius's veto of a bill that would have required a disclaimer on dairy products made without artificial growth hormones. Sebelius, recently confirmed as U.S. Secretary of Health and Human Services, vetoed the bill in late April 2009 reportedly because it would have made it more difficult for consumers to get clear information. "Supporters of the bill claim it's necessary to protect consumers from false or misleading information," she was quoted as saying. "Yet there has been overwhelming opposition by consumer groups, small dairy producers and retailers to this proposed legislation."

Under the bill, manufacturers that have stated their product is not from cows supplemented with the genetically engineered bovine growth hormone (rbGH or rbST) would have had to document the claim and put a disclaimer on the product label. State Senator Marci Francisco, (D-Lawrence) a vocal opponent of the bill, apparently sent an e-mail on May 4, 2009, to her constituents stating that the Senate Agriculture Committee considered the vetoed bill, "gutted the existing language ... that referred to milk labeling," and created a new version that combined earlier provisions of the bill and other proposals regarding pesticides, dairy fees and regulatory oversight. Francisco reported that the Senate then approved the new bill by a 40-0 vote. *See www.ethicurean.com*, May 4, 2009, and *Lawrence Journal World*, April 23, 2009.

### LITIGATION

## High Court Ruling on Identity Theft Law Affects Pleas from Immigrant Raids at Iowa Meatpacking Plant

The U.S. Supreme Court recently ruled that a conviction under the identity theft law requires a showing that those presenting false identification documents to employers knew they actually belonged to another real person. According to Justice Stephen Breyer, writing for the unanimous Court, the law was intended to crack down on classic identity theft, for example, where a defendant uses another person's information to get access to that person's bank account. Prosecutors have been using the law, which calls for a mandatory prison term, against immigrant workers to get them to plead guilty to lesser immigration charges and accept prompt deportation.



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After the Court issued its ruling on May 4, 2009, the manager of a meatpacking plant in Postville, lowa, raided in May 2008, sought to withdraw her plea to a charge of aggravated identity theft for allegedly helping illegal immigrants get jobs at the plant with documents she knew were false. Her lawyers reportedly argued that she had not been aware that the documents the plant's employees used belonged to other people and were not completely fabricated fakes. The court allowed her to withdraw the plea, but she will be sentenced May 13, 2009, on a remaining charge of conspiracy to harbor undocumented illegal immigrants for commercial and private financial gain.

After the court accepted the withdrawal of her identity theft plea, prosecutors immediately dropped the charge, an action that some say could threaten the convictions of hundreds of illegal immigrants arising from the Postville raid. An immigration lawyers' bar association has apparently called on the Department of Justice to consider dismissing the guilty pleas of nearly 300 illegal immigrant workers who were arrested during the raid. A spokesperson for the American Immigration Lawyers Association called on U.S. Attorney General Eric Holder to investigate the prosecutions and was quoted as saying, "The federal prosecutors used the law as a hammer to coerce the [Postville] workers."

According to a news source, most of the Postville immigrants who faced aggravated identity theft charges and a mandatory additional two years in prison pleaded guilty instead to charges of document fraud, served five months in prison and were deported. The aggressive use of the identity theft statute in Postville was apparently unprecedented; the workers' main offense was simply working without authorization. *See The New York Times, Meatingplace.com* and *BrownfieldNetwork.com*, May 6, 2009.

#### MDL Court Refuses to Certify Class in McDonald's French Fry Litigation

A federal court in Illinois, presiding over consolidated multidistrict litigation claims against McDonald's Corp. for allegedly advertising its French fries as gluten, wheat and dairy free while actually using small amounts of hydrolyzed wheat bran and casein in them, has denied plaintiffs' motion for class certification. *In re McDonald's*. *French Fries Litig.*, MDL No. 1784 (U.S. Dist. Ct., N.D. Ill., E. Div., decided May 6, 2009. The court determined that the class definition was indefinite and overbroad, the proposed class would be unmanageable, and individual issues would predominate over common ones.

The plaintiffs, who alleged violations of all 50 states' and the District of Columbia's consumer fraud and/or deceptive trade practices acts, breach of express warranty and unjust enrichment, sought to certify a nationwide class of all persons "who purchased Potato Products from McDonald's restaurants on or after February 27, 2002 through February 7, 2006 and who at the time of purchase had been medically diagnosed with celiac disease, galactosemia, autism and/or wheat, gluten or dairy allergies."

According to the court, by definition, "these people have suffered no injury, not even the economic one claimed in this lawsuit." The court also found that the proposed class definition was overbroad because the plaintiffs' claims required



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reliance to connect the representations with the economic harm alleged. Noting that rewriting the class definition would not resolve this certification problem, the court found a second problem, that is, the "evidentiary headache" created to prove a claim, "if the class were limited to persons with one of the stated diagnoses who purchased Potato products in reliance on defendant's representation and who would not otherwise have purchased french fries or hash browns." The court found it unlikely that millions of plaintiffs would provide a letter with a medical diagnosis to participate in a class "in which the damage was \$1.00 or \$1.50 (compounded for repeat purchases but still presumably a very small number). But assuming they did so, plaintiffs are asking the court to review and evaluate potentially millions of such letters."

While the plaintiffs specifically disclaimed any physical injury from the consumption of the company's potato products, the court briefly discussed the affidavits of defendant's experts, who stated that wheat, casein and milk products have not been shown to exacerbate autism and that those sensitive to such products generally learn what foods they may in eat in moderation without experiencing symptoms.

#### Federal Court Refuses to Seal Settlement Information in Veggie Booty Case

A federal court in New Jersey has reportedly refused to seal information about a proposed settlement involving putative class claims that the manufacturers of "Pirate's Booty" and "Veggie Booty" food products misrepresented their nutritional labeling information. *Schatz-Bernstein v. Keystone Food Prods., Inc.,* No. 1:08-cv-3079 (U.S. Dist. Ct., D. N.J., order entered April 17, 2009). The snacks were allegedly marketed as containing only 2.5 grams of fat and 120 calories per serving, when they actually contained nearly four times the fat and were 25 percent higher in calories. The plaintiff alleges breach of express warranty, unjust enrichment and a violation of consumer protection laws.

According to a news source, the defendants sought to seal settlement details that the plaintiff allegedly published improperly. The plaintiff has apparently maintained that the defendants reneged on the agreement. Denying the defendants' motion to seal, the court reportedly ruled that the defendants wrongly classified their settlement discussions with the court as mediation. He was quoted as saying, "Defendants' contentions regarding the alleged harm they would suffer from the disclosure of plaintiffs' motion are general, overbroad and conclusory. Defendants do not cite to any specific examples of harm they would suffer." *See LexisNexis*<sup>®</sup> *Mealey*'s<sup>™</sup> *Litigation Report, Food Liability*, May 2009.

#### DOJ Sues Hallmark Meat Packing and Westland Meat for Alleged Misrepresentations

The U.S. Department of Justice (DOJ) has intervened in a *qui tam*, or whistleblower, lawsuit filed in California by the Humane Society of the United States against two former suppliers to the National School Lunch Program. The suit alleges that Hallmark Meat Packing Co. and Westland Meat Co., Inc. knowingly and falsely represented that cattle at their slaughtering facility were treated humanely and that beef supplied to the schools did not include meat from disabled, non-ambulatory



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animals. Videotape of employees abusing non-ambulatory animals at the slaughterhouse resulted in the recall of 143 million pounds of beef in February 2008.

Under the False Claims Act, private parties, or "relators," may file claims on behalf of the U.S. government and may recover a portion of any recovery. The government, which will file an amended complaint now that it is a party to the action, is entitled to treble damages and civil penalties of \$5,500 to \$11,000 per violation if it prevails. According to a DOJ spokesperson, "The alleged misrepresentations by Hallmark and Westland could have impacted the health of many of our nation's most vulnerable citizens—our schoolchildren. Our intervention in this case demonstrates how seriously we will pursue allegations such as these." *See DOJ Press Release*, May 1, 2009.

#### Class Claims Filed for Deceptive Marketing of "Functional Food"

A Texas resident has filed a putative class action in a New Jersey federal court against the manufacturer of a fruit blend, which he alleges is falsely advertised as a product that helps control blood pressure and flush sodium. *Slaughter v. Unilever United States, Inc.*, No. 2:33-av-00001 (U.S. Dist. Ct., D.N.J., filed May 1, 2009). At issue is Unilever's SuperShots<sup>®</sup>, a fruit blend in three flavors sold in small "shot"-sized bottles. Each contains 350 mg of potassium and is allegedly promoted as a functional food that "will enable consumers to help control blood pressure and flush sodium from their bodies." According to the complaint, the product does not have this effect and has not been subjected to any clinical trials.

The plaintiff seeks to certify a nationwide class of product purchasers and alleges violations of New Jersey's Consumer Fraud Act, breach of implied and express warranties and unjust enrichment. He seeks restitution, disgorgement, monetary and statutory damages including treble damages, injunctive relief, costs, and attorney's fees. Listing other foods that cost considerably less than SuperShots<sup>®</sup> and contain significantly higher amounts of potassium, the complaint alleges, "Plaintiff and members of the Class would not have purchased SuperShots, or would have paid significantly less for SuperShots, but for Unilever's deceptive and misleading advertising."

#### Maple Leaf Listeriosis Litigation Settled; Claims Process Established

Courts in Saskatchewan, Ontario and Quebec have approved a nationwide settlement of <u>claims</u> filed by those allegedly affected by consuming *Listeria*-tainted meat products produced by Maple Leaf Foods. The 2008 outbreak reportedly sickened 57 people in seven Canadian provinces, and the *Listeria* strain was purportedly ruled to be the "underlying or contributing cause" in the death of 22 of them. Anyone who consumed the products, estimated at 5,200, may submit a <u>claim</u> for compensation.

With symptoms lasting no longer than 48 hours and with no medical proof, claimants can recover \$750. With physical symptoms lasting longer than 48 hours and with medical proof, claimants are eligible to recover \$3,000 to \$125,000. Psychological trauma, with medical proof, will be compensated at \$2,000 to \$17,500.

Those who wish to recover under the compensation scheme must submit their claims no later than November 2, 2009. Those who plan to pursue other legal claims



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against the company must opt out of the settlement no later than August 7, and those who do nothing will receive no payments and will waive their rights. *See The Canadian Press* and *CNW Group*, May 5, 2009; *Manitoba Cooperator* and *Meating-place.com*, May 6, 2009.

#### Healthy Menu Class Claims Filed in Texas Voluntarily Dismissed with Prejudice

The named plaintiff who brought a putative class action for false advertising of healthy menu items against a company that operates chain restaurants across the United States has reportedly agreed to dismiss with prejudice the claims she filed in a federal court in Texas. *Paskett v. Brinker Int'l Inc.*, No. 3:08-cv-942 (U.S. Dist. Ct., N.D. Tex., dismissed April 20, 2009). The plaintiff alleged that the healthy menu items at Chili's Grill & Bar, Romano's Macaroni Grill and On the Border Mexican Grill & Cantina restaurants actually contained higher levels of fat, calories and total carbohydrates than listed on the menus.

The named plaintiff has filed similar claims in California against Applebee's parent company, alleging that she dined at these restaurants because they offered a Weight Watchers menu, which was also purportedly advertised and marketed inaccurately. *See LexisNexis® Mealey's™ Litigation Report, Food Liability*, May 2009.

### LEGAL LITERATURE

### Comment, "Product Liability and Food in Washington State: What Constitutes Manufacturing?," *Seattle University Law Review*, Spring 2009

This student-authored article, prepared with the assistance of an attorney from the office of food litigator William Marler, discusses the inconsistent interpretations Washington courts have given to the definition of "manufacturer" in the state's product liability statute. The issue is critical in foodborne illness cases because those food sellers not deemed to be manufacturers can be held liable for negligence only, which requires conduct-related proof of culpability, and not under the strict liability regime, which does not. According to the author, "without consistent statutory interpretations, both food producers and consumers face unpredictable trial outcomes and costly litigation."

The author recommends the application of "a test that assesses manufacturer liability not only by the apparent physical changes an entity makes to a product, but also by the increased monetary value the entity adds to the product." This "valueadded" test could, according to the author, include simply washing and bagging produce or adding a logo or company brand to which "goodwill" is attached.

### OTHER DEVELOPMENTS

#### UK Consumer Group Claims "Junk Food" Healthier Than Baby Food

A UK-based consumer group recently released the results of a survey finding that some baby foods allegedly contain more saturated fat, salt and sugar by weight



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than popular adult snacks. The Children's Food Campaign (CFC) apparently analyzed 107 products for infants or toddlers, claiming that only one-half met the Food Standards Agency's (FSA's) requirements for low fat, salt and sugar. According to CFC, "Farley's Original Rusks contained more sugar than McVities Dark Chocolate Digestives, that Heinz Toddler's Own Mini Cheese Biscuits had more saturated fat per 100g than a McDonald's Quarter Pounder with Cheese, and that Cow & Gate Baby Balance Bear Biscuits contained *trans* fat and were not labeled in the way required." CFC also called on the government to (i) "Obtain a commitment from all companies that produce food marketed for babies and young children to reformulate products to remove *trans* fats and reduce the amount of saturated fat, salt and sugar"; and (ii)" develop labeling that enables parents to see at a glance whether the food they are buying for their baby is healthy."

"Nearly a decade on, the new survey demonstrates that some companies have taken virtually no action to improve the healthiness of products marketed for babies and young children," opined CFC Joint Coordinator Christine Haigh in a May 4, 2009, press release.

Cow & Gate has since voluntarily withdrawn its Balance Bear Biscuits from the market, but noted that its other products contain less sugar "than comparable adult varieties and other baby biscuits." In addition, H. J. Heinz Co. pointed out that the serving size comparison was misleading as the company's mini cheese biscuits have a serving size of 25g - not 100g as cited by CFC. FSA concurred that infants and young children "have different nutritional needs and do not generally need low-fat diets, as fats give them energy and provides some fat soluble vitamins." The agency advised parents to check food labels, further cautioning that children require "foods that provide a high density of calories and nutrients in a small amount of foods as they only have small stomachs." *See Reuters*, May 4, 2009; *The London Times*, May 5, 2009.

#### General Mills Taps into Power of "Mommy" Blogs to Promote Products

General Mills, Inc. has reportedly enlisted hundreds of bloggers to receive and review products as part of its MyBlogSpark<sup>™</sup> campaign, which sends free samples, coupons and other promotional materials to members in exchange for their feedback. The blog network has apparently registered approximately 900 writers – of whom more than 80 percent are mothers – to expand marketing distribution to an audience purportedly exceeding 8 million readers. One recent set of blog reviews garnered approximately 5 million "total impressions" and 8,000 comments, according to General Mills, which does not purchase ad space on the Web pages.

The blogosphere's growing influence, however, has prompted the Federal Trade Commission to propose regulations that would require bloggers to reveal any affiliations with the product under review. MyBlogSpark has thus encouraged participants to divulge their relationship to General Mills, but also asked bloggers to submit any negative reviews to the program before posting them on the Internet. "We want them to disclose they're a member," a General Mills spokesperson was quoted as saying. "We want them to be really upfront." *See AdWeek*, April 29, 2009.



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### MEDIA COVERAGE

## Lester R. Brown, "Could Food Shortages Bring Down Civilization?," Scientific American, April 22, 2009

"Our continuing failure to deal with the environmental declines that are undermining the world food economy—most important, falling water tables, eroding soils and rising temperatures—forces me to conclude that such a collapse is possible," writes Earth Policy Institute President Lester Brown in this article about how global food shortages have the potential to disrupt civilization and increase the number of failed states, which in turn become "a source of terrorists, drugs, weapons, and refugees, threatening political stability everywhere." Combined with depleted water sources, soil erosion and climate change, a "trend-driven" rise in world grain prices has exacerbated food shortages in many developing countries, according to Brown, who notes that "a fourth of this year's U.S. grain harvest – enough to feed 125 million Americans or half a billion Indians at current consumption levels – will go to fuel cars." He warns that without drastic intervention, "a dangerous politics of food scarcity is coming into play: individual countries acting in their narrowly defined self-interest are actually worsening the plight of many."

Brown ultimately urges governments to adopt a plan similar in "scale and urgency to the U.S. mobilization for World War II." His approach relies on four components: "a massive effort to cut carbon emissions by 80 percent from their 2006 levels by 2020; the stabilization of the world's population at eight billion by 2040; the eradication of poverty; and the restoration of forests, soils and aquifers." Brown predicts that this plan to "save civilization" will cost "less than \$200 billion a year, a sixth of current global military spending." "We desperately need a new way of thinking, a new mind-set," he concludes. "The thinking that got us into this bind will not get us out."

### SCIENTIFIC/TECHNICAL ITEMS

#### Study Identifies Commercial Perfluorochemicals in Human Blood

University of Toronto scientists have reportedly indentified food-wrapper chemicals known as polyfluoroalkyl phosphoric acid diesters (diPAPs) at "low part-per-billion concentrations" in human blood. Jessica C. D'eon, et al., "Observation of a Commercial Fluorinated Material, the Polyfluoroalkyl Phosphoric Acid Diesters, in Human Sera, Wastewater Treatment Plant Sludge, and Paper Fibers," *Environmental Science & Technology*, April 29, 2009. Researchers examined blood samples from both male and female donors ages 19 through 70 with various blood types. They also tested paper fibers and wastewater treatment plant sludge "as a proxy for human use and potential exposure," concluding that high diPAP concentrations in the environment "suggest diPAP materials may be prevalent in our daily lives."

According to a concurrent news release, rat studies have shown that diPAPs "can be metabolized to PFOA [perfluorooctanoic acid] and other perfluorinated carboxylic acids" after ingestion, raising questions about "their potential toxicity in humans and wildlife." The publication also noted several U.S. Food and Drug Administration (FDA)



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studies that suggest diPAPs can migrate from grease-proof wrappings into some foods "at several hundred times higher than current FDA-approved guidelines." "This finding makes it clear that we cannot just look at one single chemical or class and understand perfluorinated chemicals in the environment and in humans," stated co-author Laurence Libelo, a senior environmental engineer with the U.S. Environmental Protection Agency. *See Environmental Science & Technology News*, April 29, 2009; *The Charleston Gazette*, April 30, 2009; *The Daily Green*, May 1, 2009.

#### Study Finds Dietary Acrylamide Not Linked to Brain Cancer

A recent study has reportedly found no positive association between dietary acrylamide intake and brain cancer. Janneke G.F. Hogervorst, et al., "Dietary Acrylamide Intake and Brain Cancer Risk," *Cancer Epidemiology, Biomarkers & Prevention*, Vol. 18 (2009). Dutch researchers surveyed the dietary habits of 58,279 men and 62,573 women ages 55 through 69 who were enrolled in the Netherlands Cohort Study on Diet and Cancer. The subjects' dietary sources of acrylamide, the chemical by-product created by baking, frying and toasting foods at high temperatures, included potato chips, French fries, Dutch spiced cake, coffee, bread, and cookies. After adjusting for possible brain cancer risk factors, researchers concluded that hazard ratios for acrylamide were not significantly increased when dietary intake was analyzed as a categorical variable.

These same researchers have also concluded that dietary acrylamide is not linked to an increased risk of lung cancer. Those findings were covered in issue 302 of this Update. *See FoodNavigator-USA.com*, May 7, 2009.

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### **FOOD & BEVERAGE LITIGATION UPDATE**

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.



