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### LEGISLATION, REGULATIONS AND STANDARDS

## FDA Accepts Markey Petition, May Disallow Use of BPA in Infant Formula Packaging

The Food and Drug Administration (FDA) has <u>notified</u> Representative Edward Markey (D-Mass.) that it has accepted his petition seeking to prohibit the use of bisphenol A (BPA) in canned infant formula. If the agency is able to complete its scientific review, it will file his petition in the *Federal Register* within 90 days seeking public comment on whether the industry has actually abandoned this use of the chemical, the ground on which Markey sought the ban.

As noted in <u>Issue 433</u> of this *Update*, while FDA has confirmed the chemical's safety for continued use in food-packaging materials, the American Chemistry Council has asked the agency to prohibit its use in polycarbonate bottles and sippy cups, contending that industry no longer uses BPA in these products. Markey's <u>petition</u> echoed that rationale in relation to infant-formula packaging. According to a news source, the "abandonment" focus allows government to "sidestep the debate over BPA's safety and still eliminate its use." FDA apparently rejected Markey's related requests that BPA be prohibited in canned foods and beverage packaging and in small reusable household containers, finding that industry has not abandoned this use. *See The Washington Post*, June 12, 2012; *Press Release of Representative Ed Markey*, June 13, 2012.

### Health Canada Releases Voluntary Sodium Guidelines for Processed Foods

Health Canada recently issued "Guidance for the Food Industry on Reducing Sodium in Processed Foods" as part of its effort "to help Canadians achieve the average sodium intake goal of 2300 mg per day by 2016." According to Health Canada, which developed the voluntary guidance after receiving "significant input" from stakeholders, the benchmark sodium levels aim to help food manufacturers gradually reformulate their products to meet the nation's sodium-reduction goals.



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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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To that end, the agency calculated the Sales Weighted Average (SWA) sodium content in milligrams per 100 grams "using the sodium levels of the products within a category weighted by their Canadian volume market share in kilograms (kg)." The 2016 proposed SWA sodium levels were then established "by reducing the baseline SWA sodium content by approximately 25% to 30%."

"The phased levels typically represent, respectively, 1/3 and 2/3 of the reduction required to meet the 2016 guiding benchmark SWA levels and are meant to help guide the industry towards meeting the 2016 SWA sodium levels. The majority of the 2016 Maximum levels correspond to the 75th percentile of the sodium levels observed in each food category," states the guidance, which also encourages manufacturers to focus on foods targeted to children. "Regardless of the approach taken manufacturers are encouraged to meet the phase 3 benchmark levels by the end of 2016 and, if possible, go beyond them over time to the lowest level possible while taking into consideration factors such as microbial safety, quality and consumer acceptance."

## Philippines Department of Justice Upholds DOH Decision on Infant Formula Trademarks

According to news sources, Philippine Department of Justice Secretary Leila de Lima issued an opinion in May 2012, upholding a Department of Health (DOH) memorandum that prohibited multinational companies that make infant milk and other nutritional products from using registered trademarks that contain health and nutrition claims which may undermine breast-feeding and breast milk. The companies were not prohibited from selling or advertising their products as long as their marketing materials, including product labels, comply with DOH rules. DOH apparently took the action on the basis of data showing that the country has a weak breast-feeding culture.

In issuing her ruling, de Lima rejected the companies' contention that preventing a trademark owner from the right to use its own registered mark on its products constituted a deprivation of property without due process of law. She reportedly said, "deceptive marks and misdescriptive marks are absolutely unregistrable." See Business Mirror, June 13, 2012.

Meanwhile, in a related development, concerns over efforts to introduce plain packaging for tobacco products in the United Kingdom are reportedly extending into the food and beverage industries, which are watching such developments closely. A packaging spokesperson was quoted as saying such regulation would set an "extremely dangerous precedent" for other sectors, adding "[w]ith legislation around minimum alcohol pricing in the pipeline, high-profile debates about a 'fat tax' and calls for cigarette style health warnings on alcohol and 'junk food'; brand owners and manufacturers have to open their eyes to the very realistic threat of plain packaging being



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introduced on a wide range of consumer products." See FoodProductiondaily. com, June 15, 2012.

### California to Let Voters Decide Whether to Require GMO Labeling

California Secretary of State Debra Bowen (D) has reportedly certified that enough valid signatures were gathered to allow a genetically modified organism (GMO) food-labeling initiative on the state ballot during the November 6, 2012, general election. In May, the Committee for the Right to Know obtained 971,126 signatures, of which 555,236 had to be proven valid. The ballot initiative, aka California Right to Know Genetically Modified Food Act, was covered in Issue 438 in this *Update*.

"We're thrilled that Californians will have the opportunity this November to vote for the right to know what's in our food," said Stacy Malkan, a committee spokesperson. "It's about our fundamental right to make informed choices about the food we eat and feed our families." See California Secretary of State Debra Bowen Press Release, June 11, 2012; Law 360, June 12, 2012.

### NYC Board of Health to Consider Proposed Limit on Soft Drink Sizes

The New York City Board of Health and Mental Hygiene (DOHMH) has called a July 24, 2012, public hearing to gather feedback on Mayor Michael Bloomberg's recommendation to limit the size of sugar-sweetened beverages sold at local food service establishments. The 11-member board reportedly voted unanimously at a June 12, 2012, meeting to publish the proposal, which would amend Article 81 of the Health Code to establish a maximum serving size of 16 ounces for sugary, non-alcoholic drinks and all self-service cups. If adopted by DOHMH on September 13, the amendment would apply to restaurants, food carts, delis, movie theaters, stadiums, and arenas while also imposing a \$200 fine for each violation of the code.

According to the notice of public hearing, the proposal seeks to address rising obesity rates among city residents by "reacquainting New Yorkers with more appropriate portion sizes." The plan has apparently drawn support from public health advocates as well as individual DOHMH members, although some questioned whether the amendment would necessitate similar regulations for other menu items such as French fries or popcorn. "Some of the board members seemed to think that the proposal didn't go far enough, and I found that very alarming," one spokesperson for the New York City Restaurant Association was quoted as saying. "We believe the board is appointed by the mayor but ultimately should be accountable to the public, many of whom don't believe in this proposal." See The Associated Press and The New York Times, June 12, 2012.



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#### LITIGATION

### California Slaughterhouse Law Ruling Vacated on Remand from SCOTUS

On remand from the U.S. Supreme Court, the Ninth Circuit Court of Appeals has issued an order which reinstates a district court ruling that a California law regulating swine slaughterhouses and nonambulatory animals was preempted by federal law. *Nat'l Meat Ass'n v. Harris*, Nos. 09-15483 and -15486 (9th Cir., order entered June 8, 2012). Additional details about the case and the unanimous U.S. Supreme Court ruling appear in Issue 424 of this *Update*.

## Second Circuit Confirms Frivolous Finding in Hoisin Sauce Trademark Infringement Litigation

The Second Circuit Court of Appeals has upheld an award of \$10,000 in sanctions under Federal Rule of Civil Procedure 11 for the filing of a frivolous action related to trademark infringement litigation between companies that make and sell hoisin sauce. <a href="Star Mark Mgmt.">Star Mark Mgmt.</a>, Inc. v. Koon Chun Hing Kee Soy. <a href="&Sauce Factory">& Sauce Factory</a>, Ltd., Nos. 10-4931, 11-16 (2d Cir., decided June 13, 2012). Koon Chun prevailed, in part, on its claims of willful trademark infringement against Star Mark, based on Star Mark's sale of counterfeit versions of Koon Chun's hoisin sauce. A magistrate judge awarded damages and costs, and the Second Circuit affirmed.

In the meantime, the parties were litigating Star Mark's suit to cancel Koon Chun's mark "on the theory that Koon Chun's use of the word 'hoisin'—which translates to 'seafood'—was deceptive because the sauce did not contain seafood." When considering this matter in a motion to amend Star Mark's answer in the initial lawsuit, the magistrate expressed skepticism about the claim and noted that he would consider imposing sanctions if the motion were made. Star Mark decided not to file the motion, but asserted the claims in a new lawsuit. Koon Chun's counsel requested in writing that Star Mark withdraw the new complaint, threatening to file a Rule 11 motion. The complaint was not withdrawn, and Koon Chun moved for judgment on the pleadings as well as Rule 11 sanctions, asserting that the lawsuit was frivolous. The district court agreed and imposed a total of \$10,000 for fees and costs "based upon the showing of financial hardship by plaintiffs and their attorneys."

Finding that Koon Chun complied with the spirit of Rule 11 when giving notice to Star Mark, the court found the rule's safe harbor requirement satisfied. The court also determined that the magistrate did not abuse its discretion in finding that Star Mark's suit was frivolous. As the magistrate pointed out, "the fact that Koon Chun's product name translates to 'seafood sauce' but does not contain seafood does not make the product misleading



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because many sauces are not named after their ingredients, but are named after the foods they accompany." The Second Circuit agreed.

### Court Refuses FTC Request to Modify Definition of "Reliable Scientific Evidence"

A federal court in Florida has denied the Federal Trade Commission's (FTC's) request that it modify a stipulated final order resolving a 2006 dispute with Garden of Life, Inc. over purportedly unsubstantiated representations that its products could treat a range of serious diseases and their symptoms. FTC v. Garden of Life, Inc., No. 06-80226 (U.S. Dist. Ct., S.D. Fla., filed May 25, 2012). The parties had agreed that the company could make such claims if supported by "competent and reliable scientific evidence," defined in the stipulated final order as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

Claiming that the company was continuing to deceive consumers and that "the Stipulated Final Order has failed to achieve its intended purpose of protecting consumers from the Defendants' deceptive marketing," FTC sought to modify the order by imposing a \$25 million performance bond on the company to ensure future compliance, as well as requiring "two adequate and well-controlled human clinical studies for all absolute or comparative claims about the bone and cognitive health benefits, efficacy, performance, safety, or side effects of [Garden of Life's] products."

The court decided to apply a "significant change in factual circumstances" standard to determine whether it had the authority to modify a consent decree and, under that standard, found that it did not. The court disagreed with FTC that consent decrees have overarching purposes (i.e., to protect consumers); rather, the court said that the agreement's objective in this case was to enjoin the company from making representations without competent and reliable evidence and misrepresenting the "existence, contents, validity, results, conclusions, or interpretations of any test or study." According to the court, FTC was essentially seeking to re-define the term "competent and reliable scientific evidence." Because "it should have been foreseen that the Parties may disagree in the future about what constitutes competent and reliable scientific evidence," the court ruled that a significant change in factual circumstances had not occurred.



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### State Court Allows Cleveland to Prohibit Trans Fats in Prepared Meals

A Cuyahoga County, Ohio, court has reportedly determined that a state law prohibiting municipalities from regulating the ingredients used in prepared foods, such as restaurant meals and grocery or bakery takeout items, does not preempt Cleveland's ordinance prohibiting retail food establishments from selling foods containing *trans* fats. Cleveland announced the ban in April 2011, and several months later, Ohio's General Assembly amended the state's budget with a provision prohibiting municipalities from restricting the food at food service establishments "based on the food nutrition information."

Cleveland sued the legislature in January 2012, contending that it had encroached on its home rule authority. *City of Cleveland v. Ohio*, No. cv-12-772529 (Ohio Ct. Com. Pl., Cuyahoga Cnty., decided June 11, 2012). Additional information about the lawsuit appears in <u>Issue 422</u> of this *Update*. The court apparently agreed, noting in the case docket that the amendment was unconstitutional and that the city's enactment and enforcement of its ordinance "constitutes a proper exercise of the city's home rule authority." *See The Wall Street Journal* and *Law360*, June 13, 2012.

#### Suit Claims Costco Mislabels Potato Snacks as "0 Grams Trans Fat"

Seeking to represent a statewide class of product purchasers, a California resident has filed a putative class action against Costco, alleging that the company falsely sells its Kirkland Signature Kettle Brand Potato Chips®, which purportedly contain "more than 13 grams of fat per 50 grams," with a "0 Trans Fat" label. *Thomas v. Costco Wholesale Corp.*, No. CV12-02908 (U.S. Dist. Ct., N.D. Cal., San Jose Div., filed June 5, 2012).

Citing 21 C.F.R. § 101.13(h), plaintiff Karen Thomas contends that the defendant is "prohibited from making the unqualified nutrient claims of '0 grams Trans Fat' on its food products if they contain fat in excess of 13 grams, saturated fat in excess of 4 grams, cholesterol in excess of 60 milligrams, or sodium in excess of 480mg per 50 grams, unless the product also displays a disclosure statement that informs consumers of the product's fat, saturated fat and sodium levels." She alleges that the product label does not include a disclosure statement as required by California and federal law. This information appears in the "Nutrition Facts" panel, but the complaint alleges that Food and Drug Administration guidance requires a more prominent disclosure.

Claiming that she would not have purchased "Defendant's Misbranded Food Products had he [sic] known they were not capable of being legally sold or held," the plaintiff alleges unlawful, unfair and fraudulent business acts and practices; misleading and deceptive advertising, untrue advertising, violations of the Consumers Legal Remedies Act, Beverly-Song Act and Magnuson-Moss Act; and restitution based on unjust enrichment/quasi-contract. She seeks damages in excess of \$5 million, injunctive relief, attorney's fees, costs, and interest.



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### Shopper Claims Ralph's Grocery Co. Improperly Shared Personal Information

A California resident has filed a putative class action against Ralphs Grocery Co. alleging that it breached its promise not to share the personal information that shoppers must provide to obtain a "Ralphs rewards Card"; only cardholders may purportedly take advantage of advertised store discounts. *Heller v. Ralphs Grocery Co.*, No. BC486035 (Cal. Super. Ct., Los Angeles Cnty., Cent. Dist., filed June 6, 2012).

He contends that he would not have shopped at the grocery stores or applied for a rewards card "if not for Defendant's misrepresentation and/or nondisclosure of the fact that it was selling and/or sharing its customers' personal identification information." According to the complaint, the defendant shares customer information with Kroger and with dunnhumby, a company that allegedly "performs data mining services for more than 350 million people in 25 countries on behalf of retailers" and "uses personal identification information and data from purchase transactions gleaned from the Ralph's reward Card program to drive sales."

Seeking to certify a statewide class of consumers, the plaintiff alleges violations of the state's Supermarket Club Card Disclosure Act of 1999 and Unfair Business Practices Act; breach of contract; fraud; and intentional and negligent misrepresentation. He seeks compensatory and general damages, restitution and/or disgorgement, injunctive relief, punitive damages, attorney's fees, costs, and interest.

#### OTHER DEVELOPMENTS

### Public Health Lawyer Investigates Corporate Ties to SNAP Program

Public health lawyer Michele Simon has published a June 2012 report that raises questions about the purported influence of food and banking corporations on the U.S. Department of Agriculture's (USDA's) Supplemental Nutrition Assistance Program (SNAP). Titled "Food Stamps: Follow the Money," the report focuses on food manufacturers, food retailers and large banks with "a critical stake in debates over SNAP," which Simon describes as "the largest, most overlooked subsidy in the farm bill." In particular, she alleges that food industry lobbyists have joined with anti-hunger groups to oppose state and federal efforts to disallow soda, candy and snack food purchases under the program.

"Among the most vocal opponents of health-oriented improvements to SNAP purchases are several national anti-hunger groups, each of which accepts significant funding from major players in the food industry," opines Simon. "While it's not clear exactly how such relationships might influence policy



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positions, the potential for conflict exists. Other groups that do not take corporate money also oppose SNAP waivers to modify product purchases."

Although it ultimately asks Congress not to cut SNAP benefits "at this time of extreme need," the report nevertheless maintains that SNAP has disproportionately benefited a handful of major retailers as well as the banks that administer the ATM-style Electronic Benefits Transfer on behalf of states. While criticizing USDA for failing to gather national data about SNAP product purchases and "how much money banks make on SNAP," Simon argues that banks "are reaping significant windfalls from the economic downturn and increasing SNAP participation." She calls on USDA to improve the program's transparency by collecting information about SNAP product purchases, bank fees and retailer redemptions and making these data available to the public.

"The debate over making health-oriented improvements to SNAP purchases is currently at a standstill," concludes Simon, who also urges USDA to grant state waivers to experiment with program changes. "On one side are those who insist soda is not a food, while others argue such policy changes only hurt those in need. We must go beyond this rhetoric and examine the extent to which SNAP has become a corporate subsidy. Then advocates should work together to make improvements to SNAP that will truly benefit participants."

### PHAI Questions "Hidden Costs" of School Vending Machines

The Public Health Advocacy Institute (PHAI) has issued a June 7, 2012, <u>fact</u> <u>sheet</u> calling on school districts to consider the energy costs of cold beverage vending machines when deciding whether to renew vending contracts. Claiming that a traditional vending machine consumes approximately 3,000 kilowatt hours of electricity per year (kWh/yr), the fact sheet estimates that schools spend an average of \$313 in annual energy costs per machine.

"When multiplied over a total number of machines housed on school property, the electricity cost required to operate cold beverage vending machines amounts to a significant hidden expense for schools that should be subtracted from school beverage vending revenue," argues PHAI, which has also provided a breakdown of vending machine energy costs by state.

As an example, the fact sheet thus calculates that a large California school district with 225 traditional vending machines would accrue \$477,000 in electricity fees over five years. To ameliorate these "hidden costs," PHAI urges schools to save energy by either phasing out machines altogether or reducing their number on school property. It also recommends that districts insist on installing only the most energy-efficient machines or require the beverage company that owns the machines to pay electricity costs.

PHAI is affiliated with Northeastern University School of Law and headed by law professor and anti-tobacco advocate Richard Daynard.



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## Regulators, Retailers and Manufacturers Concerned About Pace of Product Recalls

According to a news source, more than 2,300 consumer products, pharmaceuticals, medical devices, and food, at a pace of some 6.5 each day, were recalled in 2011. This represents a reported increase of 14 percent over recalls in 2010 and compares to about 1,500 recalls in 2007. Regulators, retailers and manufacturers are apparently concerned that the surge in product recalls will produce a recall "fatigue" that means consumers could ignore or miss a recall which puts them at risk. A Rutgers study from 2009 found that 12 percent of Americans eat food they know has been recalled and 40 percent admit never looking for recalled products in their homes.

Some retailers, such as Costco, that have mechanisms to automatically notify members who have purchased recalled products, have opined that the national recall system would be more effective if a single, uniform network were in place instead of the varying recall systems used by individual agencies, such as the Consumer Product Safety Commission, U.S. Department of Agriculture (USDA) and Food and Drug Administration. USDA Secretary Tom Vilsack, pointing to the vast numbers of products made, sold or consumed every day, reportedly sought to downplay the number of announced recalls. Still, he was quoted as saying, "I think people want to know and need to know and have a right to know if there is a problem with a particular product. We're going to look at ways in which we [communicate] and constantly improve how we communicate but we're not going to stop communicating." See USA Today, June 8, 2012.

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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.



