Shook, Hardy & Bacon L.L.P.

ISSUE 532 | AUGUST 1, 2014

# FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS



## LEGISLATION, REGULATIONS AND STANDARDS

### House Lawmaker Introduces National Soft Drink Tax

U.S. Rep. Rosa DeLauro (D-Conn.) has reportedly introduced legislation (H.R. 5279) seeking to implement a nationwide sugar-sweetened beverage tax. Dubbed the SWEET Act, the measure "would institute a tax of 1 cent per teaspoon of caloric sweetener such as sugar or high-fructose corn syrup," according to a July 30, 2014, press release. Revenue raised by the proposed tax would be used to fund prevention and treatment programs, nutrition education and other initiatives designed to reduce obesity, heart disease, diabetes, and tooth decay.

"There is a clear relationship between sugar-sweetened beverages and a host of other health conditions," said DeLauro. "We are at a crucial tipping point and the SWEET Act will help correct the path we are currently on."

Meanwhile, Mark Bittman has already penned a *New York Times* opinion piece in support of the bill, arguing that a national soda tax might not pass congressional muster right now but needs to start somewhere. "The first national health care act was proposed in 1939, and the modern history of anti-tobacco legislation began in the 1960s. Yet both are now powerful realities," he writes. "DeLauro is the right person for this. She has a history when it comes to noble and seemingly ill-fated gestures. For example, she introduced a bill requiring calorie counts on restaurant menus more than 10 years ago and was then regarded, as she says, as 'the crazy aunt in the attic.' Yet a provision for menu labeling was included in the Affordable Care Act." *See The New York Times,* July 29, 2014.

### Senators Seek Update on FDA Plan to Combat Antibiotic-Resistant Bacteria

U.S. Sens. Dianne Feinstein (D-Calif.), Kirsten Gillibrand (D-N.Y.) and Elizabeth Warren (D-Mass.) have written a July 28, 2014, letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg, requesting additional information about how the agency plans to implement and evaluate new policies designed to combat the spread of antibiotic-resistant bacteria. Noting that "four times as many antibiotics are used in food animal production as are used in human medicine," the senators praise recent guidance intended to curtail the routine use of these drugs to promote animal growth, but question whether these measures go far enough.

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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



"We remain concerned, however, that many of the remaining approved uses of antibiotics to contain and prevent diseases are not strictly defined, and still allow for the continuous administration of low doses of antibiotics," they write, pointing to loosely-worded guidelines that approve antibiotics to prevent or contain disease "in times of stress." In particular, the senators have asked FDA to clarify (i) how the agency intends to determine whether the non-judicious use of antibiotics in food animal production is declining; (ii) what steps the agency will take if it observes no change in the amount of antibiotics used for food animal production; (iii) how the agency will ensure that approved labeling indications do not pose the same risks of fostering resistance as the production uses now being phased out; (iv) how the agency plans to inspect facilities for veterinary feed directive compliance; and (v) how the agency plans to collect and compile data to track how specific antibiotics are being used.

### Senators Urge Commerce Department Against Quotas on Mexican Sugar Imports

A group of 17 U.S. senators has submitted a letter to the Commerce Department warning that a proposed suspension agreement imposing quotas on Mexican sugar imports would violate the North American Free Trade Agreement, "threaten the viability of American food manufacturers and raise food prices for American families."

Led by Sens. Jeanne Shaheen (D-N.H.) and Pat Toomey (R-Penn.), the group includes Sens. John McCain (R-Ariz.) and Dianne Feinstein (D-Calif.). Following petitions by members of the American Sugar Alliance, the Commerce Department launched an April 2014 investigation into allegations that Mexico's mills are dumping subsidized sweetener in the United States, and the department is reportedly due to decide whether to impose duties on Mexican imports soon. "This mutual market access is beneficial to the United States: U.S. growers and refiners do not produce enough sugar to meet the demands of U.S. consumers, and imports are necessary to keep America's food manufacturers competitive in the global marketplace," the letter apparently said. *See Reuters* and *Law360*, July 29, 2014.

### New Poultry Inspection Rules Require Proactive Pathogen Reduction, Set Maximum Line Speeds

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has **announced** a final rule amending poultry slaughter regulations and establishing a new poultry inspection system (NPIS) for young chicken and turkey slaughter establishments. Part of USDA's response to a presidential executive order (E.O. 13563) asking agencies to review and improve existing regulations, the final rule aims to "facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter

inspection, make better use of the Agency's resources, and remove unnecessary regulatory obstacles to innovation."

Optional for young chicken and turkey establishments, which can choose to retain their current inspection system, NPIS will not replace the Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS) or the New Turkey Inspection System (NTIS), as was originally proposed. FSIS has emphasized, however, that NPIS will allow inspectors "to perform more offline inspection activities that are more effective in ensuring food safety, while providing for a more efficient and effective online carcass-by-carcass inspection." In particular, the new system will (i) "requir[e] that establishment personnel sort carcasses and remove unacceptable carcasses and parts before the birds are presented to the FSIS carcass inspector"; (ii) "shift[] Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which will allow for one offline verification inspector per line per shift and will reduce the number of online inspectors to one"; (iii) "replac[e] the Finished Product Standards (FPS), which will apply to establishments that continue operating under SIS, NELS, and NTIS, with a requirement that establishments that operate under the NPIS maintain records to document that the products resulting from their slaughter operations meet the definition of ready-to-cook (RTC) poultry"; and (iv) "authoriz[e] young chicken slaughter establishments to operate at a maximum line speed of 140 birds per minute (bpm), provided that they maintain process control."

Regardless of the inspection system used, the final rule will also require all poultry facilities "to take measures to prevent *Salmonella* and *Campylobacter* contamination, rather than addressing contamination after it occurs." To this end, poultry slaughter establishments must integrate these measures into their hazard analysis and critical control points plans and standard operating procedures, in addition to conducting microbial sampling and analysis "at the pre- and post-chill points in the process to monitor process control for enteric pathogens."

"The United States has been relying on a poultry inspection model that dates back to 1957, while rates of foodborne illness due to *Salmonella* and *Campylobacter* remain stubbornly high. The system we are announcing today imposes stricter requirements on the poultry industry and places our trained inspectors where they can better ensure food is being processed safely. These improvements make use of sound science to modernize food safety procedures and prevent thousands of illnesses each year," said USDA Secretary Tom Vilsack in a July 31, 2014, press release. Once the final rule is published in the *Federal Register,* all young chicken and turkey slaughter establishments will have six months to notify their district offices if they intend to operate under NPIS.

### USDA Rejects Petition Seeking Adulterant Designation for ABR *Salmonella*

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has **denied** the May 2011 petition filed by the Center for Science in the Public Interest (CSPI) seeking an interpretive rule declaring certain antibiotic-resistant (ABR) strains of *Salmonella* to be adulterants when found in raw ground meat and raw ground poultry. Additional information about the petition appears in Issue **396** of this *Update.* CSPI also asked the agency "to ensure adequate sampling and testing for these pathogens and to remove contaminated ground meat and ground poultry products from the human food supply."

FSIS essentially found insufficient data to distinguish ABR *Salmonella* strains from other *Salmonella* strains that are susceptible to antibiotics and thus stated that additional data on the characteristics of ABR *Salmonella* are needed to determine whether the strains identified in the petition "could qualify as adulterants under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453 *et seq.*)." The agency's July 31, 2014, letter to CSPI distinguishes the shiga toxin-producing *E-coli* (STEC) that have been declared adulterants from ABR *Salmonella*, noting that "[b]ased on current data, *Salmonella* does not appear to present the same issues as STEC, regardless of whether it is resistant or susceptible to antibiotics."

FSIS also referred to the Codex Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance in its response, noting that it is "in line with the current FSIS approach used to assess the human health risks associated with specific pathogens." According to the agency, "The Codex document clearly illustrates the types of additional information that would be necessary to declare the ABR strains of *Salmonella* Hadar, *Salmonella* Heidelberg, *Salmonella* Newport, and *Salmonella* Typhimurium as adulterants when found in raw ground meat and raw ground poultry. At this time, FSIS believes that neither the petition nor our own research provide sufficient data to support such a claim."

CSPI Food Safety Director Caroline Smith DeWaal said, "USDA's failure to act on antibiotic-resistant strains of Salmonella in the meat supply ignores vital information about the public health risk posed by these pathogens. Despite numerous examples of outbreaks linked to resistant pathogens, USDA leaves consumers vulnerable to illnesses that carry a much greater risk of hard-to-treat infections leading to hospitalization." *See CSPI Press Release*, July 31, 2014.

### Health Experts Back "Added Sugar" Labeling

The Center for Science and Democracy at the Union of Concerned Scientists has submitted a **comment** backed by more than 280 health experts asking the U.S. Food and Drug Administration (FDA) to include a percent daily value for the proposed "added sugars" declaration on food and beverage labeling.

Responding to the agency's request for comments on proposed changes to the nutrition and supplement facts labels, the letter signed by Robert Lustig, Marion Nestle and members of the Healthy Food Action network urges FDA to set a maximum daily value for added sugars at 50 grams—approximately 10 percent of recommended daily calorie intake—and to list a percent daily value on the Nutrition Facts label.

"Many food and beverage manufacturers add excessive amounts of sugar to their products, including those that they market as healthy options. In our current food environment, many people are unknowingly and unavoidably consuming excess sugar," opines the letter. "Given our soaring rates of chronic diseases and the link between sugar and these diseases, citizens have a right to know how much sugar has been added to their foods."

Noting that most percent daily values focus on minimum recommended intakes, the letter cites a similar approach used in the United Kingdom to indicate maximum sodium levels on nutrition labels. Additional details about the proposed changes appear in Issue **515** of this *Update*.

### NLRB General Counsel to Name McDonald's as Joint Employer

National Labor Relations Board (NLRB) General Counsel Richard Griffin has reportedly determined that McDonald's, USA, LLC will be named as a "joint employer respondent" if meritorious complaints alleging unfair labor practices against the company and its franchisees do not settle. According to the NLRB, 181 cases involving McDonald's have been filed since November 2012. Press reports indicate that they involve claims that workers have been wrongfully fired, threatened or suspended because they have engaged in labor protests, campaigning for a $15 hourly wage and to unionize. Sixty-eight of the cases have apparently been found to have no merit, and 64 are currently under investigation.

While Griffin's advice memorandum to the NLRB's regional offices authorizing 43 complaints brought by McDonald's workers does not have the force of a full board ruling, it has sparked a firestorm of controversy among business interests. Noting that McDonald's will contest the joint-employer allegation "in the appropriate forum," a McDonald's spokesperson said that the company "believes that this decision changes the rules for thousands of small businesses, and goes against decades of established law regarding the franchise model in the United States." She also said in a memo to franchisees, "We will vigorously argue our case at the administrative trials and subsequent appeal processes which are likely to follow from the issuance of the complaints." Other industry spokespersons reportedly characterized the decision as "outrageous" and an example of the Obama administration's anti-small-business agenda.

An attorney representing McDonald's workers in New York City said, "There's really no doubt who's in charge. McDonald's can try to hide behind its franchisees, but today's determination by the N.L.R.B. shows there's no two ways about it; The Golden Arches is an employer, plain and simple." An organizing director for Fast Food Forward, a Service Employees International Union-funded coalition seeking to organize employees in New York City's chain restaurants, was quoted as saying, "As the federal government's determination shows, McDonald's clearly uses its vast powers to control franchisees in just about every way possible." Some labor experts have commented that the general counsel's decision could affect other industries that also follow a franchise model. *See NLRB News Release*, *ABC News, The New York Times,* and *The Wall Street Journal,* July 29, 2014; *Law360*, July 30, 2014.

### FTC's Four Loko Final Order Modified

The Federal Trade Commission (FTC) has approved a modified final order in proceedings against Phusion Projects, LLC, which markets the malt beverage Four Loko, to account for the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau's (TTB's) denial of proposed changes to the company's product labels. ***In re Phusion Projects, LLC*, No. C-4382 (FTC, order entered July 24, 2014)**. Additional information about FTC's January 2014 order and agreement with the company appears in Issue **471** of this *Update*.

FTC alleged that Phusion and its principals "falsely claimed that a 23.5-ounce, 11 or 12 percent alcohol by volume can of Four Loko contains alcohol equivalent to one or two regular 12-ounce beers, and that a consumer could drink one can safely in its entirety on a single occasion." The modified final order acknowledges the company's attempt to comply with the January agreement by seeking TTB's approval to display an "Alcohol Facts" label on its products and otherwise comply with the remaining parts of the order. The modification provides for revised disclosures that comply with "TTB Ruling 2013-2, Voluntary Nutrient Content Statements in the Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages (May 28, 2013)." The modification also no longer requires Phusion to package some of its products in resealable containers. *See FTC News Release*, July 25, 2014.

## LITIGATION

### D.C. Circuit Upholds Meat-Source Labeling Requirements

In a 9-2 *en banc* decision, the District of Columbia Circuit has affirmed an earlier panel decision that the U.S. Department of Agriculture (USDA) can require meat producers to include country-of-origin labeling (COOL) on their packaging. ***Am. Meat. Inst. v. USDA*, No. 13-5281 (D.C. Cir., order entered July 29, 2014)**. The First Amendment allows for such required disclosures because

the government's interest is sufficient, the court found. Additional information on the American Meat Institute's constitutional challenge and the D.C. panel's decision appears in Issues 518 and 520 of this *Update*.

In its discussion, the court interpreted the U.S. Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) to reach beyond mandated commercial labeling necessary to correct deception to include the "factual and uncontroversial disclosures required to serve other government interests" at issue in the COOL context. The language in *Zauderer* "sweeps far more broadly than the interest in remedying deception," the court found. "To the extent that other cases in this circuit may be read as holding to the contrary and limiting *Zauderer* to cases in which the government points to an interest in correcting deception, we now overrule them."

The court then assessed whether the government had a sufficient interest in COOL that it could require meat producers to include the labels, and it found that several aspects combine to provide USDA with a substantial interest, including: "the context and long history of country-of-origin disclosures to enable consumers to choose American-made products; the demonstrated consumer interest in extending [COOL] to food products; and the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak." The court also found that the mandatory COOL disclosure is a "reasonable fit" with the government's interest in supplying the information to consumers. In concurring opinions, one judge clarified the relationship between *Zauderer* and other commercial-speech principles, while another judge emphasized his belief that the government interest in supporting American farmers, ranchers and manufacturers is alone sufficient to sustain the constitutional challenge.

In a dissent, one judge accused the majority of "delirium on a pogo stick" by misinterpreting *Zauderer*, relaxing the standard of review to below even the most lenient and deferential standard and ignoring the "clear trajectory" of the U.S. Supreme Court's jurisprudence on commercial speech. "What began as robust protection from government coercion has now been reduced to an eerie echo of a supermarket tabloid's vacuous motto: the government may compel citizens to provide, against their will, whatever information '[i]nquiring minds want to know!'" *Zauderer*, she wrote, is limited to correcting deception because requiring advertisers to provide more information than they may otherwise present is "constitutionally permissible when the government's available alternative is to completely ban that deceptive speech." She further argued that the government's interest was not substantial for requiring COOL; for example, any valid interest identifying in American-made goods, she said, would be met by producers understanding the value of this information to consumers and voluntarily providing "Made in the USA" labeling to boost sales. The court's decision "hacks the First Amendment down to fit in the government's hip pocket," she concluded. "I will not join the carnage."

### Quaker Oats Class-Action Settlement Finalized, PHOs to Be Removed

In consolidated actions pending since 2010, a federal court in California has entered a final order approving a class-action settlement that will require Quaker Oats Co. to remove partially hydrogenated oils (PHOs) from some of its oatmeal products and cease making the statement "contains a dietarily insignificant amount of *trans* fat" on any product label where the product still contains more than 0.2 grams of artificial *trans* fat per serving. *In re Quaker Oats Labeling Litig.*, No. 10-0502 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered July 29, 2014). Details about a court ruling trimming the plaintiffs' claims that the company falsely advertised products with PHOs as healthy appear in Issue **433** of this *Update*.

According to the court's order awarding $760,000 to class counsel in attorney's fees and costs, the suit and settlement conferred "a significant benefit . . . on the general public" given the product reformulations, estimated at a cost to the company of some $1.4 million. The company has also reportedly agreed not to introduce PHOs into any products at issue in the litigation or into any Quaker Chewy Bars and Instant Quaker Oatmeal products, which do not currently contain PHOs, for 10 years. Quaker Oats continues to deny the plaintiffs' allegations. *See Law360*, July 30, 2014.

### ECJ Misrepresentation Claims Dismissed Without Prejudice

A federal court in California has dismissed for lack of standing a putative class action alleging that Pacific Foods of Oregon, Inc. misleads consumers by using the term "evaporated cane juice" (ECJ) on its food labels instead of sugar. *Swearingen v. Pac. Foods of Ore., Inc.*, No. 13-4157 (U.S. Dist. Ct., N.D. Cal., order entered July 30, 2014). Plaintiffs Mary Swearingen and Robert Figy are named plaintiffs in a number of ECJ-related cases that have recently been stayed under the primary jurisdiction doctrine as the U.S. Food and Drug Administration considers its position on use of the term by food makers. Two such cases are summarized in Issue **529** of this *Update*. The court did not address this issue here, because it dismissed the case on pleading grounds.

According to the court, the plaintiffs did not allege that they purchased the company's products "in reliance on any alleged misrepresentations that evaporated cane juice is not sugar, or that they would not have purchased those products if they knew that they contained sugar. Instead, Plaintiffs claim that they 'would not have purchased these products had they known the products were illegal to sell and possess nor would they have expended the purchase price for products that were worthless due to their illegality." Because actual reliance is required under California's Unfair Competition Law and the plaintiffs did not plead reliance, the court ruled that the complaint failed as a matter of law. So ruling, the court rejected the plaintiffs' attempt to sidestep the pleading requirement by characterizing their claims as "strict

liability labeling violations." The court gave the plaintiffs 14 days to file an amended complaint.

### Plaintiffs Dismiss Lawsuit Against Gruma for Alleged "All Natural" Chips Mislabeling

A California federal court has granted the plaintiffs' request to dismiss their entire action with prejudice in a case accusing Gruma Corp. of labeling its Mission Restaurant Style tortilla chips as "all natural" despite containing genetically modified corn. *Cox v. Gruma Corp.*, No. 12-6502 (U.S. Dist. Ct., N.D. Cal., Oakland Div., order entered July 25, 2014). The plaintiffs' stipulation to dismiss did not indicate whether the parties reached a settlement agreement. In the 2012 complaint, the plaintiffs alleged that Gruma violated state consumer protection laws like the Consumer Legal Remedies Act due to its alleged mislabeling; in July 2014, they debated Gruma's motion to dismiss, in which the corporation argued that a reasonable customer would not have been misled by their labels, the complaint's claims infringed the First Amendment, the plaintiffs failed to plead their fraud claims with the particularity required, and the court lacked jurisdiction to issue an injunction. Additional information on the case appears in Issues **487**, **509** and **511** of this *Update*.

### Plaintiffs Seek U.S. Supreme Court Review of Diacetyl Ruling

In a petition for a writ of certiorari, plaintiffs alleging harm by exposure to the flavoring agent diacetyl have argued that the Third Circuit erred in ruling that Aaroma Holdings cannot be held liable for the actions of diacetyl producer Emoral Inc., which Aaroma purchased following the alleged exposures. *Diacetyl Plaintiffs v. Aaroma Holdings*, No. 14-71 (U.S., petition for writ of certiorari filed July 18, 2014). The terms of the 2010 purchase agreement confirming Aaroma's acquisition of Emoral apparently noted that Emoral may be subject to diacetyl litigation and stated that Aaroma did not assume liability for any future claims. Emoral filed for bankruptcy protection in 2011, and the bankruptcy trustee reportedly released Aaroma from future diacetyl causes of action against Emoral in exchange for $500,000. In addition to accusing the Third Circuit of diverging from binding precedent on injured creditors' claims, the plaintiffs' petition argues that the decision is contrary to public policy and creates paths for defendants to circumvent tort liability.

### Russia Sues McDonald's for Alleged Contamination and False Nutritional Information

The Russian consumer protection agency, Rospotrebnadzor, has reportedly announced that it filed a claim alleging that McDonald's has misrepresented the nutritional information of several hamburger and ice cream menu items and that two restaurant locations showed traces of *E. coli* contamination in their salads and Caesar wraps. Although Rospotrebnadzor said it filed a

lawsuit on July 3, 2014, a McDonald's representative told the media in late July 2014 that the company had not received either an official complaint from the court or a notice from the agency. The complaint allegedly accuses McDonald's of listing nutritional information that indicated its hamburgers and milkshakes had about one-half or one-third of the actual calorie, fat, protein, and carbohydrate counts. According to *The New York Times*, Russia has targeted food imports during geopolitical tension before, banning cheese and wines from post-Soviet neighbors during times of disagreement with those countries. Following Russia's annexation of the Crimean peninsula in March 2014, McDonald's closed its three Crimean restaurants, citing potential business and regulatory implications. This move reportedly led to Russian politicians calling for a ban on the country's some 400 McDonald's locations. *See The New York Times* and *Law360*, July 25, 2014.

**Jurors Seated, Tainted Peanut Outbreak Trial Begins**

While a number of jurors were dismissed because a two-month trial would create hardships for them, a 12-member jury and six alternates were selected on July 31, 2014, and opening statements began the next day in the criminal prosecution of former Peanut Corp. of America (PCA) owner Stewart Parnell, his brother Michael Parnell and the company's quality control manager Mary Wilkerson. *United States v. Parnell*, 13-cr-12 (U.S. Dist. Ct., M.D. Ga., Albany Div.).

Earlier in the week, the court denied Wilkerson's motion to dismiss or alternatively for a continuance and severance and to compel meaningful discovery. She claimed that the government's discovery disclosures "were not accompanied by easily searchable databases" and that she was not timely provided a password to access one of two discovery disclosures. The court had apparently considered some of these issues previously and found that "Wilkerson has not demonstrated any changed circumstances that would require the Court to reconsider its referenced findings." The court also found no prosecutorial misconduct and that she failed to assert any argument to support her request for a severance.

The media are closely following trial developments, and WALB news is providing live coverage from the courthouse. The prosecution reportedly opened by displaying emails from Stewart Parnell allegedly saying ". . . just ship it. I cannot afford to lose another customer." The prosecutor also discussed the companies that PCA shipped peanut paste to and examples of the wide range of products the paste was used in. He further indicated the different ways that the company allegedly manipulated product testing and testing results to appear to comply with customer specifications, as well as failed to hold product pending the outcome of *Salmonella* testing. Also addressed during his opening were the findings of the Centers for Disease Control and Prevention tracing a 2008 nationwide *Salmonella* outbreak to PCA's plant in Blakely, Georgia. More than 700 people were allegedly sickened

in the outbreak, and nine died. *See News4Georgia*, July 28, 2014; *ABC News*, July 31, 2014; and *WALB News*, August 1, 2014.

### Chobani Loses Final UK Appeal in "Greek" Yogurt Dispute

The U.K. Supreme Court has reportedly refused to consider the appeal filed by Chobani Inc. from an appeals court order dismissing its appeal of a permanent injunction prohibiting the company from designating its U.S.-made yogurt as "Greek" yogurt. Additional details about the January 2014 appeals court ruling appear in Issue 511 of this *Update*. According to a court spokesperson, three justices dismissed the application for permission to appeal "because the application [did] not raise a point of law of general public importance."

Fage U.K., Ltd., which instituted the litigation, said of the ruling, "The High Court has ended the 'Greek yogurt' case, its decision is final. Chobani is forbidden from selling US-made strained yogurt as 'Greek' in the United Kingdom." Fage also reportedly said that Chobani must pay its legal fees. Meanwhile, expressing disappointment in the outcome, Chobani has apparently indicated that it no longer sells its yogurt in Britain, stating, "We will continue to advocate our view that the population of the UK knows and understands Greek Yogurt to be a product description in terms of how it's made, not where it is made, similar to things like French fries and English muffins in the US." *See Law360* and *Money.msn.co.nz*, July 30, 2014.

## OTHER DEVELOPMENTS

### GM Salmon Debacle "A Taste of Worse to Come"?

A recent *Nature* editorial warns that the U.S. Food and Drug Administration's (FDA's) reluctance to approve genetically-modified (GM) salmon for market could hinder future research into new gene-editing techniques. Titled "Fishy Business," the article claims that even though a draft assessment found AquaBounty Technologies' GM salmon "environmentally benign," FDA conducted many of its deliberations "behind closed doors, fuelling confusion as to the cause of the setbacks, and rumors of political interference."

"As the delays have dragged on, the technology used to make AquaBounty's salmon has become outdated," explains the editorial. "In the current excitement over targeted gene editing that allows researchers to modify individual genes without leaving traces of foreign DNA, AquaBounty's salmon—which contain a gene from another species—seem like a relic."

Meanwhile, FDA has yet to decide "how it will evaluate animals engineered with gene-editing techniques." Raising questions about how these new products will fare under FDA's oversight, the article urges the agency to "bring these discussions before the public, and leave political considerations at the door." *See Nature,* July 31, 2014.

## SCIENTIFIC/TECHNICAL ITEMS

### NRC Report Classifies Styrene as "Reasonably Anticipated Human Carcinogen"

Directed by Congress to conduct an independent review of the styrene assessment in the National Toxicology Program's (NTP's) 12th Report on Carcinogens (12th RoC), the National Academies National Research Council (NRC) recently **issued** a report concurring that there is "compelling evidence… to support a listing of styrene as, at a minimum, reasonably anticipated to be a human carcinogen." Deemed "a substance of interest" because many people are exposed to it through environmental sources, styrene is used in food packaging and "a broad spectrum of products, including latex paints and coatings; synthetic rubbers; construction materials, such as pipes, fittings, and lighting fixtures; packaging; household goods, such as synthetic marble, flooring, and molded furnishings; and automotive parts."

According to NRC, which reviewed the primary literature cited in the 12th RoC, NTP "adequately documented that exposure to styrene occurs in occupational settings and in the general public regardless of smoking status." Concluding there was enough evidence based on human, animal and mechanistic studies to support NTP's conclusion "that styrene should be considered for listing in the RoC," the council also conducted an independent assessment of styrene supporting this finding. "In sum, the committee finds that compelling evidence exists to support a listing of styrene as, at a minimum, reasonably anticipated to be a human carcinogen," states the report. "That conclusion is based on credible but limited evidence of carcinogenicity in traditional epidemiologic studies, on sufficient evidence of carcinogenicity in animals, and on convincing evidence that styrene is genotoxic in exposed humans."

### NEJM Article Questions Usefulness of Nutrient-Content Claims

A recent perspective article in the *New England Journal of Medicine* (NEJM) has questioned whether nutrient-content claims—such as "sugar-free," "high in oat bran," or "contains 100 calories"—are confusing to consumers. Authored by Allison Sylvetsky and William Dietz, the article claims that sugar- and calorie-related claims "may lead parents to underestimate the products' energy content and allow their children to consume more than they otherwise would."

According to the authors, the use of nonnutritive sweeteners in sugar- and calorie-modified products "may still foster the development of a 'sweet tooth' because nonnutritive sweeteners are a hundred times sweeter than table sugar by weight." In addition, U.S. consumers have no way to gauge whether their children have exceeded the acceptable daily intake for a particular nonnutritive sweetener because the amount added to any given product is considered proprietary information.

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"We believe that adopting a more straightforward and easily understandable ingredient-labeling system in the United States and educating parents in the interpretation of sugar- and calorie-related nutrient-content claims through transparent food marketing are needed steps to empower parents to make informed choices," conclude the authors. "If the FDA [Food and Drug Administration] revised the current labeling requirements for foods and beverages bearing sugar- and calorie-related nutrient-content claims in this way, the replacement of added sugars with other sweet ingredients would be clearly highlighted." *See NEJM,* July 17, 2014.

OFFICE LOCATIONS

**Denver, Colorado**
+1-303-285-5300

**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

**Philadelphia, Pennsylvania**
+1-215-278-2555

**San Francisco, California**
+1-415-544-1900

**Seattle, Washington**
+1-206-344-7600

**Tampa, Florida**
+1-813-202-7100

**Washington, D.C.**
+1-202-783-8400

## 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.