ISSUE 535 | AUGUST 22, 2014

# FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS



## LEGISLATION, REGULATIONS AND STANDARDS

### FDA Issues Lupin Allergy Warning

The U.S. Food and Drug Administration (FDA) recently **issued** a consumer update warning that the lupin (or lupine) legume could cause allergic reactions in susceptible individuals, especially those with existing peanut allergies. According to FDA, the use of lupin-derived ingredients has increased in recent years because they are used in gluten-free products as a substitute for other flours.

"Although lupin is a food staple for many Europeans—who may be more aware of its allergenic properties and are accustomed to seeing it listed as a food ingredient—it is relatively new to the U.S. market," notes FDA, which "is actively monitoring complaints of lupin allergies." To this end, the agency has asked consumers and healthcare professionals to report lupin-related adverse events through the FDA reporting system. *See FDA Consumer Update*, August 15, 2014.

### USDA to Examine Need for Honey Standard of Identity

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service has **requested** comments "on how a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture." Noting that the Food and Drug Administration in 2011 rejected an industry-backed citizens petition seeking such a standard, USDA as charged by the 2014 Farm Bill will produce a report examining the issue, "including any current industry amendments or clarifications necessary to update the petition."

In particular, USDA points to the existence of several standards for the inspection and grading of honey, including state-level schemes designed to prevent product adulteration. "While some are following the 2006 honey industry petition and using an amended version of the Codex Standard for Honey, CODEX standard 12-1981, Rev. 2 (2001), variations in the state standards of identity for honey are inevitable," concludes the agency, which will accept comments until September 19, 2014. "The end result could lead to an assortment of standards that vary from state to state and impede interstate commerce." *See Federal Register*, August 20, 2014.

Shook, Hardy & Bacon L.L.P.

**FOOD & BEVERAGE LITIGATION UPDATE**

ISSUE 535 | AUGUST 22, 2014

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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

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

or

**Madeleine McDonough**
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

## USDA Schedules Codex Meetings on Import/Export Inspection and Certification; Food Hygiene

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service is convening a September 25, 2014, **public meeting** in Washington, D.C., to receive public comments about draft positions to be discussed at the 21st Session of the Codex Committee on Food Import and Export Inspection and Certification Systems of the Codex Alimentarius Commission in Brisbane, Australia, on October 13-17. Issues on the September 25 meeting agenda include (i) a discussion paper on Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems and (ii) draft amendments to Guidelines for the Exchange of Information between Countries on Rejections of Imported Food.

USDA and the Food and Drug Administration have a **public meeting** slated for October 23 in Washington, D.C., to provide information and receive public comments about draft positions to be discussed at the 46th Session of the Codex Committee on Food Hygiene in Lima, Peru, on November 17-21. Items on the October meeting agenda include (i) the Draft Code of Hygienic Practice for Low-Moisture Foods and (ii) Proposed Draft Guidelines for the Control of Specific Zoonotic Parasites in Meat: Trichinella spp. *See Federal Register*, August 15, 2014.

## China Yanks Approval for GM Crop Programs

The People's Republic of China Ministry of Agriculture has reportedly failed to renew the biosafety permits for two research programs growing genetically modified (GM) corn and rice, raising concerns about the future of GMO production in China. According to media sources, the Agriculture Ministry has not yet authorized any GMOs for public consumption and decided to discontinue further research after a state TV report allegedly identified illegal GM rice varieties in markets located near Huazhong Agricultural University, which was developing *Bacillus thuringiensis* (Bt) rice.

Although Greenpeace representatives and other stakeholders apparently cited public opinion as the motivation behind the announcement, Chinese Academy of Sciences' Center for Chinese Agricultural Policy Director Huang Jikun suggested that the self-sufficiency of the domestic rice market has made the commercialization of Bt rice unnecessary. In addition, critics of the ministry's decision have questioned whether the debate over GMO safety has taken a political bent. As University of Nottingham's Cong Cao opined in an August 18 article appearing in *The Conversation*, "Anti-Western sentiment has been judged more convincing than a raft of studies endorsing the merits of agro-biotechnology. Government support for GM food is dwindling fast, and it seems safe to say that the opportunity to commercialize GM rice—and with it the chance to help address some of China's most urgent problems—is all but gone." *See Science Insider* and *RT*, August 20, 2014.

### Russia Takes Further Action on Food Sanctions

Russia has relaxed its food ban against the European Union by clarifying that it will allow imports of salmon and trout hatchlings, potato and onion seed, sugar maize hybrid and peas for planting, lactose-free milk, flavor additives, and food fibers. The move follows criticism from within the country on the effects the import prohibitions would have on Russians, and according to the *Moscow Times*, it will also ease the bans' burden on neighboring Finland. To soften the effects on the markets for fruits and vegetables for the rest of Europe, the European Union has set aside €125 million to compensate producers for keeping several of their perishable products off the market to avoid a price collapse. Further information on Russia's food bans appears in Issue 533 of this *Update*. *See CNN*, August 18, 2014, and *Moscow Times*, August 21, 2014.

Within Russia, consumer protection agency Rospotrebnadzor has introduced fines—between 20,000 and 150,000 rubles, or $555 to $4,150—for violations of the genetically modified (GM) food labeling law. *RT* also reported that several Russian lawmakers seek a ban on GM ingredients in Russian-produced foodstuffs. In addition, Rospotrebnadzor has closed four McDonald's locations for alleged sanitary violations. The agency reportedly filed a lawsuit in July 2014 to enjoin McDonald's from making some of its most popular menu items because the company supposedly misrepresented nutritional information for its hamburgers and milkshakes, and in addition, two of the restaurant's locations allegedly showed signs of *E. coli* contamination. The four closings reportedly followed tests of McDonald's raw materials and food items. Additional information on Rospotrebnadzor's lawsuit against McDonald's appears in Issue 532 of this *Update*. *See RT*, August 19, 2014, and *Law360*, August 20, 2014.

## LITIGATION

### Putative Class Action to Proceed Against MonaVie

A federal court in New Jersey has denied the motion to dismiss filed by MonaVie, Inc. in consumer-fraud litigation involving its juice products, finding that the first-amended putative class-action complaint was sufficiently pleaded. *Pontrelli v. MonaVie, Inc.*, No. 13-4649 (U.S. Dist. Ct., D.N.J., decided August 19, 2014).

Attached to the complaint was a MonaVie brochure that included a number of claims about the curative health benefits of the açai berry, as well as purported customer testimonials. The plaintiff claimed that she relied on such representations, did not receive the advertised benefits and would not have

purchased the products if she had known that the representations were false. The complaint also alleged that consumers are willing to pay an inflated price for the products—$40 for a 25-ounce bottle—based on the advertised health benefits. The plaintiff also alleged that the company knows its claims are false and that the juice products will not cure any diseases.

The complaint includes allegations about the company's marketing distribution structure that relies on distributors to sell the products and to convince other individuals to become MonaVie distributors. While company policies apparently forbid distributors from making claims about the products' purported health benefits, the plaintiff alleges that the company's executives "are well-aware that their Distributors make false claims about the health benefits of MonaVie."

The court found that the plaintiff pleaded facts creating the plausible inference of an agency relationship between MonaVie and the distributors and thus that it could be held vicariously liable for the distributors' alleged misrepresentations. The court also found that the plaintiff had sufficiently met the heightened pleading standard for her statutory and common-law fraud claims. Among other matters, the court outlined the pleading deficiencies identified by the defendants but noted that "at no point do the Defendants claim that they did not receive adequate notice from the Plaintiff." Accordingly, the court concluded that the plaintiff satisfied the Rule 9(b) pleading standard. Also found sufficiently pleaded was the plaintiff's unjust enrichment claim.

### Jury Clears Flavorings Company in Consumer's Diacetyl Lawsuit

A jury in an Iowa federal court has reportedly determined that International Flavors and Fragrances Inc. (IFF) was not liable for the lung condition a man allegedly developed from microwaving popcorn containing diacetyl, a butter flavoring ingredient used in the product. *Stults v. Int'l Flavors & Fragrances Inc.*, No. 11-4077 (U.S. Dist. Ct., N.D. Iowa, verdict entered August 19, 2014). The plaintiff claimed that the company had breached the implied warranty of fitness for its butter flavoring, which had a foreseeable use in microwave popcorn packages. IFF was the only remaining defendant during the seven-day trial out of some half-dozen companies originally sued for $27 million in compensatory damages. *See Law360*, August 20, 2014.

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 535 | AUGUST 22, 2014

## Slaughterhouse Owners, Employees Charged with Distributing Diseased Cattle

Federal charges have been brought against two owners and two employees of Rancho Feeding Operations, a Petaluma, California-based livestock slaughterhouse, for distributing condemned and diseased cattle in violation of the Federal Meat Inspection Act. *United States v. Amaral*, No. 14-cr-437 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed August 14, 2014); *United States v. Singleton*, No. 14-cr-441 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed August 18, 2014). As a result of the investigation giving rise to the charges, Rancho voluntarily recalled some 8.7 million pounds of beef products in February 2014.

According to the criminal indictment and information, Jesse Amaral and Robert Singleton, who owned the operation, allegedly directed Eugene Corda, Rancho's primary yardperson, and Felix Cabrera, the facility's foreperson, to either (i) remove "USDA Condemned" stamps from cattle carcasses and to process them for transport and distribution, or (ii) place the heads of healthy cows, swapped for diseased heads—from "cancer eye cows"—next to the carcasses of diseased animals while U.S. Department of Agriculture inspectors were on break, so that the inspectors would be "unaware that the carcasses they were inspecting belonged to cancer eye cows that had escaped ante mortem inspection." The indictment also alleges that Amaral falsely advised farmers that their cattle had died or been condemned and created invoices charging the farmers "handling" fees for the carcass disposal, "instead of compensating them based on the sale price."

Singleton has been charged in the criminal information with one count of distributing adulterated, misbranded and uninspected meat and of aiding and abetting. Amaral, Corda and Cabrera have been indicted by a grand jury on eight counts, including conspiracy to distribute adulterated, misbranded and uninspected meat; conspiracy to commit mail fraud; and distribution of adulterated and misbranded meat and aiding and abetting. Amaral has also been charged with three additional counts of mail fraud and conspiracy to commit mail fraud, and the prosecutor has sought the forfeiture from him of any property traceable to the alleged crimes.

Maximum penalties for conspiracy to distribute adulterated meat are five years' imprisonment, three years' supervised release, a $250,000 fine, and $100 special assessment. Penalties for fraudulent distribution of adulterated meat are three years' imprisonment, one year of supervised release, a $10,000 fine, and $100 special assessment. And the maximum statutory penalties for mail fraud and mail fraud conspiracy are 20 years' imprisonment, three years' supervised release, a $250,000 fine, and $100 special assessment. *See U.S. Attorney's Office Press Release*, August 18, 2014.

### Food Lion Sued for Religious Discrimination

The Equal Employment Opportunity Commission (EEOC) has filed a lawsuit in North Carolina federal court against Food Lion alleging that the grocery retailer fired an employee because he was unavailable to work on Thursday evenings and Sundays, when he attended Jehovah's Witness services as a minister and elder. *EEOC v. Food Lion LLC*, No. 14-708 (U.S. Dist. Ct., M.D.N.C., filed August 20, 2014). According to the complaint, a Food Lion manager hired the employee with knowledge and acceptance of his scheduling restrictions, but after the employee was assigned to a different store location, a second manager insisted on scheduling him on days that he attended religious services. When the employee chose to attend services over working his scheduled shift, he was fired. EEOC alleged that Food Lion's employment practices violate Title VII of the Civil Rights Act of 1964 and Title I of the Civil Rights Act of 1991, and it asked the court to enjoin Food Lion from further discrimination and to order the grocery retailer to pay the employee compensatory and punitive damages as well as EEOC's attorney's fees.

### Sazerac Sued for "Double Barreled" Trademark Infringement

Prichard's Distillery Inc., maker of Benjamin Prichard's Double Barreled Bourbon, has filed a lawsuit against Sazerac Co. alleging that the liquor manufacturer has violated its trademark in "double barreled" by selling A. Smith Bowman Limited Edition Double Barrel Bourbon Whiskey and Buffalo Trace Experimental Collection Double Barreled, a bourbon. *Prichard's Distillery Inc. v. Sazerac Co.*, No. 14-1646 (U.S. Dist. Ct., M.D. Tenn., filed August 11, 2014). Prichard's claims that it has owned a trademark on the use of "double barreled" in liquor sales since 2002, and the term comes from Prichard's distilling process, which involves aging the bourbon in one barrel, diluting it to a lower proof, then aging it in a second barrel to reinforce the flavor. The company seeks an injunction preventing Sazerac from using "double barreled" on its products as well as damages multiplied due to Sazerac's "willful and wrongful conduct."

### Motion Filed to Settle White Chocolate Nationwide Class Claims

The parties to litigation alleging that Ghirardelli Chocolate Co. white chocolate products do not contain the requisite white chocolate ingredients to be labeled and promoted as such have agreed to settle the putative nationwide class action for $5.25 million and labeling changes. *Miller v. Ghirardelli Chocolate Co.*, No. 12-4936 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., motion filed August 20, 2014). Additional information about the case appears in Issues **465** and **479** of this *Update*. The settlement would also resolve claims to be alleged in a second lawsuit by an intervening named plaintiff regarding the use of "all natural" on product labels.

Under the agreement, class members who purchased the company's Classic White Chips would be able to receive $1.50 per purchase, while those purchasing 72 other "all natural" products would receive $0.75 per purchase. The claims of those with proofs of purchase would not be capped, while claimants without proof of purchase would receive a maximum of $24.00 per household. Any funds remaining would be donated to four charitable organizations. Administrative expenses, costs, incentive payments, and attorney's fees (at $1.66 million) would be paid from the settlement fund, subject to court approval. The parties have requested an October 2, 2014, hearing for preliminary approval of the proposed settlement and leave to file a third amended complaint.

### Merisant, Whole Earth Sweetener Agree to $1.65-Million Settlement and Pure Via Label Change

The parties to a putative class action against Merisant Co. and Whole Earth Sweetener Co. have agreed on settlement terms, including changes to the Pure Via sweetener's Website and packaging, class certification and a $1.65-million payment to a settlement fund. *Aguiar v. Merisant Co.*, No. 14-670 (U.S. Dist. Ct., C.D. Cal., motion filed August 18, 2014). The plaintiff had alleged that Merisant and Whole Earth label, advertise and market Pure Via products as natural, which she argued was false and deceptive. Under the terms of the proposed settlement, Merisant and Whole Earth agreed to add an asterisk to Pure Via packaging with a statement that directs consumers to the product Website, which will explain the process of producing Pure Via from stevia to provide consumers with "significant information to make their own determination as to whether they deem Pure Via to be 'natural.'" In addition, Merisant and Whole Earth have agreed to class certification for the purposes of distributing the $1.65-million settlement fund to purchasers who submit valid claims, with leftover funds donated to the American Diabetes Association.

### Defense Counsel Cross-Examine Peanut Corp. Plant Manager

Attorneys representing the former Peanut Corp. of America owner and employees charged with conspiracy, mail and wire fraud, obstruction of justice and other counts involving the distribution of adulterated or misbranded food that allegedly led to a deadly *Salmonella* outbreak, had their opportunity on August 19, 2014, to cross-examine the company's Blakely, Georgia, plant manager, Samuel Lightsey, who has been testifying as a government witness. *United States v. Parnell*, No. 13-cr-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., filed February 15, 2013).

Among other matters, the attorneys reportedly focused on the plea deal Lightsey struck with prosecutors; he was facing more than 30 years in prison, but could serve no more than six or go free if he substantially helps prosecute others. They also sought to show that (i) former owner Stewart Parnell was concerned about safety, (ii) Lightsey was responsible for plant safety, (iii) extensive retesting of samples positive for *Salmonella* came back negative, and (iv) peanut paste shipped to Kellogg met its specifications and accompanying documents would have clearly shown to the recipient, given the dates used, that they had been falsified. Stewart Parnell's attorney apparently sought to place blame on Michael Parnell, whose company purchased the peanut paste sold to Kellogg. The contract between the brothers' companies evidently said that the buyer assumes all the risk. *See WALB News* and *Associated Press*, August 19, 2014.

### Berkeley Residents Accuse Soda Tax of Bias in Lawsuit

Two residents of Berkeley, California, have filed a lawsuit in state court alleging that the proposed 1-cent-per-ounce soda tax, which will appear on the ballot in November, uses "politically charged" language and affects beverages beyond the targeted "high-calorie, sugary drinks." *Johnson v. Numainville*, No. RG14786763 (Cal. Super. Ct., Alameda Cnty., filed August 13, 2014). The complaint accuses the city council of failing to define the term "high calorie, sugary drink," and suggests "sugar-sweetened beverage" instead. The plaintiffs also argue that the tax would apply to "any beverage intended for human consumption to which one or more added caloric sweeteners has been added and that contains at least 2 calories per fluid ounce," despite that under U.S. Food and Drug Administration guidelines, a 12-ounce, 24-calorie drink would actually be considered low calorie. They request that the court order the city council to insert their suggested phrases for the allegedly biased phrases. Additional information on the proposed soda tax appears in Issue 529 of this *Update*.

## OTHER DEVELOPMENTS

### Havelka and Farnsworth Decipher New Poultry Inspection Rules in *Law360*

Shook attorneys Ann Havelka and Ryan Farnsworth have authored an August 18, 2014, *Law360* article detailing "the first major overhaul of the nation's poultry inspection system in nearly 60 years." Describing the voluntary and mandatory aspects of the final rule issued by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), the article provides an overview of the regulations most likely to affect industry as the onus for inspection shifts from government agencies to business operators.

FSIS officially published the final rule in the August 20, 2014, edition of the *Federal Register*. Additional information about the regulations appears in Issue 532 of this *Update*.

### U.S. PIRG White Paper Calls for Antibiotics Reform

The U.S. Public Interest Research Group (PIRG) Education Fund has published a white paper titled "Ending the Overuse of Antibiotics in Livestock Production: The Case for Reform." Contending that the use of antibiotics in healthy animals to accelerate their growth or "prevent disease caused by unhealthy and unsanitary conditions" has accelerated the development of antibiotic-resistant bacteria, the paper calls on the U.S. Food and Drug Administration (FDA) to act immediately to restrict the use of antibiotics in livestock production.

According to the consumer-interest group's paper, the U.S. Centers for Disease Control and Prevention has found that some 2 million Americans are sickened each year by drug-resistant bacteria, and of those, 23,000 die. The paper also states that more than "70% of antibiotics in classes used in human medicine are sold for use in food animals." FDA data reportedly indicate that in 2011, 29.9 million pounds of antibiotics were sold in the United States, but just 7.7 million pounds were sold to treat people who were sick.

Other recommended reforms include adopting a tracking system "to document the sale, use and impacts of antibiotic use in livestock production," increased drug maker investments into the development of drugs to treat resistant infections, retailer commitments to sell meat "produced on farms that reserve antibiotics for animals that are actually sick," and U.S. Department of Agriculture funding for "research on practices that reduce the need for antibiotic in food animals."

### *Consumer Reports* Challenges FDA's Fish Intake Recommendations

In its October 2014 issue, *Consumer Reports* will publish an analysis of the U.S. Food and Drug Administration's (FDA's) data that supported the agency's recommendations for fish intake by pregnant women and children, released jointly as draft guidance with the U.S. Environmental Protection Agency (EPA) in June 2014. The magazine compiled a list of low-mercury—including haddock, trout, catfish, and crab—and lowest-mercury fish—including shrimp, tilapia, oysters, and wild and Alaska salmon—and detailed the amounts considered safe for consumption for young children and women of childbearing age. The guide includes more conservative advice than the draft guidance from FDA and EPA, such as recommending that most women and young children avoid marlin and orange roughy in addition to the listed swordfish, shark, king mackerel, and gulf tilefish. The magazine cites Deborah Rice, co-author of the EPA document that established the current limit on

methylmercury consumption as 0.1 microgram per kilogram of body weight per day. Rice now believes that this limit is too high, pursuant to several studies reportedly showing that adverse effects can occur at lower mercury blood levels.

*Consumer Reports* also recommends that pregnant women do not eat tuna, departing again from the draft guidance. Even canned light tuna can contain high levels of mercury because those levels can vary greatly from can to can; as the magazine reports, "FDA's data show that 20 percent of the samples it tested since 2005 contained almost double the average level the agency lists for that type of tuna. And the highest level of mercury in its samples of canned light tuna exceeded the average mercury level for king mackerel." A recent study from the University of Hawaii at Manoa found similar results for Chilean sea bass. Peter B. Marko, et al., "Seafood Substitutions Obscure Patterns of Mercury Contamination in Patagonian Toothfish (Dissostichus eleginoides) or "Chilean Sea Bass," *PLoS ONE*, August 2014. Researchers tested fish purchased at retail seafood counters in 10 different states and apparently found that several of the fish were mislabeled as to the source and breed. Lead researcher Peter Marko argued that fish from uncertified sources were substituted, and the uncertified fish tended to have "very high mercury." Additional information about the FDA and EPA draft guidance appears in Issues **525** and **526** of this *Update*.

### Public Health Advocates to Promote SSB Warnings in Upcoming Webinar

California-based **ChangeLab Solutions**, an interdisciplinary public health advocacy group focused on policy reform, is holding a September 24, 2014, Webinar to discuss the potential impact of mandatory warning labels on sugar-sweetened beverages in reducing the rates of youth and adult obesity and diabetes.

Webinar panelists will reportedly discuss lessons learned from failed California legislation (S.B. 1000) that would have required such warnings on SSBs, resources for driving similar strategies at the state and local level, and SSB warnings' impact on the health of communities of color. Program faculty will include a senior staff attorney at ChangeLab Solutions, the executive directors of the **California Center for Public Health Advocacy** and **Latino Coalition for a Healthy California**, and the director of health promotion policy at **Center for Science in the Public Interest**. To learn more about the event, please click **here**.

## MEDIA COVERAGE

### *New Yorker* Profiles Vandana Shiva, Anti-GMO Activist

Michael Specter has profiled "the Gandhi of grain," Vandana Shiva, in a **piece** for the *New Yorker* that describes her as "a hero to anti-[genetically modified organisms (GMOs)] activists everywhere" while criticizing her inflammatory methods and unscientific arguments. Specter chronicles many of Shiva's recent provocative statements—including a speech calling fertilizer "a weapon of mass destruction" and a tweet comparing GMOs on organic farms to rape—and attempts to debunk a few of her positions. In March 2014, Shiva told a Winnipeg food-rights group that GMOs and their associated herbicides caused the rise in autism, and Specter argues that she had merely confused causation with correlation, pointing out that the rise in autism also correlates with the sale of organic produce, the sale of high-definition televisions and the number of Americans who commute to work each day by bicycle.

In addition, Shiva has apparently stated that the use of GM cotton in India has caused "genocide" in one region, claiming that farmers are committing suicide because they cannot afford to plant the GM cotton. Specter traveled to India to investigate, and he apparently found that farmers in the region had improved the health of their families because the amount of pesticides they use has fallen sharply, and further, the "suicide rate has not risen in a decade," according to a University of Manchester study, Specter writes. "In fact, the suicide rate among Indian farmers is lower than for other Indians and is comparable to that among French farmers."

Specter also criticizes India's ban on GMO crops, the passage of which he credits largely to Shiva's activism. He speaks with Deepak Pental, former vice-chancellor of the University of Delhi, who dislikes the Indian ban and its effects on the food system. "White rice is the most ridiculous food that human beings can cultivate," he told Specter. "It is just a bunch of starch, and we are filling our bellies with it. But it's natural. So it passes the Luddite test." Specter notes that one common criticism of GM crops is the creation of life unlike anything found in nature, but farmers have engineered crops outside of labs by breeding them to take on particular characteristics for millennia, sometimes to "unnatural" ends. "Corn in its present form wouldn't exist if humans hadn't cultivated the crop," he writes. "The plant doesn't grow in the wild and would not survive if we suddenly stopped eating it." Specter further takes issue with a double standard he identifies: many people object to nature's boundaries in food, but not in medicine. Synthetic insulin, he suggests, is used by millions of diabetics despite being "the first genetically modified product," and "[p]rotesters don't march to oppose those advances. In fact, consumers demand them, and it doesn't seem to matter where the replacement parts come from."

### *Washington Post* Targets Lack of Food Additive Scrutiny

Discussing the expedited approval process for food additives that took effect 17 years ago, U.S. Food and Drug Administration (FDA) Deputy Commissioner for Food Michael Taylor recently told *Washington Post* reporter Kimberly Kindy that the agency does not have "the information to vouch for the safety of many of these chemicals." According to the August 17, 2014, article, the number of additives in the food supply has increased to 9,000 from 800 over a 50-year span, in part because a voluntary certification system dependent on industry safety data has eclipsed FDA's independent review process. Under the Generally Recognized as Safe (GRAS) scheme, companies need only submit a summary of their safety research to FDA, shortening time to approval even for new and novel food additives.

In particular, the *Post* highlights how a mycoprotein marketed as "Quorn" achieved GRAS status despite one undisclosed study allegedly showing that 5 percent of test subjects experienced an adverse reaction after consuming the meat substitute. The article further claims that the voluntary process—which does not require FDA sign-off—often fails to account for the cumulative effects of food additives such as caffeine and carrageenan that may be considered GRAS in smaller amounts but problematic at the levels currently consumed. "We aren't saying we have a public health crisis. But we do have questions about whether we can do what people expect of us," Taylor concluded. "We do not know the volume of particular chemicals that are going into the food supply so we can diagnose trends. We do not know what is going on post-market."

## SCIENTIFIC/TECHNICAL ITEMS

### FDA Presents 4-MEI Exposure Assessment Data at ACS Annual Meeting

U.S. Food and Drug Administration (FDA) researchers recently **presented** dietary exposure assessments for 4-methylimidazole (4-MEI) at the 248th American Chemical Society (ACS) National Meeting held August 10-14, 2014, in San Francisco. Contributing to FDA's review of available toxicological data for 4-MEI found in Class III and IV Caramel colors produced using ammonium compounds, the scientists analyzed 4-MEI levels of caramel-containing foods and beverages using liquid chromatography-tandem mass spectrometry, then relied on intake data from the National Health and Nutrition Examination Survey (NHANES) to estimate dietary exposure levels for the following U.S. population groups: (i) "the U.S. population aged 2 years or more"; (ii) "infants (< 1 year old)"; (iii) "children aged 1 year"; (iv) "children aged 2-5 years"; (v) "children aged 6-12 years"; and (vi) "teenage boys aged 12-18 years."

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 535 | AUGUST 22, 2014

According to the presentation poster, the caramel-containing food categories contributing more than 1 percent "to the cumulative dietary exposure to 4-MEI for the US population ages 2 years or more" included carbonated beverages, breads and rolls, dairy-based desserts and drinks, iced tea and iced coffee, beer and malt beverages, beverages from mix, and sports drinks. For each population group, the researchers created three different exposure scenarios from two-day and 10-14 day dietary surveys that estimated exposure using the lowest, highest and averaged 4-MEI analytical values.

"While industry has undertaken efforts to lower 4-MEI levels in caramel-colored carbonated beverages, these products still represent a significant portion of the cumulative 4-MEI exposure," states the presentation poster. "Additional products will be analyzed for 4-MEI in order to enhance the exposure estimate… For certain product categories, trends in the levels of 4-MEI will be monitored."

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