

ISSUE 538 | SEPTEMBER 19, 2014



### **CONTENTS**

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Logiclati	on Pogu	ulations	and Star	udarde
Leuisiau	on, near	liations	anu star	ıuaıus

NNCO to Schedule Nanotech-Related
Meetings in Collaboration with EC 1
Cal/EPA Solicits Information on Potential
Regulatory Actions Under Prop. 651

#### Litigation

Defendants in Salmonella Outbreak	
Poultry Inspection Rules Changes Challenged	2
Burger Chain Settles FACTA Class Actio for \$2.7 Million	
Parties Reach Settlement in Yerba Mate ECJ Labeling Putative Class Action	
Costa Rican Court Declares GMO Approval Process Unconstitutional	4

#### **Other Developments**

JAMA Publishes Viewpoint on New York City's Soda Portion Case
San Francisco and Berkeley Pass Resolutions Condemning Nontherapeutic Use of Antibiotics in Livestock.
Rudd Center to Relocate to University of Connecticut
PETA UK Director Urges Action on Foie Gras in the EU

#### Scientific/Technical Items

Artificial Sweeteners Allegedly Linked to Glucose Intolerance6
Recent Research Links "Mood, Food and Obesity"
Article Considers Food Addiction Under DSM-5 Criteria

# LEGISLATION, REGULATIONS AND STANDARDS

### NNCO to Schedule Nanotech-Related Meetings in Collaboration with EC

The National Nanotechnology Coordination Office (NNCO) is joining with the European Commission over the next year to host meetings for the six U.S.-EU Communities of Research (CORs) that focus on environmental, health and safety concerns related to nanomaterials. CORs were established as a means by which scientists can share protocols and identify research gaps and obstacles. Before September 30, 2015, the CORs will hold teleconferences and Webinars addressing (i) exposure through product life, with material characterization; (ii) ecotoxicity testing and predictive models, with material characterization; (iii) predictive modeling for human health, with material characterization; (iv) databases and ontologies; (v) risk assessment; and (vi) risk management and control. More details about the upcoming meetings will be posted <a href="here">here</a>. See Federal Register, September 18, 2014.

### Cal/EPA Solicits Information on Potential Regulatory Actions Under Prop. 65

The California Environmental Protection Agency's (Cal/EPA's) Office of Environmental Health Hazard Assessment (OEHHA) is <u>requesting</u> public input for ways of improving the implementing regulations of the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65).

More specifically, the agency invites stakeholders' ideas about (i) alternative risk levels for chemicals in foods; (ii) revisions to the Naturally Occurring regulation; (iii) revisions and a restructuring of the Safe Use Determination process; (iv) clarification of the regulatory provisions on averaging exposures; (v) chemicals for priority consideration in the development of or update of Safe Harbor levels; (vi) new interpretive guidance; and (vii) the use of data on postnatal developmental exposures. OEHHA must receive comments and supporting documentation by 5 p.m. on November 17, 2014.



ISSUE 538 | SEPTEMBER 19, 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.

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#### **LITIGATION**

### Jurors Convict Peanut Corp. of America Defendants in Salmonella Outbreak

Following a seven-week trial in Albany, Georgia, a jury has reportedly convicted former Peanut Corp. of America owner Stewart Parnell, his brother Michael Parnell and quality assurance manager Mary Wilkerson on charges stemming from a 2008-2009 *Salmonella* outbreak that sickened hundreds of people nationwide and was linked to nine deaths. *United States v. Parnell*, No. 13-cr-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., verdict entered September 19, 2014). Details about the mail and wire fraud, obstruction and conspiracy charges appear in Issue <u>472</u> of this *Update*. The conspiracy and obstruction charges each carry a potential sentence of 20 years in prison; sentencing will occur at a later date. Two former plant managers who were also charged entered guilty pleas that required them to cooperate with the prosecution.

According to a news source, this could be the first time that corporate executives and facility workers have gone to trial in the United States on criminal charges arising from a food-contamination incident. The company's products were used as ingredients in crackers and other snack foods. While jurors heard testimony from some 50 witnesses and prosecutors introduced approximately 1,000 documents, jurors did not learn during trial that anyone died from eating contaminated products. Victims' survivors who attended the trial were surprised that prosecutors made the strategic decision not to introduce evidence about the deaths and were apparently concerned that the jurors would not be able to grasp the significance of the defendants' alleged conduct. See Associated Press, September 18 and 19, 2014.

#### Poultry Inspection Rules Changes Challenged

Nonprofit consumer advocacy organization Food & Water Watch, Inc. and two of its members have filed an action against the U.S. Department of Agriculture (USDA) and its Food Safety and Inspection Service seeking to enjoin their new National Poultry Inspection System (NPIS) rules. *Food & Water Watch, Inc. v. Vilsack,* No. 14-1547 (U.S. Dist. Ct., D.D.C., filed September 11, 2014). Details about the rules, which take effect October 20, 2014, appear in Issue <u>532</u> of this *Update*.

The plaintiffs allege that the rules violate the Poultry Products Inspection Act (PPIA) and Administrative Procedure Act (APA). They interpret the PPIA as requiring "that federal inspectors critically appraise all chicken and turkey carcasses and viscera," and set forth how increased line speeds and rules giving poultry employees, without training or certification, the authority to inspect and remove adulterated birds or parts from processing lines before inspectors see them violate this requirement. Without actual inspection of



ISSUE 538 | SEPTEMBER 19, 2014

every bird, both internally and externally, by a federal inspector, the plaintiffs claim that the official inspection legend—"Inspected for wholesomeness by U.S. Department of Agriculture"—affixed to poultry products will mislead consumers.

They also contend that the defendants failed to provide an opportunity for oral presentation of views by refusing to allow anyone other than members of USDA's Advisory Committee on Meat and Poultry Inspection to testify on the proposed NPIS rules and by failing to include for comment in the draft rules certain provisions that were adopted as part of the final rule. The plaintiffs claim that the NPIS is arbitrary and capricious in violation of the APA because the "Defendants relied on inappropriate factors which Congress has not intended them to consider under the PPIA, and they entirely failed to consider [] important aspects related to preventing adulterated and misbranded carcasses from entering commerce, offered explanations for [their] NPIS rules counter to the evidence before the agency, and offered implausible and inadequate responses to public comments."

The plaintiffs seek a declaration that the NPIS rules are illegal, orders temporarily and permanently enjoining the NPIS rules from taking effect, an order vacating the rules, and attorney's fees and costs. Food & Water Watch Executive Director Wenonah Hauter said, "These rules essentially privatize poultry inspection and pave the way for others in the meat industry to police themselves. The USDA's decision to embrace the scheme—an initiative lobbied for by the meat industry for more than a decade—flies in the face of the agency's mandate to protect consumers. What's more, we believe it's illegal." See Food & Water Watch Press Release, September 11, 2014.

### Burger Chain Settles FACTA Class Action for \$2.7 Million

Back Yard Burgers of Nebraska, Inc. has agreed to settle claims that it violated the Fair and Accurate Credit Transactions Act (FACTA) by allegedly using the last five digits of customer credit-card numbers on its older receipts, instead of the last four digits. *Keith v. Back Yard Burgers of Neb., Inc.*, No. 11-0135 (U.S. Dist. Ct., D. Neb., order preliminarily approving class settlement entered September 15, 2014). The company will pay \$2,792,400 into a settlement fund, will provide coupons for a free soft drink with the purchase of an entrée to class members who submit valid claims, will not contest class counsel fees of up to 40 percent of the consent judgment—or \$1,116,960—will quitclaim assign to the plaintiff any claim it may have against Data Cash Register (DCR) related to the class action and cooperate in pursuing collection of a consent judgment against DCR, and will comply with FACTA going forward. The class period began November 3, 2010, and ended April 15, 2011. A final fairness hearing has been scheduled for February 19, 2015.



ISSUE 538 | SEPTEMBER 19, 2014

# Parties Reach Settlement in Yerba Mate ECJ Labeling Putative Class Action

A California federal court has approved a settlement in a case accusing Guayaki Sustainable Rainforest Products Inc. of misleading its customers by listing "organic evaporated cane juice" (ECJ) as an ingredient of its yerba mate products. *Cowan v. Guayaki Sustainable Rainforest Prods. Inc.*, No. 14-1248 (U.S. Dist. Ct., N.D. Cal., order entered September 16, 2014). The terms of the settlement agreement are confidential. The plaintiff's suit was part of a deluge of putative class actions alleging product mislabeling because the companies included ECJ on their ingredient lists rather than, plaintiffs have argued, the more common and accepted term for the substance, sugar. Many of these cases have been dismissed without prejudice or stayed while courts and parties await promised guidance on the issue from the U.S. Food and Drug Administration. Additional information on recent cases appears in Issues 534, 532 and 530 of this *Update*.

# **Costa Rican Court Declares GMO Approval Process Unconstitutional**

Costa Rica's Constitutional Chamber of the Supreme Court has reportedly struck down the country's approval process for projects using genetically-modified organisms (GMOs), finding it violates the constitutional rights to a healthy environment and—because of the confidentiality of the process—freedom of information. Environmental groups challenged the process in late 2012, and the Ombudsman's Office represented their views in court, arguing that the GMO approval process prevented Costa Ricans from accessing information that could potentially affect their health and well-being. The ruling affects the Fitosanitary Law, but it does not ban GMOs or affect GMO projects that have already been approved. See Tico Times, September 11 and 16, 2014.

# OTHER DEVELOPMENTS

# JAMA Publishes Viewpoint on New York City's Soda Portion Case

Georgetown public health law professors opine in the September 15, 2014, issue of the *Journal of the American Medical Association (JAMA)* that New York's high court, in striking down the New York City Board of Health's sugary drink portion size rule, could have effectively chilled "local innovation, given local agencies' unique position to devise innovative solutions to urgent health concerns." More information about the court's ruling appears in Issue <u>528</u> of this *Update*.

The authors contend that the court narrowly construed the board's authority which "ignored its rich historical legacy" and failed to consider that "[w]ith the epidemiologic transition from infectious to noncommunicable diseases,



ISSUE 538 | SEPTEMBER 19, 2014

today's salient threats include poor diet, physical inactivity, and smoking," matters that they believe should be within the board's purview. Noting how tobacco control has involved a series of interventions, including tax increases, marketing restrictions and public smoking bans, they suggest that while "[the] portion cap, in isolation might not stem the obesity epidemic, . . . a suite of nutritional policies acting over time could reduce population weight gain."

Among other matters, the authors contend that health policy making should be able to rely on limited evidence of effectiveness, should not be measured by public support—"Agencies often have to move ahead of public opinion, which is shaped by aggressive industry lobbying and marketing"—and should enhance opportunities for people to choose a healthy life path. In their view, the portion cap rule "is minimally intrusive, returning portion sizes to reasonable historic levels," but the court's judgment will make it more difficult for public health officials to experiment with novel ideas, thus making it harder to evaluate and learn.

# San Francisco and Berkeley Pass Resolutions Condemning Nontherapeutic Use of Antibiotics in Livestock

The San Francisco Board of Supervisors and Berkeley City Council last week each passed resolutions urging federal lawmakers to pass the Preservation of Antibiotics for Medical Treatment Act of 2013 (H.R. 1150) and the Preventing Antibiotic Resistance Act of 2013 (S. 1256).

"Twenty-three thousand people die each year in the United States from antibiotic-resistant infections," a Food & Watch representative was quoted as saying. "The public and elected leaders must take action to keep antibiotics working for people."

The San Francisco <u>resolution</u> also asks the city's Department of the Environment to consider reducing purchases of agricultural products derived from animals using non-therapeutic antibiotics and residents of the city and county of San Francisco to reduce or eliminate their consumption of such products. See Food & Water Watch News Release, September 15, 2014.

# **Rudd Center to Relocate to University of Connecticut**

Yale University has announced that the Rudd Center for Food Policy and Obesity will move to the University of Connecticut's (UConn's) Center for Health, Intervention and Prevention in January 2015 to help launch a major initiative prioritizing "health, wellness, and obesity prevention as an integral part of the University's mission." According to a September 12, 2014, press release, "[t]he move will allow Rudd Center researchers to expand their work and build new collaborations with UConn experts on nutrition, public policy, psychology, agriculture, economics, and obesity."



ISSUE 538 | SEPTEMBER 19, 2014

Among other things, the partnership aims to encourage new research on a wide variety of obesity-related topics, including: (i) "economic incentives and the role of marketing in food choices"; (ii) "genetic and neurophysiological moderators of risk for obesity"; (iii) "chemosensory perception in humans and how it influences food preference and intake"; (iv) "weight management interventions for adults and children"; (v) "[the] effects of cholesterol-lowering medications on muscle performance"; (vi) "obesity prevention policies"; and (vii) "weight-based stigma and bullying."

"We are excited to join UConn and the community of world-class researchers whose work is relevant to childhood obesity and weight stigma," said Rudd Center Director Marlene Schwartz. "By joining UConn during this monumental time of growth, the Rudd Center will remain a leader in addressing how home environments, school landscapes, neighborhoods, and the media shape the eating attitudes and behaviors of children."

## PETA UK Director Urges Action on Foie Gras in the EU

Animal rights organization People for the Ethical Treatment of Animals (PETA) is currently engaged in a campaign to ban foie gras production throughout the European Union (EU). Writing in the September 17, 2014, issue of *The Parliament Magazine*, PETA UK Director Mimi Bekhechi urges readers to sign a letter to EU officials calling on them to stop the production of foie gras, produced by force-feeding ducks and geese to enlarge their livers, in Belgium, Bulgaria, France, Hungary, and Spain. Bekhechi cites scientific evidence as clear proof "that the production of foie gras is not only cruel but also incompatible with the European Commission's regulations on food production." According to PETA, more than 200,000 individuals have already signed the letter. PETA also claims that "many animals on foie gras farms are kept in cramped cages that do not comply with Council of Europe recommendations."

#### SCIENTIFIC/TECHNICAL ITEMS

### Artificial Sweeteners Allegedly Linked to Glucose Intolerance

A recent *Nature* study has reportedly concluded that non-caloric artificial sweeteners (NAS) elevate blood glucose levels and induce glucose intolerance by modifying gut bacteria. Jotham Suez, et al., "Artificial sweeteners induce glucose intolerance by altering the gut microbiota," *Nature*, September 2014. Noting that mice given drinking water prepared with either saccharin, sucralose or aspartame showed signs of metabolic problems not evident in mice that received only sucrose water, Israeli researchers evidently hypothesized that gut bacteria mediates the effect of NAS on glucose response. To test this



ISSUE 538 | SEPTEMBER 19, 2014

theory, they first showed that eradicating the gut microbiota in these mice also leveled the metabolic differences between the two groups. In addition, germ-free mice that received fecal transplants from those on the NAS diet likewise developed a reduced tolerance to glucose.

The study's authors then obtained gut-bacteria samples from seven human volunteers who consumed the maximum recommended amount of saccharin for one week. When given to germ-free mice, the fecal transplants from the four participants who showed a reduced insulin response transferred this effect to the recipients. The researchers reported that not only did NAS appear to change the types and number of bacteria present in the gut, but that the remaining population expressed DNA differently.

At the same time, however, three of the human test subjects did not develop any signs of glucose intolerance. "This underlines the importance of personalized nutrition—not everyone is the same," said the lead author of the study, which calls for "a reassessment of massive NAS usage." See Ars Technica, September 17, 2014; Nature News, September 18, 2014.

# Recent Research Links "Mood, Food and Obesity"

A review of recent research focused on food consumption and mood regulation has reported that complex biological factors engage both the peripheral and central nervous system "in a bi-directional manner linking food intake, mood, and obesity." Minati Singh, "Mood, Food and Obesity," Frontiers in Psychology, September 2014. Summarizing human and animal studies, the article addresses the following topics: (i) the relationship between stress, mood and food intake, (ii) the relationship between mood, food preference and obesity; (iii) "food reward, addiction and obesity"; (iv) "society and food addiction"; (v) the roles of ghrelin, serotonin, leptin, adiponectin, resistin, and insulin in regulating food, mood and obesity; and (vi) "epigenetics, mood and eating disorders."

"Many people find it hard to stop eating a particular food even though they are not hungry," explains the article author. "Such behaviors activate the brain reward center and alter the brain structure... Through neurobiological data, presence of food cravings, over eating, and tolerance support an addictionlike model by numerous signals that are involved in engaging both the central and peripheral nervous system in a bi-directional manner to regulate food intake."

### Article Considers Food Addiction Under DSM-5 Criteria

An article examining food addiction in light of the *Diagnostic and Statistical* Manual of Mental Disorders (DSM-5) has concluded that the latest edition's new criteria for substance use disorders (SUDs) "may be valuable for food addiction research, even if some of those symptoms may rarely be endorsed



ISSUE 538 | SEPTEMBER 19, 2014

by participants exhibiting addiction-like eating." Adrian Meule and Ashley Gearhardt, "Food Addiction in Light of the DSM-5," *Nutrients*, September 2014. Claiming that further studies are needed to evaluate the new criteria's relevance to food addiction, the article's authors explain that DSM-5 now includes the following criteria for SUDs: (i) "failure to fulfill major role obligations at work, school, or home as a result of substance use"; (ii) "continued substance use despite social or interpersonal problems caused or exacerbated by substance use"; and (iii) "recurrent substance use in situations in which it is physically hazardous." The manual has also defined a new symptom of "craving, or a strong desire or urge to use the substance," in addition to including gambling disorder as a non-substance-related disorder.

Highlighting these changes, the article identifies new research opportunities designed to draw parallels between the new DSM-5 criteria and overeating. As the authors conclude, "[F]uture investigations need to take great care that the new SUD criteria are properly translated to food and eating and that reasonable diagnostic thresholds are applied when diagnosing food addiction. Finally, we emphasize the need to think more mechanistically in the evaluation of food addiction by examining the contribution of biological, psychological, and behavioral circuits implicated in addiction to problematic eating behaviors."

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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.





