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LEGISLATION, REGULATIONS AND STANDARDS

Vermont AG Adopts Rule Mandating “Produced with Genetic Engineering” Label

Vermont Attorney General William Sorrell has reportedly adopted a **final rule** implementing the state’s new law requiring the labeling of foods produced partially or entirely with genetic engineering (GE).

“We are pleased at the amount of public input we received during the rulemaking process – from industry and consumers – and are glad that, with the formal adoption of this rule, we are giving ample time for food manufacturers and retailers to prepare for the law to take effect in just over fourteen months,” Sorrell was quoted as saying.

Among other things, Consumer Protection Rule 121 provides specific details about how the GE label must appear on processed food, exemptions from the labeling requirement, and enforcement and penalties. The rule takes effect on July 1, 2016. *See Office of the Attorney General Press Release, April 20, 2015.*

CSPI Challenges GRAS Approval Process

The Center for Science in the Public Interest (CSPI) and other organizations have **filed** a regulatory comment challenging the approval process for substances generally recognized as safe (GRAS) for use in food products, arguing that the U.S. Food and Drug Administration (FDA) has weakened the GRAS standards to the point that they violate the Food Additives Amendment of 1958.

According to the comment, “[T]he American public would likely find it both disturbing and surprising that thousands of chemicals added to food today are *not* approved or even reviewed by FDA. Instead, of the roughly 10,000 additives currently used in food, more than 3,000 have never been substantively reviewed by FDA. For an estimated 1,000 of these substances, safety decisions were made by the food industry without any notice at all to FDA.” The comment further alleges that the agency has

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Shook 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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weakened food-safety laws with its 1997 proposal to change the GRAS approval process, which was never adopted or rejected.

“The FDA’s job is to ensure the safety of our food supply; it should be doing much more to protect our health—not outsourcing decisions on the safety of thousands of chemicals in our food to industry,” said Erik Olson, director of the National Resources Defense Council’s health program. *See CSPI News Release*, April 15, 2015.

USDA Schedules Mid-June Meeting to Discuss Codex Positions

The U.S. Department of Agriculture’s Food Safety and Inspection Service has **announced** a June 17, 2015, public meeting in Washington, D.C. to provide information and receive comments about draft U.S. positions to be discussed during the 38th Session of the Codex Alimentarius Commission in Geneva, Switzerland, July 6-11.

Agenda items at the June 17 meeting include (i) proposed amendments to the procedural manual; (ii) amendments to Codex standards and related texts; (iii) implementation status of the Commission’s five-year strategic plan; and (v) relations between the Commission and other international organizations. *See Federal Register*, April 22, 2015.

Cal/EPA Workshop to Target Climate Change Indicators

California EPA’s Office of Environmental Health Hazard Assessment has **announced** a June 16-17, 2015, workshop to gather stakeholders for discussions about emerging evidence of climate change, its drivers and impacts on water resources, agriculture, fish, wildlife, and the health and well-being of California residents. Information gathered at the event is expected to inform the 2017 edition of Cal/EPA’s *Indicators of Climate Change in California* report. *See OEHHA Press Release*, April 20, 2015.

U.K. Group Deems Guinness® Tweet “Irresponsible”

The U.K. Advertising Standard Authority (ASA) has **dismissed** a complaint alleging that a message on Diageo Great Britain Ltd.’s Guinness® Twitter feed “implied that someone’s week would be improved by drinking alcohol.” Filed by Alcohol Concern, the complaint dubbed a tweet appearing on @GuinnessGB “irresponsible” for featuring a photograph of the iconic brewery’s gates with the caption, “a good week starts here.”

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Dismissing the challenge, ASA ultimately agreed with Diageo Great Britain that consumers would recognize the gates as belonging to St. James Brewery in Dublin and would not confuse the brewery with a bar or other social venue where alcohol was consumed. According to Diageo Great Britain, the followers of @GuinnessGB would also understand the tweet as part of a larger ad campaign highlighting individual workers at the brewery.

“We also noted that the photo was tweeted on Monday,” states ASA. “In this context, we considered that the ad was likely to be interpreted as having a dual meaning: as an expression of opinion from those who worked at the brewery about the week of work ahead and their enjoyment of their work; and as an indication to the public that Guinness, which began its journey to them at the brewery, could be consumed as part of a ‘good week.’”

To this end, the authority ruled that the Twitter advertisement did not breach CAP Code rules 1.3 (Responsible advertising), 18.1, 18.3, 18.6 and 18.7 (Alcohol).

Criteria to Identify Endocrine Disruptors Focus of Upcoming EC Conference

The European Commission (EC) is **convening** a meeting to “inform Member States, Members of the European Parliament, third country representatives and stakeholders about the ongoing impact assessment on criteria to identify endocrine disruptors and to provide a platform for further exchanges of views” on June 1, 2015, at the Centre Albert Burschette in Brussels, Belgium.

Sessions at the day-long event will include discussions of (i) the impact assessment vis à vis the plant protection products regulation and biocide products regulation; (ii) establishing criteria for identifying endocrine disruptors and assessing that criteria in a regulatory context; and (iii) potential impacts on health, the environment, trade, agriculture, consumers, and the food and pesticide industries. The registration deadline is May 19. *See EFSA News Release*, April 23, 2015.

Allergenicity of GMOs Focus of EFSA Workshop

The European Food Safety Authority (EFSA) has **announced** a June 17, 2015, workshop in Brussels, Belgium, to discuss supplementary guidance for the allergenicity assessment of genetically modified organisms (GMOs). According to the agency, the supplementary guidance aims

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to reflect technological and scientific advances as well as assessment methodologies developed since EFSA finalized the current guidance in 2011.

The Working Group of EFSA's GMO Panel requests feedback from member states, international partners, academia, non-governmental organizations and industry on the following topics: (i) non-IgE-mediated immune adverse reactions to foods; (ii) *in vitro* digestibility tests for allergenicity assessment; and (iii) endogenous allergenicity. The June workshop will feature the work of 90 experts with a focus on molecular allergology, protein chemistry, plant science, clinical allergy, gastroenterology, food chemistry, and risk assessment. *See EFSA News Release*, April 14, 2015.

LITIGATION

SCOTUS Hears Oral Arguments About USDA Raisin Program

The U.S. Supreme Court has heard arguments in a case brought by raisin farmers against the U.S. Department of Agriculture (USDA) alleging that a federal program requiring a portion of the yield to be set aside amounted to a taking of their property, thus requiring just compensation. *Horne v. USDA*, No. 14-275 (U.S., oral arguments heard April 22, 2015).

According to news reports, the justices appeared to favor the raisin farmers' arguments. "You come up with the truck, and you get the shovels, and you take their raisins—probably in the dark of the night," Chief Justice John Roberts reportedly said. At another point in the proceedings, he called the program's requirement "a classic, physical taking." Justice Antonin Scalia reportedly called the program "ridiculous" and compared its structure to communism ("Central planning was thought to work very well in 1937. Russia tried it for a long time."), and Justice Samuel Alito asked if the government could take ownership of a number of cell phones or cars produced by private companies. Contemplating the government's argument, Justice Stephen Breyer reportedly observed that the program did offer financial benefits to the farmers by preserving stable prices for raisins, which could sell for much less in high-yield years if all of the produced raisins entered the market. Additional details about the lawsuit appear in Issue [552](#) of this *Update*. *See Bloomberg Business* and *The Hill*, April 22, 2015.

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Plaintiffs Challenging Gerber's Probiotic Health Claims Must Provide Medical Records

A New Jersey federal court has granted Gerber's motion to compel discovery of medical records in a consumer putative class action alleging that the company misrepresented its probiotic formula as capable of improving infant immune systems. *In re Gerber Probiotic Sales Practices Litig.*, No. 12-835 (D.N.J., order entered April 10, 2015).

Gerber requested medical records for the children who ingested the products, but the plaintiffs objected that the "overly broad" request violated their rights of privacy and that the records were subject to physician-patient privilege. The court agreed with Gerber, finding "a legitimate need for medical records as there is no other source that could test the actual effectiveness of the products that claim to produce immune system health. Proof in the form of scientific studies and expert testimony may not be sufficient," the court said, so "actual facts or the lack thereof may be essential." Further, the medical records are relevant to the effectiveness of the products and no other source could accurately provide objective medical information, the court found.

Alcohol Company and Gunmaker Settle over "Tommy Guns Vodka"

Saeilo Enterprises Inc. and Alphonse Capone Enterprises Inc. have reportedly reached a settlement in a lawsuit alleging trademark and trade dress infringement for a bottle of vodka branded as "Tommy Guns Vodka" and shaped like Saeilo's Thompson submachine gun. *Saeilo Enterprises, Inc. v. Alphonse Capone Enterprises, Inc.*, No. 13-2306 (N.D. Ill., E. Div., notification of docket entry filed April 21, 2015).

The gun manufacturer alleged in its complaint that the vodka company misappropriated the trade dress and trademark of the Thompson gun with the shape of the bottle and the name, and Saeilo sought an injunction, damages and attorney's fees. A notice filed with the court indicates that the parties have reached a settlement and will file a stipulation to dismiss, but terms of the settlement were unavailable.

Second Putative Class Action Alleging Unsafe Arsenic Levels in California Wine Filed in Louisiana

A consumer has filed a putative class action in Louisiana federal court against several California wineries alleging that their products contain "dangerously high" levels of arsenic, echoing a similar lawsuit filed in California in March 2015. *Crespo-Bithorn v. The Wine Grp. Inc.*, No. 15-1424 (M.D. La., filed April 20, 2015).

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The complaint alleges that the wineries “sell and distribute wine to consumers at inorganic arsenic levels significantly higher than what the State of California considers the maximum acceptable limit for safe daily exposure” and asserts that the advertising and marketing of each wine was deceptive because it failed to warn of the arsenic levels. The plaintiff seeks national and state class certification and damages for the Louisiana cause of action of redhibition as well as alleged violations of Louisiana consumer protection statutes and the Magnuson-Moss Warranty Act. Details about the March lawsuit appear in Issue [559](#) of this *Update*.

Quinoa Crisps Not “GMO Free” Because of Corn and Soy Content, Lawsuit Claims

A consumer has filed a purported class action against Natural & Tasty LLC alleging that the company misleads consumers by labeling its Goldbaum Quinoa Crisps® as “All Natural” and free of genetically modified organisms (GMOs) despite containing ingredients made from corn and soy because “almost all corn and soy grown in the United States are grown from seeds that have been genetically modified.” *Slavinski v. Natural & Tasty LLC*, No. 15-80451 (S.D. Fla., filed April 7, 2015).

The complaint asserts that nearly all U.S. corn and soy are grown from GM seeds, “and as such, almost all corn and corn-based, as well as soy and soy-based ingredients in the United States are in fact unnatural, synthetic, artificial, and genetically modified ingredients.” The plaintiff points to several ingredients in the quinoa product as unnatural, including maltodextrin, whole grain corn flour, corn starch, and vegetable oil.

While similar lawsuits have cited the reasonable person standard in the context of what labeling information would mislead a reasonable consumer, the plaintiff argues that reasonable consumers base decisions on labels indicating the naturalness or GMO content of the product. Natural & Tasty “is well-aware that claims of food being ‘All Natural’ and/or ‘GMO Free’ is material to reasonable consumers,” the plaintiff argues, because “reasonable consumers, such as Plaintiff and members of the Class, care whether food products contain unnatural, synthetic, artificial, and/or genetically modified ingredients” and “attach importance to ‘All Natural’ and/or ‘GMO Free’ claims when making a purchasing decision.” She alleges violations of Florida’s consumer protection statute and the Magnuson-Moss Warranty Act as well as negligent misrepresentation, unjust enrichment and breach of express warranty. She seeks class certification, damages and attorney’s fees.

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Putative Class Action Targets Kind LLC's "Healthy" Claim

Days after the U.S. Food and Drug Administration (FDA) released a March 2015 letter warning Kind LLC against using the word "healthy" to describe several of its products, a consumer filed a class action against the company alleging negligent misrepresentation and violations of California consumer protection statutes. *Kaufer v. Kind LLC*, No. 15-2878 (C.D. Cal., filed April 17, 2015). The FDA Warning Letter listed the packaging of several products that an agency investigation apparently determined violated the Federal Food, Drug, and Cosmetic Act because the products' nutrient contents do not meet federal requirements to be described as "healthy." The letter also warned Kind against the use of "+" or "plus" as well as "No Trans Fats."

The putative class action complaint cites the FDA letter, arguing that the "healthy," "+" or "plus" and "no trans fats" claims mislead consumers into believing that they are purchasing a healthful product. The plaintiff seeks class certification, damages, restitution, an injunction, and attorney's fees.

Consumer Organizations Allege USDA Violated Procedure with Contaminated-Compost Rule

The Center for Food Safety, Center for Environmental Health and Beyond Pesticides have filed a lawsuit against the leaders of the U.S. Department of Agriculture (USDA), Agricultural Marketing Service and National Organic Program (NOP) arguing that USDA failed to allow public comments on a contaminated-compost rule before issuing a guidance document on the subject. *Ctr. for Env'tl. Health v. Vilsack*, No. 15-1690 (N.D. Cal., filed April 14, 2015). The 2011 guidance at issue allows organic producers to use compost materials treated with pesticides.

According to the complaint, "NOP regulations expressly prohibit fertilizers and compost from containing any synthetic substances not included on the National List" of approved exceptions, but the Contaminated-Compost decision "contravened that legal requirement, purporting to establish that organic producers may in fact use these contaminated plant and animal materials in compost under certain circumstances." The decision was never subject to public comment, the plaintiffs argue, and thus violated the Administrative Procedures Act (APA). They implore the court to enjoin USDA from authorizing the use of compost with prohibited substances, invalidate the Contaminated-Compost decision and require the agency to follow APA regulations on public comment periods.

SCIENTIFIC/TECHNICAL ITEMS

Does Consumer Awareness of Food Addiction Affect Eating Behavior?

Raising concerns about how the media portrays the concept of food addiction, a new study questions whether endorsement of this model “may cause people to perceive a lack of control over eating which could promote unhealthy dietary behaviors.” Charlotte Hardman, et al., “Food Addiction is Real: The effects of exposure to this message on self-diagnosed food addiction and eating behavior,” *Appetite*, April 2015.

To explore this hypothesis, researchers with the University of Liverpool and University of Bristol directed 60 study participants to read fake news articles describing food addiction as either a “myth” or “real.” The study then used a disguised taste test to measure consumption of “indulgent” and “non-indulgent” snack foods (potato chips, cookies, breadsticks and grapes), in addition to asking participants if they perceived themselves as food addicts.

The results evidently showed that “the proportion of self-diagnosed addicts more than doubled (57%) when participants were exposed to information that food addiction is real, relative to participants who were informed that food addiction is a myth.” The study also reported that mean intake of food did not increase after exposure to food addiction messages, although “the variability in food intake was significantly greater in the Real condition relative to the Myth condition.”

“Our study contributes to a more general debate around whether acceptance of the food addiction model is helpful or counterproductive,” conclude the authors. “On the one hand, the belief that food is addictive may offer some solace to individuals who are struggling with eating and weight... However, the alternative argument is that public health messages which imply a lack of personal control over eating may undermine beneficial self-regulatory processes, such as health-focused dieting, and result in high-calorie food choices.”

Most Packaged Foods Exceed FDA Sodium Recommendations, Says CDC Study

After examining the sodium content of packaged food products sold throughout the United States in 2009, Centers for Disease Control and Prevention (CDC) researchers have **reported** that “fewer than half

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ABOUT SHOOK

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.

Shook 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.



of selected food products met Food and Drug Administration [FDA] sodium-per-serving conditions for labeling as ‘healthy.’” Alexandra Lee, et al., “Sodium Content in Packaged Foods by Census Division in the United States, 2009,” *Preventing Chronic Disease: Public Health Research, Practice and Policy*, April 2015.

Using the 2009 Nielsen ScanTrak data to identify all branded products sold in grocery stores with annual sales of \$2 million or more, the study focused on products sold in three U.S. Census divisions—South Atlantic, East North Central and Pacific—representing approximately 50 percent of the U.S. population. These three regions also “reflect places with high (South Atlantic), medium (East North Central) and low (Pacific) prevalence of hypertension.” The authors then identified “products in the 10 food categories that contribute the most sodium to the U.S. diet,” obtaining nutritional data for those products with top sales in each census division and calculating “the mean and standard deviation of sodium content in each food category in milligrams (mg) per serving, mg per kilocalorie (density), and mg per 100 grams (concentration).”

The findings evidently revealed that mean sodium density was (i) highest in the East North Central for poultry, cheese, pasta and mixed dishes, and meat mixed dishes, (ii) highest in the South Atlantic for bread, soup and savory snacks, and (iii) highest in the Pacific for cold cuts, pizza and sandwiches. In particular, the study notes that “more than 70% of pizzas, pasta mixed dishes, and meat mixed dishes, and 50% to 70% of cold cuts, soups and sandwiches exceeded FDA ‘healthy’ labeling standards for sodium.” As the authors conclude, “[T]hese data support recent findings that suggest that meeting sodium recommendations may be difficult in the current food environment, regardless of location... In all 3 census divisions, the similarly narrow distributions of sodium density in most food categories are indicative of the lack of variation in sodium content.”