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LEGISLATION, REGULATIONS AND STANDARDS

CRS Issues Nanotechnology Policy Primer

A new report from the public policy research arm of the U.S. Congress provides an overview of federal research and development (R & D) in nanotechnology; environmental, health and safety concerns; and U.S. competitiveness in the field. According to the Congressional Research Service, Congress has appropriated nearly \$21.8 billion for nanotechnology R & D since the inception of the National Nanotechnology Initiative (NNI) in 2000, and President Barack Obama (D) has requested \$1.4 billion in NNI funding for FY2017.

“Proponents assert that nanotechnology has the potential to bring revolutionary products to market, reshaping existing industries and creating new ones,” concludes the report. “These products may bring significant economic and social benefits to the United States and to the world; however, substantial research, development, and innovation-related hurdles remain before these benefits might be realized.”

U.S. Codex Delegates Schedule CCPFV Meeting

The U.S. Department of Agriculture’s Office of the Under Secretary for Food Safety and Agricultural Marketing Service are convening an August 1, 2016, public meeting in Washington, D.C., to evaluate draft positions and receive public comments in advance of the 28th Session of the Codex Committee on Processed Fruits and Vegetables (CCPFV) slated for September 12-16 in Washington, D.C. The CCPFV sets global standards for canned, dried and frozen products as well as fruit and vegetable juices and nectars.

Agenda items for the August 1 meeting include (i) food additive provisions in Codex standards for processed fruits and vegetables, (ii) a discussion paper about the standardization of dry and dried produce, and (iii) proposed draft annexes on quick frozen vegetables. *See Federal Register*, June 30, 2016.

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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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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

EFSA Launches Web-Based Botanicals Compendium

The European Food Safety Authority (EFSA) has released a [searchable database](#) of botanicals that contain naturally occurring substances of potential concern to human health. The compendium is intended for use as a safety assessment tool for food and dietary supplement manufacturers. The compendium will reportedly be expanded to include non-European botanical species and is expected to be finalized in early 2017. See *EFSA News Release*, July 5, 2016.

LITIGATION

Eighth Circuit Upholds Prison Sentences for Egg Execs

The Eighth Circuit Court of Appeals has upheld the legality of three-month prison sentences handed down to former Quality Egg, LLC executives Austin “Jack” DeCoster and his son Peter, former officials of the company deemed responsible for a 2010 *Salmonella* outbreak traced to its Iowa egg farms. *United States v. Quality Egg, LLC*, No. 15-1890 (8th Cir., order entered July 6, 2016).

Convicted of misdemeanor violations of the federal Food, Drug, and Cosmetic Act (FDCA), the DeCosters argued their sentences were unconstitutional under the Due Process Clause and the Eighth Amendment because incarceration for their offenses is either altogether inappropriate or disproportionate to the crimes. Upon a de novo review of the case, the appeals court confirmed that “the DeCosters are liable for negligently failing to prevent the salmonella outbreak.” Further, the men’s sentences did not violate the Due Process Clause because the sentences were “relatively short” and the “convictions do not gravely damage their reputations”; in addition, no criminal intent was required to underlie the conviction because “Congress has seen fit to enforce the accountability of responsible corporate agents dealing with products which may affect the health of consumers by penal sanctions cast in rigorous terms.”

The court further found the sentences did not violate the Eighth Amendment, as the terms “fell at the low end of the prescribed statutory range of [the FDCA] (one year maximum), and we have ‘never held a sentence within the statutory range to violate the Eighth Amendment.’” Details about the criminal case appear in Issue [524](#) of this *Update*.

Settlement in Pepsi 4-MEI Suit Preliminarily Approved

A California federal court has granted preliminary approval for a settlement agreement in a lawsuit alleging PepsiCo products contain levels of 4-Methylimidazole (4-MEI) exceeding the legally permissible amount under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). *Sciortino v. PepsiCo Inc.*, No. 14-0478 (N.D. Cal., order entered June 28, 2016).

Under the settlement, PepsiCo has agreed "to require its caramel coloring suppliers to meet certain 4-MeI levels in products shipped for sale in the United States, ensuring the 4-MeI concentration levels will not exceed the level of 100 parts per billion, and to test the covered products pursuant to an agreed protocol." The court noted that the injunctive relief is the same as the agreement in an action brought by the Center for Environmental Health (CEH) alleging similar facts. "However, the Settlement Agreement will 'enhance the CEH settlement by: (1) expanding the geographic scope of the stipulated injunction from California to nationwide; (2) increasing the duration of the injunctive relief from three years to five years,'" the court stated. Further details about the case appear in Issue [568](#) of this *Update*, while addition information on CEH's lawsuit appears in Issues [427](#) and [579](#).

Court Grants Summary Judgment in "Pur Pom" Trademark Lawsuit

A California federal court has granted summary judgment to Pom Wonderful LLC in its trademark lawsuit against Pur Beverages Inc., which sells a pomegranate-flavored beverage under the name "Pur Pom." *Pom Wonderful LLC v. Hubbard*, No. 13-6917 (C.D. Cal., order entered June 29, 2016).

Pom filed a lawsuit alleging infringement of the "pom" mark, and Pur defended its use by arguing that Pom's stylized use of the mark—a heart-shaped "O"—prevented Pom from claiming ownership of the non-stylized mark. The court disagreed, finding that the "stylized lettering does not alter the pronunciation or perception of the word; the standard character mark is both aurally and visually indistinguishable from the mark bearing a heart-shaped 'O.'" Information about the Ninth Circuit decision reversing a lower court's decision in favor of Pur Beverages appears in Issue [550](#) of this *Update*.

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ALDF Files Lawsuit Against Hormel over “Natural” Claims

The Animal Legal Defense Fund (ALDF) has reportedly filed a lawsuit against Hormel Foods challenging the company’s Natural Choice® brand of lunch meats and bacon, which it advertises as “100% Natural” and “All-Natural.” In a June 30, 2016, press release, an ALDF attorney argued that the Natural Choice® meats “come from the same pigs and the same giant, factory slaughterhouses that are used for the company’s canned Spam® products” and that the products are treated with “acid starter culture” to produce artificial preservatives.

“Meat companies like Hormel have been quick to pounce on misconceptions about what ‘natural’ means,” Animal Legal Defense Fund Executive Director Stephen Wells was quoted as saying in the press release. “As an organization dedicated to transparency in animal agriculture and truth in meat advertising, the Animal Legal Defense Fund is standing up to vindicate the rights of deceived consumers and to prevent Hormel from wrongfully gaining an advantage over more humane farms.” *See Animal Legal Defense Fund Press Release and Bloomberg*, June 30, 2016.

OTHER DEVELOPMENTS

Boston Beer Co. Seeks to Trademark “Brexit”

One day after U.K. citizens voted to leave the European Union, Samuel Adams® brewer Boston Beer Co. filed an application with the U.S. Patent and Trademark Office to register “Brexit” for use on hard cider products. U.S. Trademark Application Serial No. 87083390 (filed June 24, 2016). Two other applications for Brexit marks were filed the same day in the categories of dietary supplements and clothing. A Boston Beer Co. spokesperson reportedly declined to detail the company’s plans for its Brexit mark. *See The Wall Street Journal*, June 29, 2016.

Italian Police Arrest Alleged Mafia Members in Bread-Selling Scheme

Italian police have reportedly arrested 24 people in an operation targeting the Lo Russo crime syndicate in connection with a scheme to intimidate grocers and supermarkets in Naples into buying bread at prices considerably higher than the market standard. The police also seized three bakeries allegedly identified as Lo Russo-controlled. The crime group reportedly forced merchants to buy the bread or risk

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seeing their shops burned or damaged in other ways. Lieutenant Colonel Giuseppe Furciniti, commander of the organized crime unit in Naples of the national financial police corps, said the scheme was common for the group, noting, “This time it was bread, other times it has been buffalo mozzarella.” *See Associated Press*, June 27, 2016.

Diageo to Begin Listing Nutritional Information on Johnnie Walker®

Diageo will reportedly provide nutritional information on its alcohol product packaging, beginning with Johnnie Walker® Red Label. Changes to Smithwick’s® and Guinness® packaging will follow. The global label will reportedly include the product’s alcohol by volume, serving size, calorie and sugar content and allergens, while the U.S. label will mimic the Nutrition Facts panel format regulated by the U.S. Food and Drug Administration.

In a June 30, 2016, press release, a Diageo official said the change is “based on what consumers want,” noting, “Current labeling on most alcoholic beverages does not reflect how people consume alcohol and therefore does not allow consumers to understand how much alcohol is in their favorite drink or what is in their glass.” *See Forbes*, June 30, 2016.

SCIENTIFIC/TECHNICAL ITEMS

New Meta-Analysis Targets Health Effects of Butter Consumption

A meta-analysis examining the effect of dairy fats on health has identified “a small positive association between butter consumption and all-cause mortality, no significant association with incident CVD [cardiovascular disease] or CVD subtypes, and a modest inverse association with type 2 diabetes.” Laura Pimpin, et al., [“Is Butter Back? A Systematic Review and Meta-Analysis of Butter Consumption and Risk of Cardiovascular Disease, Diabetes, and Total Mortality,”](#) *PLoS One*, June 2016.

Relying on data from nine studies that included 636,151 unique participants with 6.5 million person-years of follow-up, researchers reported that “each daily serving of butter (14g/d) was associated with a 1% higher risk of death” from all causes. The pooled data, however, also showed that each 14-gram serving of butter per day was associated with a 4-percent lower incidence of type 2 diabetes, while the studies found no association between butter consumption and stroke, coronary heart disease or total CVD.

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“These findings should be considered against clear harmful effects of refined grains, starches, and sugars on CVD and diabetes; and corresponding benefits of fruits, nuts, legumes, n-6 rich vegetable oils, and possibly other foods such as fish on these endpoints,” said the study’s authors. “In sum, these results suggest that health effects of butter should be considered against the alternative choice. For instance, butter may be a more healthful choice than the white bread or potato on which it is commonly spread. In contrast, margarines, spreads, and cooking oils rich in healthful oils, such as soybean, canola, flaxseed, and extra-virgin olive oil, appear to be healthier choices than either butter or refined grains, starches, and sugars.”

Meanwhile, the Center for Science in the Public Interest (CSPI) has criticized the findings and their representation in the media, warning that increased saturated fat consumption is associated with a higher risk of heart disease regardless of the food source. CSPI Nutrition Director Bonnie Liebman opined, “The new study acknowledges that unsaturated oils and spreads are healthier than butter—the key takeaway message for consumers. Yet most people will simply hear that butter is a harmless or healthy food, thanks to headlines with various permutations of the ‘butter is back’ myth which is based on questionable evidence.” *See CSPI Statement*, July 1, 2016.

Swedish Study Highlights Potential Flaws in fMRI Findings

Swedish researchers have warned that the software packages used to analyze the results of functional magnetic resonance imaging (fMRI) contain flaws that increase the chance of a false positive by as much as 70 percent. Anders Eklund, [“Cluster failure: Why fMRI inferences for spatial extent have inflated false-positive rates,”](#) *PNAS*, June 2016.

For more than 15 years, scientists have used fMRI analyses to explore the food addiction framework and the effect of food advertising on the brain, among other things.

The Swedish study explains that the majority of fMRI studies rely on SPM, FSL or AFNI software packages based on “parametric statistical methods that depend on a variety of assumptions,” even though these methods have only been validated with simulated—as opposed to real—data. As a result, the researchers questioned whether these methods could potentially show brain activity in its absence, raising the issue of false positives.

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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.



Using resting-state data from 499 healthy controls to conduct 3 million task-group analyses, the study's authors apparently estimated the incidence of significant results and concluded that "the parametric levels can give a very high degree of false positives" for clusterwise inference. "In theory, we should find 5% false positives (for a significance threshold of 5%), but instead we found that the most common software packages for fMRI analysis (SPM, FSL, AFNI) can result in false-positive rates of up to 70%," explain the researchers. "These results question the validity of some 40,000 fMRI studies and may have a large impact on the interpretation of neuroimaging results."

Highlighting new graphics cards with increased processing power, the study offers another statistical method "in which few assumptions are made and significantly more calculations—a thousand times more—are done, which yields a significantly more certain result," according to a June 28, 2016, Linköping University press release.

"Our results suggest that the principal cause of the invalid cluster inferences is spatial autocorrelation functions that do not follow the assumed Gaussian shape," concludes the study. "It is not feasible to redo 40,000 fMRI studies, and lamentable archiving and data-sharing practices mean most could not be reanalyzed either. Considering that it is now possible to evaluate common statistical methods using real fMRI data, the fMRI community should, in our opinion, focus on validation of existing methods."