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LEGISLATION, REGULATIONS AND STANDARDS

NRDC, CSPI File Citizen Petition on Antibiotic Use in Livestock

Several consumer-protection groups, including the Natural Resources Defense Council (NRDC) and the Center for Science in the Public Interest (CSPI), have filed a citizen petition with the U.S. Food and Drug Administration (FDA) urging the agency to withdraw approval of seven antibiotics for disease-prevention and growth-promotion use in livestock and poultry. “The use of medically important antibiotics in livestock production for growth-promotion or disease-prevention purposes is not shown to be safe,” the September 13, 2016, petition asserts. “FDA’s voluntary program will not end these drug uses. FDA must immediately begin proceedings to withdraw approval for these uses.”

The day before the groups filed the petition, FDA announced a comment period about therapeutic uses of medically important antimicrobials. The agency seeks information about (i) “[t]he underlying diseases requiring these drugs for therapeutic purposes, and periods when livestock or poultry are at risk of developing these diseases”; (ii) “[m]ore targeted antimicrobial use regimens for these diseases and husbandry practices that may help avoid the need for these antimicrobials, or that may help make more targeted antimicrobial use regimens more effective”; and (iii) “[s]trategies for updating affected labeling of drug products that do not currently include a defined duration of use.” Comments will be accepted until December 12, 2016. *See Federal Register*, September 12, 2016.

HHS Adds New Anthrax Strain to List of Select Agents and Toxins

The Centers for Disease Control and Prevention (CDC) and Department of Health and Human Services (HHS) have announced the addition of an emerging *Bacillus cereus* strain that causes anthrax-like disease to the HHS list of Select Agents and Toxins.

“*Bacillus cereus* Biovar *anthracis* is a recently recognized, emerging pathogen[] that has all the virulence characteristics and threat potential of *Bacillus anthracis*, a Tier 1 select agent,” states the interim final rule, which takes effect October 14, 2016. “This organism is not currently on

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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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the HHS List of Select Agents and Toxins; we are proposing regulating this organism as a Tier 1 select agent because of its potential for misuse and its threat to public health and safety.”

HHS defines a biovar as “a group of microorganisms that are genetically similar but differ from other members of the species by biochemical or genetic characteristics.” Isolated from gorillas and chimpanzees with anthrax-like illness, this biovar has been identified in “some African countries, one registered entity in the United States, and one facility in Germany.” The agencies will accept comments on the interim final rule until November 14, 2016. *See Federal Register*, September 14, 2016.

LITIGATION

Challenge to Organic Sunset Provision to Proceed

A California federal court has denied the U.S. Department of Agriculture's (USDA's) motion to dismiss a lawsuit brought by several activist groups challenging aspects of the Organic Food Production Act's sunset provision, which governs when substances are removed from the National List. *Ctr. for Food Safety v. Vilsack*, No. 15-1590 (N.D. Cal., order entered September 8, 2016). The plaintiffs objected to how USDA changed the process to remove a substance from the List, which documents permitted synthetic substances and prohibited non-synthetic substances in the production of organic food. Details about the complaint appear in Issue [561](#) of this *Update*.

The court first determined that the plaintiff groups had standing to sue, then considered whether it had subject matter jurisdiction. USDA argued the sunset notice changes were not part of a final agency action, but the court determined the question of jurisdiction and the merits of the action were so intertwined as to prevent dismissal at this stage.

Texas Beer-Distribution Restriction Overturned

A Texas judge has reportedly voided a 2013 law prohibiting Texas craft-beer brewers from selling territorial rights to distribute their beers, finding the state had no compelling state interest in restricting the breweries. The statute was part of a package of other laws benefitting small breweries, but the distribution limitation was apparently inserted at the behest of large Texas wholesalers. The rule prevented brewers from receiving monetary compensation for distribution rights.

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The brewer who challenged the law, a former plaintiffs' attorney, told *Texas Lawyer*, "It restores millions of dollars of value to brewers who had their rights taken from them for no justifiable reason." See *Houston Chronicle*, August 26, 2016; *Texas Lawyer*, August 29, 2016.

Beverage Groups Challenge Legal Basis for Philadelphia's Tax on SSBs

The American Beverage Association, other industry groups, retailers and distributors have filed a lawsuit against the city of Philadelphia challenging its tax on sugar-sweetened beverages (SSBs), arguing the statute unlawfully attempts to circumvent Pennsylvania's taxation supremacy. *Williams v. City of Philadelphia*, No. 160901452 (Penn. Ct. C.P., Philadelphia Cty., filed September 14, 2016).

The plaintiffs assert the statute creates "a roadmap for every local government in the Commonwealth [of Pennsylvania] to evade the Commonwealth's supreme taxation structure on thousands of products—from over-the-counter pharmaceuticals to cars—merely by imposing a duplicative tax at a different level in the distribution chain than a tax already imposed by the Commonwealth." Because the beverages subject to the Philadelphia tax are also subject to Pennsylvania tax, the city tax duplicates the state tax, the plaintiffs argue, which amounts to "seizing the taxing authority expressly reserved to the Commonwealth in contravention of the Sterling Act's prohibition on local taxation of a 'privilege, transaction, subject or occupation, or on personal property, which is now or may hereafter become subject to a State tax or license fee.'"

The plaintiffs seek an injunction preventing enforcement of the soda tax, which was enacted and became effective in June 2016, as well as declaratory judgment holding the tax as invalid and without legal effect.

Chipotle Reaches Settlement in Tainted Food Litigation; Hit with New Employment Lawsuit in California

Chipotle Mexican Grill Inc. and its customers who consumed tainted food during outbreaks of *E. Coli*, *Salmonella* and norovirus have reportedly reached a settlement agreement. Terms of the agreement were not disclosed except for one class member's request to receive vouchers for free burritos. One case in the litigation is still pending. See *The Denver Post*, September 9, 2016.

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Chipotle was also hit with an unrelated lawsuit in California alleging the company fired an employee for saying that her Latino coworkers received preferential treatment. The plaintiff argues that after a Latina woman was promoted to the district manager position, Latino employees began receiving more favorable day shifts while other employees received night shifts. When the plaintiff complained about the scheduling to a Latino manager, she was allegedly told that “black girls always have attitude.” See *CBS Los Angeles*, September 13, 2016.

OTHER DEVELOPMENTS

Sugar Industry Allegedly Funded Research Linking Dietary Fats to Heart Disease

Researchers with the University of California, San Francisco, including its Center for Tobacco Control Research and Education, published a [September 12, 2016, JAMA article](#) claiming that studies funded by the Sugar Research Foundation (SRF) “singled out fat and cholesterol as the dietary causes of CHD [coronary heart disease] and downplayed evidence that sucrose consumption was also a risk factor.”

Titled “Sugar Industry and Coronary Heart Disease Research: A Historical Analysis of Internal Industry Documents,” the special communication analyzes correspondence, internal documents, historical reports, and other statements obtained from SRF and its scientific advisors.

The article authors allege that SRF initiated its own CHD research in 1962, after preliminary studies suggested that a low-fat diet high in sugar raises serum cholesterol levels. To this end, the SRF purportedly funded a *New England Journal of Medicine* (NEJM) literature review “arguing that epidemiologic, animal, and mechanistic studies associating sucrose with CHD were limited, implying they should not be included in an evidentiary assessment of the CHD risks of sucrose.”

“Following the NEJM review, the sugar industry continued to fund research on CHD and other chronic diseases ‘as a main prop of the industry’s defense,’” write the article authors, quoting internal documents referenced in a 2012 *Mother Jones* exposé. “For example, in 1971, it influenced the National Institute of Dental Research’s National Caries Program to shift its emphasis to dental caries interventions other than restricting sucrose. The industry commissioned a review, ‘Sugar in the Diet of Man,’ which it credited with, among other industry tactics, favorably influencing the 1976 US Food and Drug Administration evalu-

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ation of the safety of sugar. These findings, our analysis, and current Sugar Association criticisms of evidence linking sucrose to cardiovascular disease suggest the industry may have a long history of influencing federal policy.”

Meanwhile, New York University Professor of Nutrition, Food Studies and Public Health Marion Nestle penned a concurrent *JAMA* editorial echoing the authors’ call “to treat industry-funded studies with some skepticism.” As she opines, “Although considerable evidence demonstrates that those industries deliberately influenced the design, results, and interpretation of the studies they paid for, much less is known about the influence of food-company sponsorship on nutrition research. Typically, the disclosure statements of sponsored nutrition studies state that the funder had no role in their design, conduct, interpretation, writing, or publication. Without a ‘smoking gun’ it is difficult to prove otherwise.”

Additional details about the *Mother Jones* article appear in Issue 459 of this *Update*.

Alcohol Information Partnership Weighs Balanced Approach to New UK Guidelines

Several companies have formed a new group to promote a balanced discussion of alcoholic beverage consumption and address implementation of U.K. labeling recommendations. The Alcohol Information Partnership (AIP) reportedly plans to draw attention to research showing that most adults consume alcohol responsibly and that binge drinking is in decline. In addition, the companies behind the new initiative reportedly plan to meet with the U.K. Department of Health before adopting its voluntary guidelines, which, in part, ask labels to declare that there is “no safe level” of alcoholic beverage consumption.

“Alcohol misuse is an incredibly serious issue,” said AIP Director-General Dave Roberts. “As a society, we should continue to have rigorous debate about how best we continue to tackle and reduce alcohol misuse. But the debate has become increasingly imbalanced and characterized by poor representation of the evidence... The Alcohol Information Partnership is here to bring balance back to the debate and remind the public that having a drink at home or in the pub can still be a part of a balanced lifestyle, as long as it is drunk in moderation.” See *The Wall Street Journal* and *The Spirits Business*, September 7, 2016.

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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.



France Bans Plastic Cups, Cutlery

France has reportedly passed a ban on plastic cups, knives, forks and plates as part of an ecological initiative, Energy Transition for Green Growth. The prohibition, which takes effect in 2020, targets the nearly 5 billion plastic cups discarded annually in France. The country is reportedly the first to target plastic dishware.

A Brussels-based organization representing European packaging manufacturers, Pack2Go Europe, has reportedly vowed to fight the ban to prevent similar measures from passing in other European countries. "We are urging the European Commission to do the right thing and to take legal action against France for infringing European law," Pack2Go Europe Secretary General Eamonn Bates told *The Associated Press*. "If they don't, we will." See *Associated Press*, September 12, 2016; *The Local*, September 13, 2016.