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## LEGISLATION, REGULATIONS AND STANDARDS

### NTP Considers Listing Sodium Fluoride in Biennial RoC

The National Toxicology Program’s (NTP’s) Office of the Report on Carcinogens and Office of Health Assessment and Translation (OHAT) are **requesting** information about six substances, including fluoride (CASRN 7681-49-4), nominated for possible review and inclusion in future editions of the Report on Carcinogens (RoC). More specifically, NTP seeks (i) data about the compound’s current production, use patterns and human exposure; (ii) exposure studies evaluating adverse health outcomes, e.g., cancer, reproductive or immunological disorders; (iii) scientific issues relevant to prioritizing adverse health outcomes; and (iv) names of scientists with proven expertise about the chemical. OHAT is also interested in obtaining material about non-cancer health outcomes related to fluoride exposure, e.g., developmental neurotoxicity and endocrine disruption. Information submissions must be received by November 6, 2015. *See Federal Register*, October 7, 2015.

### Biotechnology Product Regulation Target of Upcoming Public Meeting

Three federal agencies are **convening** an October 30, 2015, public meeting in Silver Spring, Maryland, to discuss a July 2015 memorandum issued by the Executive Office of the President (EOP) directing the agencies to clarify their roles in the oversight of biotechnology products, develop long-term regulatory strategies and commission an independent study of the biotech landscape. The EOP memo defines biotechnology products as those “developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes.” The meeting will include presentations by representatives of the Department of Agriculture, Environmental Protection Agency and Food and Drug Administration (FDA) about each agency’s current approach to biotech product regulation.

Information about registration, oral presentations and viewing the meeting via live webcast is available on **FDA’s website**. *See Federal Register*, October 16, 2015.

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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](mailto:mboyd@shb.com).

## California Governor Approves Measure Limiting Use of Livestock Antibiotics

California Governor Jerry Brown (D) has signed legislation (**S.B. 27**) that prohibits administration of a “medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency” as of January 1, 2018.

Under the statute, antibiotics may be used only when ordered by a licensed veterinarian through a prescription or veterinary feed directive.

“The science is clear that the overuse of antibiotics in livestock has contributed to the spread of antibiotic resistance and the undermining of decades of life-saving advances in medicine,” Brown said. *See Signing Message of Governor Edmund G. Brown Jr.*, October 10, 2015.

## ASA Rules on Distillery and Bread Advertisements

The U.K. Advertising Standards Authority (ASA) has released a trio of decisions upholding complaints against two distilleries and a bread company over allegedly misleading advertisements. Ruling against Summerhall Distillery Ltd. in a complaint filed by a rival company, ASA **took issue** with advertisements for “hand crafted” Pickering’s Gin that touted Summerhall as Edinburgh’s first gin distillery in more than 150 years, a claim the authority found could not be substantiated.

“We considered that linking the product to the heritage of the spirit trade in Edinburgh and to imply that it was related to a revival of this industry was likely to be of particular interest to some consumers, and that its provenance in this context was therefore material information,” states ASA’s decision, which notes the presence of distillery operations within Edinburgh since 1863. “Because the claims had not been substantiated, we concluded that the ads were misleading.”

In addition, ASA **sided** with Alcohol Concern’s Youth Alcohol Advertising Council against Sibling Distillery Ltd., which described its eldest founder and owner as “only 23” on its website. According to the authority, “CAP Code required that ads for alcohol must not feature people under 25 years playing a significant role... Whilst we recognized that was a fact and not something that could be altered, the ad nevertheless featured people aged under 25 and we considered that because they were the owners of the business and the ad referred to their experience and background, they were playing a significant role.”

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The Real Bread Campaign (Sustain) also filed a **complaint** against Iceland Foods Ltd.'s advertisements for its line of frozen bread products, challenging the phrases "artisan" and "freshly baked" as well as a display of ingredients that did not include additives. In its adjudication, ASA partly upheld the complaints in relation to Iceland Foods' online video advertisement, which appeared to show a baker working inside a windmill to prepare bread dough by hand and bake it in a brick oven. Arguing that consumers would likely believe "the products in question were instead produced by hand, before being sold for home freezing and baking," the authority found misleading the video's depiction of the baking process and its suggestion that all products contained only a few select ingredients.

"We considered the claim 'our stone baked bread is made from the best wheat, sourdough, water, salt and an amount of yeast,' particularly in the context of the depiction of the baking process [], which we considered suggested the bread was handmade, was likely to be understood to mean the stone baked products included only the ingredients referred to," the ruling reiterates. "However, we understood the stone baked range included additional ingredients, such as dextrose, wheat gluten and vegetable oil. Because it suggested the stone baked bread range included fewer ingredients than was the case, we concluded that [the online video] was misleading."

### U.K. Regulator Calls for Research on "Internet of Things" and Food Safety

The U.K. Food Standards Agency (FSA) has **issued** a call for research exploring how the Internet of Things (IoT) could affect food safety. Working with The IT as a Utility Network Plus, FSA seeks short-term pilot studies "intended to test new ideas or create novel linkages between research areas." In particular, the joint initiative seeks to focus on (i) "IoT data, data standards and sharing"; (ii) "IoT transport and food, particularly temperature control"; (iii) "organizing hackathon events to exploit, disseminate and excite opportunities of IoT from farm to table"; and (iv) "what happens to food in people's homes." FSA will accept submissions until November 2, 2015.

### EFSA Risk Profile Assesses Use of Insect Protein in Food and Feed

The European Food Safety Authority (EFSA) has **issued** a scientific opinion assessing any potential risks associated with the use of insect protein in food and animal feed. Concluding that chemical and biological



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risks depend on production method, the type of substrate used, and insect species, the expert panel specifically notes that “the occurrence of prions—abnormal proteins that can cause diseases such as Bovine Spongiform Encephalopathy (BSE) in cattle and Creutzfeldt-Jakob Disease in humans—is expected to be equal or lower if the substrate does not include protein derived from humans (manure) or ruminants.” The report also calls for more data about the possible accumulation of cadmium, arsenic, lead, mercury, and other heavy metals in farm-raised insects.

“EFSA concludes that when non-processed insects are fed with currently permitted feed materials, the potential occurrence of microbiological hazards is expected to be similar to that associated with other non-processed sources of protein,” states a concurrent press release. “There are limited data available on the transfer of chemical contaminants from different types of substrate to the insects themselves.”

In a related development, an October 16, 2015, **feature article** in *Science* magazine examines insects as “an ideal animal feed,” noting that the European Union (EU) already funds research—known as PROTeIN-SECT—designed to weigh the risks and benefits of “industrial-scale” insect farming for livestock feed. According to the article, the Food and Agriculture Organization estimates “that insect meal could replace between 25% and 100% of soymeal or fishmeal” in the diets of many fish species, crustaceans, chickens and pigs “with no adverse effects.”

But U.S. and EU regulators are still concerned that insects could concentrate environmental toxins or pass along diseases, even as proponents of insect meal cite stringent BSE regulations as a roadblock to further development. The article concludes, “On many issues, however, there’s simply not enough information... Whether maggot-fed meat eventually makes its way to the table will depend in part on public acceptance.”

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## LITIGATION

### Papa John’s Franchisees to Pay Workers for Labor Violations

The U.S. Department of Labor and New York Attorney General Eric Schneiderman have announced that four Papa John’s Pizza franchisees have agreed to pay \$469,355 for labor violations. Back wages and damages will be distributed to 250 affected workers, to whom the franchisees failed to pay minimum and overtime wages and failed to provide one week’s worth of adequate uniforms.



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“Once again, we’ve found Papa John’s franchises in New York that are ripping off their workers and violating critical state and federal laws,” Schneiderman said. “Fast food chains across the state should be on notice: we will not stop until your workers are treated with respect and paid lawful wages. Once again, I call on Papa John’s and other fast food companies to step up and stop the widespread lawlessness plaguing your businesses and harming the workers who make and deliver your food.” See *New York State Office of the Attorney General Press Release*, October 15, 2015.

### Ninth Circuit Upholds Dismissal of Tin Can Conspiracy Allegations

The Ninth Circuit Court of Appeals has rejected Stanislaus Food Products Co.’s attempt to revive a lawsuit alleging that several major manufacturers of tin cans conspired to cede the market to a single company, USS-POSCO Industries (UPI). *Stanislaus Food Prods. Co. v. USS-POSCO Industries*, No. 13-15475 (9th Cir., order entered October 13, 2015). “This appeal, which centers on tin mill products used to package food, teaches that there’s no substitute for concrete evidence,” the decision begins.

Stanislaus, a tomato cannery, alleged that UPI, a joint venture of U.S. Steel and POSCO America Steel Corp., conspired with other tin mill producers to allocate the tin can market to UPI and fix the prices of tin mill products. Stanislaus cited the fact that POSCO never entered the western U.S. market as evidence of conspiracy; the court considered the practicality of the allegations and found them lacking. “A scheme like Stanislaus alleges would not be rational unless U.S. Steel had little competition outside of the western United States or the potential payoff through ownership of UPI was likely to be significant,” the court noted. Stanislaus’ evidence was also insufficient, the court found, because the fact the companies raised prices at similar times merely reflected fluctuations in the steel market. Accordingly, the Ninth Circuit dismissed Stanislaus’ appeal.

### Court Finds Insurer Must Cover Foster Farms’ *Salmonella* Losses

A California federal court has granted Foster Farms’ request for declaratory judgment finding that Lloyd’s of London must cover \$14 million in costs related to a *Salmonella* outbreak linked to Foster Farms’ chicken processing facilities. *Foster Poultry Farms Inc. v. Certain Underwriters at Lloyd’s London*, No. 14-0446 (E.D. Cal., order entered October 9, 2015).



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Foster Farms' policy with the insurer included coverage for "Accidental Contamination," requiring the company to show (i) "an error in the production of its chicken product" and (ii) that consumption of the product "would 'lead to' bodily injury." Lloyd's challenged Foster Farms' showing of the latter requirement, arguing the destroyed products were not actually contaminated with *Salmonella*. The court concluded the company had shown the products were contaminated because at the time the U.S. Department of Agriculture's Food and Safety Inspection Service issued its Notice of Suspension, Foster Farms' products had tested positive for *Salmonella* for six months, and three of eight samples taken the day of the notice were contaminated. "The average insured reading the Policy would not reasonably expect that to receive coverage in the event its product was contaminated, it would have to prove that each and every one of its products would cause harm if consumed; a reasonable probability of such harm occurring would be sufficient," the court said.

"It would also be unreasonable to imply that a product must first be put into commerce and injure somebody before the policy will provide coverage," the court found. "The parties could not have reasonably interpreted the policy to encourage a producer to sell goods that have been deemed unfit for consumption, risking the public welfare and subjecting itself to civil liability and criminal prosecution."

### Most Claims Dismissed in ECJ Case Against Whole Foods

A California federal court has dismissed without leave to amend several claims in a lawsuit alleging that Whole Foods Market fraudulently and misleadingly labeled its 365 Everyday Value ketchup, oatmeal and chicken broth as containing "evaporated cane juice" (ECJ) rather than "sugar." *Pratt v. Whole Food Mkt. Cal., Inc.*, No. 12-5652 (N.D. Cal., San Jose Div., order entered September 30, 2015).

The plaintiff alleged that because Whole Foods failed to use the most common name for the ingredient—as mandated by U.S. Food and Drug Administration rules—the products were misbranded and "cannot be legally sold, possessed, have no economic value, and are legally worthless." The court first dismissed strict liability allegations, finding that the plaintiff sought to impose a requirement inconsistent with federal law. Turning to the plausibility of the plaintiff's allegations, the court found his reliance claims contradictory because one claim required him to know nothing about ECJ while the other required him to know it was a sweetener. Neither allegation was plausibly pled, the court found. Accordingly, the court granted Whole Foods' motion to dismiss the strict liability claims and ECJ claims.

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The court allowed a misrepresentation claim about the use of artificial colors, flavors or preservatives in 365 Everyday Value Root Beer, Cola and Ginger Ale as well as Natural Italian Soda in green apple and blood orange flavors. Additional details about the case appear in Issue [519](#) of this *Update*.

### European Court Rejects “Halloumi” as Community Trade Mark

The European Union’s General Court has rejected an appeal to register “Halloumi” and its Greek alphabet equivalent as Community Trade Marks, deeming the terms descriptive of the cheese product. *Republic of Cyprus v. Office for Harmonisation in the Internal Mkt.*, Nos. T-292/14 and T-293/14 (Gen. Ct., order entered October 7, 2015). The application would have granted trademark protection for “Halloumi” within the European Union. Halloumi is set to receive Protected Designation of Origin status as a cheese produced on the island of Cyprus after the European Commission published the application to register the name in July 2015. As a trademark, however, the term is merely descriptive of the cheese product, the court found. “[T]he applicant acknowledges that the marks applied for have always been perceived by Cypriot consumers and by consumers across the European Union as referring to a particular type of cheese exported from Cyprus, made in a certain way and with particular taste, texture and cooking properties,” the court found. Because “Halloumi” does not indicate a particular manufacturing source, the court rejected the application, affirming a lower court’s ruling.

### CSPI Sues FDA for Failure to Act on Salt Petition

The Center for Science in the Public Interest (CSPI) has [filed](#) a lawsuit against the U.S. Food and Drug Administration (FDA) to compel the agency to act on the advocacy group’s 2005 citizen petition requesting regulations about the use of salt as a food additive. *Ctr. for Sci. in Pub. Interest v. FDA*, No. 15-1651 (D.D.C., filed October 8, 2015).

The petition called for FDA to revoke salt’s status as generally recognized as safe, amend prior approvals of salt use, require food manufacturers to reduce sodium levels in processed foods, and mandate labeling messages about the health effects of salt in foods containing more than half an ounce of the substance. The complaint alleges that while “[n]early all Americans consume more sodium than is safe,” “[c]onsumers can exert relatively little control over their sodium intake by adjusting discretionary use of salt” because such use amounts to only 5 to 10 percent of consumption; instead, the majority of the average American’s salt intake

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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.



is consumed via processed foods and restaurant food, CSPI argues. The organization asserts that the use of salt in food has resulted in “widespread” hypertension and pre-hypertension diagnoses.

Since CSPI filed its petition, FDA has held a public hearing and multiple comment periods about the use of salt and effects of sodium on health but has not issued any guidance or regulations, the complaint says. “For more than 35 years, FDA has dragged its feet and refused to do anything to protect Americans from excess sodium in the food supply,” CSPI Executive Director Michael Jacobson said in an October 8, 2015, press release. “The government’s inaction condemns hundreds of thousands of Americans to early deaths due to preventable strokes and heart attacks.”

### SCIENTIFIC/TECHNICAL ITEMS

#### Study Targets Arsenic Levels in U.S. Wine

A University of Washington study has allegedly found that many red wines produced in California, Washington, New York and Oregon contain arsenic levels exceeding the U.S. Environmental Protection Agency (EPA’s) limit for drinking water of 10 parts per billion (ppb). Denise Wilson, “Arsenic Content in American Wine,” *Journal of Environmental Health*, October 2015.

Authored by an electrical engineering professor, the study purportedly finds that all samples taken from 65 representative wines contained inorganic arsenic, with an average arsenic level of 23.3 ppb. In addition, 58 percent of the samples contained lead and 5 percent exceeded EPA’s lead limits for drinking water. A companion study notes that adults who consume high quantities of rice and infants who consume organic brown rice syrup could also be ingesting arsenic at levels that exceed maximum recommended amounts.

The research ultimately raises concerns about dietary exposure to arsenic from multiple sources, urging wineries to test for lead and arsenic in irrigation and processing water. As author Denise Wilson explains in a September 28, 2015, press release, “Unless you are a heavy drinker consuming wine with really high concentrations of arsenic, of which there are only a few, there’s little health threat if that’s the only source of arsenic in your diet. But consumers need to look at their diets as a whole. If you are eating a lot of contaminated rice, organic brown rice syrup, seafood, wine, apple juice—all those heavy contributors to arsenic poisoning—you should be concerned, especially pregnant women, kids and the elderly.”