Food Regulatory Update

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by

Melvin S. Drozen
Eve Pelonis
Fatima Aslam

KELLER AND HECKMAN LLP
1001 G Street, N.W.
Washington, D.C. 20001
Phone: (202) 434-4222
Fax: (202) 434-4646
drozen@khlaw.com

FOOD REGULATORY UPDATE

I. U.S. ACTIVITIES

A. FDA

FDA Publishes Operational Strategy for Implementing FSMA

On May 2, FDA published its "Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)," which will be considered the Agency's launching pad for all food safety efforts moving forward. The strategy is an overview of FDA's new approach to implement FSMA in food and feed facilities, produce safety operations, and import operations. The Agency's new plan is to "significantly expand its inspection and surveillance tools to include a wider range of inspection, sampling, testing, and other data collection activities conducted through its own field force and through collaboration with partner agencies and the food industries." The plan permits voluntary corrections of problems at the facility level (which will be achieved during inspections by FDA communicating with firm management), and at the district level through deficiency letters and follow up to verify correction. With respect to produce safety, the Agency will focus its efforts on "a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance, coupled with accountability for compliance from multiple public and private sources, including partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers." The document also reveals FDA's approach towards import oversight for which the Agency plans to use new and traditional tools to achieve FSMA compliance, such as commodity specific guidelines, outreach, technical assistance, reliable third-party audits, and compliance incentives such as less frequent or intense inspections for good performers. FDA's new operational plan is available at http://www.fda.gov/Food/GuidanceRegulation/FSMA /ucm395105.htm.

FDA Extends Comment Period for Proposed Rule on Sanitary Transportation

After requests from many food companies and trade groups, FDA has extended the comment period for the sanitary food transport rule by 60 days. The comment period is now open until July 30, 2014. Under the Food Safety Modernization Act (FSMA), shippers, receivers, and carriers that transport food by motor or rail vehicles must implement safeguards to prevent food contamination, such as certain refrigeration, cleaning, and protection measures. *See* the docket for the Sanitary Transportation of Human and Animal Food Proposed rule at http://www.regulations.gov/#!docketDetail;D=FDA-2013-N-0013, and for the Federal Register Notice *see* 79 Fed. Reg. 29699 (May 23, 2014) at https://www.federalregister.gov/articles/ 2014/05/23/2014-12002/sanitary-transportation-of-human-and-animal-food-extension-of-comment-period.

FDA Approves Use of New Sweetener, Advantame

A food additive petition for advantame, a sweetener derived from aspartame, has been approved by FDA. The petition was filed by Ajinomoto in 2009 for the use of advantame

in foods excluding meat and poultry products. FDA indicated that advantame can be used at self-limited levels, due to the fact that it is 20,000 times sweeter than conventional sugar. The acceptable daily intake (ADI) level for advantame is 1,970 mg per person per day, substantially higher than the estimated daily intake of only 10 mg per person per day for all persons of all ages at the 90th percentile. Ajinomoto plans to sell advantame to food manufacturers, rather than consumers. *See* the Federal Register Notice regarding FDA's approval of advantame at 79 Fed. Reg. 29078 (May 21, 2014) at https://www.federalregister.gov/articles/2014/05/21/2014-11584/food-additives-permitted-for-direct-addition-to-food-for-human-consumption-advantame.

Senator Schumer (D-NY) Urges FDA to Enact Ban on Powdered Alcohol

In a letter to FDA Commissioner Margaret Hamburg, Senator Chuck Schumer (D-NY) urged the Agency to ban the sale of Palcohol, a powdered alcohol substance. Palcohol is sold in ounce-size packets of freeze-dried vodka or rum. Because FDA regulates the safety of ingredients added to alcohol, Schumer wants FDA to utilize that power to ban Palcohol, as the Agency had done in 2010 with Four Loko, an alcoholic beverage with added caffeine. Palcohol is owned by Lipsmark, Inc., which says it was asked by the Alcohol Tax and Trade Bureau (TTB) to voluntarily withdraw the seven certifications of label approvals (COLA) it received from the TTB due to public outcry over the product. *See* Senator Schumer's press release regarding his request to ban powdered alcohol at http://www.schumer. senate.gov/record.cfm?id=3 50687&.

Over 4,800 Illnesses Caused by Pet Jerky Treats

FDA's latest update on the illness outbreak related to pet jerky treats imported from China states that it has received more than 4,800 complaints of illness in cats and dogs that ate chicken, duck, or sweet potato jerky treats, as well as complaints of illness in three humans who were also affected by the product. The Centers for Disease Control and Prevention (CDC) has not determined the root cause of the reported illnesses to date. The investigation for further conclusive data is still underway. Reports of illness originally surfaced in 2007. Petco and PetSmart recently announced plans to discontinue sales of pet treats made in China in response to FDA's latest report. Some manufacturers have also recalled their products, but reports of illnesses continue to surface. FDA plans to update its online case spreadsheets with information obtained from working with veterinarians at a later time. *See* FDA's update on the issue surrounding pet jerky treats at http://www.fda.gov/AnimalVeterinary /NewsEvents/CVMUpdates/ucm397713.htm.

Senate & House Appropriations Committees Advise FDA on How to Implement FSMA

The Senate Appropriations Committee said FDA should re-propose all of the produce safety and preventive controls for human and animal foods under FSMA, not just the most controversial parts. In the report for USDA and FDA spending for fiscal year 2015, the Committee expressed concern that FDA is only focusing on addressing portions of the proposed rules, and asked FDA to ensure that the public can comment on all preventative controls for food requirements, accompanied by economic analyses.

The Committee also raised concerns about imports, noting that some food companies have expressed problems and delays with clearing shipments. The Committee suggested ensuring there are sufficient personnel and developing a process by which highly compliant importers may be released with minimal administrative disruption. FDA also was directed by the Committee to publish final advice for pregnant women on seafood consumption, a draft of which was published in early June. Furthermore, the committee approved an amendment to the spending bill that would require labeling of any genetically modified salmon.

The House has also directed FDA in how to implement FSMA. The House report recommends ways to label calories, determine nutrient content for variable standard menu items, and disclose nutrient content using a remote-access menu. Guidance on the use of natural claims on food products was also requested. The House report also cautions FDA's Dietary Guidelines Advisory Committee about going outside the scope of the panel with evaluations of sustainability, climate change, and other environmental factors. It further indicated that, if the advisory group moves forward with recommendations on those bases, as opposed to purely nutritional science, USDA should reject the recommendations of the committee for labeling. Aside from food for human consumption, the House also requested an update on the ongoing pet jerky treat contamination issue. *See* the Senate Committee's report at http://www.appropriations.senate.gov/news/committee-approves-fy-2015-spending-allocations-military-construction-and-veterans-affairs, and the House Committee's report at http://appropriations.house.gov/news/documentsingle.aspx?DocumentID=380251.

OMB Publishes FDA Semi Annual Regulatory Agenda

Final menu and vending machine calorie disclosure rules are expected this month, according to the spring 2014 Unified Agenda released by the White House. In July, FDA expects to publish supplemental FSMA regulations regarding produce safety, preventive controls for human and animal foods, and the Foreign Supplier Verification Program.

Below is a list of the status of other forthcoming rules from FDA:

- FSMA Amendments to Reportable Food Registry (RFR Requirements)(0910-AG97): Prerule stage; comments due June 9; FDA has not provided a proposed rulemaking date.
- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; and Modifying the Reference Amounts Customarily Consumed (RACCs) (0910-AF23): Proposed rule stage; rule proposed. March 3; regulatory agenda does not include projected final rule date.
- Updated Standards for Labeling of Pet Food (0910-AG09): Proposed rule stage; proposed rule expected October 2014, five months later than the June 2014 deadline set by FDA in last regulatory agenda.
- Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Animal Food (0910-AG10): Proposed rule stage; comment period has been

extended twice; plans to publish supplemental proposal in July, and final rule in August 2015.

- Produce Safety Regulation (0910-AG35): Proposed rule stage; rule proposed January 16, 2013; comment period extended three times, Environmental Impact statement underway; plans to re-propose certain parts of the rule in July and final rule by October 2015.
- Reports of Distribution and Sales Information for Antimicrobial Active Ingredients Used in Food-Producing Animals (0910-AG45): Proposed rule stage; proposed rule expected September 2014, four months later than last regulatory agenda.
- Foreign Supplier Verification Program (0910-AG64): Proposed rule stage; rule proposed July 29, 2013; supplemental due July 2014, final rule scheduled for October 2015.
- Registration of Food Facilities: Amendments to Food Facility Registration Requirements (0910-AG69): Proposed rule stage; proposal planned by September 2014, five months later than last regulatory agenda.
- Sanitary Transportation of Human and Animal Food (0910-AG98): Proposed rule stage; proposed rule issued February 5, 2014 and final rule expected March 2016.
- Food Labeling: Gluten-free Labeling of Fermented, Hydrolyzed, or Distilled Foods (0910-AH00): Proposed rule stage; proposal expected in September 2014, 5 months later than last regulatory agenda. Final Rule required under the Food Allergen and Consumer Protection Act was due in 2008.
- Food Labeling: Nutrition Labeling for Food Sold in Vending Machines (0910-AG56): Final rule stage; proposed rule published April 6, 2011; final rule anticipated June 2014.
- Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants (0910-AG57): Final rule stage; proposed rule published April 6, 2011; final rule expected June 2014.
- Veterinary Feed Directive (0910-AG63): Final rule stage; proposed rule published December 12, 2013; final rule expected by April 2015.
- Focused Mitigation Strategies to Protect against Intentional Adulteration (0910-AG63): Long-term action; proposed rule on December 24, 2013; final rule not expected until May 2016.
- Accreditation of Third Parties to Conduct Food Safety Audits and for Other Related Purposes (0910-AG66): Long-term action; proposed rule July 29, 2013; final rule not expected until October 2015.

See the semi-annual regulatory agenda at: http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&Image58.x=59&Image58.y=22&Image58=Submit.

FDA Extends Comment Period on Nutrition Facts Label Proposal

The comment period for the proposed nutrition facts labeling rule has been extended for 60 days until August 1. FDA has proposed to change the facts panel to include added sugar for the first time, new daily value listings, as well as changes to serving portions and references to amounts customarily consumed (RACCs). *See* FDA's press release on the comment period extension at http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm 398174.htm.

B. USDA

Memorandum of Understanding between USDA and CDC on Foodborne Illness

USDA's Food Safety and Inspection Service (FSIS) and CDC's Agency for Toxic Substances and Disease Registry (ATSDR) have entered into a Memorandum of Understanding (MOU) regarding foodborne illnesses. Both Agencies agreed the MOU will remain in effect for five years. The MOU lays out the roles of the respective agencies in investigating and identifying the sources of foodborne illnesses. FSIS has already begun implementing the MOU by providing training on FSIS regulations, statutes and outbreak investigation procedures to epidemiologists, environmental health scientists, and other experts from ATSDR. *See* the MOU at http://www.fsis.usda.gov/wps/wcm/connect/f09a7013-bb5b-4a2f-bb67-2a61928f77c9/MOU-FSIS-CDC-ATSDR.pdf?MOD=AJPERES.

USDA Study Evaluates Pesticide Trends

USDA's Economic Research Service (ERS) found that pesticide use in the U.S. grew three-fold between 1960 and 1981, and then began to decline from 1981 to 2008. Fluctuations in pesticide use between 1982 and 2008 were attributable to several factors, including changes in planted acreage, crop and input prices, weather, pesticide regulations, and the introduction of new pesticides and genetically modified crops. The types of pesticides used over the years have also varied considerably. Insecticide use has gone down dramatically, while the use of herbicides has gone up, and fungicide use has remained relatively stable. Corn, soybeans, cotton, wheat, and potatoes represented approximately 80% of the total volume of pesticides used on the 21 crops examined by ERS. *See* ERS's report on trends of pesticide use at www.ers.usda.gov/ersDownloadHandler.ashx?file=/media/1424185/eib124.pdf.

USDA to Test All Raw Beef Samples for *Salmonella*

All raw beef samples that are collected for routine *E. coli* testing by USDA's Food Safety and Inspection Service (FSIS) will now be tested for *Salmonella* as well. FSIS will also collect larger samples – now 325 grams, instead of 25 grams – in an effort to collect better data. FSIS is also considering a "moving window" approach to *Salmonella* testing, where it would evaluate a preset number of sequential samples from a single establishment in order to determine if the facility has sufficient control over *Salmonella* in raw products. Industry has asked FSIS to keep in mind that larger sample sizes may lead to an increase in the positive rate. *See* USDA's progress report for further details on its plans to test all raw

beef for *Salmonella* at http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/ topics/data-collection-and-reports/microbiology/annual-progress-reports.

OMB Publishes USDA Semi-Annual Regulatory Agenda

The semi-annual regulatory agenda for USDA features updates on the Department's expected publication dates for several proposed rules including: a proposed rule for the use of "natural" claims on meat and poultry (July 2014); a proposed rule for the recordkeeping requirements which establishes that grind raw beef products (July 2014); a proposed rule to permit the sharing of non-public safety, effectiveness, quality or investigatory data about FSIS-regulated products to other state and federal agencies and foreign governments (December 2014); and a proposed rule to add Namibia to the list of countries eligible to export meat products to the U.S. (December 2014); USDA will also issue an advanced notice of proposed rulemaking on control of *Listeria monocytogenes* in ready-to-eat meat and poultry products (December 2014); a final rule for the modernization of poultry slaughter inspection (July 2014); and a final rule on inspection of catfish (December 2014). *See* USDA's semi-annual regulatory agenda at http://resources.regulations.gov/public/component/main?__dmfClientId=1402688233825&__dmfTzoff=240.

Lawsuit Pushes USDA to Deem Drug-Resistant *Salmonella* Strains Adulterants

On May 28, the Center for Science in the Public Interest (CSPI) filed a lawsuit in the U.S. District Court for the District of Columbia to compel USDA to act on CSPI's 2011 petition, requesting the Department to declare four strains of antibiotic-resistant *Salmonella* as adulterants. The four strains were singled out by CSPI because of their prevalence, virulence, and association with several high-profile outbreaks in recent food-borne illness outbreaks. The suit claims USDA has violated the Administrative Procedure Act (APA) for failing to act in response to the petition, and asks for the court to order a response within 30 days of a court order. A previous court decision in 1974, *American Public Health Association v. Butz*, held that the presence of *Salmonella* was not an adulterant and that consumers should know raw meat and poultry has potential to carry such pathogens. *See* CSPI's press release on the lawsuit at https://www.cspinet.org/new/201405281.html.

C. General

NYC Mayor Continues Bloomberg's Efforts to Ban Sugar-Sweetened Beverages

New York City Mayor Bill de Blasio is urging the state's highest court to impose former Mayor Michael Bloomberg's proposed ban on sugar-sweetened beverages sold in containers larger than 16 ounces. Bloomberg had argued that the ban was needed, as more than half of the adult residents of New York City are overweight (57.5%), as well as nearly 40% of public school children in the city in grades K-8. The New York State Court of Appeals had upheld a lower court's decision, further supported by a state Supreme Court justice, that found Bloomberg's efforts illegal and an overreach of power, stating that he should have sought approval from the City Council before the city's Board of Health enacted the ban in September 2012. More recently, several groups including the National

Association for Hispanic Health, Mount Sinai Medical Center and Montefiore Medical Center, have filed an *amicus* brief in support of the ban. As soon as the brief was filed, it became the subject of a lawsuit against the City brought by the American Beverage Association and a collation of other groups, including a branch of the Teamsters Union, that are opposed to the proposed beverage limits. *See* Mayor Blasio's announcement at http://online. wsj.com/articles/new-york-city-soda-ban-fate-weighed-1401931286.

Children Found to Consume More Artificial Dyes than Previously Thought

A Purdue University study examined samples of over 100 food items and compared the levels of artificial colors found to the levels found in foods in a 1968 Certified Color Industry (CCI) study. Researchers found that the amount of per capita artificial food colors is over five times the amount of artificial colors found in the previous study, from 12 mg/capita/day to 62 mg/capita/per day. An FDA spokesperson said the Agency is undergoing an exposure assessment of certified color additives for food, and plans to present the results at the American Chemical Society annual meeting in August. Drinks are among the highest source of artificial colors in the American diet, due to the amount of beverages with artificial colors consumed in a single serving. *See* Purdue's study at http://cpj.sagepub.com/content/early/2014/04/21/000 9922814530803.abstract.

Industry Issues Guidelines for Protein Added to Dietary Supplements and Functional Foods

The Council for Responsible Nutrition (CRN), a Washington, D.C. based trade association that represents dietary supplement manufacturers and ingredient suppliers, has released guidelines for how manufacturers and marketers should calculate and declare the amount of protein for nutrition labeling purposes. CRN's members, which produce a large portion of the dietary supplements marketed in the U.S. and globally, are urged to comply with the guideline within a year. CRN's guidelines encourage the dietary supplement industry to include in their products protein that consists of a chain of amino acids connected by peptide bonds. If protein is being measured by nitrogen content, the guidelines suggest subtracting non-protein nitrogen containing substances, such as taurine or creatine, from the total nitrogen content to portray more accurate protein content. *See* the guidelines at http://www.crnusa.org/pdfs/CRN-Protein-Labeling-Guidance-BoardApproved0413.pdf.

"Natural" Claims Removed from Kashi Products

As part of the terms of the settlement of a class action lawsuit, Kellogg's has agreed to eliminate "All Natural" and "Nothing Artificial" from its Kashi line of products. Kellogg's is the latest of many food companies to opt to settle class action suits over natural claims, rather than engage in protracted litigation. In addition to removing the labels from products that contain alpha-tocopheral acetate, pyridoxine hydrochloride, calcium pantothenate, and hexane-processed soy ingredients, Kellogg's has agree to pay $5 million to the plaintiffs. The plaintiffs contend that they were misled by the natural claims and deceived into believing the products were worth the premium price paid for them because they lacked

synthetic or artificial ingredients. *See* additional details regarding Kellogg's decision at http://www.nbcnews.com/business/consumer/suit-prompts-kelloggs-drop-natural-labels-kashi-products-n100391.

NEHA Report Raises Questions about Ability of State and Local Investigators to Respond to Foodborne Illnesses

The National Environmental Health Association (NEHA), a national professional society for environmental health practitioners, has released a report on the Assessment of Foodborne Illness Outbreak Response and Investigation Capacity in U.S. Environmental Health Food Safety Regulatory Programs. NEHA's report is based on survey responses from food safety managers and directors within local, tribal, and state departments that conduct environmental investigations during foodborne disease outbreaks. It describes an on-going shortage of experienced environmental health professionals, due in part to shrinking budgets and an increasing numbers of retirements. *See* NEHA's report at http://www.neha.org/pdf/NEHA_FBIOutbreakCapacityAssessment_ResultsReport.pdf.

II. INTERNATIONAL NEWS

A. Europe

EFSA Raises Concerns Over the Increase in Mycotoxin Levels in Corn

EFSA has warned the European Commission that a temporary increase in the level of mycotoxins in corn and corn products can be a concern for human health. Mycotoxins are chemical compounds produced naturally by fungi, which can cause adverse health effects in humans and animals. EFSA's concerns stemmed from its review of data supplied by France, which reflects levels of mycotoxins in the 2013 corn harvest. France also expressed concerns in light of the new data, and requests a temporary derogation to the maximum levels of mycotoxins in corn and corn products. The Commission said it will consider several factors, including EFSA's recent advisory, in its decision regarding France's request. *See* EFSA's advisory regarding mycotoxin levels in corn at http://www.efsa.europa.eu/en/topics/topic/mycotoxins.htm.

EU Sets Limits on Cadmium in Chocolate and Infant Formula

The European Commission (EC) issued a new Regulation (EU) No 488/2014 on May 12 on the amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs. Cadmium is a heavy metal allowed in chocolate and other cocoa products. The amended regulation sets new limits on the maximum amount of cadmium, which will become effective January 1, 2019. It has also set limits on the amount of cadmium allowed in infant formula, which will become effective January 1, 2015. *See* the amended regulation at ec.europa.eu/dgs/health_consumer/docs/com_cadmium_201405_ en.pdf.