Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

FDA Issues Draft Guidance on Mandatory Food Recalls

Last week, FDA announced the availability of a draft guidance to instruct industry on the implementation of FDA's mandatory food recall authority. The Food Safety Modernization Act ("FSMA") enacted in January 2011 gave FDA recall authority with respect to FDA-regulated foods, other than infant formulas. Prior to enactment of FSMA, FDA relied on manufacturers to voluntarily recall food products. Now, FDA has the authority to recall food if it believes the food is adulterated or misbranded and the use of or exposure to such food will cause serious adverse health consequences or death to humans or animals. The new draft guidance, in Q&A format, answers questions such as, what foods are subject to FDA's mandatory food recall authority, what are the criteria for a mandatory recall, and what is the process FDA must follow for a mandatory recall. FSMA also requires the Department of Health and Human Services ("HHS") to submit annual reports to Congress on the use of the recall authority. This past February, FDA reported that since 2011, it has exercised its food recall authority only twice—in a 2013 recall of *Salmonella*-tainted pet treats and in a 2014 recall of dietary supplements.

Senators and Food Industry Urge $109.5M Funding for FSMA

Spurred by the ongoing *Listeria* outbreak linked to Blue Bell ice cream products, seven Democratic senators recently requested the Senate Appropriations Committee to fully fund FSMA by

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approving President Obama's Fiscal Year 2016 budget request for an additional $109.5M.

The senators said the funding "would enable FDA to retrain inspectors … hire technical experts to assist growers and food manufacturers … and build the new comprehensive food import oversight system provided for in the law." They also stressed that "having measures like this in place … [is] absolutely necessary to prevent future life-threatening outbreaks and costly recalls." Twenty-two major food and beverage companies and food industry associations have also asked for Senate support to increase funding for FDA's food safety budget.

Chocolate Maker Advocates for New Line for Added Sugars on Nutrition Labels
Mars Inc. recently announced its support for FDA's February 2014 proposal to include a new line item on nutrition facts labels for added sugars. The Agency's proposal received broad opposition from many big food companies, which have said that breaking out added sugar could mislead consumers because the body reacts the same to naturally occurring sugar as it does to added sugar, the change is unlikely to influence consumer behavior, and the requirement would be costly to industry. Mars has countered that more information won't harm consumers and voiced its support for the World Health Organization's and U.S. Dietary Advisory Committee's February 2015 recommendations that people limit added sugar to 10 percent of daily calories. Sugar is one of the few nutrients without a specific consumption level limit, and the February 2015 recommendations marked the first time the U.S. Dietary Guidelines Advisory Committee has recommended a specific limit for sugar. FDA has commented that it "appreciates the support and engagement of Mars and other companies in the important effort to reduce added sugar in the American diet." In addition to Mars, other candy and snack companies are vowing to increase the percentage of snacks and candy with 200 calories or less on the package, or to remove artificial flavors and colorings from candy.

California Senate Panel Crushes Sugary Drink Labeling Bill
Last week, a California senate panel defeated a proposal to introduce warning labels on sugary drinks after the measure failed to obtain the requisite number of votes needed to pass the senate's committee on health. The bill would have required manufacturers of beverages (such as sodas, sweet teas, sports drinks, and energy drinks) that have added sweeteners and contain 75 or more calories per 12 ounces to label their products with the statement "STATE OF CALIFORNIA SAFETY WARNING: Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." A similar measure was introduced in February 2014 but was also defeated months later.

European Commission Changes its Position on Transatlantic Cosmetics Trade
The European Commission ("Commission") recently published a new version of its position paper on cosmetics in the Transatlantic Trade and Investment Partnership negotiations with the United States. In contrast to the earlier version published in May 2014, the paper no longer contains a reference to "mutual recognition" of banned and authorized substances in cosmetics. Instead, the Commission calls for "collaboration in scientific safety assessment methods." This change calls into question the mutual recognition of substances banned in cosmetic substances in the EU but allowed in the United States. Indeed, the European Consumer Organisation noted that more than 1,300 substances are prohibited in cosmetics in the EU, compared to only 11 in the United States.

Other News
Food Industry Appeals Federal Court Ruling on Vermont GMO Labeling Law

Panera to Ban Artificial Ingredients from Food

USDA on Track to Approve Another GM Potato

Chicken Manufacturer to Eliminate Use of Antibiotics

Bill to Ban Horse Slaughter Introduced in Congress

EU Commission Authorizes 10 New GM Products

Regulatory Updates

FDA Publishes Risk Assessment Relating to Animal Drug Residues in Milk and Milk Products
In the April 30, 2015, *Federal Register*, FDA announced the availability of a risk assessment titled "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." The assessment provides a ranking model that considers the likelihood of various animal drug residues appearing in milk and milk products and will assist with reevaluating which animal drug residues should be included in milk testing programs. ***Comments are due July 29, 2015***.

AMS Reviews and Confirms Continuation of USDA Organic Regulations
In the May 6, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") issued a summary of its review of the National Organic Program ("NOP"), which determined the NOP is not overly complex and does not significantly overlap or conflict with other regulations. This document summarizes the findings of the AMS review and confirms continuance of USDA organic regulations and NOP rulemaking and development of guidance documents. ***The rule was effective on May 6, 2015***.

AMS Proposes to Amend Origin of Livestock Requirements for Dairy Animals
In the April 28, 2015, Federal Register, the AMS proposed to amend the origin of livestock requirements for dairy animals under the USDA organic regulations. The proposed action would allow a producer to transition dairy animals into organic production once, but after this one-time transition, any new dairy animals added to a dairy farm would need to be managed organically from the last third of gestation or sourced from diary animals that already completed their transition into organic production. The proposed rule also clarifies how breeder stock should be managed on organic livestock farms. ***Comments are due July, 27, 2015***.

FSIS Responds to Comments on Risk-Based Sampling of Beef Manufacturing Trimmings for *E. Coli*
In the April 29, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") announced the Agency is responding to comments on the September 19, 2012, Federal Register notice, "Risk-Based Sampling of Beef Manufacturing Trimmings for *Escherichia coli* O157:H7 and Plans for Beef Baseline" and is providing updates on how it is scheduling sampling for beef manufacturing trimmings. Additionally, the Agency announced it is changing its existing algorithms for sampling of bench trim and raw ground beef components other than trim to make them more risk-based. Finally, the Agency is making available the following report: "Effective Implementation of Beef Manufacturing Trimmings Sampling Redesign (MT60)." ***Design changes in bench trim and other ground beef components will be implemented July 28, 2015***.

FSIS Responds to Comments on Ongoing Equivalence Verifications of Foreign Food Regulatory Systems
In the May 8, 2015, *Federal Register*, FSIS responded to comments on the January 25, 2013, Federal Register notice, "Ongoing Equivalence Verifications of Foreign Food Regulatory Systems," which described how FSIS conducts ongoing activities that ensure imported meat, poultry, and egg products continue to meet U.S. standards after FSIS decides the foreign country's regulatory system meets all U.S. requirements in the same or an equivalent manner.

APHIS Issues Final Rule Amending Virus-Serum-Toxin Act Regulations
In the May 11, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") announced a final rule amending Virus-Serum-Toxin Act regulations. The final rule requires veterinary biologics, prepared under the veterinary practitioner exemption, to be prepared at the same facility the veterinarian utilizes in conducting the day-to-day activities associated with his or her practice. This exemption applies to veterinary biologics prepared by a veterinary practitioner solely for administration to animals in the

course of a state-licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship. ***The rule is effective July 10, 2015***.

RBCS Announces Final Rule for VACPG Program and Accepts Applications
In the May 8, 2015, *Federal Register*, *here* and *here*, USDA's Rural Business-Cooperative Service ("RBCS") published a final rule for the Value-Added Producer Grant ("VAPG") program. The final rule modifies the interim rule for VAPG based on comments received on the interim rule published on February 23, 2011, on the 2014 Farm Bill, and on an April 24, 2014, listening session on the VAPG provisions in the 2014 Farm Bill. The notice also announced the opening of the applications period. ***The rule was effective on May 8, 2015; comments are due July 7, 2015***.

NRCS Proposes Changes to National Handbook of Conservation Practices and Requests Comments
In the May 6, 2015, *Federal Register*, USDA's Natural Resources Conservation Center ("NRCS") announced its intention to issue a series of revised conservation practice standards in the National Handbook of Conservation Practices. Among others, these standards include: Amending Soil Properties with Gypsum Products, Animal Mortality Facility, Contour Orchards and Other Perennial Crops, and Controlled Traffic Farming. ***Comments are due June 5, 2015***.

APHIS Solicits Comments on Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research
In the May 1, 2015, *Federal Register*, APHIS announced receipt of a petition requesting to amend regulations to specify ethologically appropriate standards researchers must adhere to in order to promote the psychological well-being of nonhuman primates used in research, and solicited comments on the petition. ***Comments are due June 30, 2015***.

FNS Extends Comment Period for Proposed Revisions to Meal Patterns for Food Programs
In the April 27, 2015, *Federal Register*, USDA's Food and Nutrition Service ("FNS") announced an extension of the comment period for the January 15, 2015, proposed rule to change meal pattern requirements for the Child and Adult Care Food Program ("CACFP"). The proposed rule, required by the Healthy, Hunger-Free Kids Act of 2010, suggested changes based on the Dietary Guidelines for Americans, a report by the Institute of Medicine, and input from stakeholders, as well as cost and practical considerations for CACFP institutions and facilities. Several of the changes would be extended to the National School Lunch Program, School Breakfast Program, and Special Milk Program to increase consistency across all Child Nutrition Programs. ***Comment period is extended to May 27, 2015***.

FNS Publishes Correction to Final Rule on Professional Standards for State and Local School Nutrition Programs Personnel
In the May 7, 2015, *Federal Register*, FNS announced a correction to the final rule published in the March 2, 2015, *Federal Register*, "Professional Standards for State and Local School Nutrition Programs Personnel as Required by the Healthy, Hunger-Free Kids Act of 2010." The correction provides the missing regulatory text of hiring standards criteria for local educational agencies with 2,499 or fewer enrolled students. ***The final rule is effective on July 1, 2015***.

FNS Proposes Unified Accountability System to Ensure Compliance with National School Lunch Program and School Breakfast Program Requirements
In the May 11, 2015, *Federal Register*, the FNS proposed, in accordance with provisions of the Healthy, Hunger-Free Kids Act of 2010, revisions to the state agency's administrative review process to establish a unified accountability system designed to ensure that participating school food authorities comply with the National School Lunch Program and School Breakfast Program requirements. Among other procedures, the proposed administrative review process would retain key existing requirements from the Coordinated Review Effort and the School Meals Initiative, provide new review flexibilities and efficiencies for state agencies, and simplify fiscal action procedures. ***Comments are due July 10, 2015***.

APHIS Reopens Comment Period to Discuss Agricultural Coexistence Workshop
In the April 28, 2015, *Federal Register*, APHIS announced it reopened the comment period for issues and proposals discussed during the workshop on agricultural coexistence, held on March 12–13, 2015. ***Comments are due May 11, 2015***.

USDA Issues Proposed Rule Clarifying U.S. Antitrust Laws, Immunity, and Liability under Marketing Order Programs
In the May 6, 2015, *Federal Register*, USDA issued a proposal to amend general regulations for federal fruit, vegetable, and specialty crop marketing agreements and marketing orders accentuating the applicability of U.S. antitrust laws to marketing order programs' domestic and foreign activities. This proposed rule, which is issued under the general regulations for federal marketing agreements and orders, would also advise marketing order board and committee members and personnel of the restrictions, limitations, and liabilities imposed by those laws. ***Comment are due June 5, 2015***.

FDA Withdraws Draft Guidance Documents
In the May 6, 2015, *Federal Register*, FDA announced the withdrawal of 47 draft guidance documents, published before December 31, 2013, that have never been finalized. The Agency stated it was withdrawing the draft documents in order to improve the efficiency and transparency of the guidance development process. ***Comments are due June 5, 2015***.

Other USDA Announcements
• APHIS Prepares Pest Risk Analysis of Fresh Pitahaya Fruit Imported from Israel
• APHIS Proposes Amendments to Regulations to Allow Citrus Fruit from Peru into the United States
• APHIS Requests Comments on Preliminary Plant Pest Risk Assessment and Draft Environmental Assessment for Innate™ Potato
• APHIS Authorizes Interstate Movement of Fresh Sea Asparagus Tips from Hawaii into the United States
• AMS Requests Comments on Expanding Membership of U.S. Highbush Blueberry Council under the Blueberry Promotion, Research, and Information Order
• Agricultural Researcher Service Requests Comments on Intention to Grant Exclusive License to Field Pea

USDA Announced the Following Requests for Information
• Forest Products Removal Permits and Contracts
• Annual State Report on Verification of Supplemental Nutrition Assistant Program Participation
• Child Nutrition Program Operations Study-II (CN-OPS-II)
• 7 CFR part 215, Special Milk Program for Children
• Assignments of Payments and Joint Payment Authorizations
• Substantially Underserved Trust Areas (SUTA), 7 CFR 1700, Subpart D
• Data on Nonresident
• Consumer Complaint Monitoring System; the Food Safety Mobile Questionnaire
• Specialty Crop Block Grant Program—2008 Farm Bill
• Export Inspection and Weighing Waiver for High-Quality Specialty Grains Transported in Containers

USDA Announced the Following Proposed Information Collections
• Volunteer Service Agreements and Volunteer Service Time and Attendance Record

USDA Announced the Following Information Collections Have Been Revised and/or Extended
• Domestic Quarantine Notices

USDA Announced the Following Information Collections for Review and/or Extension
• Requirements for Requests to Amend Import Regulations
• User Fee Regulations

FDA Announced the Following Information Collections Have Been Submitted to OMB
• Administrative Practices and Procedures

FDA Announced the Following Collections Have Been Approved by OMB
• Premarket Notification for a New Dietary Ingredient

FDA Issued the Following Draft and Final Guidance Documents
Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls, May 7, 2015, *Federal Register*.

European Regulatory Updates

European Parliament Resolution Calls for a New EU Alcohol Strategy
On April 29, 2015, the European Parliament adopted a Resolution calling on the Commission to present a new EU Alcohol Strategy to cope with health harm for 2016–2022. The Resolution stresses the importance of better labeling of alcoholic drinks and the need to raise awareness of the dangers of drinking during pregnancy and drunk driving.

Food Fraud: Eurojust and Member States Succeed in Stopping Illegal Horsemeat Trade
On April 24, 2015, the European Union's judicial cooperation unit, Eurojust, and judicial authorities from France, Belgium, Germany, Ireland, Luxembourg, the Netherlands, and the UK succeeded in stopping an organized criminal network involved in the trade of illegal horsemeat. French authorities estimate that between 2010 and 2013, 4,700 horses unfit for human consumption were slaughtered and introduced into the food chain.

Commission Regulation (EU) 2015/647 on the Use of Certain Food Additives
On April 24, 2015, the Commission published Regulation No. 2015/647 amending and correcting Annexes II and III to Regulation (EC) No. 1333/2008 regarding the use of certain food additives.

Other European Regulatory Updates
• EFSA Extends Use of Extracts of Rosemary (E 392) in Fat-Based Spreads
• EFSA Reevaluates Dodecyl Gallate (E 312) as a Food Additive
• EFSA Reevaluates Ascorbic Acid (E 300), Sodium Ascorbate (E 301), and Calcium Ascorbate (E 302) as Food Additives

Upcoming Meetings, Workshops, and Conferences

Public Meeting titled *USDA's Receipt for Service Initiative to be held by the Office of Advocacy and Outreach*, **June 3, 2015**, in Washington, D.C.

Public Meeting to Discuss 38th Session of Codex Alimentarius Commission, **June 17, 2015**, in Washington, D.C.

FDA and AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*, **June 20–24, 2015**, in Indianapolis, IN.

General Conference Committee of the National Poultry Improvement Plan, **July 23, 2015**, in Salt Lake City, UT.

EFSA's 2nd Scientific Conference, **October 14, 2015**, in Milan, Italy.

Enforcement Updates

Recent Product Recalls
Recent food recalls involved undeclared ingredients, potential microbial contamination, and foreign matter contamination, among others.

Undeclared allergens accounted for fewer recalls than discussed in previous *Updates*, with only seven manufacturers recalling FDA-regulated products for this reason since we last reported on recalls in April 2015. The undeclared ingredients include raw cashews, coconut, milk, and eggs. USDA also reported several recalls for this reason (see below).

Microbial contamination accounted for several recalls since our April 2015 issue. FDA is investigating *Listeria* in ice cream products from several facilities of a creamery whose products were distributed to more than 20 states, as well as internationally. Walnuts, macadamia nuts, salad dressing, pasta salad, pine nuts, ice cream, frozen yogurt, sherbet, apple slices, frozen vegetables, and dog chew bones were recalled for being potentially contaminated with *Salmonella* or *Listeria*. In addition, queso fresco was recalled for potential contamination with *Staphylococcus aureus*. Medicated poultry feed was recalled for excess salt.

USDA also reported several recent recalls involving undeclared allergens in beef, chicken, sausage, and pork products. Other USDA-regulated product recalls included beef products due to *E. coli* contamination, pork products due to possible *Staphylococcal enterotoxin* contamination, and beef, chicken, sausage, turkey, and pork products for misbranding. Ground beef, grilled chicken, sausage, and baby food products were recalled due to possible foreign matter contamination. A meat processing company recalled several products due to excess nitrite levels and possible processing deviations. Finally, various products were recalled for containing chicken from an ineligible country.

View a complete list of product recalls for FDA-regulated products and USDA-regulated products.

Recent Warning Letters
Since we last reported on enforcement actions in April 2015, FDA posted warning letters to seafood processors, dairies, and other food companies for violations related to CGMP (current good manufacturing practice), commodity-specific regulations, labeling, illegal drug residues, unapproved drug claims, and cosmetics, among others.

FDA warned four seafood processing facilities for failing to comply with hazard analysis and critical control points regulations, for various CGMP violations, and for processing seafood in insanitary conditions. One bakery was warned for various CGMP violations, including failure to follow hygienic practices and failure to exclude pests from processing areas. An animal food manufacturer was warned for adding an unapproved food additive to its feed. FDA also warned nine dairy farms for selling cattle adulterated with illegal drug residue for slaughter.

FDA continues to review product labels for incorrect or incomplete claims. FDA cited a snack bar manufacturer and an organic pop maker for improperly labeling their products as "healthy" when the product does meet the requirements to make the nutrient content claim.

FDA ramped up its enforcement of dietary supplement manufacturers since our April 2015 issue. Five manufacturers were warned because their products contained Beta-methylphenethylamine, which is not a dietary ingredient, nor is it approved as a food additive. An additional 14 manufacturers were warned because their products contained 1,3-Dimethylbutylamine, which has not been approved as a dietary ingredient. One dietary supplement manufacturer was warned for various CGMP violations and for marketing unapproved drugs because its product is promoted for therapeutic claims.

Finally, in a rare warning letter to a cosmetics manufacturer, FDA warned a manufacturer of eye shadow products because the products contained the ocular pathogen *Bacillus cereus* and for manufacturing the cosmetics in insanitary conditions.

View FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

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