Food, Dietary Supplement & Cosmetics Regulatory Update
Vol. II | Issue 2 | January 2015 JONES DAY

Top Stories

FDA Publishes Draft EIS on Proposed Produce Safety Rule

Earlier this month, FDA published the draft Environmental Impact Statement ("Draft EIS") for the Proposed Rule for *Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption*. The proposed produce safety rule is one of five major rules under the Food Safety Modernization Act ("FSMA") expected to be finalized this year. Issuance of an EIS is required because of the significant scope of the proposal.

The Draft EIS focuses on four provisions of the proposed rule that could significantly affect the environment: the definition of "covered farms," water quality standards, the use of raw manure and compost, and provisions affecting domesticated and wild animals. Only the water standards were found to have a potentially significant adverse environmental impact. Even so, most covered farms would not have to switch from surface water to groundwater or treat their water with chemicals because the proposal provides flexible measures allowing time for potentially dangerous microbes in agricultural water to die off. The agency plans to hold a public meeting on the draft EIS on February 10, 2015, and will accept public comments through March 13, 2015.

European Parliament Passes Law Allowing Member States to Ban Bioengineered Crops

On January 13, 2015, the European Parliament approved legislation to allow individual

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member states the right to restrict or ban the cultivation of bioengineered crops within their own borders, even if their cultivation is permitted at the EU level. Tabled since 2010 because of disagreements among various interested parties, the legislation was finally approved by a vote of 480 to 159.

Under the new law, the European Food Safety Authority ("EFSA") will still assess bioengineered crops for health and environmental risks, but member states have the authority to ban such crops on other grounds, such as land planning, socioeconomic, and farm policy objectives. Member states may impose a ban unilaterally or negotiate particular restrictions with affected crop producers. The legislation also includes provisions to help prevent cross-product and cross-border contamination by bioengineered crops. The new law goes into effect this spring.

Public Interest Groups Urge FDA to Ban Retail Sale of Powdered Caffeine Products
Consumer groups and some lawmakers are pushing FDA to regulate the sale of powdered caffeine, following concerns that overdoses of the substance led to at least two deaths last year. In December 2014, the Center for Science in the Public Interest petitioned the FDA for a outright ban on the retail distribution of pure and highly concentrated caffeine as a dietary supplement. The petition argues these substances pose a "significant or unreasonable risk of illness or injury." A group of Democratic senators has called for similar action by the agency. FDA addressed the recent fatalities in a blog post last month and published a consumer advisory warning highlighting the serious risks of using pure caffeine products. The agency already regulates caffeine in coffee and other food products, and in 2009, FDA reminded several manufacturers that the addition of caffeine to alcoholic beverages has not been generally recognized as safe ("GRAS"). Currently, there are no formal rules regarding the sale of caffeine in its pure form.

2014 USDA Recall Summary Shows Significant Uptick in Products Recalled for Undeclared Allergens
According to its most recent annual recall summary, USDA recorded 94 meat and poultry recalls in 2014, up from 75 recalls in the prior year. Forty-three products were recalled for undeclared allergens, affecting more than six million pounds of meat and poultry—a staggering nine-fold increase in quantity compared to 2013. Other significant categories included contamination with Shiga toxin-producing *E. coli*, *Listeria*, or *Salmonella*. USDA classifies most recalls as Class I, the highest-risk level, which denotes a reasonable probability that eating the food would cause health problems or death.

Other News
Dietary Supplement Manufacturer Settles FTC Case Alleging Deceptive Claims About Speech-Disorder Treatment

Citing Preemption Reasons, Federal Court Overturns California's Foie Gras Ban

States Modify Inspection Laws to Accommodate Food Startups and Accelerators

Sen. Lamar Alexander Selected to Chair Senate Committee that Oversees FDA

FDA Announces Partnership with NIFA to Fund Food Safety Training and Technical Assistance

Regulatory Updates

FDA Releases Draft Environmental Impact Statement on FSMA Proposed Rule on Produce Safety
In the January 14, 2015, *Federal Register*, FDA announced the availability of a Draft EIS for the proposed rule establishing standards for the growing, harvesting, packing, and holding of produce for human consumption under the FSMA (see above story for additional details). FDA will hold a public meeting on the Draft EIS on February 10, 2015. ***Comments due March 13, 2015***.

FSIS Releases Establishment-Specific Data Release Strategic Plan
In the January 15, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") is announcing the availability of the draft Establishment-Specific Data Release Strategic Plan for sharing data on federally inspected meat and poultry establishments with the public. FSIS developed the Strategic Plan in response to memoranda released by President Obama and the Office of Management and Budget ("OMB"), an Executive Order, and internal agency recommendations that called for increased data sharing. ***Comments due March 16, 2015***.

USDA Proposes Revisions to Meal Patterns for Food Programs
In the January 15, 2015, *Federal Register*, USDA issued a proposed rule to change meal pattern requirements for the Child and Adult Care Food Program ("CACFP"), as required by the Healthy, Hunger-Free Kids Act of 2010. The proposed changes are 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. ***Comments due April 15, 2015***.

USDA Makes Determination of Nonregulated Status of Herbicide-Resistant Soybean and Cotton, Announces Availability of Petition for Nonregulated Status of Bioengineered Maize
In the January 20, 2015, *Federal Register*, USDA announced its determination that soybean and cotton genetically engineered for herbicide resistance by a particular company are no longer considered regulated articles under rules governing the introduction of certain bioengineered crops. USDA made the determination based on evaluation of publically available scientific data, data submitted by the company petitioning for a determination of nonregulated status, public comments, and environmental impact and plant pest risk assessments. The same day, in another *Federal Register* notice, USDA announced the availability of a citizen petition submitted for determination of nonregulated status of maize designated as event MON 87403, which has been genetically engineered for increased ear biomass. ***Comments due March 23, 2015***.

FSIS Announces 2015 Rate Changes for Inspection, Certification, and Laboratory Services
In the January 14, 2015, *Federal Register*, FSIS announced the 2015 rates that it will charge meat and poultry establishments, egg products plants, and importers and exporters for providing voluntary, overtime, and holiday inspection and identification, certification, and laboratory services. The 2015 services rates will be applied beginning in late February 2015.

USDA Withdraws Interim Rule on Importation Restrictions on Fish Susceptible to Viral Hemorrhagic Septicemia
In the January 16, 2015, *Federal Register*, USDA announced it is withdrawing an interim rule that established regulations to restrict the interstate movement and importation into the United States of live fish that are susceptible to viral hemorrhagic septicemia, a highly contagious disease of certain fresh and saltwater fish. USDA made the decision after reviewing public comments on publication of the interim rule.

FDA Releases Sunscreen Feedback Letters
In the January 7, 2015, *Federal Register*, FDA announced the availability of letters containing its initial determinations and feedback on safety and effectiveness data submitted by sunscreen manufacturers. The letters sought to demonstrate that certain active ingredients are generally recognized as safe and effective and not misbranded for use in over-the-counter sunscreen drug products (including cosmetics that are also over-the-counter sunscreen drug products). FDA is taking this action under the Sunscreen Innovation Act. ***Comments due February 23, 2015***.

FDA Announces Filing of Food Additive Petition for Use of Humic Substances as

Source of Iron in Animal Food
In the January 6, 2015, *Federal Register*, FDA announced the filing of a citizen petition that the food additive regulations be amended to provide for the safe use of humate, fulvic acid, and humic substances as a source of iron in animal feed. ***Comments due February 5, 2015***.

Other USDA Announcements
- USDA Announces Guarantee Fee Rates for Guaranteed Loans for Fiscal Year 2015
- USDA Extends Comment Period on Proposed Modifications to Organic Assessment Exemption Regulations

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections
- Food and Cosmetic Export Certificate Application Process

FDA Announced the Following Information Collections Have Been Submitted to OMB
- Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

FDA Announced the Following Information Collections Have Been Approved by OMB
- Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

USDA Announced the Opportunity to Comment on the Following Approved, Revised, and/or Extended Information Collections
- Pale Cyst Nematode
- Nomination Request Form for Animal Disease Training
- Animal Welfare
- Export Bonus Programs
- Rural Development Loan Servicing

USDA Announced the Following Information Collections Have Been Submitted to OMB
- Agricultural Labor Survey

Upcoming Meetings, Workshops, and Conferences

Meeting of the Codex Committee on Methods of Analysis and Sampling, **February 5, 2015**, in Washington, D.C.

FDA Public Meeting Regarding Draft Environmental Impact Statement on FSMA Produce Safety Proposal, **February 10, 2015**, in College Park, MD.

Meeting of the Codex Committee on Food Additives, **February 12, 2015**, in College Park, MD.

Meeting of the Codex Committee on Contaminants in Food, **February 23, 2015**, in College Park, MD.

Meeting of the FDA Science Board, **March 4, 2015**, in Silver Spring, MD.

Meeting of the Codex Committee on Residues of Veterinary Drugs in Food, **March 19, 2015**, in Washington, D.C.

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 misbranding, among others.

Undeclared allergens continue to be a major trigger of food recalls, with 20 manufacturers recalling products for this reason since we last reported on recalls in December 2014. According to FDA's website, more than half of such recalls were due to undeclared peanuts. Manufacturers and grocery stores also recalled products because of undeclared fish, shellfish, almonds, and foreign material.

There has been a major recall of Granny Smith and Gala apples due to *Listeria* contamination. Various products that used the contaminated apples have also been recalled, such as caramel apples and apple pistachio salads.

Several other products, including ice cream, sprouts, nutrition bars, fresh curds, cheeses, cookies, rice, bruschetta, smoked salmon, and walnuts, were recalled due to potential *Salmonella* or *Listeria* contamination.

Additionally, two weight-loss supplements were recalled after FDA discovered the products contained drug ingredients.

FDA recalled an eye-color cosmetic product for possible bacterial contamination and an anti-aging eye mask due to mold contamination.

Since we last reported on recalls, USDA reported more than 10 recalls involving undeclared allergens in beef products, pork products, canned soup, chicken, and chili. As noted in "Top News" above, this is a significant increase in recalls for undeclared allergens compared to 2013. Other recalls included beef for lack of inspection and possible foreign matter contamination, uncured bacon for labels that did not bear the USDA mark of inspection, smoked bacon for undeclared ingredients, and sausage pasta for undeclared pork.

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 December 2014, FDA posted warning letters to canned food processors, seafood processors, dairies, dietary supplement manufacturers, a pet food manufacturer, a cosmetics manufacturer, and other food companies for violations related to CGMP (current good manufacturing practice), commodity-specific regulations, labeling, illegal drug residues, and unapproved drug claims, among others.

FDA warned one food manufacturing facility for various CGMP violations, including packaging food in insanitary conditions and failure to protect against contamination of food by pests. Five acidified foods manufacturers, three located overseas, and one a manufacturer of canned dog and cat food were warned for various violations of the Acidified Foods and Emergency Permit regulations. One of these, a sauce manufacturer, was also warned for failing to declare major food allergens on the label. Seven seafood processing facilities, including three overseas, were cited for failing to comply with hazard analysis and critical control points regulations and for various CGMP violations. Some of the seafood processing facilities were additionally warned for processing seafood in insanitary conditions. FDA also warned eight dairy farms for selling cattle for slaughter adulterated with illegal drug residue. A juice manufacturer was cited for failing to comply with juice hazard analysis and critical control points regulations, for CGMP violations, and for insanitary conditions. Another manufacturer was warned because its products contained salicylic acid, an unapproved food additive.

FDA continues to review product labels for incorrect or incomplete claims. In recent warning letters, the agency cited two manufacturers for making "healthy" claims on chocolate products when those products failed to meet the nutrient content requirements

for such claims.

FDA also posted six warning letters to dietary supplement manufacturers, one located abroad. All six dietary supplement manufacturers were cited for CGMP violations, and three for marketing unapproved drugs because their products are promoted for therapeutic claims. Five of the dietary supplement manufacturers were also warned for insufficient labels, such as failing to list capsule ingredients on the label, failing to properly format a "Supplement Facts" label, failing to label the product as "dietary supplement," and failing to declare all common or usual names of each ingredient.

Finally, FDA is increasingly taking enforcement actions in the area of cosmetics regulation, reflected by an uptick in cosmetics recalls and warning letters in the last months. Most recently, FDA warned a skin care products manufacturer that therapeutic claims on its website—which FDA reviewed following a facility inspection—rendered the products unapproved new drugs.

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

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