Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

Commissioner Hamburg Resigns After Six-Year Tenure as FDA Head
Dr. Margaret Hamburg has announced she will resign from her post as FDA Commissioner in March 2015, citing her long service to the agency and the heavy demands it entailed. Until President Obama nominates a new commissioner, FDA's chief scientist Dr. Stephen Ostroff will fill the position.

Federal Court Dismisses Case Challenging USDA's New Poultry Inspection System
On February 9, 2015, the U.S. District Court for the District of Columbia dismissed a lawsuit challenging USDA's New Poultry Inspection System ("NPIS"), a rule finalized last summer to allow for more offline inspections at poultry processing plants. Food & Water Watch had filed a complaint alleging the new rule threatens public health by eliminating inspection resources and allowing slaughterhouses to dramatically increase their processing line speeds. In dismissing the case, the judge described the allegations as based "on anecdotes and speculation."

Under the rule, establishments may elect to adopt NPIS by February 23, 2015. Slaughterhouses adopting NPIS would be required to sort poultry carcasses before they are sent down the line for inspection by USDA—a new allocation of responsibility intended to free up federal inspectors to concentrate on offline inspection activities, such as verifying sanitation standards and conducting Food Safety Assessments.

CONTACTS

Mark Mansour
Washington

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Emily K. Strunk
Washington

Katherine M. Llewellyn
Brussels

Ales Bartl
Brussels

Stephanie L. Resnik
Washington

Brigid C. DeCoursey
Washington

Matthew R. Bowles
Washington

Detailed Contact Information

UPCOMING EVENTS

February 23–24, 2015: **Mark Mansour** will speak at the Food and Drug Law Institute's program *Introduction to Food Law and Regulation: The Legal Framework for Food Regulation*.

February 25, 2015: **Tracy Stitt** will moderate at the Food and Drug Law

GenomeTrakr Helps FDA Pinpoint Source of Foodborne Outbreaks
This month, FDA unveiled new technology the agency is using to trace bacterial pathogens back to their sources faster and more precisely than traditional testing methods. The GenomeTrakr database combines big data analytics and whole genome sequencing to compare pathogens in food samples to pathogens isolated from sick patients.

Institute's program *Counterfeiting: Strategies for Supply Chain Security, Patient Safety and Brand Protection*.

RELATED PRACTICES

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Alice Welch, director of FDA's Technology Transfer Program, described the new initiative in a recent blog post: "If the isolates from food or environmental samples match the pathogens taken from the sick patients, scientists can establish a reliable link that helps characterize the size and location of the foodborne disease outbreak." This real-time information will help public health officials home in on contaminated ingredients and remove them from the food supply. It is estimated that foodborne illnesses contribute to 325,000 hospitalizations and 3,000 deaths in the United States every year.

Belgian Regulator Provides Safety Advice on Insects Intended for Human Consumption
The Belgian Food Safety Agency recently provided advice on the microbial and chemical safety of insects intended for human consumption. According to the agency, the presence of pathogenic bacteria and spores from the production environment bearing the potential to infect both the insects and consumers cannot be ruled out. The report advises that a heating step is indispensable before products are put on the market or consumed and that labels should appropriately warn consumers of possible allergic reactions. Currently, there are no specific regulations in Belgium or in Europe regulating insects for human consumption.

FDA Issues Constituent Update on Microbiological Safety of Cosmetics
Earlier in February 2015, FDA issued a constituent update on the microbiological safety of cosmetics, describing the agency's ongoing investigation of the health risks of bacterial and fungal contamination of cosmetics and the industry's best practices for addressing these risks. Under the law, cosmetic manufacturers must ensure their products are free of harmful microorganisms, or such products will be considered adulterated or misbranded. This update builds upon earlier work by FDA to gather information on microbiological safety and provides links to related guidances, FAQs, import surveillances, and consumer alerts.

Other News
Federal Court Approves Consent Decree Against Food Producer for Manufacturing Soy Products in Unsanitary Conditions

Dietary Supplement Maker Subjected to Permanent Injunction Because of Unsubstantiated Claims

Democratic Lawmakers Introduce Bill to Require Labeling of Bioengineered Foods

FDA, AFDO to Host Conference on Science Transforming Policy in Food, Drug, and Medical Device Regulation

CFSAN Teams Up with University of Maryland for Webinar Series on Dietetics and Nutrition

Regulatory Updates

FDA Announces Withdrawal of Guidance, Replaced by Final Rules on Menu and Vending Machine Labeling

In the February 9, 2015, *Federal Register*, FDA announced the withdrawal of a guidance titled *Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws*, dated August 2010. The withdrawn guidance has been superseded by FDA's issuance of final rules on menu and vending machine labeling.

FDA to Host Public Meeting, Solicit Comments on Feasibility of Revisions to Combination Drug Medicated Feeds Regulation
In the February 13, 2015, *Federal Register*, as part of its Animal Drug User Fee Amendments of 2013 goals, FDA announced a public meeting and a request for comments to explore the feasibility of statutory revisions to requirements on the use of multiple new animal drugs in a single medicated feed. The meeting will be held March 16, 2015, in Rockville, MD. ***Comments due March 31, 2016***.

USDA Announces Proposed Changes to NPIP Program Standards
In the February 6, 2015, *Federal Register*, USDA issued a notice that proposed changes to the National Poultry Improvement Plan ("NPIP") program standards are available for review and comment. The NPIP program is a cooperative federal-state-industry mechanism for controlling certain poultry diseases, and participation by industry is voluntary. The proposed updates include changes to blood testing procedures for mycoplasma, bacteriological examination procedure changes for Salmonella, and the addition of newly approved diagnostic test kits. ***Comments due March 9, 2015***.

USDA Issues Final Rule Removing Packers and Stockyards Act Regulations
In the February 5, 2015, *Federal Register*, USDA issued a final rule removing certain regulations promulgated under the Packers and Stockyards Act, 1921. The revisions are required by sections of the Consolidated and Further Continuing Appropriations Act, 2015, and are being made without notice-and-comment rulemaking because it would be impracticable and unnecessary since Congress has ordered the rescission of these specific sections.

USDA Solicits Nominations for Advisory Committee on Agriculture Statistics
In the February 12, 2015, *Federal Register*, USDA issued an invitation for nominations to the Advisory Committee on Agriculture Statistics. Committee members serve two-year terms and advise the Secretary of Agriculture on the scope, timing, and content of the periodic censuses, surveys of agriculture, and other related surveys. ***Nominations due February 27, 2015***.

USDA Announces Review of Federal Milk Marketing Orders Pursuant to Regulatory Flexibility Act
In the February 11, 2015, *Federal Register*, USDA's Agricultural Marketing Service announced it is reviewing the federal milk marketing order ("FMMO") program using criteria under the Regulatory Flexibility Act. The FMMO program is designed to ensure a stable supply of fresh fluid milk for fluid processors and consumers by providing a framework to make buying and selling milk a more orderly process. The instant review seeks to determine whether the FMMO program should be continued without change, amended, or rescinded to minimize any significant economic impact of rules upon a substantial number of small entities. ***Comments due April 13, 2015***.

FDA Announces the Filing of Color Additive Petition for Egg Decorating Kits
In the February 5, 2015, *Federal Register*, FDA announced that a petition has been filed proposing that the color additive regulations be amended to provide for the safe use of mica-based pearlescent pigments in egg decorating kits for coloring eggshells.

USDA Reopens Comment Period for Proposed Rule on Fruits and Vegetables Notice Process
In the February 6, 2015, *Federal Register*, USDA announced it is reopening the comment period for a proposed rule, published September 9, 2014, that would amend the agency's fruits and vegetables regulations to provide for approval of all new fruits and vegetables for importation or interstate movement into or within the United States using a notice-based process. ***Comments now due March 10, 2015***.

AMS Announces Referendum on Honey Packers and Importers Order
In the February 12, 2015, *Federal Register*, USDA's AMS announced a referendum will be conducted April 13–24, 2015, among eligible first handlers and importers of honey or honey products to determine whether they favor continuance of the Honey Packers and Importers Research, Promotion, Consumer Education, and Industry Information Order.

Other USDA Announcements

- APHIS Releases Draft Environmental Assessment on Control of Emerald Ash Borer
- AMS Announces Continuance Referendum for Mango Promotion, Research, and Information Order
- USDA Announces Opportunity for Grain Inspection Designation in the Topeka, KS; Cedar Rapids, IA; Minot, ND; and Cincinnati, OH, Areas
- USDA Announces that Republic of Croatia is Free of Foot-and-Mouth Disease, Swine Vesicular Disease, and Rinderpest and Is Low Risk for Classical Swine Fever

USDA Announced the Following Information Collections Have Been Revised and/or Extended

- Agricultural Resources Management Survey and Chemical Use Surveys
- Importation of Peppers from the Republic of Korea
- Citrus Canker, Citrus Greening, and Asian Citrus Psyllid; Interstate Movement of Regulated Nursery Stock

USDA Announced the Following Information Collections Have Been Submitted to OMB

- Importation of Baby Squash and Baby Courgettes from Zambia

FDA Announced the Following Information Collections Have Been Submitted to OMB

- Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act
- Food and Drug Administration Recall Regulations
- Export of Food and Drug Administration Regulated Products: Export Certificates

European Regulatory Updates

Amendment to Regulation on Plastic Food Contact Materials
On February 5, 2015, Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance) was issued amending Annex 1, which establishes the Union list of authorized substances permissible for manufacture of plastic materials and articles.

EFSA Publishes Updates to Risk Communication Guidelines
On February 10, 2015, EFSA announced the publication of its updated *When Food Is Cooking Up a Storm—Proven Recipes for Risk Communications* guideline, which is aimed at promoting cooperation and coherence in risk communications. The new edition is available in EFSA's four working languages: English, French, German, and Italian.

EFSA Launches Public Consultation on Health Claims Related to Gut and Immune Function
On February 9, 2015, EFSA launched a public consultation giving stakeholders and other interested parties the opportunity to comment on the draft update of its guidance for health claims related to gut and immune function. ***Interested parties are invited to submit written comments by March 23, 2015***.

Upcoming Meetings, Workshops, and Conferences

Public Meetings on U.S. Positions for Codex Committees

- Contaminants in Food, **February 23, 2015**, in College Park, MD
- General Principles, **February 25, 2015**, in Washington, D.C.
- Pesticide Residues, **March 16, 2015**, in Arlington, VA
- Residues of Veterinary Drugs in Foods, **March 19, 2015**, in Washington, D.C.

Interagency Food Safety Analytics Collaboration Meeting, **February 24, 2015**, in Washington, D.C.

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

USDA Invitation-Only Workshop on Agricultural Coexistence, **March 12–13, 2015**, via webcast.

FDA Meeting on Regulation of Combination Drug Medicated Feeds, **March 16, 2015**, in Rockville, MD.

FDA-JIFSAN Dietetics and Nutrition Spring Webinar Series, **March 24 and April 20, 2015**, via webcast.

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

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

Enforcement Updates

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

Undeclared allergens continue to be a major trigger of food recalls, with more than 20 manufacturers recalling FDA-regulated products for this reason alone since we last reported on recalls in January 2015. The undeclared ingredients included egg, soy, peanuts, tree nuts, milk, and shellfish. USDA also reported several recalls for this reason (see below).

Microbial contamination also accounted for several recalls. Cheese, sour cream, seed mix, sunflower seeds, soybean sprouts, macadamia nuts, pecans, and walnuts were recalled for being potentially contaminated with *Salmonella* or *Listeria*. A line of dog food, beef trachea pet treats, and beef jerky pet treats were also recalled for potential *Salmonella* contamination. A protein powder and a sacha inchi powder were recalled for potential *staphylococcus enterotoxin* contamination, and red thread fish was recalled for potential *clostridium botulinum* contamination.

Several dietary supplement products were recalled after FDA discovered the products contained undeclared drug ingredients. A veterinary company also recalled a supplement marketed for horses for containing an unapproved new animal drug.

USDA also reported several recent recalls involving undeclared allergens in chili products, burritos, quesadillas, beef products, pork products, sausage, chicken breast fritters, and chicken steak. Other USDA-regulated product recalls included poultry, pork, and chicken stew products for lack of inspection. Bratwursts, chili products, burrito products, quesadillas, pork products, sausage products, chicken breast fritters, and chicken steak products were recalled for misbranding. Salami products were recalled due to possible temperature abuse, and boneless beef trims were recalled due to possible *E. coli* contamination.

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 January 2015, FDA posted warning letters to seafood processors, dairies, dietary supplement manufacturers, 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 two food manufacturing facilities for various CGMP violations, including packaging food in insanitary conditions and failure to protect against contamination of food by pests. Two seafood processing facilities were cited for failing to comply with hazard analysis and critical control points regulations, for various CGMP violations, and for processing seafood in insanitary conditions. FDA also warned eight dairy farms for selling cattle adulterated with illegal drug residue for slaughter. A manufacturer of medicated animal feeds was cited for various CGMP violations, including failing to properly identify, store, handle, and control drugs in the mixing areas.

FDA continues to review product labels for incorrect or incomplete claims. FDA cited a Japanese manufacturer of dumpling skin products for labeling violations related to serving size, saturated fat content, and calcium, iron, and calorie declarations. The manufacturer was further cited for failing to use the common or usual name on the label and for failing to include all required information in English.

Dietary supplement manufacturers have been the subject of increased enforcement action on several fronts. In early February 2015, a federal court granted summary judgment in favor of FDA and entered a permanent injunction against a dietary supplement manufacturer, effectively shutting it down for making unsubstantiated claims that its products could treat Alzheimer's disease, autism, fibromyalgia, and other medical conditions. In New York, the Attorney General issued letters to four major retailers "for allegedly selling store brand herbal supplement products in New York that either could not be verified to contain the labeled substance, or which were found to contain ingredients not listed on the labels" and is requesting that these retailers submit detailed information on each of the products. Finally, FDA posted seven warning letters to dietary supplement manufacturers. Four supplement manufacturers were cited for CGMP violations, and five supplement manufacturers were warned for marketing unapproved drugs because the products are promoted for therapeutic claims. Four of the dietary supplement manufacturers were also warned for insufficient labels, such as incorrect serving sizes, failure to include all required information in two languages, failure to identify the part of the plant from which ingredients are derived, failure to properly format a "Supplement Facts" label, and failure to include adequate directions for the supplement's intended use.

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

Jones Day FDA Regulatory & Compliance Counseling Contacts

Mark Mansour
Washington
+1.202.879.3883
mmansour@jonesday.com

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Emily K. Strunk
Washington
+1.202.879.3778
estrunk@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Ales Bartl
Brussels
+32.2.645.14.52
abartl@jonesday.com

Stephanie L. Resnik
Washington
+1.202.879.5458
sresnik@jonesday.com

Brigid C. DeCoursey
Washington
+1.202.879.3651
bdecoursey@jonesday.com

Matthew R. Bowles
Washington
+1.202.879.3604
mbowles@jonesday.com

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