**Food, Dietary Supplement & Cosmetics Regulatory Update**
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## Top Stories

**President's Budget Allocates $1.2 Billion for Programs Addressing Antibiotic Resistance and $110 Million to Implement Food Safety Modernization Act**

On February 2, 2015, President Obama released his proposed budget for fiscal year 2016. Among the items for food safety, the budget would nearly double the current level of funding devoted to combating antimicrobial resistance and would allocate additional money for FDA's ongoing implementation of the Food Safety Modernization Act ("FSMA"). Following a similar proposal by congressional Democrats, the budget also seeks to consolidate all federal food safety functions within a single agency under the U.S. Department of Health & Human Services.

The budget proposes more than $1.2 billion across various agencies for purposes of improving antibiotic stewardship, strengthening risk assessments and reporting, and promoting research in the health and agricultural sectors. These proposals, subject to congressional review and approval, would build on the administration's efforts to address a growing threat to public health. In September 2014, President Obama signed an Executive Order and issued a national strategy for coordinating efforts to stem the rise in antibiotic-resistant bacteria. According to the Centers for Disease Control and Prevention ("CDC"), antibiotic resistance is responsible for two million illnesses and 23,000 deaths in the United States every year.

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Additionally, the budget for FDA includes $109.5 million for FSMA implementation efforts. If approved in whole, 75 percent of these funds would go toward three primary initiatives: modernizing food inspection processes and training new employees; establishing a National Integrated Food Safety System for coordination among local, state, and federal regulators; and developing import safety systems as part of the Foreign Supplier Verification Program. Remaining funds would support technical staffing and efforts to improve the agency's risk analytics.

**USDA Proposes New Standards to Reduce *Salmonella*, *Campylobacter* in Poultry**
USDA's Food Safety and Inspection Service ("FSIS") recently issued and is seeking public comment on proposed standards designed to reduce *Salmonella* and *Campylobacter* in ground chicken, ground turkey, and poultry parts. The proposals are being made to implement the agency's 2013 action plan for reducing bacterial contamination in meat and poultry.

The pathogen reduction performance standards include goals for reducing illnesses from *Salmonella* by at least 30 percent and *Campylobacter* contamination by between 19 and 37 percent. The proposed regulations also would replace existing testing methods with a more routine sampling approach for all FSIS-regulated products subject to *Salmonella* and *Campylobacter* verification testing. *Salmonella* and *Campylobacter* bacteria, often found in the intestinal tracts of birds and other animals, are among the most frequent causes of food sickness. FSIS estimates the new regulations, combined with other initiatives, will help prevent about 50,000 cases of foodborne illness each year.

**Federal Lawmakers Introduce Bill Calling for Creation of Single Food Safety Agency, Private Enforcement of Food Regulations**
On January 28, 2015, a group of Democratic senators and representatives introduced the "Safe Food Act of 2015," a bill largely aimed at creating a new Food Safety Administration that would absorb and consolidate the food safety functions currently split between FDA and USDA—a reorganization plan mirroring the proposal outlined in President Obama's budget. The bill also contains provisions designed to encourage lawsuits against food manufacturers, as explained in a recent Jones Day *Alert*.

If enacted, the legislation would consolidate food safety authority for labeling, inspections, enforcement, and recalls. Sponsoring lawmakers hope this bill will continue to build on the progress made by FSMA, which was enacted in 2011 to refocus food regulators on the goal of preventing contamination rather than simply responding to outbreaks. It is unclear when or if the bill will be considered for a vote, as many of its provisions are likely to garner opposition from Republican lawmakers who control both chambers of Congress.

**Europe Reevaluates Controversial Use of BPA**
Recently, the European Food Safety Authority ("EFSA") reevaluated Bisphenol A ("BPA") exposure and toxicity, concluding there is "no health concern for any age group from dietary exposure or from aggregated exposure." This action coincides with similar findings in the United States, including an update by FDA late last year that BPA remains safe for "current approved uses in food containers and packaging." BPA is a chemical compound widely used in food contact materials, such as reusable plastic tableware and can coatings, but its residues can migrate to food and be ingested by consumers. BPA has been the subject of much debate in Europe in recent years, resulting in an EU-wide ban for use in infant feeding bottles since 2011 and France's ban on its use in all food packaging that went into effect earlier this year. In addition, EU authorities are currently assessing a proposal for restricting BPA in thermal cash register receipts.

**Susan Mayne Discusses New Role as Director of CFSAN**
In January 2015, FDA welcomed Susan Mayne, Ph.D., as its new Director of the Center for Food Safety and Applied Nutrition ("CFSAN"). An expert in nutrition, toxicology, and epidemiology, Mayne takes over the position from Michael Landa, who recently retired. In a question-and-answer posted on FDA's website, Mayne discusses her expectations about transitioning from academic research to public policy, and she explains that her focus in

the first 100 days will be listening to advisors inside and outside of FDA to develop key priorities for CFSAN. The post also indicates Mayne has recused herself from working on issues involving the dietary supplement industry because of a family connection to the industry.

**USDA to Host Interagency Meeting on Food Safety Analytics**
FDA, USDA, and CDC recently announced a joint, public meeting scheduled for February 24, 2015, to provide updates on interagency efforts for improving foodborne illness source attribution. Specifically, the Interagency Food Safety Analytics Collaboration will discuss harmonizing the agencies' source attribution estimates and other work undertaken since 2011. The all-day meeting will take place at USDA's offices in Washington, D.C. and will also be accessible via live webcast. Stakeholders must register in advance to participate in the meeting.

**Other News**
FDA Warning Letters Highlight Differences Between Cosmetics and Medical Devices

USDA Begins Organic Survey of All Known Organic-Certified and Exempt Producers

Legislators in Florida Introduce Labeling Bill for Bioengineered Foods

Colorado Lawmakers Consider Joining Five Other States in Ban on Powdered Alcohol

FDA Extends Comment Period on Updates to Redbook

U.S. Senator Demands FDA Investigation of Fatal *Listeria* Outbreak in Prepackaged Apples

## Regulatory Updates

**FSIS Announces Changes to *Salmonella* and *Campylobacter* Verification Testing Programs**
In the January 26, 2015, *Federal Register*, USDA's FSIS announced and requested comments on new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat ground chicken and turkey products (see story above for additional details). The notice also discusses plans to begin sampling raw chicken parts to gain additional information on the prevalence and microbiological characteristics of the two bacteria in those products. FSIS will post individual establishment category information for poultry carcasses beginning July 1, 2015. In addition, in March 2015, FSIS intends to begin an exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms. ***Comments due March 27, 2015***.

**FDA Extends Comment Period for Updates to the Redbook**
In the February 2, 2015, *Federal Register*, FDA announced an additional 90-day extension of the comment period for notification of public meeting and request for comments regarding its guidance titled *Toxicological Principles for the Safety Assessment of Food Ingredients*, also known as the Redbook. FDA is seeking to expand the scope of the Redbook to emphasize principles of safety and risk assessment shared across different regulatory contexts for foods and cosmetics, while still providing specific guidance for applying these principles in particular contexts. Stakeholders may provide suggestions for revising the Redbook, which was last updated in 2007. ***Comments due May 10, 2015***.

**USDA Announces Surplus Foods Available for 2015 Emergency Food Assistance Program**
In the January 21, 2015, *Federal Register*, USDA issued a notice announcing the surplus of purchased foods the agency expects to make available for donation to states for use in nutrition assistance under the Emergency Food Assistance Program in fiscal year 2015. Foods made available under this notice are distributed to eligible recipient agencies for use in preparing meals and/or for distribution to households for home consumption.

**FDA Extends Nomination Period for Nonvoting Member of CFSAN Advisory Committee**
In the February 2, 2015, *Federal Register*, FDA announced an extension of its call for nominations and for industry organizations to participate in the selection of nonvoting industry representatives to serve on the Food Advisory Committee for CFSAN. ***Nominations and participation letters due February 27, 2015***.

**FDA Solicits Nominations for Science Board**
In the January 23, 2015, *Federal Register*, FDA issued a notice requesting nominations for members to serve on the Science Board to FDA's Office of the Commissioner, Office of the Chief Scientist. The Science Board provides advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. ***Nominations due March 24, 2015.***

**USDA Amends Regulations to Allow Imports of Hybrid Unshu Oranges from Korea**
In the January 30, 2015, *Federal Register*, USDA issued a final rule amending citrus fruit importation regulations to allow the importation of commercial consignments of two Unshu orange hybrids from the Republic of Korea into the continental United States, subject to certain conditions. The final rule is effective immediately.

**USDA Issues Interim Rule Relaxing Handling Requirements of Certain Irish Potatoes Grown in Colorado**
In the January 22, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") issued an interim rule revising the minimum quantity exception for Irish potatoes handled under the Colorado potato marketing order, Area No. 3 (order). The interim rule increases the quantity of potatoes that may be handled under the order, without regard to the order's handling regulation requirements, from 1,000 to 2,000 pounds. ***Comments due March 23, 2015***.

**USDA Releases Pest List for Interstate Movement of Fresh Sea Asparagus Tips from Hawaii to Continental United States**
In the January 23, 2015, *Federal Register*, USDA announced the release of a pest list and risk management document regarding risks associated with the interstate movement of fresh sea asparagus tips from Hawaii into the continental United States. The agency has determined that application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the movement of fresh sea asparagus tips from Hawaii. ***Comments due March 24, 2015***.

**USDA to Grant Exclusive Licenses for Switchgrass, Smooth Bromegrass Varieties**
In separate notices in the January 22, 2015, *Federal Register*, USDA announced it intends to grant to the University of Nebraska-Lincoln exclusive licenses to the smooth bromegrass variety named "NEWELL" and the switchgrass variety named "LIBERTY." ***Comments due February 23, 2015***.

**Other USDA Announcements**
- USDA Makes Technical Correction to Exemption from Retail Pet Store Licensing
- AMS Decreases Assessment Rate for Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas
- AMS Announces Revision of Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for 2014–2015 Marketing Year
- USDA Provides Adjustments to Reimbursement Rates for Summer Food Service Program 2015

**USDA Announced the Opportunity to Comment on the Following Proposed Information Collections**
- Feral Swine Survey
- Data on Nonresident Applicants
- Assignment and Joint Payment Elections

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

- Interstate Movement of Sheep and Goats and Recordkeeping for Approved Livestock Facilities and Slaughtering and Rendering Establishments

**USDA Announced the Following Information Collections Have Been Submitted to OMB**

- Waivers Under Section 6(o) of the Food and Nutrition Act

## European Regulatory Updates

**EU Commission Issues Regulation on Carbohydrate Claim**
On January 6, 2015, Commission Regulation (EU) 2015/7 of 6 January 2015 authorizing a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012, was issued authorizing the claim that carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.

**EU Commission Issues Regulation Rejecting Certain Glucose Claims**
On January 6, 2015, certain health claims relating to glucose were rejected by Commission Regulation (EU) 2015/8 of 6 January 2015 refusing to authorize certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

**EFSA Launches Consultation on Caffeine Assessment**
EFSA announced it is seeking comments and feedback on a draft assessment finding that single doses of caffeine up to 200 mg and daily intakes of up to 400 mg do not raise safety concerns for adults in Europe. The public consultation is open until March 15, 2015, with a stakeholder meeting planned for the first week of March.

**EFSA Develops New Risk Toolbox**
EFSA's experts have developed a toolbox for risk ranking for prioritization of food and feed-related issues, on the basis of the size of anticipated health impact.

**European Parliament Calls for Country of Origin Labeling of Meat in Processed Foods**
In the wake of the EU horsemeat scandal, members of European Parliament have urged the European Commission to come up with a legislative proposal to make country-of-origin labeling mandatory for meat in processed foods. The nonbinding resolution made by the Environment, Public Health and Food Safety Committee on January 22, 2015 aims at ensuring more transparency throughout the food chain and restoring public confidence.

**Pesticides: Experts Endorse New EU List of Candidates for Substitution**
On January 27, 2015, EU Member State experts endorsed a European Commission proposal to establish a list of 77 candidates for substitution, i.e., pesticides for which national authorities need to carry out an assessment to establish whether more favorable alternatives to using the plant protection product exist, including nonchemical methods.

**EFSA to Reopen Opinion on Perchlorate in Fruits and Vegetables**
On January 23, 2015, EFSA announced it would reexamine its 2014 scientific opinion on perchlorate in food following confirmation there was a technical error in the estimation of consumer exposure to perchlorate in the diet.

**EFSA Announces More Open Plenary Meetings in Brussels**
On January 22, 2015, EFSA announced it would make it easier for external observers to attend open plenary meetings by increasing its scientific panels and Scientific Committee open plenary meetings to be held in Brussels. EFSA has also adjusted its Guidelines for Observers with the aim of simplifying participation.

**Commission Addresses Importing Organic Products from Korea into the EU**
Following the conclusion that the rules governing production and controls of organic production of processed agricultural products for use as food in the Republic of Korea are equivalent to those laid down in Regulation (EC) No 834/2007, the European Commission on January 23, 2015 issued Commission Implementing Regulation (EU) 2015/131, which amends Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries to include Korea.

## Upcoming Meetings, Workshops, and Conferences

Public Meetings on U.S. Positions for Codex Committees

- Methods of Analysis & Sampling, **February 5, 2015**, in Washington, D.C.
- Food Additives, **February 17, 2015**, in College Park, MD
- 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.

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

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.

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

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