Top Stories

White House Regulatory Agenda Forecasts Food Safety Regulations for 2015
The White House's most recent Unified Agenda outlines several major food regulatory initiatives by FDA and USDA for the coming year. The Unified Agenda is generally a good indicator of the administration's priorities for the coming year; however, these priorities can shift, and thus the dates are not firm.

According to the agenda, FDA is expected to finalize five major rules under the Food Safety Modernization Act: preventive controls for manufacturing human food (expected August 2015) and animal food (August 2015), produce safety standards (October 2015), foreign supplier verification program (October 2015), and third-party auditor accreditation rules (October 2015). The agency also anticipates publishing the Veterinary Feed Directive to require veterinarian supervision of certain antimicrobial drugs added to animal feed and water (April 2015) and plans a proposed rulemaking to consider conditions under which meat and poultry producers may use the voluntary claim "natural" on product labeling (September 2015).

USDA's 2015 initiatives include a proposed rulemaking to address contamination controls in cattle slaughterhouses (July 2015) and finalization of recordkeeping rules for establishments and retail stores that grind raw beef products (July 2015).
USDA Issues Rule for Raw Meat, Poultry Products that Contain Added Solutions
In a year-end announcement, USDA’s Food Safety and Inspection Service (“FSIS”) issued new labeling requirements for raw meat and poultry products that contain added solutions, such as saltwater and marinades. Under the final rule, such products must include descriptive labels disclosing the percentage of added solution and individual ingredients. The new requirements, which include specific words, font sizes, and type styles for the labels, are intended to ensure added solutions are "clearly and conspicuously" identified on each package. Approximately 60 percent of all raw meat and poultry products contain added solutions. Food producers must comply with the rule by January 1, 2016.

FDA Releases Final Guidance on Labeling of Certain Non-Malt Beers
On December 23, 2014, FDA issued final guidance on the labeling of certain non-malt beers, which are subject to FDA labeling requirements after a 2008 ruling by the Alcohol and Tobacco Tax and Trade Bureau declared that beers not meeting the definition of "malt beverage" are not subject to Federal Alcohol Administration Act labeling provisions. In this guidance, FDA clarifies that non-malt products must conform to FDA labeling regulations, including, among others, the requirement for a statement of identity, ingredient declaration, nutrition facts panel, and appropriate allergen labeling. Additionally, the Government Health Warning Statement under the Alcoholic Beverage Labeling Act continues to apply to these products. This guidance was issued in draft form in 2009, at which time FDA allowed manufacturers until January 1, 2012, to revise non-malt beer labels. The final guidance explains that all labels for these products should now comply with all applicable laws and regulations.

New EU Food Labeling Rules Take Effect
On December 13, 2014, the European Union's new food labeling rules, applicable to all food business operators concerning provision of information to consumers, came into effect. In particular, the rules require cafes and restaurants to list allergens, such as milk, soy, gluten, and nuts, on their menus. Prior to the new rules, allergen labeling was required only for prepackaged foods. The new rules, aimed at preventing misleading practices as well as ensuring that consumers receive clearer, more comprehensive and accurate information on food content, also require improved legibility of information, the listing of nano components as ingredients in certain foods, an indication of defrosted products, an indication of "formed meat" or "formed fish," and origin labeling for fresh meats.

FDA Reaffirms BPA Is Safe for Approved Uses in Food Packaging
Last month, FDA announced that current levels of the synthetic compound bisphenol A ("BPA") in food supplies do not pose a health risk in their currently approved uses. BPA is commonly used in disposable food and beverage containers, such as plastic bottles and metal can coatings, but the compound is banned by FDA for use in baby bottles, sippy cups, and infant formula packaging. Prompted by consumer group concerns, FDA's National Center for Toxicological Research initiated a four-year review of more than 300 scientific studies regarding the safety of BPA in food packaging. FDA's most recent announcement reaffirms earlier findings by the agency that BPA is generally safe for most food contact applications. Most study participants, including humans, metabolized ingested BPA into a nonharmful compound or quickly excreted it.

Other News
In Consent Decree Over Unsanitary Conditions, Food Processor Agrees to Cease Operations
House Committee Considers Legislation to Preempt Vermont's Bioengineered Food Labeling Law
FDA Food Advisory Committee Focused on Protecting Consumers from Chemical Contaminants
Responding to Citizen Petition, Cosmetics Manufacturer Says It Won't Use Certain Parabens in Products
**Regulatory Updates**

**USDA Proposes Rule on Livestock Marketing Facilities**
In the January 2, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service published a proposed rule to amend regulations governing facilities receiving livestock moved in interstate commerce through livestock marketing facilities, such as auction barns and buying stations. The proposal would revise several conditions under which livestock may move to such facilities without official identification or prior issuance of an interstate certificate of veterinary inspection or alternative documentation. **Comments due March 3, 2015.**

**USDA Issues Final Rule on Descriptive Designation for Raw Meat, Poultry Products Containing Added Solutions**
In the December 31, 2014, *Federal Register*, USDA's FSIS issued a final rule regarding the use of a descriptive designation as part of the product name on the labels of raw meat and poultry products that contain added solutions and that do not meet a standard of identity. The descriptive designation must include the percentage of added solution and the individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight. **The final rule is effective January 1, 2016.**

**FDA Issues Final Guidance on Labeling of Non-Malt Beers**
In the December 23, 2014, *Federal Register*, FDA announced the availability of final guidance titled *Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*. The document provides guidance to industry on how to label bottled or otherwise packaged beers subject to FDA labeling laws and regulations (see above news story for additional details).

**FDA Issues Compliance Policy Guide for Processed Seafood Products Made With Fish Protein**
In the December 23, 2014, *Federal Register*, FDA announced the availability of *Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein*. The final guide provides guidance for FDA staff on the agency's labeling requirements for processed and blended seafood products made primarily with fish protein.

**FDA Issues Draft Compliance Policy Guide for Crabmeat Contaminated with *E. Coli***
In the December 16, 2014, *Federal Register*, FDA announced the availability of a draft guidance for FDA staff, titled *Compliance Policy Guide Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of Escherichia coli*. This revised draft provides guidance for FDA staff on the level of *E. coli* in crabmeat at which the agency may consider the crabmeat adulterated with filth under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

**USDA Releases Draft Guidance on National Organic Program**
In the December 29, 2014, *Federal Register*, USDA announced the availability of a National Organic Program ("NOP") draft guidance document, titled *Natural Resources and Biodiversity Conservation for Certified Organic Operations (NOP 5020)*. This draft guidance document is intended for use by accredited certifying agents and certified operations and provides NOP's current thinking on the topic. Once finalized, this guidance document will be available from the NOP through *The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations*. **Comments due February 27, 2015.**

**USDA Issues Proposed Rule on Dairy Tariff-Rate Import Quota Licensing Program**
In the December 23, 2014, Federal Register, USDA announced a proposed rule regarding the issuance of licenses to import certain dairy articles under tariff-rate quotas as set forth in the Harmonized Tariff Schedule of the United States. The proposal would suspend, for an additional seven years, the historical license reduction provision (which is currently slated to expire with the beginning of 2016 quota year), modify procedures for collecting licensing fees, and require exclusive use of electronic communications in the application, reporting, and payment processes. Comments due February 23, 2015.

USDA Publishes Semiannual Regulatory Agenda for Fall 2014
In the December 22, 2014, Federal Register, USDA published its semiannual regulatory agenda, summarizing significant and other regulations being developed in agencies of USDA. The agenda is provided pursuant to Executive Orders 12866 and 13563, and also describes regulations being reviewed under the Regulatory Flexibility Act. USDA's complete regulatory agenda is available online at www.reginfo.gov.

USDA, Other Agencies Issue Joint Interim Rule on OMB's Uniform Requirements for Federal Award Programs
In the December 17, 2014, Federal Register, USDA and several other federal agencies issued a joint interim final rule implementing the final guidance Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance), published by the Office of Management and Budget on December 26, 2013. This interim rule applies to all federal financial award programs of USDA and other agencies, and it is expected to reduce administrative burden and risk of waste, fraud, and abuse for the approximately $600 billion annually in federal assistance. Comments due February 17, 2015.

USDA Proposes Rule Exempting Organic Products from Assessment Under Commodity Promotion Law
In the December 16, 2014, Federal Register, USDA announced a proposed rule to modify the organic assessment exemption regulations under 23 federal marketing orders and 22 research and promotion programs. Under the proposal, the regulations would be amended to allow persons that produce, handle, market, or import certified organic products to be exempt from paying assessments associated with commodity promotion activities, including paid advertising, conducted under a commodity promotion program administered by the Agricultural Marketing Service. The exemption would cover all "organic" and "100 percent organic" products certified under the National Organic Program regardless of whether the person requesting the exemption also produces, handles, markets, or imports conventional or nonorganic products. Currently, only persons that exclusively produce and market products certified as 100 percent organic are eligible for an exemption from assessments under commodity promotion programs. Comments due January 15, 2015.

USDA Issues Interim Rule on Noninsured Crop Disaster Assistance Program
In the December 15, 2014, Federal Register, USDA announced an interim rule implementing changes to the Noninsured Crop Disaster Assistance Program as required by the Agricultural Act of 2014. The interim rule includes changes to eligible crops, provisions governing eligibility of native sod acreage, additional coverage levels, and waivers of service fees and premium reductions for beginning, limited resource, and socially disadvantaged producers. Furthermore, the interim rule clarifies that the Farm Service Agency may set separate market prices for organic crops and for direct-to-consumer sales. The interim rule is effective immediately, with comments due February 13, 2015.

FDA Solicits Nominations for Voting Members of Food Advisory Committee

FDA Announces Filing of Advisory Committee Reports
In the December 30, 2014, Federal Register, FDA announced it has filed with the Library
of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2014.

**FDA Responds to Objections to Food Additive Final Rule**

In the December 24, 2014, Federal Register, FDA issued a notice responding to objections received on its final rule providing for the safe use of advantame as a non-nutritive sweetener and flavor enhancer in foods generally, except in meat and poultry. After reviewing the objections to the final rule, FDA concluded they do not provide a basis for modifying or revoking the regulation. FDA confirmed the effective date of May 21, 2014, for the final rule.

**Other USDA Announcements**

- USDA Amends Regulations on Importing Plants for Planting from Turkey, Canada, the Netherlands
- FSIS Proposes Allowing Lithuania to Export Meat to United States
- USDA Announces Renewal of National Advisory Committee on Microbiological Criteria for Foods
- USDA Solicits Nominations for Plant Variety Protection Board
- USDA Publishes Final Supplemental Environmental Impact Statement for the Conservation Reserve Program
- USDA Announces Availability of an Environmental Assessment and Finding of No Significant Impact for a Biological Control Agent for Asian Citrus Psyllid in the Contiguous United States
- USDA Issues Rule on Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance
- AMS Announces Decreased Assessment Rate for Domestic Dates Produced or Packed in Riverside County, California

**FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:**

- State Petitions for Exemption from Preemption
- Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types
- Guidance on Consultation Procedures: Foods Derived from New Plant Varieties
- Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant Facility Types

**FDA Announced the Following Information Collections Have Been Submitted to OMB:**

- Veterinary Feed Directive

**FDA Announced the Following Information Collections Have Been Approved by OMB:**

- Infant Formula Recall Regulations

**USDA Announced the Opportunity to Comment on the Following Proposed Information Collections:**

- USDA Foods in Schools Cost Dynamics
- Evaluation of Demonstration Projects to End Childhood Hunger
- Agriculture Wool Apparel Manufacturers Trust Fund

**USDA Announced the Opportunity to Comment on the Following Approved, Revised, and/or Extended Information Collections:**

- Emergency Management Response System
- Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products
- Importation of Tomatoes from the Souss-Massa-Draa Region of Morocco
- Marking, Labeling, and Packaging
- Advisory Committee and Research and Promotion Background Information
- Specialty Crop Block Grant Program
USDA Announced the Following Information Collections Have Been Submitted to OMB:

- Child and Adult Care Food Program Sponsor and Provider Characteristics Study
- Guidelines for the Transfer of Excess Computer or Other Technical Equipment Pursuant to Section 14220 of the 2008 Farm Bill
- Application of Laboratories, Transactions, and Exemptions
- Self-Certification Medical Statement

Upcoming Meetings, Workshops, and Conferences

Meeting to Discuss U.S. Positions for Codex Committee on Fats and Oils (Codex Alimentarius Commission), **January 13, 2015**, in College Park, MD.


EFSA Info Session on Applications—FIP Technical Meeting on Food Flavorings Applications, **January 20, 2015**, in Parma, Italy.

Meeting of the Codex Committee on Methods of Analysis and Sampling, **February 5, 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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