Top Stories

FDA Issues Draft Guidance On Food Allergen Labeling Exemption Petitions and Notifications
On May 7, 2014, FDA issued draft guidance, published in the May 8, 2014 edition of the *Federal Register*, entitled *Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications*. The guidance is intended to assist industry in preparing submissions that seek exemptions from the labeling requirements for ingredients derived from major food allergens. Federal law requires that food labels identify products containing major food allergens, such as milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. However, because ingredients derived from major food allergens may be modified to the extent that they do not trigger an allergic response, the law allows for two pathways through which a manufacturer can obtain an exemption from allergen labeling. The guidance attempts to address the relevant issues for manufacturers seeking an exemption. ***Comments must be submitted by September 5, 2014, to ensure consideration by FDA before it begins to work on the final version of the guidance.***

Preps for International Cosmetics Meeting
On June 4, 2014, FDA will hold a public meeting entitled "International Cooperation on Cosmetics Regulation ("ICCR")--Preparation for ICCR-8 Meeting" with the purpose of collecting public input on various topics related to the regulation of cosmetics. The feedback may be used by FDA in preparing for the ICCR-8 meeting in Canada this July.

FDA Releases FSMA Operational Strategy Document
On May 2, 2014, FDA released the Food Safety Modernization Act ("FSMA") Operational Strategy document, which, as required under FSMA, outlines the drivers of change in FDA's approach to food safety and the strategy FDA will use to implement that change. The document signals a shift to the next phase of FSMA implementation: the development of approaches to achieving industry compliance with FSMA. This next phase, and the basis for the Operational Strategy document, will also involve implementing a modernized strategic and risk-based framework for industry oversight. The Operational Strategy document will serve as a "launching pad" for all food safety efforts moving forward. In addition, FSMA is being implemented in two new FDA blogs: We're Reinventing Ourselves to Keep Your Food Safe and FDA Operations Team Prepares to

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Resources

- *Food, Dietary Supplement & Cosmetics Regulatory Update* Printable Version
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

Implement Food Safety Laws.

FDA Finalizes Rule Prohibiting Certain Nutrient Content Claims for DHA, EPA, and ALA Omega-3 Fatty Acids
On April 28, 2014, FDA finalized a rule prohibiting certain claims about omega-3 fatty acids on food and dietary supplement labels. FDA says certain nutrient content claims about omega-3 fatty acids interfere with the public's ability to comprehend the nutritional value of the product in violation of the Federal Food, Drug and Cosmetics Act ("FDCA"). FDA proposed the rule in 2007 after several seafood and fish oil producers notified FDA of their intention to make claims about omega-3 fatty acids in their products. The final rule, which adopts the proposed rule without substantive changes, requires compliance by January 1, 2016.

Vermont Enacts Nation's First Stand-Alone GMO Food-Labeling Law; New York May Be Next
On April 24, 2014, Vermont's legislature passed the first state law requiring food made with genetically modified organisms ("GMOs") to be labeled. Vermont's governor signed the bill on May 8, 2014, saying he agrees with the state legislature that residents "deserve to know what is in their food." The state is preparing to defend the new law against lawsuits contesting the measure on three constitutional grounds. The bill would specifically require that foods retailed in Vermont after July 1, 2016, that contain genetically modified ("GM") ingredients in an amount over 0.9 percent of the total weight of the food carry a label stating that the product "may be partially produced with genetic engineering." The bill exempts restaurant food and meat, milk, and raw agricultural commodities not grown with GM seed from the labeling requirement. Violators would face fines up to $1,000 per day. In New York last week, a mandatory GMO labeling bill cleared a legislative hurdle in the New York Assembly.

Flawed FDA Guidance on Evaporated Cane Juice Has Caused Chaos in Industry, Argues GMA, Chobani
According to a 92-page comment submitted by the Grocery Manufacturers Association ("GMA"), Chobani, Amy's Kitchen, Kind Healthy Snacks, and other food manufacturers on May 6, 2014, FDA's 2009 draft guidance on evaporated cane juice has contributed to a wave of class action lawsuits against manufacturers. The FDA guidance, which is often cited in such lawsuits, advises manufacturers not to use the term "evaporated cane juice" because "that term falsely suggests that the sweeteners are juice," urging industry to instead to use the term "dried cane syrup." The comment urges FDA to "declare evaporated cane juice as the name for the ingredient" and end the uncertainty among the industry and public that is fueling the class action suits.

FDA Issues 4th Annual RFR Report
On May 5, 2014, FDA issued the 4th Annual Reportable Food Registry ("RFR") report, covering the period September 8, 2012, to September 7, 2013. FDA uses the report as a valuable tool in tracking patterns of food adulteration in an effort to remove dangerous products from the marketplace. During Year 4, *Salmonella* from peanut butter, *Listeria monocytogenes* from imported salmon, and *E. coli* from various frozen foods resulted in the greatest number of reports.

Other News
FDA Releases Report on Efforts to Improve Compliance, Enforcement Data Transparency
FDA Warns of False or Misleading Claims for Treating Autism
FDA Issues Q&A for Brewers/Distillers on the FSMA Proposed Rule for Preventive Controls for Animal Food
FTC Urges Advertisers to Police False Weight-Loss Claims (*National Law Review*)
Partnership for Food Safety Education Seeks Abstracts for 2014 National Food Safety Education Conference
After Teen's Online Petition, Coke Removes BVO from Powerade
FDA Announces May 13 Webinar on Temporary Tattoos
Kellogg Agrees to No Longer Label Kashi Products as "All-Natural"

Regulatory Updates

FDA Issues Final Rule on Nutrient Content Claims for Omega-3 Fatty Acids
In the April 28, 2014 *Federal Register*, FDA issued a rule prohibiting certain nutrient content claims for foods containing omega-3 fatty acids, specifically ALA (alpha-linolenic acid), DHA (docosahexaenoic acid), and EPA (eicosapentaenoic acid). ***Effective January 1, 2016.***

FDA Issues Draft Guidance on Allergen Labeling Exemption Petitions and Notifications
In the May 8, 2014 *Federal Register*, FDA issued draft guidance for industry on the preparation of petitions and notifications for exemptions from the labeling requirements for major food allergens. ***Comments due September 5, 2014.***

FDA and FSIS Establish Congressionally Mandated MOU Transferring Siluriformes Fish Regulation to FSIS
On April 30, 2014, FDA and USDA–FSIS signed a Memorandum of Understanding ("MOU") to transfer regulatory oversight over Siluriformes fish and fish products, including commercial catfish, basa, pangasius, and swai/tra, from FDA to FSIS. The 2014 Farm Bill directed USDA to enter into an MOU with FDA to accomplish this transfer of regulatory responsibility. The MOU addresses the phased transition of responsibilities, dual-jurisdiction establishments, coordination in regulations, guidance, and outreach, as well as FDA's continued primary role in regulating all other fish and fish products.

USDA Issues Final Guidance on Products in the "Made with Organic" Labeling Category
In the May 1, 2014 *Federal Register*, USDA issued its final guidance intended for use by accredited certifying agents and certified organic operations. ***Effective May 2, 2014***.

USDA Issues Guidance on Substances Used in Post-Harvest Handling of Organic Products
In the April 25, 2014 *Federal Register*, AMS issued guidance on substances used in post-harvest handling of organic products. ***Comments due June 24, 2014***.

USDA Issues Proposed Rule on User Fees for Quarantine and Inspection Services
In the April 25, 2014 *Federal Register*, USDA proposed amending the user fee regulations by adding new fee categories and adjusting current fees charged for certain agricultural quarantine and inspection services. FDA also proposes adjusting or removing the fee caps associated with commercial trucks, commercial vessels, and commercial railcars. ***Comments due June 24, 2014.***

USDA Amends Select Agent and Toxin List Under Bioterrorism Protection Act
In the May 12, 2014 *Federal Register*, USDA made a technical amendment to its Select Agent and Toxin list, subject to biennial review and republication under the Agricultural Bioterrorism Protection Act of 2002. ***Effective May 12, 2014***.

FDA Issues Notice of Petition on L-Selenomethionine for Animal Feed
In the April 23, 2014 *Federal Register*, FDA issued a notice of petition proposing that the food additive regulations be amended to provide for the safe use of L-selenomethionine as a dietary source of selenium in feed for poultry, swine, and ruminants. ***Comments due May 23, 2014.***

FDA Issues Notice of Petition on Ethoxyquine for Animal Feed
In the April 25, 2014 *Federal Register*, FDA issued a notice of petition proposing that the food additive regulations be amended to provide for the safe use of ethoxyquin in rendered fats and oils used in animal feed. ***Comments on the environmental assessment due May 27, 2014.***

USDA Issues Final Rule on Trafficking Controls and Fraud Investigations for SNAP
In the April 24, 2014 *Federal Register*, USDA issued its final rule governing trafficking controls and fraud investigations. The final rule affirms the interim rule without change. ***Effective April 24, 2014.***

USDA Issues Final Rule on Chronic Wasting Disease Herd Certification Program
In the April 29, 2014 *Federal Register*, USDA issued its final rule establishing a program to control chronic wasting disease in farmed and captive deer, elk, and moose. ***Effective April 29, 2014***.

USDA Issues Direct Final Rule on Post-Inspection Adjustments
In the April 29, 2014 *Federal Register*, USDA issued a direct final rule to require that the scales used by stockyard owners, market agencies, dealers, packers, and live poultry dealers to weigh products must meet the requirements in the 2013 NIST Handbook 44. ***Effective June 30, 2014.***

USDA Issues Final Rule on Importation of Cape Gooseberry from Colombia
In the May 2, 2014 *Federal Register*, USDA issued its final rule on importing cape gooseberries from Colombia into the United States, focusing on protection against the introduction of plant pests. ***Effective June 2, 2014.***

USDA Amends Rule on Technical Assistance for Specialty Crops
In the May 6, 2014 *Federal Register*, USDA's Foreign Agricultural Service and Commodity Credit Corporation amended an existing provision of the regulations for the Technical Assistance for Specialty Crops program to comport with the 2014 Farm Bill. ***Effective June 5, 2014***.

USDA Issues Interim Rule on Irish Potatoes Grown in Washington
In the May 7, 2014 *Federal Register*, USDA's AMS issued an interim rule to exempt yellow fleshed and white skin (white types) potatoes from minimum quality, maturity, pack, marking, and inspection requirements for 2014–2015. ***Comments due July 7, 2014.***

FDA announced the opportunity to comment on the following proposed information collections:
• Voluntary Cosmetic Registration Program (***comments due May 23, 2014***)
• Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet (***comments due May 23, 2014***)
• Color Additive Certification Requests and Recordkeeping (***comments due May 29, 2014***)

USDA announced the opportunity to comment on the following proposed information collections:
• Environmental Monitoring Form (***comments due May 22, 2014***)
• Voluntary Labeling Program for Biobased Products (***comments due May 22, 2014***)
• U.S. Origin Health Certificate (***comments due May 23, 2014***)
• Blood and Tissue Collection at Slaughtering Establishments (***comments due May 23, 2014***)
• Animal Disease Traceability (***comments due May 23, 2014***)
• Nutrition Labeling of Major Cuts of Single-Ingredient Raw Meat or Poultry Products and Ground or Chopped Meat and Poultry Products (***comments due May 28, 2014***)
• Child and Adult Care Food Program Sponsor and Provider Characteristics Study (***comments due May 28, 2014***)
• Local Food Marketing Directories and Survey (***comments due May 29, 2014***)
• Importation of Animals and Poultry, Animal and Poultry Products, Certain Animal Embryos, Semen, and Zoological Animals (***comments due May 29, 2014***)
• National Research, Promotion, and Consumer Information Programs (***comments due June 6, 2014***)
• Citrus Canker; Interstate Movement of Regulated Nursery Stock and Fruit from Quarantined Areas (***comments due June 27, 2014***)
• Importation of Fruits and Vegetables (***comments due July 1, 2014***)
• National Animal Health Monitoring System Emergency Epidemiologic Investigations (***comments due July 1, 2014***)
• United States Standards for Grades of Maple Sirup (***comments due July 7, 2014***)
• Supplemental Nutrition Assistance Program High Performance Bonuses (***comments due July 23, 2014***)

USDA announced the following AMS Marketing Orders:
• Milk in the Appalachian and Southeast Marketing Areas
• Spearmint Oil Produced in the Far West; Additional Allotment Base
• Handling of Spearmint Oil Produced in the Far West; Salable Quantities and Allotment Percentages for the 2014–2015 Marketing Year
• Decreased Assessment Rates for Irish Potatoes Grown in Idaho and Oregon

Upcoming Meetings, Workshops, and Conferences

USDA's Rural Business Cooperative Service will host a public listening session in Washington, D.C. on **May 30, 2014. *Register by May 26, 2014. Written comments due May 30, 2014*.**

Public Meeting in preparation for the International Cooperation on Cosmetics Regulation Meeting (ICCR-8), **June 4, 2014** in College Park, MD.

Meeting of the Codex Alimentarius Commission, **June 18, 2014**, Geneva, Switzerland.

The General Conference Committee of the National Poultry Improvement Plan (NPIP) and the NPIP's 42nd Biennial Conference will be held on **July 10–12, 2014** in Charlotte, NC. Topics for discussion at the upcoming meeting include a *Salmonella* update from the industry and CDC and approval of rapid testing devices as well as APHIS budget and cooperative agreements updates.

The International Association for Food Protection will host its Annual Meeting on **August 3–6**, **2014** in Indianapolis, IN. The attendees will receive information on current and emerging food safety issues, the latest science, innovative solutions to new and recurring problems, and the opportunity to network with thousands of other food safety professionals.

Enforcement Updates

Recalls
Several ice cream products and baked goods were recalled for undeclared eggs. A variety of products were recalled for possible *Salmonella* and *Listeria* contamination. One type of cat food was recalled for *Salmonella* contamination, while a poultry feed was recalled for low vitamin and mineral content. Two kinds of processed meat, from different manufacturers, were recalled due to misbranding and undeclared allergens, while another was recalled because it was produced without import inspection.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.

Warning Letters
FDA again posted letters issued to dairies for illegal drug residues in their cows and to bakeries for unsanitary conditions. This week, FDA posted five letters addressed to seafood processing facilities in three states indicating they failed to comply with various HACCP and CGMP regulations. Additionally, two letters were posted for dietary supplement manufacturers whose products made therapeutic claims that render the products unapproved drugs under the Federal Food, Drug, and Cosmetic Act. FDA posted one letter noting violations of the low acid canned food regulations.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.