JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
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Top News

FDA Announces a $19M Budget for State Implementation of FSMA
FDA recently announced a funding opportunity of $19M to states that support the implementation of the Food Safety Modernization Act ("FSMA") Produce Safety rule, which became final last November and sets safety standards for the growing, harvesting, packing, and holding of produce for human consumption. FDA solicits applications for cooperative agreements with state regulatory agencies that help design a plan and infrastructure to implement the rule. The $19M allocated funds, which are available to any of the states and territories of the United States, can be utilized for planning, infrastructure building, training and education, and any other related activities the states believe will support produce safety. FDA considers collaboration with the states to be crucial for the successful implementation of the rule and therefore intends to allocate funds not only for fiscal year 2016 but for the following five years as well.

Ostroff to Lead FDA's Foods and Veterinary Medicine Program
When Michael Taylor leaves the post of FDA's Deputy Commissioner for Foods and Veterinary Medicine on June 1, 2016, Dr. Stephen Ostroff, former acting FDA Commissioner, will become the Deputy Commissioner for the program.

Mr. Taylor, a nationally recognized food safety expert, led the implementation of FSMA. He had previously served as administrator of USDA's Food Safety and Inspection Service ("FSIS"), where he spearheaded public health-oriented reform of FSIS, guided the

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development of new safety requirements for meat and poultry products, and addressed the hazard associated with *E. coli* O157:H7 in beef products.

Dr. Ostroff, before serving as acting FDA Commissioner, was named the agency's chief scientist in 2014 and was responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts. Dr. Ostroff joined FDA in 2013 as chief medical officer in the Center for Food Safety and Applied Nutrition ("CFSAN"), where he was a senior public health advisor to Mr. Taylor.

COOL Meat Labels Formally Repealed
On March 2, 2016, USDA formally issued a final rule amending the controversial country-of-origin labeling ("COOL") rule to remove beef and pork products from the requirement to indicate where animals were born, raised, and slaughtered before the meat could be considered domestic. Since 2008, Mexico and Canada have been fighting against the COOL rule, arguing the labeling requirements were unfairly discriminatory against their imports. Several alternatives were suggested over the years, such as implementing a voluntary COOL labeling program instead of a mandatory one. However, the United States lost this battle when the World Trade Organization ruled in favor of Mexico and Canada authorizing them to impose $1B in retaliatory tariffs on U.S. products. To avoid paying this sanction, Congress repealed the rule last December. The final rule ends a lengthy arbitration fight. *See* Regulatory Updates section for more information regarding this rule.

Senate Blocks Voluntary Biotech Food Labeling Bill
On March 16, 2016, the Senate failed to approve, with a vote of 48–49, a bill introduced by Sen. Roberts (R-Kan), chairman of the Senate Committee on Agriculture, Nutrition and Forestry, that aimed at providing a biotechnology labeling solution. The bill sought to create voluntary national standards for labeling food with genetically modified organisms ("GMOs") and to preempt states, such as Vermont, from passing laws that require food companies to label their biotech food or seed products as bioengineered. The approval of a voluntary versus a mandatory biotech labeling law has been under discussion for some time. The decision of the Senate could be considered a win for those environmental groups, organizations, and Democrats that refer to voluntary GMO labeling bills as "deny Americans the right to know" or "DARK" Acts. Alternatively, Republicans and major food and biotech companies claim mandatory disclosure would negatively affect the food industry as it could give consumers the misimpression that the government itself thinks genetically engineered food is not safe for consumers. Despite the bill having been rejected, Sen. Roberts, who thinks GMO labeling is a market issue, and clearly not a safety or health issue, said he will continue "to work on a solution to a critical problem that will face every American every day."

The House Agriculture Committee passed similar legislation on July 14, 2015, and is still awaiting the Senate's vote. For more details about this bill, see our previous Jones Day *Update*.

FDA Further Postpones Enforcement of Menu Labeling Rule
Dr. Susan Mayne, director of FDA's CFSAN, announced on March 9, 2016, that the compliance date for the menu labeling final rule would be delayed from December 1, 2016, "to the date that is one year after [FDA] issues final, Level 1 guidance on menu labeling." FDA was required to take this step as a result of language in a December 18, 2015, appropriations bill (Public Law 114-113). FDA is currently reviewing comments it received on the draft Level 1 guidance issued on September 11, 2015, but stated it will finalize it as soon as possible. Last July, enforcement of the final rule was also extended from December 1, 2015, to December 1, 2016, due to the complexity of its implementation. The rule requires calorie information to be listed on menus and menu boards of restaurants and other retail food establishments that are part of a chain of 20 or more locations, do business under the same name, and offer for sale substantially the same menu items.

Other News

Steven Tave, New Director of FDA's Office of Dietary Supplement Programs

South Africa Finally Accepts Meat Exports from the U.S.

Peru Lifts Restrictions on U.S. Beef Exports

Health Canada Approves J.R. Simplot GMO Potato

Regulatory Updates

FDA Issues Final Rule Prohibiting Certain Cattle Materials on Foods and Cosmetics
In the March 18, 2016, *Federal Register*, FDA issued a final rule prohibiting the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy ("BSE") in human food, including dietary supplements, and cosmetics. BSE is a fatal neurological disorder of cattle that has a long incubation period and that is transmitted when cattle ingest protein meal containing the BSE infectious agent. FDA has designated the following items as prohibited cattle materials: (i) specified risk materials, (ii) the small intestine from all cattle (unless the distal ileum has been removed), (iii) material from nonambulatory disabled cattle, and (iv) material from cattle not inspected and passed, or mechanically separated. ***The rule is effective April 18, 2016***.

FDA Issues Guidance on Acrylamide in Foods
In the March 11, 2016, *Federal Register*, FDA announced the availability of a guidance for industry titled "Acrylamide in Foods." The guidance finalizes the "Draft Guidance for Industry on Acrylamide in Foods" of 2013, which has been modified in response to comments the Agency received. Acrylamide, categorized by the National Toxicology Program as "reasonably anticipated to be a human carcinogen," is a chemical that may form in certain foods such as potato-based foods, cereal-based foods, and coffee during high-temperature cooking, such as frying, baking, and roasting. This guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods, which may mitigate potential human health risks from exposure to acrylamide.

FDA Issues Guidance for Animal Feed Safety
In the March 9, 2016, *Federal Register*, FDA issued a guidance for industry titled "Ensuring Safety of Animal Feed Maintained and Fed On-Farm," which intends to help animal producers (persons who feed animals) develop and implement on-farm practices to ensure the safety of animal feed maintained and fed to animals on the farm.

FDA Issues Dietary Supplement Labeling Guide
In the March 7, 2016, *Federal Register*, FDA issued a revised guidance for industry titled "A Dietary Supplement Labeling Guide: Chapter II. Identity Statement." This guidance is part of a longer guidance titled "A Dietary Supplement Labeling Guide," which covers the most frequently raised questions about the labeling of dietary supplements using a question-and-answer format and is intended to help ensure that the dietary supplements sold in the United States are properly labeled. The agency is revising the guidance to correct an inaccurate statement.

FDA Seeks Comments and Data on Assessing the Risk of Raw Manure as Fertilizer
In the March 4, 2016, *Federal Register*, FDA requested scientific data, information, and comments to assist the Agency in its plan to develop a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil of animal origin (including raw manure). The risk assessment will evaluate and, if feasible, quantify the risk of human illness associated with consumption of produce grown in fields or other growing areas amended with untreated biological soil that are potentially contaminated with enteric pathogens, such as *E. coli* O157:H7 or *Salmonella*. In addition, the risk

assessment will evaluate the impact of certain interventions, such as use of a time interval between application of the soil amendment and crop harvest, on the predicted risk. The risk assessment is intended to inform policy decisions with regard to produce safety. ***Comments are due May 3, 2016***.

AMS Amends COOL Regulations
In the March 2, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") amended the COOL regulations to remove muscle cut beef and pork and ground beef and pork from mandatory COOL requirements. Accordingly, changes have been made to the relevant Code of Federal Regulations sections, including definitions, country-of-origin notification, and recordkeeping. ***The rule was effective March 2, 2016***.

AMS Proposes to Amend Beef Promotion and Research Rules and Regulations
In the March 16, 2016, *Federal Register*, USDA's AMS proposed a rule to amend the Beef Promotion and Research Order established under the Beef Promotion and Research Act of 1985 to increase assessment levels for imported veal and veal products based on revised determinations of live animal equivalencies. The proposed rule would also update and expand the Harmonized Tariff System numbers and categories, which identify imported products to conform with recent updates in the numbers and categories used by the U.S. Customs and Border Protection. ***Comments are due May 16, 2016***.

FNS Proposes Rule Affecting the Supplemental Nutrition Assistance Program
In the March 14, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") proposed to implement Section 4018 of the Agricultural Act of 2014, which creates limitations on the use of federal funds authorized in the Food and Nutrition Act of 2008 ("FNA") for the Supplemental Nutrition Assistance Program ("SNAP") promotion and outreach activities. Among other things, Section 4018 prohibits, with some exceptions, the use of federal funds from being used for recruitment activities designed to persuade an individual to apply for SNAP benefits. Television, radio, or billboard advertisements that are designed to promote SNAP benefits and enrollment are also prohibited. Entities that receive funds cannot compensate any person engaged in outreach or recruitment activities based on the number of individuals who apply to receive SNAP benefits. This proposed rule would also affect the Food Distribution Program on Indian Reservations and the Emergency Food Assistance Program, both of which receive funding and/or foods authorized under the FNA. ***Comments are due May 13, 2016***.

FNS Issues Final Rule Related to the Special Supplemental Nutrition Program for Women, Infants, and Children
In the March 1, 2016, *Federal Register*, USDA's FNS issued a final rule in response to the proposed rule, published on February 28, 2013, implementing the provisions set forth in the Healthy, Hunger-Free Kids Act of 2010 ("HHFKA") related to electronic benefit transfer ("EBT") for the Women, Infants, and Children ("WIC") Program. EBT provisions of the HHFKA and other EBT implementation requirements included in this final rule are: (i) a definition of EBT; (ii) a mandate that all WIC state agencies implement the EBT delivery method by October 1, 2020; (iii) system management and reporting requirements; (iv) revisions to current provisions that prohibit imposition of costs on vendors; (v) a requirement for the Secretary of Agriculture to establish minimum lane equipage standards; (vi) a requirement for the Secretary of Agriculture to establish technical standards and operating rules; and (vii) a requirement that state agencies use the National Universal Product Code database. ***The rule is effective May 2, 2016***.

European Regulatory Updates

European Court Rules Against "Pro-Sugar" Advertising
In 2011, Dextro Energy, a company that produces energy tablets made up almost entirely of glucose sugar, requested authorization under the European Commission's ("EC") Health Claims Regulation to use the following health claims in advertising its products: "glucose is metabolized within the body's normal energy metabolism," "glucose contributes to normal energy yielding metabolism," "glucose supports physical activity," "glucose

contributes to normal energy yielding metabolism during exercise," and "glucose contributes to normal muscle function during exercise." Although the European Food Safety Authority ("EFSA") considered that a cause-and-effect link could be established between the consumption of glucose and normal energy-yielding metabolism, the EC refused to authorize such health claims in January 2015. The EC claimed the requested health claims conveyed a contradictory and ambiguous message to consumers, encouraging the consumption of sugar, which should instead be reduced. On March 16, 2016, the EU General Court confirmed the EC's decision.

EFSA Issues Guidelines for Food Crisis Communication
On March 15, 2015, EFSA published recommendations for communicating during a crisis. The guidelines are targeted to EU Member States' national food safety authorities, and they aim to ensure effectiveness, consistency, and coherence when communicating in a crisis. EFSA drafted the guidelines together with EU Member States based on best practices gained from previous food-related crises. Some of the recommendations include communicating in a clear and transparent manner and collaborating with foreign countries since a food-related crisis may not stop at the border.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the Fruit and Vegetable Industry Advisory Committee, **April 6–7, 2016**, in Arlington, VA.

Public Meeting of the National Organic Standards Board to assist development of standards for substances to be used in organic production and advise on the implementation of the Organic Foods Production Act, **April 25–27, 2016**, in Washington, D.C.

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