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

**FDA Issues Final Rule to Ensure Food Safety During Transport**
In early April 2016, FDA finalized the sixth major rule implementing the FDA Food Safety Modernization Act ("FSMA"). This latest rule, "Sanitary Transportation of Human and Animal Food," is designed to prevent food contamination during transportation. The rule will require shippers, receivers, loaders, and carriers involved in transporting human and animal food by motor or rail vehicle to follow recognized best practices for sanitary transportation, such as properly refrigerating food and maintaining temperatures necessary for the safe transport of food, adequately cleaning vehicles between loads, and properly protecting food during transportation. Other key requirements will be to train carrier personnel in sanitary transportation practices and to maintain records of written procedures, agreements, and training. Industry expects FDA will publish waivers to the final rule for the transportation of certain food or from certain establishments that are already regulated by other programs, such as the National Conference on Interstate Milk Shipments Grade "A" Milk Safety program and the Retail Food Program.

The Agency is also reviewing whether a waiver should be granted for transportation of molluscan shellfish, which is governed by the National Shellfish Sanitation Program. Food companies are generally expected to comply within one year from the final rule's publication date (April 6, 2016). However, those food companies considered small businesses under the rule may take up to two years from the publication date.

**USDA Proposes Better Organic Livestock and Poultry Practices**

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RELATED PRACTICES

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USDA has announced a proposed rule that would amend organic livestock and poultry production requirements, such as livestock handling and transport for slaughter, and avian living conditions. The rule would also expand and clarify livestock health care practices. Among other proposals, the rule intends to clarify how producers and handlers must treat livestock and poultry to ensure their health and well-being. For instance, the proposed rule prohibits castrating chicken, turkeys, pheasants, and other avian species, or de-beaking or beak-trimming them (which means removing the bird's beak tip, or the curved tip of the beak, to prevent it from pecking other birds). The rule also proposes minimum indoor and outdoor space requirements, which will determine the allowed stocking density of birds in the farms, and requirements such as having at least 50 percent of the outdoor space in soil, which may be used by birds for dust-bathing. In a market quantified by the Agency to be at $39 billion and growing, USDA aims to protect the value of the USDA Organic Seal to consumers, ensure consistency and consumer transparency, and facilitate the level of enforcement of organic livestock and poultry standards. Agricultural Marketing Service's ("AMS") Administrator Elanor Starmer stated in early April 2016 that "this proposal sets clear standards for organic animals, providing clarity to organic operations and certifying agents, and establishing a level playing field for all producers."

**FDA Limits Inorganic Arsenic in Infant Rice Cereal**
On April 1, 2016, FDA issued a draft guidance proposing to limit inorganic arsenic to 100 parts per billion in infant rice cereal, a leading source of arsenic exposure in infants. The proposed limit, which will now meet Europe's established limit, stems from extensive testing of rice and non-rice products, a 2016 FDA risk assessment, and an evaluation of the feasibility of reducing inorganic arsenic in infant rice cereal. The FDA found that inorganic arsenic exposure in infants and pregnant women can result in a child's decreased performance on developmental tests. However, according to the Agency, the majority of infant rice cereal currently on the market either meets or is close to the proposed action level. FDA is accepting public comments on the proposed action level and the risk assessment for 90 days after the draft guidance document's publication date.

**FDA Sued Over AquAdvantage Salmon Approval**
On March 30, 2016, several organizations, including commercial and recreational fishing groups, and the Center for Food Safety sued the FDA over its November 2015 approval of the AquAdvantage Salmon. These salmon are genetically engineered ("GE") to grow faster. The plaintiffs challenge FDA's authority to approve and regulate GE animals as "animal drugs" under the federal Food, Drug and Cosmetic Act, arguing that such provisions apply only to veterinary drugs administered to treat animals. They also argue, among other things, that the FDA failed to consult with federal fish and wildlife agencies to ensure its approval would not jeopardize endangered or threatened species or critical habitats, as required by federal law. For more information, please see our previous Jones Day *Update*.

**Environmental Groups Sue FDA to Ban Perchlorate in Food Packaging**
On March 31, 2016, a coalition of six public health and environmental organizations, including the Center for Food Safety and the Natural Resources Defense Council, filed suit in the Ninth Circuit to force the FDA to act on its 2014 petition to ban perchlorate in food packaging after the FDA missed a June 2015 deadline to respond. The plaintiffs argue, among other things, that perchlorate poses a health threat to fetuses, infants, and children and increases the risk of breast cancer. The FDA has approved perchlorate for specific uses, including as an anti-static agent in plastic packaging for dry foods. The plaintiffs asked for a court order giving the FDA 90 days to make a decision on whether to issue, amend, or repeal the regulation.

**German Environmental Minister Proposes "Smart" Packaging to Prevent Food Waste**
Christian Schmidt, German Minister of Food and Agriculture, has proposed the use of electronic labels in food packaging, such as in yogurt cups, to show consumers how products have aged. The food packaging would use a color-coded scale to analyze the content of foods and would gradually change from green to red, allowing consumers to

decide for themselves whether the product is still edible or not. This should prevent food waste related to the use of a "best before date" and the consequential misinterpretation of this term by consumers. Schmidt is confident that his Ministry will be in a position in a few months to bring the proposal at the EU level, launching a European initiative on how to make changes to expiration dates in the short-term and how to proceed with "smart" packaging in the long-term.

**Other News**
BPA Added to the Proposition 65 List of Chemicals Known to Cause Reproductive Toxicity

FDA Withdraws Approval of Swine Drug Carbadox Due to Safety Concerns

USDA Deregulates Monsanto Genetically Engineered MON87419 Corn and Syngenta MZIR098 Corn

EU Requests Geographic Protection for 201 Food Items and 22 Spirits under the TTIP

Brazil to Export Beef to the U.S. While in Negotiations to Unlock Imports of U.S. Beef

France Increases Bluetongue Virus Restriction Zone to Protect Beef and Sheep Livestock

## Regulatory Updates

**FDA Issues Final Rule Related to Sanitary Transportation of Human and Animal Food**
As discussed above, in the April 6, 2016, *Federal Register*, FDA announced a final rule to establish requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. This action is part of the Agency's implementation of the Sanitary Food Transportation Act of 2005 and FSMA, which focuses on the prevention of food safety problems throughout the food chain. ***This rule is effective June 6, 2016***.

**FDA Issues "Inorganic Arsenic in Rice Cereals for Infants: Action Level" Guidance**
As discussed above, in the April 6, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Inorganic Arsenic in Rice Cereals for Infants: Action Level" as well as a supporting document and a risk assessment report. The draft guidance, which currently proposes to limit inorganic arsenic in infant rice cereal to 100 parts per billion, will, when finalized, identify an action level for inorganic arsenic in rice cereals for infants that is achievable with the use of current good manufacturing practices. ***Comments are due July 5, 2016***.

**FDA Amends OTC Drug Regulations**
In the April 4, 2016, *Federal Register*, FDA proposed to amend its nonprescription ("OTC") drug regulations. The proposed rule, if finalized as proposed, would supplement the time and extent application ("TEA") process for OTC drugs by establishing timelines and performance metrics for FDA's review of non-sunscreen TEAs, as required by the Sunscreen Innovation Act ("SIA"). The TEA process, established by regulations finalized in 2002, provides a pathway for drugs to be marketed under an OTC drug monograph. Drugs eligible for such approvals under the TEA process include newer active ingredients that previously had no U.S. marketing history or that were marketed in the United States after the OTC Drug Review began. FDA is also proposing other changes to make the TEA process more efficient, such as: (i) adding provisions concerning filing determination requirements with regard to the content and format of safety and effectiveness data submissions; (ii) addressing withdrawal of consideration of TEAs and safety and effectiveness data submissions; (iii) adding related definitions; and (iv) clarifying and conforming changes to the TEA regulation. FDA is addressing timelines for review of

sunscreen active ingredients and other related topics regarding sunscreens separately, under other provisions of the SIA. ***Comments are due June 3, 2016***.

**APHIS Amends Black Stem Rust Quarantine Regulations**
In the March 22, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") confirmed the effective date of the direct final rule published January 22, 2016, which amended the black stem rust quarantine and regulations by adding nine varieties to the list of rust-resistant *Berberis* species and varieties. Black stem rust is one of the most destructive plant diseases of small grains that is known to exist in the United States. The disease is caused by a fungus (*Puccinia graminis*) that reduces the quality and yield of infected wheat, oat, barley, and rye crops. In addition to infecting small grains, the fungus lives on a variety of alternate host plants that are species of the genera *Berberis*, *Mahoberberis*, and *Mahonia*. The fungus is spread from host to host by windborne spores. ***The rule was effective March 22, 2016***.

**APHIS Proposes to Amend the National Poultry Improvement Plan and Regulations**
In the March 24, 2016, *Federal Register*, USDA's APHIS proposed to amend the National Poultry Improvement Plan ("NPIP"), its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to clarify participation in the NPIP and amend participation requirements, definitions for poultry and breeding stock, the approval process for new diagnostic tests, and laboratory inspection and testing requirements. These changes aim to align the regulations with international standards and make them more transparent. ***Comments are due May 23, 2016***.

**USDA Extends Period to Comment on Identifying and Reducing Regulatory Burdens**
In the March 25, 2016, *Federal Register*, USDA issued a proposed rule to extend the public comment period for documents published on January 26, 2016, titled "Improving Regulation and Regulatory Review" and "Identifying and Reducing Regulatory Burdens." Comments regarding which regulations should be modified, expanded, streamlined, or repealed to make the USDA's regulatory program more effective or less burdensome in achieving the regulatory objectives were received by March 28, 2016. ***USDA extended the public comment period until April 27, 2016***.

**FSIS Proposes to Eliminate Trichinae Treatment Requirements for Pork and Pork Products**
In the March 28, 2016, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") proposed to amend the federal meat inspection regulations to eliminate requirements for ready-to-eat and not-ready-to-eat pork and pork products to be treated to destroy trichinae, both because the regulations are inconsistent with the Hazard Analysis and Critical Control Point ("HACCP") regulations and because these prescriptive regulations are no longer necessary. In addition, FSIS proposed to consolidate the regulations on thermally processed, commercially sterile meat and poultry products (i.e., canned food products containing meat or poultry). If the rule is finalized, FSIS will end its Trichinella Approved Laboratory Program for the evaluation and approval of non-federal laboratories that use the pooled sample digestion technique to analyze samples for the presence of trichinae. ***Comments are due May 27, 2016***.

**FNS Proposes to Codify Several Provisions of Healthy, Hunger-Free Kids Act**
In the March 31, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") proposed to codify several provisions of the Healthy, Hunger-Free Kids Act of 2010 affecting the integrity of the Child Nutrition Programs (the "Programs"). Specifically, the proposed rule sets criteria for assessments against state agencies and program operators who jeopardize the integrity of the Programs. The proposed rule also establishes certain procedures, such as for the termination and disqualification of entities in the Summer Food Service Program, and to prohibit the participation of entities or individuals terminated from any of the Programs. It also establishes state liability for reimbursements incurred as a result of a state's failure to conduct timely hearings in the Child and Adult

Care Food Program ("CACFP"), and establishes criteria for increased state audit funding for CACFP, among others. In addition, the proposed rule makes several operational changes to improve oversight of an institution's financial management. ***Comments are due May 31, 2016***.

**FNS Publishes Final Rule Implementing SNAP Nutrition Education and Obesity Prevention Grant Program**
In the March 31, 2016, *Federal Register*, USDA's FNS issued a final rule to implement the Supplemental Nutrition Assistance Program ("SNAP") nutrition, education, and obesity prevention grant program. The rule also amends SNAP regulations to implement Section 28 of the Food and Nutrition Act of 2008 to award grants to states for the provision of nutrition, education, and obesity prevention programs. These programs provide services for eligible individuals that promote healthy food choices consistent with the current Dietary Guidelines for Americans. The final rule describes the grant award process and the process for allocating the federal grant funding for each state's approved SNAP-Ed plan. This final rule also implements section 4028 of the Agricultural Act of 2014, authorizing physical activity promotion in addition to promotion of healthy food choices as part of this nutrition education and obesity prevention program. ***The rule was effective March 31, 2016***.

**AMS Proposes to Amend Number of Dairy Board Importer Members**
In the April 1, 2016, *Federal Register*, USDA's AMS proposed to amend its Dairy Promotion and Research Order to modify the number of National Dairy Promotion and Research Board ("Dairy Board") importer members. The total number of domestic Dairy Board members would remain the same at 36, and the total number of importer members would be reduced from two to one. The Dairy Order requires that importer representation on the Dairy Board be reviewed and adjusted at least once every three years to reflect the proportional shares of the U.S. market served by domestic production and imported dairy products. ***Comments are due May 2, 2016***.

**FNS Extends Period to Comment on Enhancing Retailer Standards in SNAP**
In the April 5, 2016, *Federal Register*, USDA's FNS announced an extension to comment on a proposed rule, published on February 17, 2016, pertaining to the eligibility of retail food stores for SNAP. Among other things, the Agricultural Act of 2014 ("2014 Farm Bill") amended the Food and Nutrition Act of 2008 (the "Act") to increase the requirement that certain SNAP-authorized retail food stores have available on a continual basis at least three varieties of items in each of four staple food categories, to a mandatory minimum of seven varieties. The 2014 Farm Bill also amended the Act to increase, for certain SNAP-authorized retail food stores, the minimum number of categories in which perishable foods are required from two to three. FNS responded to questions about certain aspects of the proposed rule, which would codify these mandatory requirements. ***USDA extended the comment period until May 18, 2016***.

## European Regulatory Updates

**EFSA Issues Opinion Regarding Use of Sweetener Acesulfame K in Dietary Foods for Children**
On April 5, 2016, the European Food Safety Authority ("EFSA") issued a scientific opinion regarding the safety of using food sweetener acesulfame K (E 950) in dietary foods for young children aged one to three years. Acesulfame K is a sugar substitute, and according to the applicant, its use in these foods is warranted to improve palatability. EFSA has concluded that the use of acesulfame K is not a safety concern, provided it is consumed in a concentration of no more than 450 mg/kg (L) in the final product.

**EFSA Re-Evaluates Safety of Four Food Additives**
On March 8, 2016, EFSA issued a scientific opinion re-evaluating the safety of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212), and calcium benzoate (E 213) when used as food additives. After conducting several studies, EFSA concluded

that the four substances continue to be considered safe food additives in the EU. In addition, EFSA stated that exposure to the four substances has been augmented, resulting in an increase of the Acceptable Daily Intake in toddlers and children. The main food categories contributing to the consumption of these food additives are unprocessed fruits and vegetables, and flavored drinks. EFSA's opinion may be used as a basis for a future decision by the Commission to decrease the maximum permitted levels of the four substances as food additives in foods.

## 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 in 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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