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

FDA Publishes Final Rule Against Intentional Adulteration
FDA has published its last major regulation implementing the Food Safety and Modernization Act ("FSMA"): a final rule on mitigation strategies to protect food against intentional adulteration. This rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Under the new rule, both domestic and foreign food facilities, for the first time, are required to complete and maintain a risk-reducing written food defense plan that assesses potential vulnerabilities and mitigation strategies, establish food defense monitoring procedures and corrective actions, verify the system is working, and ensure personnel assigned to the vulnerable areas receive appropriate training and maintain certain records. The final rule requires companies to perform a vulnerability assessment based on the evaluation of: (i) the severity and scale of the potential public health impact; (ii) the degree of physical access to the product; and (iii) the ability to successfully contaminate the product, which represents a change as compared to the proposed rule.

In addition, the final rule extends the list of exempt facilities. It also give those companies subject to the rule more time to comply. For instance, most companies have three years to comply with the new rule, small companies (500 employees or less) have four years, and very small companies (sales of less than $10 million per year during three consecutive years) must comply in five.

FDA has published a summary of the final rule covering key requirements and a diagram

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intended to assist companies in understanding whether the new rule applies to them. Additionally, FDA will host a webinar on the topic on June 21, 2016.

FDA Issues Draft Guidance for Voluntarily Reducing Sodium
On June 1, 2016, FDA issued a draft guidance that provides voluntary sodium reduction targets for the food industry. The draft proposes to set a short-term and a long-term target to reduce sodium content in 150 categories of food, such as snacks, sandwiches, bakery products, fruits, vegetables, and legumes. The guidance seeks to decrease people's sodium intake to about 3,000 mg per day in two years, and to 2,300 mg in a longer, 10-year period. The current intake of sodium in the United States is 3,400 mg per day (50 percent more sodium than what most experts recommend). Seventy-five percent of that sodium intake comes from processed and commercially prepared (e.g., restaurant) foods. With the goal of reducing the rate of hypertension and a major risk factor for heart disease and stroke, FDA is asking the food industry, especially major food manufacturers and food chains, to comment on FDA's suggested food categories, methods for quantifying sodium content and developing recommended targets, and challenges of implementing the voluntary goals. FDA seeks to gradually reduce the intake of sodium without affecting consumer preferences and expectations of saltiness in foods, and without affecting the nutritional quality of foods by modifying other nutrient levels, such as added sugars or saturated fat, to less-healthy levels. Although comments are accepted at any time, to ensure that the agency considers comments on this draft guidance before it begins work on the final version of the guidance, comments must be submitted within 90 days (by August 31, 2016) for the short-term target and within 150 days (by October 31, 2016) for the long-term. FDA will hold a webinar on the final rule on June 21, 2016.

Additionally, FDA responded on the same day to a 2005 Center for Science in the Public Interest ("CSPI") citizen petition regarding revisions to the regulatory status of salt. CSPI requested that FDA: (i) revoke the GRAS status of salt; (ii) amend any prior sanctions for salt; (iii) require food manufacturers to reduce the amount of sodium in all processed foods; (iv) require health messages on packages of salt one-half ounce or larger; and (v) reduce the Daily Value for sodium from its current level of 2,400 mg to 1,500 mg. FDA denied the petition, explaining its view that the voluntary guidelines are "the most effective and appropriate approach at this time based on the scientific and technical information currently available…."

Finally, on May 26, 2016, a New York state appeals court lifted a stay on New York City's salt warning rule. The rule, which is now enforceable, requires chain restaurants in New York with at least 15 locations nationwide to place the image of a salt shaker in a black triangle next to items on their menu with more than 2,300 mg of sodium.

FSIS Receives Several Petitions for Labeling of Raw Chicken
On May 24, 2016, the National Chicken Council ("NCC") petitioned USDA's Food Safety and Inspection Service ("FSIS") to adopt regulations concerning the labeling of raw, stuffed chicken products. NCC is requesting that FSIS require that not-ready-to-eat ("NRTE") stuffed chicken breast products that appear ready-to-eat ("RTE") be labeled to "clearly inform consumers that the products are raw and how to properly handle and cook them." Specifically, NCC requests that FSIS amend 9 C.F.R. Part 381 to add a new section that: (i) defines a NRTE stuffed chicken breast product that appears RTE; (ii) requires the product name to contain the term "raw" and an accurate description of the poultry component; (iii) requires the principal display panel of the product to bear a "raw product" safety statement, a raw chicken safety icon with the statement "oven bake only," and a serving suggestion explaining that the label illustrates the suggested serving of the product *after* baking; and (iv) requires the labels to contain validated cooking instructions containing the proper cooking method, the endpoint temperature, instructions to measure the internal temperature using a meat thermometer, the "do not microwave" icon, the "oven bake only" icon, and the statement "raw—do not microwave" followed by the explanation "to help prevent foodborne illness caused by eating raw poultry."

In addition, the petition calls for FSIS to publish a compliance guidance explaining how to

validate cooking instructions for such NRTE stuffed chicken breast products that incorporates NCC's "Best Practices for Cooking Instruction Validation for Frozen NRTE Stuffed Chicken Breast Products." NCC's Best Practices are consistent with and expand upon FSIS's recommendations for validation. For example, NCC's Best Practices advise that cooking instructions for each product should include guidance for the appropriate metal cooking utensil to support consistent cooking results, appropriate product spacing to support even heating of the product, and the standard placement of the product in the oven, all of which should be validated accordingly.

In a similar but unrelated citizen petition on May 31, 2016, the Safe Food Coalition also requested that FSIS revise its labeling requirements for raw chicken, as well as for raw and partially cooked meat and poultry products and siluriformes fish. Specifically, the petition requests that the rules require labels to provide more specific information about safe handling practices for such products, including: (i) an endpoint temperature, as well as any "rest time" requirement; (ii) instructions to use a thermometer to verify the product has reached the recommended internal temperature; (iii) information on safe handling practices to minimize risks associated with improper sanitation, handling, storage, and temperature control; (iv) the four core "check your steps" safe food handling graphics featured on the food safety website, instead of the graphics currently displayed; and (v) a web address for additional information.

Other News
An Interview with FDA's New Deputy Commissioner for Foods and Veterinary Medicine
Russia Plans to Extend Food Import Ban

Regulatory Updates

FDA Issues Final Rule on Food Additives in Feed and Drinking Water of Animals
In the June 3, 2016, *Federal Register*, FDA amended the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of chromium propionate as a source of chromium in broiler chicken feed. This amendment was made in response to a food additive petition filed by Kemin Industries, Inc. on March 10, 2014. ***The rule was effective June 3, 2016***.

FDA Announces Availability of Sodium Reduction Guidance
In the June 2, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods." The draft guidance, when finalized, seeks to help Americans achieve the Dietary Guidelines-recommended sodium levels (less than or equal to 2,300 mg of sodium per day) by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in processed, packaged, and prepared foods. The draft guidance identifies both short-term (upper bound) and long-term (sales-weighted target mean and upper bound) sodium level goals that, once finalized, will allow both FDA and the food industry to have a common system for defining and measuring progress in reducing sodium in the food supply. The goals are intended to address the excessive intake of sodium in the current population and promote improvements in public health. ***Comments on Issues 1-4 of Section IV of the draft guidance are due August 31, 2016. Comments on Issues 5-8 of Section IV are due October 31, 2016***.

FDA Issues Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration
In the May 27, 2016, *Federal Register*, as part of FSMA implementation, FDA issued a final rule requiring registered food facilities to address hazards that may be introduced with the intention to cause wide-scale public health harm. Among other things, these food facilities must conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps, as well as implement mitigation strategies to significantly minimize or prevent vulnerabilities identified at actionable process steps in a food

operation. ***Rule is effective July 26, 2016***.

FCIC Finalizes Common Crop Insurance Regulations
In the June 13, 2016, *Federal Register*, USDA's Federal Crop Insurance Corporation ("FCIC") finalized the Common Crop Insurance Regulations, Texas Citrus Fruit Crop Insurance Provisions, to provide policy changes to better meet the needs of policyholders, clarify existing policy provisions, and reduce vulnerability to program fraud, waste, and abuse. Specifically, this final rule modifies or clarifies certain definitions, clarifies unit establishment, clarifies substantive provisions for consistency with terminology changes, modifies the insured causes of loss, clarifies required timing for loss notices, modifies portions of loss calculation formulas, and addresses potential misinterpretations or ambiguity related to these issues. The changes will be effective for the 2018 and succeeding crop years. ***Rule is effective July 13, 2016***.

USDA Issues Spring 2016, Semiannual Regulatory Agenda
In the June 9, 2016, *Federal Register*, USDA published summary descriptions of significant and not significant regulations being developed in USDA agencies in conformance with Executive Orders 12866 "Regulatory Planning and Review," and 13563 "Improving Regulation and Regulatory Review." The agenda also describes regulations affecting small entities and identifies regulatory actions that are being reviewed in compliance with section 610(c) of the Regulatory Flexibility Act, Public Law 96-354. USDA has attempted to list all regulations and regulatory reviews pending at the time of publication except for minor and routine or repetitive actions. USDA invites the public to comment.

AMS Extends Comment Period on Organic Livestock and Poultry Practices Proposed Rule
In the June 8, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") extended the comment period from June 13, 2016, to July 13, 2016, for a proposed rule published on April 13, 2016, on organic livestock and poultry practices. The proposed rule would amend the organic livestock and poultry production requirements to add new provisions for livestock handling, transport for slaughter, and avian living conditions. The proposed rule also aims to expand and clarify existing requirements covering livestock health care practices and mammalian living conditions. The amendments seek to improve upon the current standards by setting separate standards for mammalian and avian livestock living conditions to better reflect the needs and behaviors of the different species and related consumer expectations. ***Comments are due July 13, 2016***.

FNS Extends Comment Period to Codify Several Provisions of Healthy, Hunger-Free Kids Act
In the June 7, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") extended the comment period from May 31, 2016, to July 7, 2016, for a proposed rule published on March 31, 2016, which aims to codify several provisions of the Healthy, Hunger-Free Kids Act of 2010 that affect the integrity of the Child Nutrition Programs ("Programs"). Specifically, the proposed rule sets criteria for assessments against state agencies and program operators who jeopardize the integrity of the Programs, establishes certain procedures such as for the termination and disqualification of entities in the Summer Food Service Program, and prohibits 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 July 7, 2016***.

APHIS Issues Final Rule Amending Mexican Hass Avocado Import Program
In the May 27, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") amended a current regulation allowing commercial consignments of Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico from the

Mexican State of Michoacán to permit importation of fresh Hass avocado fruit from all of Mexico, provided individual Mexican states meet the requirements set out in the regulations and the operational workplan. The fruit will also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization of Mexico with an additional declaration stating the consignment was produced in accordance with the systems approach described in the operational workplan. This final rule will allow for the importation of fresh Hass avocado fruit from Mexico while continuing to provide protection against the introduction of plant pests into the continental United States, Hawaii, and Puerto Rico. ***Rule is effective June 27, 2016***.

FAS Updates WTO Agricultural Quantity-Based Safeguard Trigger Levels
In the May 25, 2016, *Federal Register*, USDA's Foreign Agricultural Service ("FAS") listed the updated quantity-based trigger levels for products that may be subject to additional import duties under the safeguard provisions of the World Trade Organization ("WTO") Agreement on Agriculture. FAS also adds the relevant period applicable for the trigger levels on each of the listed products. ***Update was effective May 25, 2016***.

EU Regulatory Updates

New EU Health Claims Approved
On May 30, 2016, the European Commission ("EC") approved the use of the claim "consumption of foods/drinks containing <name of all used nonfermentable carbohydrates> instead of fermentable carbohydrates contributes to the maintenance of tooth mineralization" for products containing nonfermentable carbohydrates, and the use of the claim "consumption of foods/drinks containing <name of all used nondigestible carbohydrates> instead of sugars induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks" for products containing nondigestible carbohydrates. The use of both claims is subject to certain conditions set forth in the Annex to Regulation (EU) No. 432/2012. Additionally, on May 31, 2016, the EC rejected the use of a claim for high-fiber sourdough rye bread in foods for being misleading to consumers. The claim asserted high-fiber sourdough rye bread reduced post-prandial glycemic responses (i.e., feeling sleepy after eating) compared with glucose.

Members of the European Parliament Vote Against GM Carnations and Maize
On June 8, 2016, Members of the European Parliament ("MEPs") objected, by 430 votes to 188 with 33 abstentions, to an EC decision authorizing the import, distribution, and retailing of cut flowers of the genetically modified ("GM") carnation SHD-27531-4, which is resistant to sulfonylurea herbicide, for ornamental use. MEPs also objected, by 426 votes to 202 with 33 abstentions, to a separate proposal to authorize the sale of products containing, consisting of, or produced from GM maize Bt11 × MIR162 × MIR604 × GA21, and their combinations. MEPs argued that authorizing GM carnations would encourage the use of a diabetes medicine as a herbicide, and authorizing GM maize, resistant to glyphosate, would encourage the sale of a maize classified as "probably carcinogenic" by the World Health Organization.

EFSA Consults on Nutrient Sources in Manufactured Food
The European Food Safety Agency ("EFSA") launched a public consultation on a Concept Paper that reviewed a "Guidance on submissions for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods." EFSA assesses two topics on this evaluation: (i) the safety of the source and (ii) the bioavailability of the nutrient from the source. According to EFSA, the current guidance needs to be updated in light of EFSA's experts' experience on nutrient sources obtained over the years and the evolving principles of risk assessment in the area of food ingredients. EFSA invites interested parties to submit written comments by July 20, 2016.

EFSA's Scientific Opinion on GM Oilseed Rape Open for Comment

On May 20, 2016, EFSA published an opinion on GM oilseed glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 and subcombinations not previously authorized (i.e., MS8 × GT73 and RF3 × GT73), with independence of their origin, for food and feed uses and for import and processing. The opinion excludes GM isolated seed protein for food. In accordance with Regulation (EC) No 1829/2003 concerning GM food and feed, the public has a month to make any comments on the opinion.

Upcoming Meetings, Workshops, and Conferences

Public Workshop of the FDA to provide a forum for the "openFDA" system user community, **June 20, 2016**, in Silver Spring, MD and via webcast.

Public Meetings of the FDA to discuss implementation of the FDA Food Safety Modernization Act import safety programs, **June 21, 2016**, in Detroit, MI.

Public Conference of the EC on EU Food Authenticity and Integrity, **June 24, 2016**, in Brussels.

Public Meeting of the FNS's National Advisory Council on Maternal, Infant and Fetal Nutrition, **July 12–14, 2016**, in Arlington, VA.

Public Meeting of the FDA to discuss menu labeling, **July 7–8, 2016**, in College Park, MD; **September 28–28, 2016**, in St. Louis, MO; and **late 2016 (date TBD)**, in Oakland, CA.

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