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

United States and 11 Nations Sign Trans-Pacific Partnership Trade Deal
After more than six years of negotiations, last week the United States and 11 other Pacific Rim nations (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam) formally signed the Trans-Pacific Partnership ("TPP") agreement. The TPP has been named by many as the largest trade deal in history, expected to cover 40 percent of the world economy.

As previously published in our Jones Day *Update*, although supported by President Obama, the TPP has encountered multiple oppositions from both Democrats and Republicans. The TPP aims to eliminate more than 18,000 tariff taxes other countries put on Made-in-America products.

Many steps still remain in finalizing the trade deal. The TPP still needs to be ratified by at least six countries (including the United States), which account for 85 percent of the combined gross domestic production of the 12 TPP nations, and Congress will need to vote on final ratification of the legislation.

FDA Requests $5.1B for FY 2017, Includes Food Safety Funds
Earlier this week, FDA requested a total budget of $5.1 billion as part of President Obama's FY 2017 budget—an 8 percent increase over FDA's FY 2016 budget. The request includes funds for further implementation of the Food Safety Modernization Act ("FSMA").

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RELATED PRACTICES

FDA Regulatory & Compliance Counseling

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FDA recently finalized major rules that implement the core of FSMA (*see* previous Jones Day *Updates* here and here), including rules requiring food companies to undertake safety measures designed to prevent outbreaks of foodborne illness and rules focusing on current good manufacturing practices ("CGMPs") and preventative control requirements. FDA's FY 2017 budget request includes funds to "build[] on this work by supporting federal and state efforts to establish enforceable safety standards for produce farms." The funding will also "enable the [Agency] to continue progress to hold importers accountable for verifying that imported food meets U.S. safety standards, as well as conduct food safety audits of foreign food facilities."

FDA Bans Imports of GM Salmon

Just months after approving genetically modified ("GM") salmon, FDA has issued a ban on the import and sale of the fish until the agency can publish guidelines for how the fish should be labeled. In November 2015, FDA approved the first GM salmon, which contains a growth hormone gene to help the fish grow faster, after determining the salmon was as safe to consume as non-GM salmon (see our previous Jones Day *Update*). The ban was prompted by language, inserted at the request of Sen. Lisa Murkowski (R-Alaska), in the recently passed federal spending bill. As reiterated in a November 2015 draft guidance, FDA's current policy is to require labeling of GM foods only if a material difference exists between the GM food and its unaltered counterpart. Although FDA found no such differences here, it intends to comply with the mandate and halt imports of the GM salmon until it issues labeling guidelines.

USDA Revokes "Grass Fed" and "Naturally Raised" Marketing Claims

Last month, USDA's Agricultural Marketing Service ("AMS") withdrew its standards for the marketing claims "grass fed" and "naturally raised," marking a departure from a previous service offered by the agency. AMS maintains many standards related to quality, condition, class, and packaging of carcass beef, shell eggs, poultry, and other commodities, and federal law gives AMS authority to develop, maintain, and apply these standards. However, Congress has given AMS only authority to develop marketing claims standards in a few limited instances, such as those associated with organic products. As AMS recently explained, the agency verifies nearly 200 marketing claims, including controversial claims such as "non-GMO," but only the claims "grass fed" and "naturally raised" had an AMS standard. This, according to AMS, caused people to "wrongly think[] AMS had standing statutory authority to determine what standards would merit those other, very controversial claims," such as non-GMO. In fact, AMS conceded that it "does not have authority to regulate those terms." Instead, AMS's role is to assist firms by auditing processes such as grass fed, "providing transparency to the claims [firms] make by making their standards available on the AMS website *and* providing the marketplace with assurance that firms are adhering to their standards…."

The grass-fed marketing claim standard will remain on the agency's website for reference, but the withdrawal means there is no longer a federal standard defining "grass fed." AMS's withdrawal of the two marketing claims standards has no impact on a manufacturer's ability to apply to USDA's Food Safety and Inspection Service ("FSIS") for a grass-fed claim on its label. FSIS already allows companies to make marketing animal raising claims (such as "grass fed") based on documentation supplied with the label application, and the agency will continue to do so.

USDA Issues Stricter Food Safety Measures to Reduce *Salmonella* and *Campylobacter* in Poultry

Last week, USDA's FSIS announced new federal standards aimed at reducing *Salmonella* and *Campylobacter* in ground chicken and turkey products, raw chicken breasts, legs, and wings. *Salmonella* bacteria on raw poultry and fresh produce causes an estimated one million illnesses in the United States each year and has proven challenging to reduce due to the bacteria's presence in the environment. For instance, even when processors wash chicken carcasses after slaughter, USDA has found *Salmonella* on about 25 percent of

chicken parts headed to grocery stores. The new standards will require companies to limit the frequency of contaminated chicken parts to 15 percent or less, which should, according to USDA, reduce annual sicknesses by 50,000 a year. FSIS has also updated its microbial testing schedule at poultry facilities and plans to publicly list noncompliant companies on its website as a further incentive to comply with the new limits.

FDA Announces Intention to Review Criteria for Raw Milk Cheese
FDA announced its intention to reevaluate its criteria for testing raw milk cheese for the presence of non-toxigenic *E. coli*. The announcement is in response to cheesemakers' concerns about FDA's application of safety criteria that, the cheesemakers claim, may limit the production of raw milk cheese without benefitting public health. Although most domestic and imported raw milk cheeses meet the established criteria, FDA has historically tested raw milk cheese for the presence of *E. coli* because bacteria above a certain level could indicate unsanitary conditions in a processing plant. The cheesemakers' concerns include the application of test results and scientific foundation of these criteria. FDA will reevaluate its criteria under the framework of the Food Safety Modernization Act ("FSMA") and in light of FSMA's Preventive Controls for Human Food rule, finalized in September 2015, which requires food processors to identify hazards in their product and operations, and to establish controls to prevent or minimize those hazards. In the meantime, while FDA continues to inspect cheese manufacturing plants and testing for pathogens, the agency will pause its testing program for non-toxigenic *E. coli* in cheese.

Other News
Peanut Product Maker Asks FDA for Qualified Health Claim on Relationship Between Consumption of Peanut Flour by Infants and Reduced Risk of Developing Peanut Allergies

NOAA Proposes Creation of U.S. Seafood Traceability Program

FDA Releases Interview with Center for Safety and Applied Nutrition ("CFSAN") Director Susan Mayne After First Year

FDA Announces Two New Funding Opportunities Under FSMA

Canned Tuna Maker Petitions FDA to Amend the Canned Tuna Standards of Identity

Regulatory Updates

FDA Announces Reorganization of Offices to Reflect New Office of Dietary Supplement Programs
In the February 8, 2016, *Federal Register*, FDA announced the reorganization of CFSAN's Office of Foods and Veterinary Medicine by establishing the new Office of Dietary Supplement Programs (discussed in a previous Jones Day *Update*). Previously, the dietary supplements program existed as a division of FDA's Office of Nutrition Labeling and Dietary Supplements ("ONLDS"). The reorganization resulted in the retitling of ONLDS to the Office of Nutrition and Food Labeling and the abolishment of the Division of Dietary Supplement Programs under ONLDS.

APHIS Revises Regulations Pertaining to the Exportation of Livestock
In the January 20, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") issued a final rule revising the regulations pertaining to the exportation of livestock from the United States. Among other things, APHIS is removing from the regulations most of the requirements for export health certifications, tests, and treatments, and it is instead directing exporters to follow the requirements of the importing country regarding such processes and procedures. The agency is retaining only those export health certification, testing, and treatment requirements it considers necessary to ensure the health and welfare of livestock exported from the United States. It is also providing solutions for pre-export inspection and pre-export health certificates of

livestock so exporters have more flexibility in arranging for the export of healthy livestock. Finally, APHIS is making editorial amendments to the regulations to make them easier to understand and comply with. ***The rule is effective February 19, 2016***.

APHIS Announces Intent to Prepare EIS on Regulation of GMOs
In the February 5, 2016, *Federal Register*, USDA's APHIS announced its plan to prepare a programmatic environmental impact statement ("EIS") in connection with potential changes to the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. APHIS's notice identified reasonable alternatives and potential issues to be evaluated in the environmental impact statement and requested public comments to further define the scope of the alternatives and environmental impacts and issues for APHIS to consider. ***Comments are due March 7, 2016***.

FDA Reopens Comment Period for Proposed Rule on Gluten-Free Labeling of Fermented or Hydrolyzed Foods
In the January 22, 2016, *Federal Register*, FDA corrected an error made in the proposed rule published November 18, 2015, titled "Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods." One section of the proposed rule provided a 30-day period for submitted comments in the information collection provisions of the proposed rule, but another section provided 60 days. FDA reopened the comment period to address the error. ***Comments on information collection issues are now due February 22, 2016; other comments are due February 16, 2016***.

FDA Amends Regulations to Update Location of References Cited in Food Regulations
In the February 3, 2016, *Federal Register*, FDA amended certain regulations to update the location of references cited in its food regulations. The amendments reflect the transfer of the references from the agency's College Park, Maryland, facility to its library at its main Silver Spring, Maryland, campus. ***The rule was effective February 3, 2016***.

FDA Corrects and Amends Final Rule on CGMPs, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
In the January 22 and January 25, 2016, *Federal Registers*, FDA corrected and amended a final rule published in the September 17, 2015, *Federal Register* amending the regulation for CGMPs in manufacturing, packing, or holding human food to modernize it and add requirements for domestic and foreign facilities required to register under the U.S. Food, Drug, and Cosmetic Act ("FDCA") to establish and implement hazard analysis and risk-based preventive controls. The final rule also revised certain definitions in the regulation to clarify the scope of the exemption from registration requirements provided by FDCA for "farms." The January 22 and 25, 2016, notices correct editorial and inadvertent errors in the final rule.

FDA Amends Final Rule on CGMPs, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food to Correct Errors
In the January 22, 2016, *Federal Register*, FDA amended a final rule published in the September 17, 2015, *Federal Register*, establishing requirements for domestic and foreign facilities required to register under the FDCA for CGMPs, hazard analysis, and risk-based preventive controls for animals to correct editorial and inadvertent errors. ***The amendments were effective on January 22, 2016***.

GIPSA Requests Comments on the U.S. Standards for Mixed Grain, Triticale, Rye, and Flaxseed
In the January 21, 2016, *Federal Register*, here, here, here, and here, USDA's Grain Inspection, Packers, and Stockyards Administration ("GIPSA") sought comments on the U.S. Standards for Mixed Grain, Triticale, Rye, and Flaxseed under the United States Grain Standards Act. To ensure that standards and official grading practices remain relevant, GIPSA invites interested parties to comment on whether the current mixed grain, triticale, rye, and flaxseed standards and grading practices need to be changed. The grading

standards and testing procedures allow buyers and sellers to communicate quality requirements, compare mixed grain, triticale, rye, and flaxseed quality using equivalent forms of measurement, and assist in price discovery. ***Comments on U.S. Standards for Mixed Grain and Triticale are due April 20, 2016, and comments on U.S. Standards for Rye and Flaxseed are due April 21, 2016***.

FSA Issues Final Rule to Amend Existing Direct Loan Program
In the January 21, 2016, *Federal Register*, USDA's Farm Service Agency ("FSA") issued a final rule to add Direct Farm Ownership Microloan ("DFOML") to the existing Direct Loan Program. The revisions to the Direct Loan Program regulations consist of application, eligibility, repayment terms, and security requirements to better serve the unique operating needs of small family farm operations. The existing microloans ("MLs") in the Direct Loan Program already include MLs for operating loans. DFOML is expected to make farm ownership loans available and more attractive to small operators through reduced application requirements, more timely application processing, and added flexibility for youth loan borrowers in meeting the farm experience eligibility requirement. ***The rule was effective January 21, 2016; comments are due April 20, 2016***.

APHIS Affirms Final Rule Establishing Definitions Under the Lacey Act Implementation Plan
In the January 25, 2016, *Federal Register*, USDA's APHIS adopted as final an interim rule that specifically requested comments on definitions of two terms: "commercial scale" and "tree." These terms are related to the terms "common cultivars" and "common food crops," which are among the categorical exclusions to the Lacey Act. The 2008 amendments to the Lacey Act (i) expanded its protection to a broader range of plant species, (ii) extended its reach to encompass products, including timber, that derive from illegally harvested plants, and (iii) required that importers submit a declaration at the time of importation for certain plants and plant products. However, the Act does not define the terms "common cultivar" and "common food crop," but instead gives authority to USDA and the U.S. Department of the Interior to define these terms by regulation. This document responds to comments APHIS received on the definitions of "commercial scale" and "tree." ***The rule was effective January 25, 2016***.

GIPSA Proposes Rule to Revise Regulations Under Grain Standards Act
In the January 25, 2016, *Federal Register*, USDA's GIPSA proposed to revise existing regulations and add new regulations under the United States Grain Standards Act ("USGSA"), as amended, in order to comply with amendments made by the Agriculture Reauthorizations Act of 2015. Specifically, the rulemaking proposed to (i) eliminate mandatory barge weighing, (ii) remove the discretion for emergency waivers of inspection and weighing, (iii) revise GIPSA's fee structure, (iv) revise exceptions to official agency geographic boundaries, (v) extend the length of licenses and designations, and (vi) impose new requirements for delegated states. ***Comments are due February 24, 2016***.

USDA Requests Comments to Evaluate Burdens and Effectiveness of Regulatory Programs
In the January 26, 2016, *Federal Register*, USDA announced continued review of its regulatory programs and evaluation of their burdens and effectiveness. As part of this effort, USDA welcomes public comment regarding which regulations should be modified, expanded, streamlined, or repealed to make USDA's regulatory program more effective or less burdensome in achieving the regulatory objectives. The 2015 Fall Regulatory Agenda provides a summary of the USDA regulations under development or review during the coming year. Similarly, USDA's 2015 Statement of Regulatory Priorities provides a list of important regulatory actions that USDA is considering for issuance in proposed or final form during the FY 2016. ***Comments are due March 28, 2016***.

FNS Codifies SNAP Requirement for National Directory of New Hires Employment Verification and Annual Program Activity Reporting
In the January 26, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS")

announced an interim rule that requires state agencies to verify applicant employment data through the National Directory of New Hires ("NDNH") for the determination of Supplemental Nutrition Assistance Program ("SNAP") eligibility and correct amount of benefits. This interim final rule requires that state agencies access employment data through the NDNH at the time of SNAP certification, including recertification, and aims to improve Program integrity by reducing the risk of improper payments due to unreported or misreported income. This rule further changes the reporting frequency requirement for the "Program and Budget Summary Statement Part B—Program Activity Statement" from an annual submission to a quarterly submission. ***Comments are due March 28, 2016***.

APHIS Proposes to Amend the Animal Welfare Act Regulations
In the February 3, 2016, *Federal Register*, USDA's APHIS proposed to amend the Animal Welfare Act regulations concerning the humane handling, care, treatment, and transportation of marine mammals in captivity to ensure regulations are based on current industry and scientific knowledge and experience. These proposed changes would affect sections in the regulations relating to variances and implementation dates, indoor facilities, outdoor facilities, space requirements, and water quality. APHIS is also proposing to revise the regulations that relate to swim-with-the-dolphin programs. ***Comments are due on April 4, 2016***.

Other USDA Announcements

- APHIS Amends Regulations to Allow Importation into the U.S. of Fresh Apple and Pear Fruit from Certain Countries in the EU
- AMS Issues Final Rule to Decrease Assessment Rate of Washington Apricots Handled for 2015–2016 and Subsequent Fiscal Periods
- APHIS Issues Final Rule to Amend Black Stem Rust Quarantine and Regulations by Adding Nine Varieties to the List of Rust-Resistant *Berberis* Species and Varieties
- USDA Accepts Affidavits to Substantiate Eligibility for Distribution from the Refund of Duties Paid on Imports of Certain Wool Products Program
- AMS Increases Assessment Rate of Kiwifruit Grown in California for FY 2015–2016 and Subsequent Fiscal Periods
- The National Institute of Food and Agriculture ("NIFA") Issues Final Rule to Update List of Institutions Granted HSACU Certification
- APHIS Amends Regulations Governing Importation of Plants and Plant Products to Add Orchid Plants from Taiwan
- NIFA Issues Final Rule Setting General and Specific Administrative Requirements Applicable to Competitive and Non-Competitive Non-Formula Programs

FDA Announced the Opportunity for Public Comment on the Following Proposed Information Collections:

- Prevention of *Salmonella Enteritidis* in Shell Eggs During Production

FDA Announced the Following Information Collection Activities Have Been Approved by OMB:

- Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants
- Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use
- Improving Food Safety and Defense Capacity at the State and Local Level: Review of State and Local Capacities

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

- Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Food Contact Substance Notification Program
- Recommended Recordkeeping for Exempt Infant Formula Production

USDA Announced the Following Requests for Information:

- Review of Child Nutrition Data and Analysis for Program Management
- Noninsured Crop Disaster Assistance Program
- Community Eligibility Provision Characteristics Study
- Performance Reporting System, Management Evaluation

USDA Announced the Following Information Collections Have Been Revised and/or Extended:

- Importation of Wooden Handicrafts From China

USDA Announced Its Intent to Reinstate, Revise, or Renew the Following Previously Approved Information Collections:

- Local Food Directories and Survey
- Importation and Transportation of Meat, Poultry, and Egg Products

USDA Announced the Following Information Collections Have Been Submitted to OMB:

- 7 CFR 764, Direct Loan Making
- Reporting Requirements for State Plans of Work for Agricultural Research and Extension Formula Funds
- Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting, and Notices
- Small Business Innovation Research Program
- Uniform Grant Application for Non-Entitlement Discretionary Grants
- Importation of Citrus from Peru
- 7 CFR 1717 Subpart Y, Settlement of Debt Owed by Electric Borrowers
- Reporting Requirements for State Plans of Work for Agricultural Research and Extension Formula Funds
- Electronic Mailing List Subscription Form—Nutrition and Food Safety
- Foreign Market Development Cooperator Program and Market Access Program

European Regulatory Updates

Members of the European Parliament Object to Three GM Soybean Authorizations

On February 3, 2016, the European Parliament decided that the European Commission ("Commission") should not authorize the use of glyphosate-tolerant GM soybeans in food and feed. Members of European Parliament ("MEPs") noted that glyphosate, a herbicide, is classified as "probably carcinogenic" by the World Health Organization ("WHO") and that GMOs are being authorized in the European Union ("EU") without the support of Member States. The three genetically modified soybeans at issue are FG72, MON 87708 x MON 89788, and MON 87705 x MON 89788.

Members of the European Parliament Veto Draft Rules on Baby Food

On January 20, 2016, the European Parliament vetoed draft EU rules that would allow baby foods to continue to contain up to three times more sugar than is recommended by the WHO. The MEPs claim the draft rule fails to protect infants and young children against obesity. Instead, MEPs advocate reducing the EU sugar content limit to match the WHO recommendations, which limit intake of free sugars to less than 10 percent of total energy intake. The Commission's proposal, on the other hand, permits sugars to provide up to 30 percent of the energy intake from baby foods. This vote sends the legislative act back to the drawing board.

Political Agreement on a New Framework for Transatlantic Data Transfers Reached

On February 2, 2016, EU and U.S. regulators reached a political agreement on a new "Safe Harbor 2.0" that could provide thousands of companies with a legal basis for transatlantic data transfers. The framework—referred to as the "EU–U.S. Privacy

Shield"—is the result of lengthy negotiations between EU and U.S. policymakers aimed at developing an alternative to the now defunct Safe Harbor program. Read more in Jones Day's *Alert*.

EFSA Issues Opinion on Food Contact Materials
European Food Safety Authority ("EFSA") experts recommend refining the safety assessment of substances used in food contact materials, including the introduction of a more comprehensive approach to estimate consumer exposure, particularly for infants and toddlers. The next step in this process is for the Commission to address the implications of these refinements for risk management with authorities in Member States. The Commission will then advise EFSA on the necessary levels of protection for consumers. EFSA will use the Commission's advice to develop guidance on data requirements for applications for the safety assessment of substances in food contact materials.

EFSA Publishes Two Scientific Opinions on Environmental Risk Assessments
EFSA performs Environmental Risk Assessments ("ERA") as part of its evaluations of "regulated products"—pesticides, genetically modified organisms, and additives in food and animal feed, as well as of invasive alien species that are harmful to plant health. The aim of the current documents is to harmonize the way in which EFSA approaches ERA. The opinions identify three areas in particular where EFSA should establish common approaches: (i) the specification of biodiversity-related protection goals at the start of the assessment, (ii) coverage of endangered species, and (iii) the potential for ecological recovery following damage. Risk assessors and risk managers will now discuss how to make best use of these common frameworks.

EFSA Consults on Dietary Reference Values for Vitamin B6
EFSA has launched a public consultation on its draft scientific opinion on dietary reference values for vitamin B6. The document proposes dietary reference values for adults, children and infants, and pregnant and lactating women. EFSA invites interested parties to submit written comments by March 16, 2016.

Other European Regulatory Updates
Reporting on Open Plenary Meetings: EFSA Revised Guidelines for Observers

Japan's Food Safety Commission Visits EFSA

EFSA Appoints Senior Communications Manager

Upcoming Meetings, Workshops, and Conferences

Public Meeting to Provide Information and Receive Public Comments Regarding 48th Session of the Codex Alimentarius Commission Committee on Food Additives, **February 16, 2016**, in College Park, MD.

Public Meeting of the Secretary's Advisory Committee on Animal Health, **February 23–25, 2016**, in Dallas, TX.

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