JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
Vol. II | Issue 19 | October 2015 JONES DAY

Top News

U.S. Reaches One of the Largest Trade Agreements in History: the TPP
On October 6, 2015, after five years of negotiations, the U.S. closed the Trans-Pacific Partnership ("TPP") deal with Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. According to Agriculture Secretary Tom Vilsak, "[T]he agreement would eliminate or significantly reduce tariffs on our products and deter non-science based sanitary and phytosanitary barriers that have put American agriculture at a disadvantage in TPP countries in the past." The TPP, which is intended to boost exports of meat, poultry, dairy, fruit, vegetables, grains, oilseed, cotton, and processed foods, has been supported by most trade bodies, including the National Cattlemen's Beef Association. That association's president, Philip Ellis, said, "… TPP is a major win not only for the beef industry, but for all U.S. export products, growing the economy while supporting jobs and investments in agriculture and technology" and stated that the TPP is a "21st century agreement." The TPP is one of the largest trade agreements, with a total gross domestic product ("GDP") of the current TPP parties of approximately US$27.5 trillion. This comprises 40 percent of global GDP and one third of world trade.

USDA released fact sheets illustrating state-by-state benefits of the TPP and how it would increase U.S. exports by, for example, eliminating 18,000 taxes countries levy on U.S. products, requiring Japan to reduce its beef tariff from 50 percent to 9 percent, and requiring Vietnam to eliminate its own tariffs for beef. Additionally, USDA released documents describing the specific financial benefits for the U.S. trade of each agricultural commodity and product.

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The TPP will not become effective until lawmakers of each member country approve it. In the U.S., President Obama will need the approval of Congress, which will have 90 days to deliberate after the President provides appropriate notice. Although the TPP is not supported by many in Congress, President Obama is confident the agreement will become law, stating that it will help "sell more Made in America goods and services around the world."

For more information, see our previous Jones Day *Alert*, "Fast-Track Negotiating Authority May Spur Free Trade Agreements."

California Adopts the Nation's Strictest Standard for Use of Antibiotics in Livestock

California Governor Jerry Brown has signed Bill SB-27 prohibiting the administration of antibiotics to livestock unless it is prescribed by a licensed veterinarian to treat or control the spread of a disease or infection, or unless necessary in relation to a surgery or medical procedure. This means the prohibition of the use of antibiotics for the sole purpose of fattening livestock or improving feed efficiency. In addition, the bill would require the Department of Food and Agriculture to develop antimicrobial stewardship guidelines and best practices on the proper use of antibiotics and would give it authority to gather information on antimicrobial drug sales and usage, antimicrobial resistant bacteria, and livestock management practice data.

The bill results from a growing concern that the overuse of such antibiotics contributes to drug-resistant infections. Such infections lead to 23,000 deaths per year according to the U.S. Centers for Disease Control and Prevention. This bill will take effect on January 1, 2018, and would make California the first state to abolish use of antibiotics in healthy livestock.

FDA Releases Strategy for FSMA Training

FDA has released its training strategy to support implementation of the Food Safety Modernization Act ("FSMA"), with a special focus on ensuring domestic and foreign food facilities are well trained to implement the recently published Preventive Controls for Human and Animal Food (see our previous Jones Day *Update*) and the forthcoming Produce Safety Rule, which is scheduled to be published by the end of this month. FDA recognizes FSMA compliance may pose a challenge to some members of industry and, therefore, wants to facilitate compliance by providing training. FDA has created alliances with public and private partners in industry, academia, and state, federal, tribal, and international governments that will develop training programs for food facilities. In addition, FDA has designed alternative training programs for specific target audiences utilizing state partners to create a collaborative plan to implement the Produce Safety Rule. FDA has also established national coordination and regional centers aiming to ensure farmers, processors, and wholesalers receive the assistance they need. To avoid duplication and maximize limited resources, FSMA has created a collaborative training forum where the different agencies, centers, and associations helping with training can share information about the programs. For more information regarding the FSMA training strategy, go here.

Europe's Environmental Committee Opposes National Ban on Use of GM Food and Feed

On October 13, 2015, the European Parliament's Environmental Committee ("Committee") voted against the adoption of the European Commission's ("EC") legislative proposal to enable any EU Member State to restrict or prohibit the sale and use of EU-approved genetically modified ("GM") food or feed in its territory. The members of the Committee were concerned that the proposal might prove unworkable and lead to the reintroduction of border controls between pro- and anti-GMO countries. The proposal will be put to a European Parliament plenary vote at the October 26–29 meeting.

EU Court Clarifies Notification Obligation of SVHC in Articles

On September 10, 2015, the EU Court of Justice delivered a key decision on the concept of an "article" containing Substances of Very High Concern ("SVHC"), which are included in the Candidate List. The decision examined the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH") obligations. This regulation requires that the European Chemicals Agency ("ECHA"), the recipients of the article, and customers (upon request) be notified of any article placed on the EU market that contains SVHC in a concentration above 0.1% w/w. The legal issue has been whether the 0.1% w/w threshold should apply to either (i) a complex product, consisting of several separate component articles, or (ii) each of such component articles. The court held that the obligations apply to any article, including those incorporated as component articles of a complex product. Thus, any EU supplier of food packaging, including any food business operator that supplies packaged foods, must have sufficient information about the content of SVHC in all the packaging components (lids, gaskets, decorative components, etc). To address the court's findings, ECHA has already announced it will update the current Guidance by the end of this year.

Other News
CSPI Sues FDA to Receive Answer on a 2005 Citizen Petition Challenging GRAS Status of Salt

FDA Replaces Old Process Filing Forms with New Ones to Submit Information to FDA on Acidified and Low Acid Canned Food

USDA Announces $3M in Funding for Critical Agriculture Production Research and $21M in Funding for Organic Production Research

ITC Starts Process to Amend Harmonized Tariff Schedule Import Categories for Certain Fish

FDA Makes Available New Food-Related Emergency Exercises, Titled "Wat'er You Thinking" and "Foul Fodder"

USPOULTRY Foundation Seeks Proposals on Alternative Killing Methods

Saudi Arabia Lifts 15-Year Ban on French Beef

Regulatory Updates

FDA Reopens Period to Comment on Nutrition and Supplement Facts Labels
In the October 20, 2015, *Federal Register*, FDA announced it reopened the comment period for certain documents associated with the proposed rule to amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts and Supplement Facts labels. FDA also reopened the comment period for a supplemental proposed rule to revise the Nutrition Facts and Supplement Facts labels. FDA took this action due to technical difficulties at the Federal eRulemaking Portal on October 13–14, 2015. ***Comments are due October 23, 2015***.

FDA Amends Color Additives Regulations
In the September 30, 2015, *Federal Register*, FDA announced the amendment of color additive regulations to provide for the safe use of mica-based pearlescent pigments, prepared from titanium dioxide and mica, as color additives in certain distilled spirits. ***Comments are due October 30, 2015***.

FDA Confirms Effectiveness of Rule on Infant Formula
In the October 13, 2015, *Federal Register*, FDA confirmed the effectiveness of the final rule, published on June 23, 2015, that amended the regulations on nutrient specifications and infant formula labeling to (i) add the mineral selenium to the list of required nutrients, and (ii) add 2.0 µg selenium per 100 kilocalories ("/100 kcal") as the minimum

level of selenium in infant formulas, and 7.0 µg/100 kcal as the maximum level. ***The rule is effective June 22, 2016***.

USDA Issues Final Rule Revising Delegations of Authority
In the September 29, 2015, *Federal Register*, USDA issued a final rule amending the existing delegations of authority by adding (i) a new delegation of authority from the Secretary to the Chief Financial Officer to provide guidance on implementation of prize competition, (ii) a new delegation of authority from the Secretary to the Assistant Secretary for Civil Rights to award grants and enter into cooperative agreements, and (iii) a specific delegation from the Secretary to the Under Secretary for Research, Education, and Economics to consult with the Foundation for Food and Agriculture Research. The rule also revises and amends the existing delegations (iv) from the Secretary to the Under Secretary for Farm and Foreign Agricultural Services ("FFAS"), and (v) from the Under Secretary for FFAS to the Administrator of Farm Service Agency. ***The rule is effective September 29, 2015***.

AMS Calls for Nominations to Fill the National Organic Standards Board
In the September 30, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") requested nominations to fill an unexpected vacancy on the National Organic Standards Board ("NOSB") for an environmentalist/resource conservationist position. The Secretary of Agriculture will appoint one person to this position for the remainder of the position's term, which began in January 24, 2015, and goes through January 23, 2020. The NOSB was established to assist in the development of standards for substances to be used in organic production and to advise the Secretary on the implementation of the Organic Foods Production Act of 1990. ***Nomination applications are now accepted***.

APHIS Develops Pilot Plan to Test International Trade Data System
In the October 2, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS"), in coordination with U.S. Customs and Border Protection ("CBP"), developed a pilot plan to test and assess the International Trade Data System for the electronic submission of data required by APHIS Animal Care, Biotechnology and Regulatory Services, Plant Protection and Quarantine, and Veterinary Services for processing in the Automated Commercial Environment ("ACE"). The pilot test will use the APHIS Partner Government Agency ("PGA") Message Set and the Automated Broker Interface to transmit, and ACE to process, trade data required for the importation of plants, animals, and their products regulated by APHIS. Under this test, PGA Message Set data may be filed only at certain ports. ***Test will commence no earlier than October 2, 2015***.

FNS Seeks Nominations for The National Advisory Council on Maternal, Infant and Fetal Nutrition
In the October 2, 2015, *Federal Register*, USDA's Food and Nutrition Service ("FNS") sought nominations for eight vacancies on the National Advisory Council on Maternal, Infant and Fetal Nutrition ("Council"), which include: (i) a State Commodity Supplemental Food Program ("CSFP") Director, (ii) a State Health Officer, (iii) a State Public Health Nutrition Director, (iv) an Official from a State Agency Serving Predominantly Indians, (v) a Local CSFP Project Director, (vi) a CSFP Parent Participant, (vii) a Person Involved at the Retail Sales Level of Food, and (viii) an Expert in Drug Abuse Education and Prevention. The Council studies the operation of the Special Supplemental Nutrition Program for Women, Infants and Children, and related programs such as the Commodity Supplemental Food Program. ***Nominations must be mailed by November 2, 2015***.

APHIS Increases Fees for Overtime Services
In the October 2, 2015, *Federal Register*, USDA's APHIS announced an increase for fiscal years 2016 through 2018 of the hourly rates charged for Sundays, holidays, or other overtime work performed by employees of APHIS for any person, firm, or corporation having ownership, custody, or control of regulated commodities or articles subject to agricultural inspection, laboratory testing, certification, or quarantine under the regulations. ***The rule is effective November 2, 2015***.

APHIS Finds No Significant Impact for Field Use of Vaccines Against Avian Influenza H5 Virus Strains
In the October 7, 2015, *Federal Register*, USDA's APHIS announced an environmental assessment had been prepared relative to the use of one or more veterinary biological products as a treatment for and as an aid in the reduction of highly pathogenic avian influenza, caused by strains such as Eurasian H5 viruses of clade 2.3.4.4 lineage. Based on the environmental assessment, the agency has concluded that the use of vaccines will not have a significant impact on the human environment. ***Comments are due November 6, 2015***.

APHIS Proposes to Revise Wildlife Services Management Information System
In the October 8, 2015, *Federal Register*, USDA's APHIS proposed to revise the Wildlife Services Management Information System, USDA-APHIS-9, to rework the routine uses, expand the categories of records in the system, and the location of the system. This system of records is used to maintain a record of activities conducted by the agency pursuant to its mission and responsibilities, such as providing wildlife damage management services to federal, state, tribal, and local governments. ***Comments are due November 9, 2015***.

NRCS Issues Final Rule on Procedures for Granting Equitable Relief
In the October 16, 2015, *Federal Register*, USDA's Natural Resources Conservation Service ("NRCS") issued a final rule implementing the equitable relief authority, and the procedures set forth in section 1613 of the Farm Security and Rural Investment Act of 2002, relating to relief for participants for covered programs administered by NRCS. The rule grants relief where the program participant took action to his or her detriment based on action or advice from an NRCS employee, and situations where the participant acted in good faith but failed to fully comply with program requirements. ***The rule is effective October 16, 2015***.

Other USDA Announcements:

- AMS Requests Comments on a California Desert Grape Administrative Committee Recommendation to Revise the Administrative Rules and Regulations of the Federal Marketing Order for Grapes Grown in a Designated Area of Southeastern California and the Table Grape Import Regulation
- APHIS Issues Final Rule Authorizing Importation of Tomato Plantlets in Approved Growing Media from Mexico Subject to a System Approach
- APHIS Removes Areas in Orleans, Nassau, and Suffolk Counties in the State of New York from the Golden Nematode Regulations
- Foreign Agricultural Service Imposes Special Agricultural Safeguard Measures on Certain Imports of Butter and Fresh/Sour Cream
- AMS Issues Proposed Rule and Referendum Order to Handle Table Grapes Grown in Southeastern California
- AMS Proposes Amendments to Marketing Order Regulating Handling of Raisins Produced from Grapes Grown in California

USDA Announced the Following Requests for Information:

- Importation of Pork-Filled Pasta Products
- Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling
- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery
- Web Forms for Research Data, Models, Materials, and Publications as well as Study and Event Registration
- Agricultural Foreign Investment Disclosure Act Report
- Farm Loan Programs, Direct Loan Making
- Location of Irradiation Treatment Facilities in the United States
- Quality Control Review Schedule
- USDA Foods in Schools Cost Dynamics

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

- Importation of Baby Corn and Baby Carrots from Zambia
- Importation of Shelled Peas from Kenya

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

- Floriculture Survey
- USDA/1890 National Scholars Program Application
- Petitions for Rulemaking

USDA Announced Its Intent to Renew the Following Previously Approved Information Collections:

- Representations Regarding Felony Conviction and Tax-Delinquent Status for Corporate Applicants and Awardees in Nonprocurement Programs
- Food Contact Substance Notification Program
- Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

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

- Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use
- Guidance for Industry on Formal Dispute Resolution

FDA Issued the Following Draft and Final Guidance Documents:
Guidance for Industry: Veterinary Feed Directive Regulation Questions and Answers, **September 30, 2015**, *Federal Register*.

Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format, **October 8, 2015**, *Federal Register*.

Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, **October 8, 2015**, *Federal Register*.

European Regulatory Updates

EFSA Issues Reevaluation of Tocopherols (E 306–E 309) as Food Additives
On September 30, 2015, the European Food Safety Authority("EFSA") issued a scientific opinion on the reevaluation of certain food additives tocopherols, which are used as antioxidants in foods to inhibit the peroxidation of fats and lipids. EFSA recommended that the maximum limits for the impurities of toxic elements like arsenic, lead, and mercury in the EU specifications for tocopherols be revised to ensure the use of tocopherols as food additives will not be a significant source of exposure to these elements in food. The Panel also recommended reassessing the appropriateness of scientific evaluation of tocopherols as new data on γ- and δ-tocopherols becomes available.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the Codex Alimentarius Commission Committee of Nutrition and Foods for Special Dietary Uses, **October 27, 2015**, in College Park, MD.

Annual Meeting of the Grain Inspection, Packers and Stockyards Administration Advisory Committee, **October 27–28, 2015**, in Kansas City, MO.

Public Meeting of the National Organic Standards Board, **October 26–29, 2015**, in

Stowe, VT.

Public Meeting of the National Agricultural Statistics Service Advisory Committee on Agriculture Statistics, **November 4–5, 2015**, in Louisville, KY.

Public Meeting of the Plant Variety Protection Board on Work and Outreach Plans, Subcommittee activities, and Proposals for Procedure Changes, **December 7–8, 2015**, in Chicago, IL.

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