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

President Obama Releases TPP Final Text
As previously published in our Jones Day *Update*, the United States recently closed the Trans-Pacific Partnership ("TPP") agreement with 11 other nations: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. The full TPP text was released on November 4, 2015, and comprises 30 chapters and hundreds of provisions related to agriculture and other economic areas and issues, such as intellectual property rights, labor conditions, and environmental protection. As expected, there have been different reactions regarding the free-trade deal; for instance, Democrat Hillary Rodham Clinton and Republican Donald Trump have opposed the deal. President Obama has stated that the TPP "puts American workers first" and that "[W]hen it comes to Asia, one of the world's fastest-growing regions, the rule book is up for grabs. And if we don't pass this agreement—if America doesn't write those rules—then countries like China will. And that would only threaten American jobs and workers and undermine American leadership around the world."

President Obama will sign the agreement in 90 days. Under the "fast-track" procedures, signed into law on June 29, 2015, Congress will have the opportunity to deliberate over the TPP's terms but not to amend or recommend amendments to it.

Once the agreement is signed, a series of legislative hearings will be held before the free-trade deal is enacted. If the Senate lacks a two-thirds vote majority, it could shut off "fast-track" approval. For more information on the "fast-track" rules, see our previous

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RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

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Jones Day *Alert,* "Fast-Track Negotiating Authority May Spur Free Trade Agreements."

FDA Explores Use of Term "Natural" on Human Food Labeling
FDA is requesting public comments on (i) whether it is appropriate to define the term "natural" and, if so (ii) how the agency should define "natural," and (iii) whether it should determine appropriate use of the term on food labels. FDA considers a human food to be "natural" if "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food."

FDA states that the landscape of food ingredients and production is changing, and thus a coordinated revision of the term "natural" between FDA and USDA is needed. The agency intends to work with USDA's Agricultural Marketing Service ("AMS") and Food Safety and Inspection Service ("FSIS"), which would revise the word "natural" as used in meat, poultry, and egg products.

In recent years, there has been substantial litigation regarding the meaning of the term "natural" and whether its use on various labels is misleading. Litigated issues include (i) the extent to which a "natural" food can be subject to processing, (ii) whether a food derived from genetically modified organisms can be deemed natural, (iii) whether a food (or some of its ingredients) can be deemed "natural" if some ingredients are produced through chemical processes, and (iv) whether a food is "natural" if it is "artificially" colored with natural products such as beet juice, etc. Some courts have requested guidance from FDA.

FDA Stays Portions of Investigational New Drug Applications Guidance Relating to Health Claims for Foods
FDA has stayed two portions of the September 2013 "Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards ("IRBs") on Investigational New Drug Applications ("INDs")—Determining Whether Human Research Studies Can Be Conducted Without an IND." The stays relate to (i) studies that evaluate a conventional food's effect or non-nutritional effect on the structure or function of the body, and (ii) studies that support health claims for conventional foods or dietary supplements, except as to studies intended to evaluate whether a food substance reduces the risk of a disease in individuals less than 12 months old, those with altered immune systems, and those with serious or life-threatening medical conditions. FDA has expressly highlighted that investigations of conventional foods or dietary supplements studies for use in the diagnosis, cure, mitigation, treatment, or prevention of disease would not be affected. With this partial stay, FDA intends to encourage scientific research into the relationship between diet and health.

Obama to Suspend Duty-Free Treatment for South African Food
On November 6, 2015, President Obama sent a letter to Congress notifying them of his intention to suspend the duty-free treatment of all South African goods covered under the African Growth and Opportunity Act ("AGOA"), if South Africa does not eliminate, within 60 days, barriers South Africa imposed upon U.S. agricultural exports. President Obama explained he decided to take this action because "South Africa is not making continual progress toward the elimination of barriers to United States trade and investment as required by section 104 of AGOA." At the core of the dispute are "anti-dumping" duties on U.S. poultry, pork, and beef, imposed 15 years ago after an outbreak of bird flu. The U.S. renewed the AGOA five months ago, for 10 more years, in connection with South African exports. Under the agreement, South Africa vowed to allow 65,000 metric tons of U.S. meat imports a year.

WTO and FAO to Enhance Trade and Food Safety
The World Trade Organization ("WTO") and the Food and Agriculture Organization ("FAO") met on November 2, 2015, to announce they are strengthening their collaboration on food safety and sanitary and phytosanitary standards to facilitate international food trade and to promote development in the poorest countries. The WTO Director-General Roberto

Azevêdo said that the WTO seeks "to ensure that the global trading system works for all, that it is fair and balanced […] and allows people to access the goods and services that they need." In addition, Azevêdo stressed the importance of the 10th WTO Ministerial Conference to be held in Nairobi on December 15–18, 2015, to support the elimination of agricultural export subsidies and to tackle forces to promote other methods such as export credits, state trading enterprises, and food aid. Graziano Da Silva, the FAO Director-General, stated they "look forward to ensuring fair trade of agricultural and food products through this stronger (FAO–WTO) cooperation," which will be accompanied by a joint report on the subject by next year.

European Parliament Rejects GMO Food and Feed Proposal
On October 29, 2015, the Members of the European Parliament voted to reject a draft legislation that would enable EU members to restrict or prohibit the sale and use of EU-approved Genetically Modified Organism ("GMO") food or feed on its territory. The recommendation of Rapporteur Giovanni La Via (Italian member of the European People's Party) to reject the proposal was approved by 577 votes to 75, with 38 abstentions. See our previous Jones Day *Updates*, here and here. The European Commission ("Commission") suggested that this proposal be extended to another EU law of April 2015, which allows member states to ban the cultivation of EU-approved GMOs on its territory. While cultivation necessarily takes place on a member state's territory, GMO food or feed trade typically crosses. This means a national "sales and use" ban could be difficult or impossible to enforce without reintroducing border checks on imports. In spite of the Commission's suggestion, four large seed companies will no longer grow GMO maize in Germany since it would have negative consequences on conventional and organic crops.

Europe, China, and the United States Adopt Food Safety Agreement
On November 2, 2015, the U.S. FDA, the Directorate-General for Health and Food Safety of the European Commission, and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China adopted an agreement to enhance cooperation on food safety. After several years of discussion, the text was finalized and endorsed during a visit to Beijing. This agreement gives an official basis for a reinforced cooperation on (i) food safety information exchange, including technical and scientific information exchange, (ii) strengthening the capacity to respond to food safety problems, and (iii) establishing joint food safety meetings or forums when needed. In addition to this agreement, the European Food Safety Authority ("EFSA") and the Food Safety Commission of Japan renewed their memorandum of cooperation on food safety this week. The two food safety bodies agreed to build upon the 2009 memorandum and to support cooperation on collection and sharing of technical and scientific data related to risk assessment, monitoring, and communication, among others.

New EU–New Zealand Veterinary Agreement to Increase Trade of Animal Products
On November 10, 2015, the European Commission announced that technical amendments to the EU–New Zealand Agreement on sanitary measures in live animals and animal products have recently been made with the aim of boosting existing trade relations. Some of the new key features consists of (i) enhancing equivalence provisions including EU standards for raw milk products, (ii) mutual recognition of microbiological controls and chemical testing standards for seafood, (iii) establishing trade conditions to permit trade during disease outbreaks, (iv) reducing physical inspection rates on products, (v) resuming fresh pig meat exports to New Zealand, and (vi) simplifying certification requirements and moving to electronic certification in 2016. It is hoped that the amendments to the veterinary agreement will lead to further trade opportunities while reducing costs for exporters.

European Parliament Votes on Novel Foods
On October 28, 2015, the Members of the European Parliament approved a revised text regarding "novel foods" regulations, with a 359 to 202 vote and 127 abstentions. "Novel foods" are officially defined as food that has not been consumed to a significant degree by humans in the EU prior to 1997, which is the year when the first regulation on novel foods

came into force. Novel foods are either newly developed, innovative foods or foods that have been produced using new technologies and production processes. This includes not only products such as insects and nanomaterials but also fungi, algae, and new colorants. It can also include food that is regularly consumed in other parts of the world but that has never been traditionally eaten in the EU. The proposal still has to be approved by the Council of Ministers before it can enter into force. For more information, see our previous Jones Day *Update*.

Other News
The Safe and Accurate Food Labeling Act of 2015 Passes to the Senate

U.S. Extends Import Controls on Pigmeat to Poland and Baltic States

China Will Soon Resume U.S. Pork Imports

Canada Reopens European Beef Trade Route Closed Due to a BSE Outbreak

EU and N.Z. Negotiate a Future Free Trade Agreement

The European Consumer Organization Reports Misleading Meat Labeling

European Commission Delays Report on Alcohol Labeling

Regulatory Updates

FDA Seeks Comments on Use of Term "Natural" on Human Food Labeling
As discussed above, in the November 10, 2015, *Federal Register*, FDA requested the public to provide information and comments on the use of the term "natural" in the labeling of human food updates. ***Comments are due within 90 days from publication date***.

FDA Files Food Additive Petition for Partially Hydrogenated Oils
In the October 28, 2015, *Federal Register*, FDA announced the filing of a food additive petition, which was submitted by the Grocery Manufacturers Association on August 5, 2015. The petition proposes that the food additive regulations be amended to provide for the safe use of partially hydrogenated vegetable oils ("PHOs") in various food applications. For more information, see our previous Jones Day *Update*. ***Comments are due November 27, 2015***.

AMS Issues Final Rule Defining Bona Fide Cotton Spot Markets
In the October 22, 2015, *Federal Register*, USDA's AMS issued a final rule amending the regulatory language to designate which bona fide cotton spot markets will be used to establish actual commercial differences in value for various grades above or below the basis grade in the settlement of world cotton futures contracts on the Intercontinental Exchange ("ICE"). This will allow AMS to collect spot market price data and publish spot quotes for the settlement of these specific contracts. ***The rule is effective November 23, 2015***.

AMS Issues Final Rule Adjusting Representation on United Soybean Board
In the October 22, 2015, *Federal Register*, USDA's AMS issued a final rule adjusting the number of members on the United Soybean Board ("Board") to reflect changes in production levels. This change will result in an increase in Board membership for three states, resulting in an increase in the total number of Board members from 70 to 73. These changes will be reflected in the Soybean Promotion and Research Order and will be effective for the 2016 appointment process. ***The rule is effective October 23, 2015***.

FSA Establishes Regulation for the Agriculture Priorities and Allocations System
In the October 22, 2015, *Federal Register*, USDA's Farm Service Agency ("FSA")

established the regulation for the Agriculture Priorities and Allocations System ("APAS") to avoid civilian hardship during national defense emergencies. Through the APAS rule, USDA will respond to requests to place priority ratings on contracts or orders (establishing priority on which contracts or orders are filled first) for agriculture commodities up through the wholesale levels, including agriculture production equipment, and allocate resources if the necessity arises. ***The rule is effective December 21, 2015***.

NIFA Issues Final Rule for the Food Insecurity Nutrition Incentive Grant Program

In the October 23, 2015, *Federal Register*, USDA's National Institute of Food and Agriculture ("NIFA") published a final rule for the Food Insecurity Nutrition Incentive Grant Program that adds a subpart titled "Food Insecurity Nutrition Incentive Grant Program" to the part entitled "Competitive and Noncompetitive Non-Formula Federal Assistance Programs—General Award Administrative Provisions." NIFA's development and publication of this part serves to enhance its accountability and to standardize procedures across the federal assistance programs it administers, while providing transparency to the public. ***The rule is effective October 23, 2015***.

APHIS Adds and Adjusts Fee Categories for Agricultural Quarantine and Inspection Services

In the October 29, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") issued a final rule amending the user fee regulations by adding new fee categories and adjusting current fees charged for certain agricultural quarantine and inspection services that are provided in connection with certain commercial vessels, trucks, railroad cars and aircraft, and international passengers arriving at ports in the customs territory of the United States. APHIS is also adjusting or removing the fee caps associated with commercial trucks, vessels, and railcars. This is necessary to recover the costs of the current level of activity, to account for actual increases in the cost of doing business, and to more accurately align fees with the costs associated with each fee service. ***The rule is effective December 28, 2015***.

FSIS Announces an Export Verification Program for Ready-to-Eat Products Destined for Canada

In the November 2, 2015, *Federal Register*, USDA's FSIS established an Export Verification Program. The program is designed to verify establishments' control of FDA-regulated closed-faced sandwiches destined for Canada. Under the program, the sandwiches will be produced in establishments that are under FSIS's voluntary reimbursable inspection service and that are operating under conditions that are as consistent as practical with those under which other post-lethality exposed meat and poultry products are produced. This program has been established because, in contrast to U.S. regulations, Canada requires that closed-faced sandwiches be produced under a Hazard Analysis and Critical Control Point ("HACCP") plan. Once the program is implemented, only establishments participating in this program will be able to export closed-faced sandwiches to Canada. ***The program will be implemented February 1, 2016***.

APHIS Updates the National Poultry Improvement Plan Program Standards

In the November 3, 2015, *Federal Register,* USDA's APHIS updated the National Poultry Improvement Plan ("NPIP") Program Standards document, a cooperative federal-state-industry mechanism for controlling certain poultry diseases. A previous notice described (i) the changes to blood testing procedures for mycoplasma, (ii) the bacteriological examination procedure changes for *Salmonella*, and (iii) the addition of new approved diagnostic test kits, which are part of the updated NPIP. ***The program is effective January 4, 2016***.

NRCS Proposes to Revise Section I of the Illinois Field Office Technical Guide

In the November 5, 2015, *Federal Register*, USDA's Natural Resources Conservation Service ("NRCS") proposed to revise Section I of the Illinois Field Office Technical Guide to include "Guidance for Illinois Food Security Act Wetland Determinations Including Offsite

Methods," which would replace the existing "Wetland Mapping Conventions NRCS Illinois" (commonly referred as State Wetland Mapping Conventions), and would be used as part of the technical documents and procedures to conduct wetland determinations on agricultural land. ***Comments are due December 7, 2015***.

ARS Intends to Grant Exclusive License
In the November 5, 2015, *Federal Register*, USDA's Agricultural Research Service ("ARS") gave notice that it intended to grant to Microarray Equipment & Supplies, LLC of Cupertino, California, an exclusive license to U.S. Patent Application Serial No. 14/724,736, "Oligonucleotide Probes For Specific Identification Of Noroviruses And Other Pathogens," filed on May 28, 2015. The prospective exclusive license, which would be royalty-bearing, may be granted unless, within 30 days from the date of this published Notice, the ARS receives written evidence and argument establishing that grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. ***Comments are due December 7, 2015***.

Other USDA Announcements:

- APHIS Authorizes Importation of Fresh Peppers into the U.S. from Ecuador
- APHIS Adds Croatia to the List of Regions Considered Free of Foot-and-Mouth Disease, Rinderpest, and Swine Vesicular Disease, and to the List of Regions Considered Low Risk or Free of Classical Swine Fever
- APHIS Authorizes Importation of Fresh Pitahaya into the Continental U.S. from Israel
- APHIS Determines Genetically Engineered Maize MON-87411 is No Longer Regulated by 7 CFR Part 340
- APHIS Seeks Comments on its Determination to Consider Genetically Engineered Genective VCO-01981-5 Corn and Pioneer 4114 Corn Non-Regulated under 7 CFR Part 340
- AMS Proposes Issuance of Marketing Order to Cover Pecans Grown in the States of AL, AR, AZ, CA, FL, GA, KS, LA, MO, MS, NC, NM, OK, SC, and TX
- AMS Terminates Rulemaking Proceeding to Establish a Hardwood Lumber and Hardwood Plywood Promotion, Research and Information Order
- AMS Increases Assessment Rates of Walnuts and Kiwifruit Grown in California
- AMS Decreases Assessment Rates of Dates Produced and Packed in Riverside County, California, and Requests Comments
- The Commodity Credit Corporation Estimates Peanuts and Peanut Products Will Be Available for Donation During FY2016
- AMS Relaxes Handling Requirements for Grapes Grown in Southeastern California and Imported Table Grapes
- AMS Revises Exemption Requirements for Tart Cherries Grown in MI, NY, PA, OR, UT, WA, and WI

USDA Announced the Following Requests for Information:

- Phytosanitary Export Certification
- Importation of Tomatoes from Certain Central American Countries
- Importation of Papaya from Colombia and Ecuador
- Special Supplemental Nutrition Program for Women, Infants, and Children Infant and Toddler Feeding Practices Study-2 ("ITFPS-2") Age 5 Extension

USDA Announced the Following Proposed Information Collection:

- Local Foods Survey

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

- Laboratories
- Importation of Citrus From Peru
- ARS Animal Health National Program Assessment Evaluation Form

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

- Petitions for Rulemaking
- Cost of Pollination Survey
- Food Security Supplement to the Current Population Survey
- Strategic Economic and Community Development
- Application for Plant Variety Protection Certificate and Objective Description of Variety
- Special Need Request Under the Plant Protection Act
- 7 CFR part 215—Special Milk Program for Children
- Bee and Honey Survey
- Federal-State Special Supplemental Nutrition Program Agreement

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:

- Food Additive Petitions and Investigational Food Additive Exemptions
- Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Act

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

- Financial Disclosure by Clinical Investigators
- Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration
- Interstate Shellfish Dealers Certificate

FDA Announced that the Following Collections Have Been Approved by OMB:

- Administrative Practices and Procedures; Formal Evidentiary Public Hearing
- Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities
- Survey on Occurrence of Foodborne Illness Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

FDA Issued the Following Draft and Final Guidance Document:
Draft Guidance for Industry and Food and Drug Administration Staff: Manufacturing Site Change Supplements, October 21, 2015, *Federal Register*.

European Regulatory Updates

Isoflavones in Food Supplements for Post-Menopausal Women: No Evidence of Harm
EFSA has concluded that a comprehensive review of the available scientific evidence shows there is no indication that isoflavones, at levels typically found in food supplements, cause harm to post-menopausal women. Isoflavones are naturally occurring substances that are found, among other sources, in soy, red clover, and kudzu root. Their extracts are often used as ingredients in nutritional supplements.

Upcoming Meetings, Workshops, and Conferences

Science Board to the Food and Drug Administration Advisory Committee, **November 18, 2015**, in Silver Springs, MD.

Food Advisory Committee, **December 7–8, 2015**, in Silver Springs, MD.

Public Meeting of the Council for Native American Farming and Ranching Advisory Committee, **December 8–9, 2015**, in Las Vegas, NV.

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