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

President Signs Federal GMO Legislation Into Law Preempting State Laws
On July 29, 2016, President Obama signed into law S.764, the bill that creates the "National Bioengineered Food Disclosure Standard." As discussed in our previous *Update*, the bill attempts to head off the state-by-state labeling requirement for genetically modified foods (also referred to as genetically modified organisms, or GMOs) by setting a mandatory uniform national standard for biotechnology labeling of food.

Specifically, the bill directs the Secretary of Agriculture to establish regulations within the next two years requiring the form of disclosures on foods to be a text, symbol, or electronic or digital link, with alternative reasonable disclosure options for food contained in small or very small packages. The federal law explicitly preempts similar state laws, including (presumably) the one recently passed in Vermont.

FTC Approves Consent Orders Against Four Companies Making False All-Natural Claims
On July 13, 2016, the Federal Trade Commission ("FTC") approved final consent orders against four companies that allegedly misrepresented personal care products such as skin care products, shampoos, and sunscreens as all-natural.

Specifically, the complaints alleged that each of the four companies—Trans-India Products, Inc. d/b/a ShiKai, Erickson Marketing Group d/b/a Rocky Mountain Sunscreen, ABS Consumer Products, LLC d/b/a EDEN BodyWorks, and Beyond Coastal—advertised,

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labeled, offered for sale, sold, and distributed products labeled as "All Natural" or "100% Natural," despite the fact that such products contained synthetic ingredients. Under the final settlements, each of the companies is barred from making similar misrepresentations in the future and must have competent and reliable evidence to substantiate any ingredient-related, environmental, or health claims it makes. The FTC vote approving the final orders was 3–0.

FDA Amends Regulations for Registration of Food Facilities
On July 7, 2016, FDA issued a final rule amending its regulations for the registration of food facilities. This rule, like its predecessor, requires domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. The final rule amends and updates FDA's registration regulations to implement the FDA Food Safety Modernization Act, which added new provisions with the aim of improving the accuracy of the food facility registration database. Specifically, this final rule provides that registrations must include more information (e.g., email address), establishes a two-year renewal period, and provides that all food facility registrations must contain an assurance that FDA will be permitted to inspect the facility. In addition, the final rule requires that all food facility registrations be submitted to FDA electronically by January 4, 2020, amends the definition of the term "retail food establishment," and requires facilities to disclose the type of activity conducted at the facility for each food product category by July 14, 2016. The rule, which will be effective on September 12, 2016, intends to support FDA's efforts "to act quickly in response of food-related emergencies and will help the FDA to use its inspectional resources more efficiently."

FDA Publishes Web Page to Help Businesses Comply with the New Nutrition Facts Label Requirements
FDA has published a Nutrition Facts label "Industry Resources" web page to help businesses comply with the requirements of the final rules on Nutrition Facts and Service Size Regulations, which were issued in May 2016. For information regarding the final rules, please see our previous Jones Day *Update*.

The Industry Resources page provides information including: (i) a non-exhaustive list of Frequently Asked Questions; (ii) annotated graphic illustrations of new label specifications for the most commonly used label formats; (iii) high-resolution examples of label formats (find them here and here); (iv) tables showing daily values for vitamins, minerals, and food components, as well as reference amounts customarily consumed per eating occasion; and (v) links to final rules and reference materials. The Frequently Asked Questions include whether FDA plans to update the Food Labeling Guide, which FDA said it is working on but "will take some time." FDA also stated it will publish two guidance documents on Nutrition Facts labeling requirements later this year or early next year. FDA stated that businesses have until July 26, 2018 (or July 26, 2019, for manufacturers with less than $10 million in annual food sales) to comply with both final rules. However, business may voluntarily comply with the new requirements now.

Brazil Reopens its Doors to U.S. Beef After 13 Years
This month, USDA reached an agreement with Brazil to finally allow exports of U.S. beef and beef products to the Brazil market. Brazil banned U.S. trade of beef in 2003 due to the detection of bovine spongiform encephalopathy ("BSE") or "mad cow disease" in U.S. beef. Since then, the United States has been working to regain access to the Brazilian and other beef markets. This deal reflects the view that the United States has a negligible risk classification for BSE, as defined by the World Trade Organization for Animal Health. Agriculture Secretary Tom Vilsack stated that "USDA has eliminated BSE-related restrictions in 16 countries, regaining market access for U.S. beef and pumping hundreds-of-millions of dollars into the American economy." This year, the United States has regained access to the Saudi Arabia and Peru beef markets, South Korea poultry market, and South Africa poultry, pork, and beef markets. The agreement with Brazil also aligns with USDA's Food Safety and Inspection Service ("FSIS") recognition of Brazilian food safety standards as equivalent to those in the United States, enabling Brazil's fresh

beef to be exported to the United States. Both countries have to update their administrative procedures to enable the trade agreement to be effective in 90 days.

European Court Clarifies Scope of EU Nutrition and Health Claims Regulation
On July 14, 2016, the European Court of Justice ("ECJ") ruled that Regulation (EC) No 1924/2006 of the European Parliament and of the Council on food nutrition and health claims, passed December 20, 2006 and amended by Commission Regulation (EU) No 1047/2012 on November 8, 2012 (the "Regulation"), applies to business and commercial communications. Specifically, the ECJ held that Article 1(2) applies to commercial communications regarding nutrition or health claims of a food intended to be delivered as such to the final consumer, even if such communications are not addressed to the final consumer but exclusively to health professionals. The ECJ followed the opinion of the Advocate General, which found that even in cases where consumers do not receive the communication containing claims covered by the Regulation, the communications are in fact aimed indirectly at the consumers. The professionals who receive the advertising are "mere intermediaries who are contacted by a food business precisely because they are capable of promoting the product that it is selling by passing on the commercial information concerning that product to potential buyers, and even recommending that they purchase the product."

Other News
FDA Releases Foods and Veterinary Medicine Strategic 10-Year Plan

FDA Shares Completed Survey and Data from Ongoing Sampling Program on Raw Milk Cheese and Cucumbers and Hot Peppers

FDA Announces an Electronic System for Milk Products Export Lists

Bromodichloroacetic Acid Listed Effective July 29, 2016, as Known to the State of California to Cause Cancer

Environmental Groups Complain About EPA's Advice on Aquatic Life Ambient Water Quality Criterion for Selenium in Freshwater

EU approves Imports of Monsanto's Roundup Ready 2 Xtend Genetically Modified Soybeans

Regulatory Updates

FDA Announces 2017 Fee Rates for Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection
In the August 1, 2016, *Federal Register*, FDA announced the fiscal year 2017 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), as amended by the FDA Food Safety Modernization Act ("FSMA"). ***These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017***.

FDA Issues Guidance on Human Food Safety Evaluation of New Animal Drugs
In the July 21, 2016, *Federal Register*, FDA announced the availability of a draft revised guidance for industry titled "General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals." The guidance describes the types of information that FDA's Center for Veterinary Medicine recommends sponsors provide to address the human food safety of new animal drugs used in food-producing animals. Specifically, the guidance provides an overview of the process for the human food safety evaluation, including: (i) determination of an acceptable daily intake; (ii) calculation of safe concentrations; (iii) assignment of a tolerance; (iv) calculation of a withdrawal period and a milk discard time; and (v) evaluation of carcinogenic compounds.

Comments are due September 19, 2016.

FDA Amends Food Additive Regulations to Expand Use of Vitamin D_2 and D_3
In the July 18, 2016, *Federal Register*, FDA issued a final rule amending the food additive regulations to expand the safe uses of Vitamin D_2 as a nutrient supplement in edible plant-based milk and yogurt alternatives, and of Vitamin D_3 as a nutrient supplement in milk at levels higher than those currently permitted. The final rule was issued in response to a food additive petition filed by the Dean Foods Company and WhiteWave Foods Company. ***The rule was effective July 18, 2016***.

FDA Makes Technical Amendments to Emergency Permit Control Regulations
In the July 19, 2016, *Federal Register*, FDA issued a final rule making technical amendments to certain regulations pertaining to registration and process filings of acidified foods and thermally processed low-acid foods packaged in hermetically sealed containers. The amendments reflect the new FDA process filing form numbers, make changes to addresses or locations where such forms can be found or must be sent, and remove obsolete references to the effective dates that occurred years ago. ***The rule is effective August 18, 2016***.

FDA Reopens Comment Period of Ortho-Phthalates Food Additive Petition
In the August 8, 2016, *Federal Register*, FDA reopened the comment period for a notice of filing of May 20, 2016, where the agency requested comments on a filed food additive petition, submitted by the Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council. The petition proposes that FDA amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates. ***Comments are due September 19, 2016***.

AMS Amends Cotton Board Rules and Regulations
In the August 5, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") amended the Cotton Board Rules and Regulations, decreasing the value assigned to imported cotton for the purposes of calculating supplemental assessments collected for use by the Cotton Research and Promotion Program. This amendment is required each year to ensure that assessments collected on imported cotton and the cotton content of imported products will be the same as those paid on domestically produced cotton. ***Unless significant adverse comments are received by September 6, 2016, the rule is effective October 4, 2016***.

AMS Proposes Amendment to Marketing Orders for Cranberries Grown in Certain States
In the August 4, 2016, *Federal Register*, USDA's AMS invited comments on a proposed amendment to Marketing Orders, which regulates the handling of cranberries grown in the states of Massachusetts, Rhode Island, Connecticut, New Jersey, Wisconsin, Michigan, Minnesota, Oregon, Washington, and Long Island in the state of New York. The Cranberry Marketing Committee, which is responsible for the local administration of the order and comprises growers of cranberries operating within the production area, recommended adding authority to accept donations from domestic contributors. Contributed funds would be used solely for research and development activities authorized under the regulation of the order and would be free from any encumbrances that a donor attempts to put on their usage. ***Comments are due October 3, 2016***.

AMS Establishes Marketing Agreement and Order for Pecans Grown in Certain States
In the August 4, 2016, *Federal Register*, USDA's AMS established a marketing agreement and order for pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas. The order provides authority to collect industry

data and to conduct research and promotion activities. In addition, the order provides authority for the industry to recommend grade, quality, and size regulation, as well as pack and container regulation, subject to approval by the USDA. The program will be financed by assessments on handlers of pecans grown in the production area and will be locally administered, under USDA oversight, by a Council of 17 growers and shellers (handlers) nominated by the industry and appointed by USDA. ***The rule was effective August 5, 2016***.

AMS Updates U.S. Standards for Fruits, Vegetables, Nuts, and Specialty Crops
In the August 4, 2016, *Federal Register*, USDA's AMS revised 41 U.S. Standards for Grades of fresh fruits and vegetables, fruits and vegetables for processing, nuts, and specialty crops by removing the "Unclassified" category from each standard. This revision brings these grade standards in line with other recently amended standards and current terminology. The change also updates the standards to more accurately represent today's marketing practices and provide the industry with greater flexibility. ***The rule is effective September 6, 2016***.

APHIS Proposes to Allow Imports of Fresh Mango Fruit from Vietnam
In the August 4, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to amend the regulations to allow the importation of fresh mango fruit from Vietnam into the continental United States. As a condition of entry, fresh mango fruit from Vietnam would be subject to a systems approach that would include orchard requirements, irradiation treatment, and port of entry inspection. The fruit would also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization of Vietnam with an additional declaration stating that the consignment was inspected and found free of *Macrophoma mangiferae* and *Xanthomonas campestris pv. mangiferaeindicae*. ***Comments are due October 3, 2016***.

AMS Amends National List under the National Organic Program
In the August 3, 2016, *Federal Register*, USDA's AMS announced a final rule that addresses recommendations submitted to the Secretary of Agriculture by the National Organic Standards Board ("NOSB") following their April 2015 meeting. These recommendations pertain to the 2016 sunset review of substances on the USDA National List of Allowed and Prohibited Substances ("National List"). Consistent with the recommendations from the NOSB, this final rule removes five nonorganic nonagricultural substances from the National List for use in organic handling: egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate. ***The rule is effective September 12, 2016***.

FSA Revises Compliance with National Environmental Policy Act Regulations
In the August 3, 2016, *Federal Register*, USDA's Farm Service Agency ("FSA") consolidated, updated, and amended its regulations implementing the National Environmental Policy Act of 1969, as amended ("NEPA"). FSA's previous NEPA regulations had been in place since 1980. The changes are intended to better serve the change to FSA's structure and scope of its programs, and to align FSA's NEPA regulations with the President's Council on Environmental Quality NEPA regulations and meet the FSA responsibilities for periodic review of their categorical exclusions ("CatExs"). CatExs involve proposed actions that typically do not result in individual or cumulative significant environmental effects or impacts and therefore do not merit further environmental review in an Environmental Assessment or Environmental Impact Statement. This final rule also expands and clarifies the list of proposed actions that require an Environmental Assessment. The FSA NEPA implementing regulations also cover the Commodity Credit Corporation ("CCC") programs that FSA administers on behalf of CCC.

The revisions to the FSA NEPA implementing regulations are intended to improve transparency and clarity of the FSA NEPA process for FSA program participants, and to provide for a more efficient environmental review that will lead to better decisions and outcomes for stakeholders and the environment. Finally, in coordination with the Rural

Housing Service, Rural Business-Cooperative Service, and Rural Utilities Service, this rule removes the old NEPA regulations. ***The rule was effective August 3, 2016***.

AMS Issues Final Rule on Quality and Handling Standards for Peanuts Marketed in the U.S.
In the August 1, 2016, *Federal Register*, USDA's AMS issued a final rule to revise the minimum quality and handling standards for domestic and imported peanuts marketed in the United States. Specifically, the rule, among other things, revises the minimum quality, positive lot identification, and reporting and recordkeeping requirements under the standards. The rule implements a recommendation from the Peanut Standards Board. ***The rule is effective August 31, 2016***.

Reauthorization of the United States Grain Standards Act
In the July 29, 2016, *Federal Register*, USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA") issued a final rule to bring its regulations into compliance with amendments to the United States Grain Standards Act made by the Agriculture Reauthorization Act of 2015. Specifically, the final rule eliminates mandatory barge weighing, removes the discretion for emergency waivers of inspection and weighing, revises GIPSA's fee structure, revises exceptions to official agency geographic boundaries, extends the length of licenses and designations, and imposes new requirements for delegated states. ***The rule was effective July 29, 2016***.

FNS Issues Four Final Rules Regarding School Lunch and Breakfast Programs
In the July 29, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") issued four final rules regarding school nutrition programs: (i) the Administrative Reviews in the School Nutrition Programs final rule, which revises the state agency administrative review process of the National School Lunch Program and School Breakfast Program to establish a unified accountability system and ensure that school meals comply with program requirements (effective September 27, 2016); (ii) the Local School Wellness Policy Implementation under the Healthy, Hunger-Free Kids Act final rule, which requires all local educational agencies that participate in the National School Lunch and School Breakfast Programs to meet expanded local school wellness policy requirements, such as establishing minimum content requirements for the local school wellness policies, ensuring stakeholder participation in the development and updates of such policies, and periodic disclosure (effective August 29, 2016); (iii) the Eliminating Applications through Community Eligibility as Required by the Healthy, Hunger-Free Kids Act final rule, which establishes requirements for state agencies, local educational agencies, and schools operating the Community Eligibility Provision, a reimbursement option that allows the service of school meals to all children at no-cost in high-poverty schools without collecting household applications (effective August 29, 2016); and (iv) the Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act final rule, which adopts interim National School Lunch Program and School Breakfast Program regulations as final, addressing nutrition standards for all foods sold in schools, including food not sold under the lunch and breakfast programs (effective September 27, 2016).

APHIS Proposes to Amend National Environmental Policy Act Regulations
In the July 20, 2016, *Federal Register*, USDA's APHIS proposed to amend the regulations setting out its National Environmental Policy Act implementing procedures. Specifically, the amendments would clarify the categories of action for which APHIS would normally complete an environmental impact statement or an environmental assessment, expand the list of actions subject to categorical exclusion from further environmental documentation, and set out an environmental documentation process that could be used in emergencies. ***Comments are due September 19, 2016***.

FSIS Issues Final Rule Regarding Disposition of Non-Ambulatory Disabled Veal Calves
In the July 18, 2016, *Federal Register*, USDA's FSIS issued a final rule amending its regulations on ante-mortem inspection to remove a provision that permits establishments

to set apart and hold for treatment veal calves that are unable to rise from a recumbent position and walk because they are tired or cold. In addition, the amendments require all non-ambulatory disabled cattle to be promptly disposed of after they have been condemned. The final rule is intended to improve compliance with the Humane Methods of Slaughter Act of 1978 and its implementing regulations. ***The rule is effective September 16, 2016***.

APHIS Proposes Regulations Regarding Importation of Sheep and Goats
In the July 18, 2016, *Federal Register*, USDA's APHIS proposed to amend its regulations to remove bovine spongiform encephalopathy-related import restrictions on live sheep and goats and most of their products and add import restrictions related to transmissible spongiform encephalopathies for certain wild, zoological, or other non-bovine ruminant species. The import conditions are based on internationally accepted scientific literature and are intended to align U.S. regulations with guidelines set out in the World Organization for Animal Health's Terrestrial Animal Health Code. ***Comments are due September 16, 2016***.

AMS Issues Proposed Rule for Soybean and Beef Promotion and Research
In the July 15, 2016, *Federal Register*, USDA's AMS issued a proposed rule to amend the Soybean Promotion, Research, and Consumer Information Order and the Beef Promotion and Research Order. Specifically, the amendments would add provisions allowing soybean and beef producers to request, under certain circumstances, that their authorized assessments paid to a state board or council be redirected to the national program. ***Comments are due September 13, 2016***.

USDA Issues Final Rule for Designation of First Assistants
In the July 15, 2016, *Federal Register*, USDA issued a final rule authorizing the Secretary of Agriculture to establish a First Assistant to each office within the USDA to which appointment is required to be made by the President with the advice and consent of the Senate. Federal law provides that when an officer of an executive agency whose appointment is required to be made by the President with the advice and consent of the Senate dies, resigns, or is otherwise unable to perform the functions and duties of the office, the First Assistant to the office of such officer may perform temporarily the functions and duties of the office in an acting capacity. ***The rule was effective July 15, 2016***.

AMS Requests Comments on U.S. Standard for Grades of Catfish and Catfish Products
In the July 14, 2016, *Federal Register*, USDA's AMS invited catfish producers, suppliers, processors, retailers, food services operators, and other interested stakeholders to provide background information, comments, and data to assist in the development of voluntary U.S. standards for grades of catfish and catfish products. ***Comments are due September 12, 2016***.

FSIS Determines Namibia Eligible to Export Meat Products to the U.S.
In the July 13, 2016, *Federal Register*, USDA's FSIS amended the federal meat inspection regulations to allow Namibia to export meat and meat products to the United States. Under the final rule, Namibia will be able to export to the United States only boneless (not ground) raw beef products (such as primal cuts, chuck, blade, and beef trimmings) that are processed in certified Namibian establishments. Namibia will need to submit additional information for FSIS to review before it may export other beef product or product from other types of livestock to the United States. ***The rule is effective September 12, 2016***.

APHIS Proposes Changes to National Poultry Improvement Plan Program Standards
In the July 12, 2016, *Federal Register*, USDA's APHIS announced the availability of proposed changes to the National Poultry Improvement Plan Program Standards for review and comment. The proposed updates would add provisions for

compartmentalization of primary breeding poultry establishments and approval of compartment components such as farms, feedmills, hatcheries, and egg depots. Included in the proposed additions are requirements for applying for compartmentalization of facilities and for facility design and management, as well as an outline of the auditing system APHIS will use to evaluate compartments and their component operations. ***Comments are due August 11, 2016***.

APHIS Issues Interim Rule to Amend Bovine Tuberculosis Regulations
In the August 8, 2016, *Federal Register*, USDA's APHIS announced an interim rule amending the bovine tuberculosis regulations regarding state and zone classifications by reclassifying the state of California as accredited-free. Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium *Mycobacterium bovis*. APHIS has determined that the state meets the criteria for accredited-free status. This action relieves certain restrictions on the interstate movement of cattle and bison from the state of California. ***The rule is effective August 8, 2016, and comments are due October 7, 2016***.

AMS Proposes Modification to Handling Regulation for Irish Potatoes Grown in Colorado
In the August 1, 2016, *Federal Register*, USDA's AMS proposed a rule to revise the grade requirement currently prescribed for Size B potatoes (1½ inch minimum to 2¼ inch maximum) under the Colorado potato marketing order. The rule, which would implement a recommendation from the Colorado Potato Administrative Committee, Area No. 2, would relax the current minimum grade requirement for Size B red potatoes from U.S. commercial grade or better to U.S. No. 2 or better. ***Comments are due September 30, 2016***.

APHIS Releases Pest Risk Analysis for Imported Fresh Star Apple Fruit from Vietnam
In the July 19, 2016, *Federal Register*, USDA's APHIS announced the availability of a pest risk analysis for review and comment. The analysis, which evaluates the risks associated with the importation of fresh star apple fruit from Vietnam into the continental United States, concludes that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via such importation of the fruit. ***Comments are due September 19, 2016***.

AMS Issues Interim Rule Regarding Olives Grown in California
In the July 18, 2016, *Federal Register*, UDSA's AMS issued an interim rule to suspend the incoming size-grade authority under the California olive marketing order. The rule, which implements a recommendation from the California Olive Committee, also makes conforming changes to the corresponding size-grade requirements in the order's rules and regulations to adapt them to the suspension. The suspension and revisions are intended to allow the Committee time to develop new incoming size-grade authority that will reflect currently available technology and meet the industry's future needs. ***The rule was effective July 19, 2016; comments are due September 16, 2016***.

AMS Proposed Increased Assessment Rate for Almonds Grown in California
In the July 18, 2016, *Federal Register*, USDA's AMS issued a proposed rule to increase the assessment rate established for the 2016–17 through the 2018–19 crop years from $0.03 to $0.04 per pound of almonds handled under the marketing order. Of the $0.04 per pound assessment, 60 percent (or $0.024 per pound) would be available as credit-back for handlers who conduct their own promotional activities. The crop year begins August 1 and ends July 31. Beginning August 1, 2019, the assessment rate would return to $0.03 and would remain in effect indefinitely unless modified, suspended, or terminated. ***Comments were due August 2, 2016***.

APHIS Amends Regulations for Importation of Mangoes from India
In the July 14, 2016, *Federal Register*, USDA's APHIS made technical amendments to its

regulations regarding the importation of mangoes from India. A previous technical amendment amended the regulations to allow mangoes treated with irradiation in the United States to be inspected by the national plant protection organization ("NPPO") of India in India, and subsequently by APHIS at the port of entry in the United States, rather than being jointly inspected in India in all cases. The previous technical amendment neglected to remove two references to preclearance inspections within India; this document corrects that error. ***The rule is effective July 14, 2016***.

EU Regulatory Updates

EFSA Consults on Health Claims Guidance
On July 18, 2016, the European Food Safety Authority ("EFSA") launched a public consultation on its revised scientific and technical guidance for the preparation and presentation of a health claim application. The revised guidance aims to assist applicants in preparing and presenting their applications for authorization of health claims on food. According to EFSA, the changes are intended to increase the efficiency and consistency of the application process. ***Comments are due September 12, 2016***.

EU Commission Approves UV-Treated Milk
On July 19, 2016, the European Commission approved UV-treated milk as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council ("Novel Food Regulation"). Under the Novel Food Regulation, any food that has not been consumed to a significant degree by humans in the EU prior to 1997 is considered a "Novel Food" and is subject to a prior authorization before it can be sold in Europe. Novel Foods will be approved for use in the EU only if they do not present a risk to public health, are not nutritionally disadvantageous when replacing a similar food, and are not misleading to the consumer. In addition, novel foods must undergo a scientific assessment prior to authorization to ensure their safety.

EFSA Launches Public Consultation on Dietary Reference Values for Potassium
On July 13, 2016, EFSA announced the launching of a public consultation on its draft scientific opinion on dietary reference values for potassium. Potassium is an essential mineral in the human diet and plays an important role in many physiological functions. The document proposes dietary reference values for adults, children and infants, and pregnant and lactating women. ***Comments are due August 24, 2016***.

EFSA Launches Public Consultation on GM Plant Allergenicity Guidance
EFSA has launched a public consultation on its draft guidance for the allergenicity assessment of genetically modified ("GM") plants. The new guidance document on allergenicity reflects scientific advances as compared to the current guidance. Updates in the guidance are based in part on extensive literature reviews, which revealed new methodologies that could be applied in assessing allergenicity. The new guidance also reflects recent EU legislation on GM food and feed by addressing new requirements for the authorization of GM plants for the European market. These requirements refer to the inclusion of certain allergens in the compositional analysis of the allergenicity assessment of a GM plant. ***Comments are due September 25, 2016***.

Other EU Regulatory Updates
EFSA Adopts Scientific Opinion on Copper in Animal Feed

EFSA's Working Group Finalizes Honeybee Colony Health Model Details

Upcoming Meetings, Workshops, and Conferences

Public Meeting of FDA to Update Stakeholders on the Agency's Discussions on the User-Fee Program for Nonprescription (over-the-counter or OTC) Monograph Drugs, **September 6, 2016**, via webinar.

Public Meeting of FDA and USDA to discuss agenda items and draft U.S. positions to be discussed at the 23rd Session of the Codex Committee on Residues of Veterinary Drugs in Foods, **September 22, 2016**, in Washington, D.C.

Public Meeting of FDA to discuss menu labeling, **September 27–28, 2016**, in St. Louis, MO, and **late 2016 (Date TBD)**, in Oakland, CA.

Public Meeting of the National Organic Standards Board to discuss implementation of the Organic Foods Production Act, **November 16–18, 2016**, in St. Louis, MO.

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