Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

FDA Finds that Artificial Trans Fats are Unsafe
Last week, FDA finalized its determination that partially hydrogenated oils ("PHOs") are not "generally recognized as safe" ("GRAS") for use in human food. This finding effectively bans PHOs, which are the primary source of artificial trans fat in processed foods. FDA has set a compliance date of June 18, 2018, allowing industry three years to adjust to the order.

Although the FDA's action will not eliminate naturally occurring trans fats from the American diet (found in small amounts of some meat and dairy products), it will drastically reduce the amount of artificial trans fat in the U.S. food supply and, according to FDA's Acting Commissioner Stephen Ostroff, M.D., "prevent thousands of fatal heart attacks every year." For more details, please refer to Jones Day's *Alert* on the determination.

FDA Finalizes Guidance on Food Allergens Labeling Exemptions
Last week, FDA issued a final guidance to help food manufacturers provide adequate data to support exemptions from the labeling requirements for ingredients derived from major food allergens. Food labels identifying products that contain major food allergens, such as milk, eggs, peanuts, fish, crustaceans, shellfish, tree nuts, wheat, and soybeans, are required by the Food Allergen Labeling and Consumer Protection Act of 2004.

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The guidance allows manufacturers to avoid labeling products with major food allergens if they can modify the ingredient so it no longer presents a risk to consumers with food allergies. As part of this process, manufacturers would be required to submit scientific information demonstrating an ingredient derived from a major food allergen "does not cause an allergic response that poses a risk to human health" or "does not contain allergenic protein." These modifications would give consumers with allergenic reactions a greater variety of food options without fear of triggering an allergic reaction.

FDA Issues Final Rule on Adding Selenium to Infant Formula
On June 22, 2015, FDA announced a final rule to add selenium to the list of required nutrients for infant formula and to establish both minimum and maximum levels of selenium in infant formula. Among other benefits, selenium helps the body defend against oxidative stress and aids the regulation of thyroid hormones. Manufacturers in the United States have been adding selenium to infant formula since 1989, after the Institute of Medicine recognized the nutrient, found in breast milk, as essential for infants. All infant formulas sold today in the United States contain selenium. The final rule requires a selenium range between 2.0 micrograms selenium/100 kilocalories and 7.0 micrograms selenium/100/kilocalories and amends the labeling requirements for infant formula to require the listing of selenium in micrograms per 100 kilocalories on the formula labels. Under the final rule, FDA requires manufacturers to add the nutrient within this range of safety, as well as require any new manufacturer entering the U.S. market to adopt this practice. The rule makes selenium the 30th nutrient required by law to be included in infant formula.

U.S. Fights Canada's Bid for Retaliatory Tariffs in Response to Controversial Meat Labeling Rules
During a special session of the World Trade Organization's ("WTO") Dispute Settlement Body, the United States formally opposed Canada's bid for US$2.5 billion in annual retaliatory tariffs. Canada is imposing the tariffs in response to USDA's controversial country-of-origin meat labeling ("COOL") requirements, an effort to help consumers make informed choices by requiring producers to label beef, pork, chicken, and other meat products to reveal where the animals were born. The WTO recently found the requirements in the final rule, issued in May 2013, to violate global trade rules, specifically discriminating against Canadian and Mexican producers. Now that the United States has exhausted the appeals process, it must either repeal the COOL rules or face tariffs from Canada and Mexico on various products. During last week's arbitration, the United States told the WTO that Canada's request was excessive when compared to actual costs triggered from the COOL labeling. The arbitration will continue, with Canada reiterating its demand for the United States to bring its meat labeling regime into compliance with WTO rules. This process is already underway in Congress. On June 11, 2015, the House voted 300 to 131 to repeal the COOL labels, but the Senate has instead indicated a preference for altering the rules to remove their discriminatory effects.

European Parliament Votes Against Production and Import of Cloned Animals
Last week, the European Parliament ("Parliament") approved a ban on producing and importing cloned animals and reproductive material (semen and embryos), their descendants, and any products derived from them, such as milk or meat, citing public discomfort that such products could eventually make their way into supermarkets. The proposal from Parliament's environmental and agricultural committees builds off of the European Commission's draft animal welfare laws of December 2013 but extends the draft laws to cover the germinal product of animal clones. According to Parliament, "[d]ue to the negative effects on animal welfare, cloning for farming purposes is rejected by a large majority of consumers." Moreover, "we do not need cloning to ensure meat supplies in the EU. Prohibiting cloning is therefore a matter of European values and principles …." The committees' recommendations passed with 82 votes for and eight against, and the proposal heads to a full Parliament vote in early September 2015. The proposal will not ban cloning for research, conservation of rare breeds and endangered species, or the production of pharmaceuticals and medical devices.

Other News
Vermont GMO Labeling Law Could Trigger Fines of $10M a Day

USDA Proposes New Egg Inspection Rules to Streamline Egg Imports

San Francisco Approves Soda Ad Warning Labels

FDA Warns About Safety of Raw Pet Food

USDA Report Investigates Spread of Bird Flu

Regulatory Updates

FDA Determines PHOs Are Unsafe in Human Food
In the June 17, 2015, *Federal Register*, FDA published its determination that PHOs are not safe for use in human food. PHOs are the primary source of artificial trans fat in processed foods. FDA has given industry three years to adjust to the order. ***The compliance date is June 18, 2018***.

FDA Amends Regulations for Food Additives in Animal Feed and Drinking Water
In the June 22, 2015, *Federal Register*, FDA announced amendments to the regulations for food additives permitted in feed and drinking water of animals to allow for the safe use of seed meal from a variety of bioengineered safflower in cattle and poultry feeds. The safflower variety has been bioengineered to include a gene responsible for the production of gamma-linolenic acid in seed oil. FDA concluded that the data establish the safety and utility of gamma-linolenic acid safflower meal for use. ***The rule is effective June 22, 2015; objections and requests for hearings are due by July 22, 2105***.

FDA Amends Food Additive Regulations Restricting TBHQ
In the June 16, 2015, *Federal Register*, FDA announced an amendment to the food additive regulations removing the upper bound of the melting point for the antioxidant tertiary butylhydroquinone ("TBHQ") in response to a petition. TBHQ is an additive to preserve processed foods through an antioxidant effect. Recent studies have shown that an upper bound is unnecessary since TBHQ can have a higher melting point than the previous rule allowed but still have an acceptable purity. As such, FDA is adding a purity acceptance criteria of not less than 99 percent to ensure the safe use of TBHQ in food. ***The rule is effective June 16, 2015***.

FSIS Releases Guidance on Controlling Listeria in Delicatessens
In the June 11, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") announced the availability of an updated guidance, "Best Practices Guidance for Controlling Listeria monocytogenes ("Lm") in Retail Delicatessens," which discusses steps retailers should take to prevent certain ready-to-eat ("RTE") foods prepared or sliced in retail delicatessens and consumed in the home from becoming contaminated with Lm. FSIS encourages retailers to review the guidance and evaluate the effectiveness of their retail practices and intervention strategies in reducing the risk of listeriosis to consumers from RTE meat and poultry deli products.

FSIS Affirms Rule on Control of Lm in Ready-to-Eat Meat and Poultry Products
In the June 19, 2015, *Federal Register*, FSIS affirmed the June 2003 interim final rule "Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products." FSIS clarified that establishments may not release into commerce product that has been in contact with Lm-contaminated surfaces without first reprocessing the product. FSIS is removing the requirement for establishments to report production volume and related information to FSIS because this information is now collected through the Public Health Information System. ***Comments are due August 18, 2015; the rule is effective September 17, 2015***.

USDA Issues Final Rules Amending Regulation of Biobased Products
In the June 15, 2015, *Federal Register*, here and here, USDA issued two final rules amending its regulation of biobased products. The first rule amended the Guidelines for Designating Biobased Products for Federal Procurement, including a revision to the BioPreferred program definitions, addition of reporting requirements, addition of targeted

biobased-only purchasing requirement, and addition of criteria for evaluating innovative approaches. The second rule amended regulations to the Voluntary Labeling Program for Biobased Products, including revisions to definitions, criteria for product eligibility to use the certification mark, initial approval process, violations, and oversight and monitoring. Both final rules incorporate statutory changes to section 9002 of the Farm Security and Rural Investment Act that went into effect as part of the 2014 Farm Bill. ***The rules are effective July 15, 2015***.

USDA Addresses National Organic Standards Board's Organic Regulations
In the June 19, 2015, *Federal Register*, USDA addressed the 2015 Sunset Review submitted by the National Organic Standards Board following its May and October 2014 meetings. Three synthetic substances (sodium carbonate peroxyhydrate, aqueous potassium silicate, and sulfurous acid) and two nonsynthetic substances (gellan gum and tragacanth gum) were renewed on the National List of Allowed and Prohibited Substances in organic production and handling. ***The rule is effective June 22, 2015***.

CCC and FSA Provide Record of Decision on the Conservation Reserve Program
In the June 18, 2015, *Federal Register*, USDA's Commodity Credit Corporation ("CCC") and Farm Service Agency ("FSA") provided a summary of the Record of Decision regarding the Conservation Reserve Program ("CRP"), which supports the implementation of long-term conservation measures designed to improve the quality of ground and surface waters, control soil erosion, and enhance wildlife habitat on environmentally sensitive agricultural land. FSA decided to implement changes to CRP resulting from the 2014 Farm Bill. Among other changes, the provision authorizing emergency haying or grazing on "Rare and Declining Habitat" during severe drought conditions will not be implemented. ***The rule is effective July 20, 2015***.

FSA Notifies Intent to Prepare Programmatic Environmental Impact Statement for Biomass Crop Assistance Program
In the June 12, 2015, *Federal Register*, USDA's FSA, on behalf of the CCC, notified its intent to prepare a Programmatic Environmental Impact Statement ("PEIS"), as required by the National Environmental Policy Act of 1969. The PEIS would assess the potential environmental consequences associated with proposed changes to the Biomass Crop Assistance Program ("BCAP"). The BCAP is a voluntary program intended to assist agricultural and forest land owners and operators with the establishment and production of eligible crops in selected project areas for conversion to bioenergy. The input received will enable the development of alternatives for implementing the proposed changes and evaluate the impacts of those alternatives. ***Comments are due July 13, 2015***.

FSIS Publishes Codex Standards in Accordance with International Standards
In the June 11, 2015, *Federal Register*, USDA's FSIS published the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission ("Codex"), in accordance with the Trade Agreements Act of 1979, as amended, and the Uruguay Round Agreements Act. The FSIS notice also provides a list of other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts.

CCC Proposes Rule to Revise and Amend Administration of FGP
In the June 15, 2015, *Federal Register*, USDA's CCC proposed a rule to revise and amend the regulations used to administer the Facility Guarantee Program ("FGP"). Under the FGP, CCC provides payment guarantees to facilitate the financing of manufactured goods and U.S. services to enhance sales of U.S. agricultural commodities and products to emerging markets where the demand for such commodities and products may be limited due to inadequate storage, processing, handling, or distribution. The proposed amendments incorporate statutory changes from the Food, Conservation, and Energy Act of 2008 and modifications intended to reduce burdens on participants and improve program efficiency and effectiveness. Certain revisions of the proposed rule are intended to ensure the FGP is operated in compliance with the Organisation for Economic Co-operation and Development's Arrangement on Officially Supported Export Credits. ***Comments are due August 14, 2015***.

GIPSA Seeks Comments on Regulations Regarding the Packers and Stockyards Act
In the June 15, 2015, *Federal Register*, USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA") sought comments on regulations regarding the Packers and Stockyards Act. Specifically, GIPSA is concerned about when a market agency is allowed to sell livestock on a commission basis to its owners, officers, and employees. GIPSA wants to determine whether additional information is needed in clarifying the circumstances under which key employees of the market agency, those designated as an auctioneer, weighmaster, or salesman, may purchase livestock. ***Comments are due August 14, 2015***.

CCC Announces Availability of Biofuel Infrastructure Partnership Grants to States
In the June 16, 2015, *Federal Register*, USDA's CCC announced the availability of competitive grants to fund activities designed to expand the infrastructure for renewable fuels. The funds must be used to pay a portion of the costs related to the installation of fuel pumps and related infrastructure dedicated to the distribution of higher ethanol blends at vehicle fueling locations, including, but not limited to, local fueling stations, convenience stores, hypermarket fueling stations, or fleet facilities. Grantees must provide matching contributions that may be used for additional related costs such as additional infrastructure to support pumps, marketing, education, data collection, program evaluation, and administrative costs associated with the application process. ***Applications are due July 15, 2015***.

USDA Provides Semiannual Regulatory Agenda for Spring 2015
In the June 18, 2015, *Federal Register*, USDA provided summary descriptions of regulations being developed in USDA agencies. The complete regulatory agenda is available online at www.reginfo.gov. USDA's printed agenda entries include only: (i) rules that are likely to have a significant economic impact on a substantial number of small entities; and (ii) rules identified for periodic review under section 610 of the Regulatory Flexibility Act.

USDA Requests Nominations for Advisory Committee on Beginning Farmers and Ranchers
In the June 18, 2015, *Federal Register*, the USDA requested nominations for the Advisory Committee on Beginning Farmers and Ranchers ("Committee"). The Committee advises the Secretary of Agriculture on matters broadly affecting new farmers and ranchers, including strategies, policies, and programs that will enhance opportunities and create new farming and ranching operations. ***Nominations are due July 17, 2015***.

Other USDA Announcements
• USDA's Agricultural Marketing Service ("AMS") Proposes Revision to Electronic Submission of Import Request of Shell Eggs
• USDA Announces Fiscal Year 2016 WTO Tariff-Rate Quotas for Raw Cane Sugar at 1,117,195 MTRV and Certain Sugars, Syrups and Molasses at 132,000 MTRV
• USDA Announces Increase of 20,000 MTRV in Fiscal Year 2015 Refined Sugar Tariff-Rate Quota
• AMS Proposes Rule to Adjust Representation on the United Soybean Board

USDA Announced the Following Requests for Information
• Generic Clearance for the Collection of Qualitative Customer Feedback on Farm Service Agency Service Delivery
• Policy on Audits of RUS Borrowers
• Advance of Loan Funds and Budgetary Control and Other Related Burdens

USDA Announced the Following Information Collections Have Been Revised and/or Extended
• Research, Education, and Extension Project Online Reporting Tool (REEport)
• National Agricultural Statistics Service Stocks Report
• Regulations Governing the Application for Plant Variety Protection Certificate and Reporting Requirements under the Plant Variety Protection Act
• Citrus Greening and Asian Citrus Psyllid: Quarantine and Interstate Movement

Regulations
• Importation of Hass Avocados from Peru

USDA Announced the Following Information Collections Have Been Submitted to OMB
• Grazing Permit Administration Forms
• Importation of Peppers from the Republic of Korea
• Pesticide-Use Proposal Form
• National Universal Product Code Database

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections
• Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

FDA Announced the Following Information Collections Have Been Submitted to OMB
• Regulations Under the Federal Import Milk Act
• Irradiation in the Production, Processing, and Handling of Food
• Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

FDA Announced that the Following Collections Have Been Approved by OMB
• Risk and Benefit Perception Scale Development
• Food Allergen Labeling and Reporting
• Food and Cosmetic Export Certificate Applications Process

FDA Issued the Following Draft and Final Guidance Documents
Guidance for Industry: Recommendations for Preparation and Submission of Animal Food Additive Petitions, June 12, 2015, *Federal Register*.

Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications, June 19, 2015, *Federal Register*.

European Regulatory Updates

EFSA Publishes Guidance for Renewal Applications of GMOs
On June 18, 2015, the European Food Safety Authority ("EFSA") published a guidance document for renewal applications of genetically modified ("GM") food and feed authorized under Regulation (EC) No 1829/2003. The document describes the data requirements for renewal applications for GM food and feed for import and processing in the European Union, excluding cultivation.

EU Council Presents New Compromise Text on Novel Foods
On June 10, 2015, the European Council's Permanent Representatives Committee approved a final compromise text on EU rules on novel foods that includes the European Parliament's amendments. A "novel food" is food that was not used for human consumption to a significant degree within the EU before May 15, 1997. The text aims at improving the current rules on novel foods, making it faster to bring such products to the market while preserving a high level of protection of human health. The Latvian presidency will now inform the European Parliament and propose an agreement at "first reading" on the basis of the text approved by the Permanent Representatives Committee. The European Parliament is expected to consider and vote on the Council's compromise text during the week of July 4, 2015.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the Beginning Farmers and Ranchers Advisory Committee's Subcommittee on Land Tenure, **June 22–24, 2015**, in Des Moines, IA.

Public Meeting: Demo Day for the 2014 Food and Drug Administration Food Safety Challenge, **July 7, 2015**, in College Park, MD.

General Conference Committee of the National Poultry Improvement Plan, **July 23, 2015**, in Salt Lake City, UT.

Public Meeting of the Codex Alimentarius Commission Committee on Fresh Fruits and Vegetables, **August 6, 2015**, in Washington, D.C.

Public Meeting of the Codex Alimentarius Commission Committee on Spices and Culinary Herbs, **August 19, 2015**, in Washington, D.C.

EFSA's 2nd Scientific Conference, **October 14, 2015**, in Milan, Italy.

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