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

### U.S. and Canada: Comparable Food Safety Systems

On May 4, 2016, FDA announced that both the U.S. and Canada have recognized each other's food safety systems as comparable to each other. This is the second time that FDA has given this recognition to a country, the first being New Zealand in 2012. The FDA, the Canadian Food Inspection Agency ("CFIA"), and the Department of Health Canada ("Health Canada") have used the International Comparability Assessment Tool ("ICAT"), which contains standards to evaluate whether a country's system of protections is similar to the other, and whether their food safety authority or authorities provide similar oversight and monitoring activities for food produced under their jurisdiction. In fact, the ICAT would issue system recognition of only two countries' food safety systems after evaluating the countries' domestic and export food safety system, including: its regulatory foundation; training, inspection, program assessment and inspection audit, and compliance and enforcement program; food-related illness and outbreaks; industry and community relations; program resources; international communication and harmonization; and laboratory support.

The fact that the described operations are similar helps enhance food safety and facilitates trade between both countries. For instance, FDA states that FDA, CFIA, and Health Canada "have confidence that they can leverage each other's science-based regulatory systems."

### FDA Issues Final Guidance on Menu Labeling

At the end of April 2016, FDA released the final guidance on menu labeling providing

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recommendations on compliance with the menu labeling rule, which requires calorie information to be listed on menus, menu boards, and displays of restaurants and other retail food establishments that are part of a chain of 20 or more locations. This guidance covers many of the topics for which FDA received questions and which were not addressed by the rule on menu labeling or the draft guidance, or for which the information provided was unclear. For instance, FDA answers questions related to covered establishments that are a chain of restaurants that operate under different names depending on location; menu and menu board calorie declaration requirements that apply to catered events, combination meals, "all-you-can-eat" buffets, or grab-and-go items; determination of nutrient values general criteria; whether USDA or FDA caloric or other nutrient determination requirements apply to alcoholic beverages and in which cases; and recordkeeping of substantiation of nutrient values. In addition, FDA clarifies that prisons and mobile vendors are not covered by the final rule.

Release of the final guidance also signals that the countdown to implementation of the final rule on menu labeling will begin soon. The final rule will become effective one year from the publication date of this guidance, as indicated by the FDA's Center for Food Safety and Applied Nutrition ("CFSAN") director at the beginning of March 2016 (*see* our previous Jones Day *Update*). Publication in the *Federal Register* is expected on May 5, 2016.

**FDA Issues Guidance on Labeling and Marketing of Animal Food Diets Intended for Treatment or Prevention of Diseases**

FDA has issued a guidance for FDA staff intended to ensure animal safety related to direct-to-consumer or retail sales of dog and cat food products intended for use in treatment or prevention of disease. FDA has seen an increase of such products recently. The guidance summarizes FDA's concerns with the safety and effectiveness of these products, which are not evaluated by the FDA, and pet owners' misinterpretation of claims. For example, a pet owner might purchase a food that claims to treat obesity when in fact the product may not be formulated to meet the pet's daily nutrient requirements.

Although animal food products intended to diagnose, cure, mitigate, treat, or prevent diseases are regulated as drugs, and hence need to be registered and listed with and approved by the FDA, FDA has exercised enforcement discretion in the past when those products provided all or most of the nutrient in support of the animal's total required daily nutrient needs, did not claim to treat or prevent disease when made available to the general public, and were distributed only through licensed veterinarians, who know the health history of the pet and the nutrient, food, or drugs (if any) the pet needs to consume. FDA concludes that it will enforce applicable rules as to food manufacturers that sell these products directly to the consumer where the manufacturer makes health claims that are not scientifically substantiated or that could pose a health safety risk to the pet, where the product contains ingredients that are not generally recognized as safe or contain unapproved food additives, or where the product does not comply with food regulations, such as food labeling, establishment registration, or good manufacturing practices.

**OSHA Issues Food Safety Whistleblower Rule**

The U.S. Occupational Safety and Health Administration ("OSHA") has released a final rule governing the employee protection provision of Section 402 of the FDA Food Safety Modernization Act ("FSMA"), which protects employees against retaliation by an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food for engaging in certain protected activities. Protection is needed when an employee has provided or is about to provide to his or her employer, the federal government, or the attorney general of a state information relating to any violation of the Federal Food, Drug and Cosmetic Act ("FDCA"); has testified or is about to testify in a proceeding concerning such violation; has assisted or participated, or is about to assist or participate, in such a proceeding; or has objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of any provision of the FDCA. Among other things, the rule establishes

procedures and time frames for the handling of retaliation complaints under FSMA and to OSHA, which must be filed within 180 days of the alleged violation, the procedures for the investigation of the complaint by OSHA, appeals of OSHA's determinations to an administrative law judge ("ALJ") for a hearing de novo, hearings by ALJs, review of ALJ decisions by the Administrative Review Board, and judicial review of the Secretary's final decision. The rule further states that the complainant need not show that the conduct complained of constituted an actual violation of law.

**U.S. to Profit from China's Termination of Export Subsidies**
On April 14, 2016, U.S. Trade Representative ("USTR") Michael Froman announced that the United States and China signed a memorandum of understanding ("MOU") terminating export subsidies provided under China's "Demonstration Bases-Common Service Platform" Program, which provided prohibited export subsidies to Chinese enterprises located in 179 industrial clusters throughout China. The agreement resolves a challenge filed by the United States in the World Trade Organization ("WTO") against the program early last year, in which the United States stated that hundreds of Chinese government legal instruments violated WTO rules. Since then, China has terminated, amended, replaced, or allowed to expire all 175 instruments, and has issued 136 measures to implement the terms of the MOU. The move is expected to benefit American workers across multiple industries, including the agriculture industry, by leveling the global playing field and creating more jobs. According to the USTR, agriculture products that will lose Chinese subsidies include apples, beef, mushrooms, pork, tea, tomatoes, beans, ginseng, poultry, seaweed, and garlic.

**EFSA to Review Bisphenol A Safety for the Immune System**
On April 26, 2016, the European Food Safety Authority ("EFSA") announced that it would be conducting a study for the potential effects of Bisphenol A ("BPA") on the immune system. The announcement followed the publication of a report by the Dutch National Institute for Public Health and the Environment ("RIVM") that specifically raised concerns on the effects of BPA on the immune systems of fetuses and young children. BPA is a chemical that is frequently used to manufacture plastics and resins to make food containers such as returnable beverage bottles, infant feeding bottles, tableware, and storage containers. BPA can migrate in small amounts into food and beverages.

In December 2014, EFSA's expert Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids ("CEF Panel") reduced the tolerable daily intake for BPA from 50 micrograms per kilogram of body weight per day (µg/kg bw/day) to 4 µg/kg bw/day, and determined that BPA posed no health risk to consumers of any age group at current exposure levels. The new RIVM report critically examines two studies describing pre- and perinatal effects of BPA on the immune system that were unpublished when EFSA reviewed the available scientific literature for its 2014 risk assessment of BPA. The RIVM report recommends supporting research on alternatives to BPA and advises consumers to reduce exposure to food and other sources that may contain BPA. EFSA aims to issue a statement in the next few months.

**European Parliament Urges Restrictions on Reauthorization of Glyphosate**
In a nonbinding resolution, members of the European Parliament ("MEP") voted for the European Commission ("EC") to renew the EU market approval for glyphosate, an active substance widely used in herbicides, for only seven years and not 15 as originally proposed, and for professional uses only. Safety of this substance has been recently debated by the World Health Organization ("WHO") and EFSA, which reached differing conclusions on the carcinogenicity of glyphosate (see Jones Day's previous *Update*). The national experts of the Phytopharmaceuticals Section of the European Commission's ("EC") Standing Committee on Plants, Animals, Food and Feed will vote to adopt or reject the MEP's proposal. If a qualified majority is not reached, the EC will decide on the matter.

**Other News**
FDA Transfers Siluriformes Fish (Catfish) Inspection to USDA's Food Safety and Inspection Service

US to Fund $6M for Antimicrobial Resistance Research

While American Beef Exporters Urge Congress to Vote on the TPP, 161 Farm Groups Reject it Fearing Flood of Imports Will Negatively Impact their Sales

China to Expand Genetically Modified Crops

## Regulatory Updates

**FDA Issues CPG on Labeling and Marketing of Certain Dog and Cat Foods**
As discussed above, in the May 2, 2016, *Federal Register*, FDA announced the availability of Compliance Policy Guide ("CPG") Sec. 690.150 titled "Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases." The document provides guidance to FDA staff on issues related to dog and cat diets that are labeled and/or marketed as intended for use to diagnose, cure, mitigate, treat, or prevent diseases and are also labeled and/or marketed to provide all or most nutrients in support of meeting the animal's total daily nutrient requirements. The guide, which finalizes a draft Compliance Policy Guide dated September 10, 2012, lists the factors FDA intends to consider in determining whether to exercise enforcement discretion if the diets are sold or marketed inappropriately.

**FDA Issues Compliance Policy Guide on Fresh and Frozen Crabmeat Adulteration**
In the April 28, 2016, *Federal Register,* FDA announced the availability of revised CPG Sec. 540.275 relating to fresh and frozen crabmeat adulteration with filth involving the presence of *Escherichia coli*. The CPG clarifies and updates the format of the previously issued CPG on this topic. The CPG provides guidance for FDA staff on the level of *E. coli* in crabmeat at which FDA may consider the crabmeat to be adulterated with filth. Revisions generally include the addition of sections on Background and Policy, updates to the sections on Regulatory Action Guidance and Specimen Charges, and FDA office names. The CPG also contains information that may be useful to the regulated industry and to the public.

**FDA Issues Final Rule Amending Food Additive Regulations**
In the April 15, 2016, *Federal Register*, FDA issued a final rule to amend the food additive regulations at 21 C.F.R. § 172.345 to provide for the safe use of folic acid in corn masa flour at levels not to exceed 0.7 milligrams per pound. The rule was issued in response to a food additive petition filed by Gruma Corporation, a manufacturer of corn flour and tortillas, and others, including health organizations. ***The rule was effective April 15, 2016***.

**FDA Issues Exempt Infant Formula Production Guidance**
In the April 15, 2016, *Federal Register*, FDA announced the availability of guidance for industry titled "Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports." The guidance is intended to provide information on FDA's current thinking on the manufacturing of exempt infant formulas, and generally recommends that exempt formulas be produced using manufacturing practices, quality control procedures, audit procedures, and records and reporting protocols that are at least equivalent to those used for products consumed by healthy, full-term infants.

**FDA Makes Technical Amendment to the FSVP for Importers of Food for Human and Animals**
In the April 28, 2016, *Federal Register,* FDA amended final rule "Foreign Supplier Verification Programs ("FSVP") for Importers of Food for Humans and Animals" published in the *Federal Register* on November 27, 2015. The final rule established requirements for importers to verify that food they import into the U.S. is produced consistent with the hazard analysis and risk-based preventive controls and standards for produce safety

provisions of the FDCA, is not adulterated, and is not misbranded with respect to food allergen labeling. The final rule was published with some editorial and inadvertent errors. This document corrects those errors. ***The amendments are effective April 28, 2016***.

**FDA Announces Filing of Food Additive Petition**
In the April 29, 2016, *Federal Register,* FDA gave notice of the submission of a food additive petition on behalf of 3M Corporation to no longer provide for the use of two different perfluoroalkyl-containing substances as components of paper and paperboard in contact with aqueous and fatty foods. The petitioner requests amendment of the FDA's food additive regulations because these uses have been intentionally and permanently abandoned. ***Comments are due June 28, 2016***.

**FDA Extends Comment Period on Risk Assessment of Foodborne Illness Associated with Pathogens from Certain Produce**
In the April 22, 2016, *Federal Register*, FDA announced an extension of the comment period for the notice that appeared in the *Federal Register* on March 4, 2016, wherein FDA requested scientific data, information, and comments that would assist in the development of a risk assessment for produce grown in fields or other growing areas amended with untreated biological soil amendments of animal origin (including raw manure). ***Comments are due July 5, 2016***.

**FNS Issues Final Rule Updating Meal Pattern Requirements for the Child and Adult Care Food Program**
In the April 25, 2016, *Federal Register,* USDA's Food and Nutrition Service ("FNS") issued a final rule updating the meal pattern requirements for the Child and Adult Care Food Program to better align them with the Dietary Guidelines for Americans, as required by the Healthy, Hunger-Free Kids Act of 2010. This rule requires centers and day care homes participating in the Child and Adult Care Food Program to serve more whole grains and a greater variety of vegetables and fruit, and to reduce the amount of added sugars and solid fats in meals. In addition, this final rule supports mothers who breastfeed and improves consistency with the Special Supplemental Nutrition Program for Women, Infants, and Children and with other Child Nutrition Programs. Several of the changes are extended to the National School Lunch Program, School Breakfast Program, and Special Milk Program. ***The rule is effective June 24, 2016***.

**AMS Issues Notice of Public Hearing on Proposed Rulemaking for California Raisins**
In the April 22, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") announced a public hearing to receive evidence on proposed amendments to Marketing Order No. 989, which regulates the handling of raisins grown in California. Amendments proposed by the Raisin Administrative Committee would (i) authorize production research, (ii) establish new nomination procedures for independent grower and alternate member seats, (iii) add authority to regulate quality, (iv) add authority to establish different regulations for different markets, and (v) add a continuance referenda requirement. In addition, amendments proposed by AMS would remove order language pertaining to volume regulation and reserve pool authority, and would establish term limits for Committee members. ***The hearing will be held on May 3–4, 2016, in Clovis, CA***.

**AMS Proposes Amendments to Regulations Governing the Voluntary Grading of Shell Eggs**
In the April 20, 2016, *Federal Register*, USDA's AMS proposed amendments to the regulations governing voluntary grading of shell eggs to clarify the definition of "condition," to remove any food safety implications resulting from the use of the term "wholesomeness," and to clarify that AMS's role in grading and certification of shell eggs is solely for a quality determination. The proposed rule would also prohibit the use of *Salmonella Enteritidis*-adulterated or recalled shell eggs from being presented to USDA for voluntary grading and certification. ***Comments are due June 20, 2016***.

**FSIS Proposes Allowing Poland to Export Poultry Products to the United States**

In the April 20, 2016, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") proposed to add Poland to the list of countries eligible to export poultry products to the U.S. After reviewing Poland's poultry laws, regulations, and inspection system as implemented, FSIS tentatively determined that they are equivalent to the Poultry Products Inspection Act ("PPIA"), the regulations implementing this statute, and the U.S. food safety system for poultry. ***Comments are due June 20, 2016***.

**FSIS Proposes Allowing Honduras to Export Poultry Products to the United States**
In the April 13, 2016, *Federal Register*, USDA's FSIS proposed to add Honduras to the list of countries eligible to export certain poultry products, such as slaughtered poultry or poultry parts, to the United States. After reviewing Honduras's laws, regulations, and inspection system, FSIS determined that they are equivalent to PPIA and its implementing regulations. Because the United States has assessed only Honduras's poultry slaughter establishments, however, Honduras would be eligible to export only raw poultry products to the United States should the rule become final. ***Comments are due June 13, 2016***.

**FNS Issues Final Rule Clarifying Requirements for Distribution and Control of Donated Foods**
In the April 19, 2016, *Federal Register*, USDA's FNS issued a final rule revising and clarifying requirements to ensure that USDA donated foods are distributed, stored, and managed in a safe, efficient, and cost-effective manner. In addition, the rule (i) reduces administrative and reporting requirements for state distributing agencies, (ii) revises and clarifies regulatory provisions relating to accountability for donated foods, and (iii) revises and clarifies specific requirements to conform to related requirements in corresponding regulations and current law. ***The rule is effective June 20, 2016***.

**USDA Issues Final Rule Implementing Revised Marketing Order for Tart Cherries**
In the April 18, 2016, *Federal Register*, USDA issued a final rule implementing a recommendation from the Cherry Industry Administrative Board to revise provisions of the marketing order for tart cherries grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. Specifically, the rule (i) intends to encourage handlers to participate in new market and market expansion activities, (ii) changes the number of years that new market development and market expansion projects are eligible for handler diversion credit from one year to three years, and (iii) revises the composition of the subcommittee that reviews exemption requests. ***The rule was effective April 19, 2016***.

**AMS Removes Obsolete Specialty Crop Block Grant Program Regulations**
In the April 18, 2016, *Federal Register*, USDA's AMS issued a final rule rescinding and removing 7 C.F.R. Part 1290, which established regulations for the Specialty Crop Block Grant Program for the fiscal years 2006 to 2008. ***The rule was effective April 19, 2016***.

**APHIS Reopens Comment Period for Proposed Apple and Pear Importation**
In the April, 15 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") announced it was reopening the comment period for a proposed rule that would amend the regulations to allow for importation of fresh apple and pear fruit from certain countries in the European Union into the continental United States, provided that the fruit is produced in accordance with a systems approach. This rule would provide an alternative to importation under the current preclearance program. ***Comments are due May 5, 2016.***

**AMS Proposes Amending Organic Livestock and Poultry Production Requirements**
In the April 13, 2016, *Federal Register*, USDA's AMS proposed to amend the organic livestock and poultry production requirements to add new provisions for livestock handling and transport for slaughter and avian living conditions, and expand and clarify existing requirements covering livestock health care practices and mammalian living conditions.

The amendments seek to improve upon the current standards by setting separate standards for mammalian and avian livestock living conditions to better reflect the needs and behaviors of the different species and related consumer expectations. ***Comments are due June 13, 2016***.

**FSIS Issues Final Rule Amending Definition for "Roaster" Poultry Class**
In the April 13, 2016, *Federal Register*, USDA's FSIS issued a final rule amending the definition and standard of identity for the "roaster" or "roasting chicken" poultry class to better reflect the characteristics of roaster chickens in the market today. Due to genetic changes and management techniques that have reduced the grow-out period and increased the ready-to-cook ("RTC") weight for roasters, FSIS is amending the "roaster" definition to remove the eight-week minimum age criterion and increase the RTC carcass weight from 5 pounds to 5.5 pounds. ***The rule is effective January 1, 2018***.

**Commodity Credit Corporation Issues Final Rule Amending MPP-Dairy Regulations**
In the April 13, 2016, *Federal Register*, USDA's Commodity Credit Corporation issued a final rule amending the regulations for the Margin Protection Program for Dairy ("MPP-Dairy") to allow dairy operations to update their production history when a son, daughter, grandchild, or spouse of a child or grandchild of a current producer participating in the MPP-Dairy program joins the operation. The rule also provides for a later due date for the payment of the entire premium and clarifies that dairy operations that purchase buy-up coverage on less than 90 percent of their production history will also receive catastrophic coverage on the balance, up to 90 percent of the production history. ***The rule was effective April 13, 2016***.

## European Regulatory Updates

**EFSA Announces Apricot Kernels Pose Risk of Cyanide Poisoning**
At the end of April 2016, EFSA published its opinion that eating more than three small raw apricot kernels or less than half of one large kernel in a serving can exceed safe levels of risk of cyanide poisoning. In the case of toddlers, there is a risk of poisoning after ingesting as little as one small apricot kernel. Apricot kernels contain a naturally occurring compound, amygdaline. which converts to cyanide after eating. Cyanide is poisonous and can cause nausea, fever, headaches, insomnia, thirst, lethargy, nervousness, various joint and muscle aches and pains, and falling blood pressure. In extreme cases, it is fatal. EFSA is discussing with EU Member States its scientific opinion and previous assessments of national authorities, and it will decide whether further measures are needed to protect public health from consumption of raw apricot kernels.

**EU Sets Emergency Measures for the Import of Citrus Fruits from Certain Non-EU Countries**
On April 15, 2016, Member State experts endorsed emergency measures proposed by the Commission with stricter requirements for the importation of citrus fruits from Brazil, South Africa, and Uruguay. The measures are intended to increase the protection against fruits contaminated with citrus black spot, a harmful plant disease not native to Europe.

## Upcoming Meetings, Workshops, and Conferences

Public Meeting of the Secretary's Advisory Committee on Animal Health, **May 2, 2016**, and **June 16, 2016**, via multisite teleconferences.

Public Meeting of the Minority Farmers and Ranchers Advisory Committee, **May 10–12, 2016**, in New Orleans, LA.

Public Meeting of the Codex Alimentarius Commission, **June 10, 2016**, Washington, D.C.

Public Meeting of the FDA titled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-10 Meeting" to receive public input on various topics pertaining to the regulation of cosmetics, **June 15, 2016**, in Bethesda, MD.

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