Food, Dietary Supplement & Cosmetics Regulatory Update
Vol. III | Issue 10 | July 2016 JONES DAY

Top News

Bipartisan Senate Agreement to Require Mandatory GMO Labeling
On June 23, 2016, Senator Pat Roberts (R-Kansas) and Senator Debbie Stabenow (D-Michigan) reached an agreement to solve 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. The senators' proposed bill would give several options to food manufacturers to comply with the mandatory disclosure requirements. The options include adding to the package certain text, a symbol, or an electronic link to a website. In the last case, the bill states the package could not include any denigrating text toward biotechnology and would require the use of the descriptive language, "Scan here for more food information."

Very small companies would be exempt from compliance with the mandatory labeling requirement, and small companies would have the alternative of including a toll-free number and website instead of using a digital code.

The disclosure requirement would apply to all human food, including some meat and poultry products, but would exclude foods where meat, poultry, and egg products are the main ingredient, or foods that are derived from an animal that ate bioengineered food. The mandatory requirements would also apply to dietary supplements. The bill also states that products certified GMO by USDA could be labeled as non-GMO, but products that are exempt from disclosure under the bill would not automatically be allowed to make non-biotech claims on their food.

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RELATED PRACTICES

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The bill will need to pass the Agriculture Committee, the full Senate, and the U.S. House, which passed a bill last July establishing a voluntary labeling system for GMO foods. If the bill is finally approved, it will preempt other similar state laws, such as Vermont's law, which entered into force on July 1, 2016.

Congress Considers Lifting Bans on Food Exports to Cuba
On June 16, 2016, the U.S. Senate Appropriations Committee approved bipartisan amendments during its markup of the Fiscal Year 2017 Financial Services and General Government Appropriations bill that would ease trade barriers with Cuba. Specifically, S. 3067, introduced by Senator John Boozman (R-Arkansas), would lift the ban on private banks and companies offering credit for the export of agricultural commodities to Cuba. According to Sen. Boozman, the amendment "helps level the playing field for American farmers and allows U.S. agriculture products to more easily enter the Cuban market." According to the Office of the United States Trade Representative, the top export categories to Cuba in 2015 were meat ($78 million), food waste and animal feed ($44 million), and miscellaneous grain, seeds, and fruit ($22 million). In addition, U.S. exports of agricultural products to Cuba totaled $150 million in 2015, with leading categories including poultry ($78 million), soybean meal ($55 million), soybeans ($10 million), corn ($5 million), and dairy products ($412,000). The appropriations bill now advances to the full Senate for consideration.

IFSAC Analyzes Foodborne Illness Attribution
The Interagency Food Safety Analytics Collaboration ("IFSAC"), created in 2011 to study the most common food sources linked to specific foodborne illnesses, has recently published a paper in emerging infectious diseases, titled "Comparing Characteristics of Sporadic and Outbreak-Associated Foodborne Illnesses, United States, 2004–2011." This article compares some characteristics of outbreak and sporadic (non-outbreak) human illnesses caused by *Salmonella*, *Escherichia coli* (*E. coli*) O157, *Listeria monocytogenes*, and *Campylobacter*. The analysis indicates that *Campylobacter*, *Listeria monocytogenes*, and *E. coli* O157 outbreak illnesses are not significantly different from sporadic illnesses with respect to patients' illness severity, gender, and age. With regard to *Salmonella* outbreak illnesses, these are not significantly different from sporadic illnesses with respect to illness severity and gender; however, the percentage of outbreak illnesses in the youngest age category (0–3 years) was substantially lower compared with the other age groups. Such analyses are essential to advancing scientific progress in the field.

In an unrelated effort on pathogen informatics, on June 27, 2016, FDA published videos of FDA's GenomeTrakr network—a network that was established to facilitate the sharing of pathogen sequence data among public health agencies, academia, and the food industry, with the goal of preventing large-scale foodborne illness outbreaks.

Philadelphia Issues Sugar-Sweetened Beverage Tax
On June 16, 2016, Philadelphia's City Council approved by a 13–4 vote a 1.5 percent per ounce tax on sweetened soft drinks. The tax will be applied to any nonalcoholic beverage, syrup, or other concentrate that lists as an ingredient any form of caloric sugar-based sweetener, including, but not limited to, sucrose, glucose, and high fructose corn syrup. The tax also applies to beverages containing artificial sugar substitutes, such as stevia, aspartame, sucralose, neotame, acesulfame potassium (known as Ace-K), saccharin, and advantame. The rule excludes the application of the tax to sweetened baby formulas, medical foods, drinks made from at least 50 percent milk or fruit or vegetables, drinks to which a purchaser can add, or can request that a seller add, sugar at the point of sale, and any syrup or other concentrate that the customer combines with other ingredients to create a beverage.

The first city to impose a soda tax was Berkeley, California, and other neighboring cities, such as San Francisco, Oakland, and Albany, have introduced similar tax proposals to be voted in November 2016. Other cities, such as New York City, have unsuccessfully tried to pass similar tax laws in the past. Philadelphia's rule will be effective January 1, 2017.

European Commission to Open Public Consultation on Review of Health Claims Regulation
On June 21, 2016, the European Commission ("Commission") announced a public consultation and online survey to review the Health Claims Regulation 1924/2006 in early September 2016, as anticipated by the "RoadMap" published in November 2015. The review focuses on two areas of the Health Claims Regulation: health claims made on botanicals and nutrient profiles. The consultation will explore whether the respective provisions should be implemented as planned or repealed (and replaced by another framework). The consultation will focus on quantitative data and objective evidence supporting either a "full implementation" scenario or a "no-implementation" scenario.

The Health Claims Regulation covers two types of health claims: health claims made on botanicals and health claims "on other foods." Provisions on health claims "on other foods" have already been fully implemented and can be used only if they are authorized by the EU. By contrast, health claims on botanicals are still "on hold," which means that prior claims to the Health Claims Regulation can be used as long as the evaluation by the European Food Safety Authority ("EFSA") over the new proposed claims is still ongoing. With regard to nutrient profiles, foods will be able to bear a nutrition or health claim only if they meet the maximum thresholds imposed by the regulation for certain nutrients in foods. For example, if breakfast cereals or sport drinks surpass a certain level of sugar or fat, an operator would not be able to label them with any health claims, such as claims related to the addition of vitamins, or nutrition claims, including claims that the food is a source of potassium. In 2009, the Commission issued a working document that sets out proposed nutrient profiles for selected foods, such as beverages, milk products, cereals, etc.

Ales Bartl of Jones Day's Brussels Office is a representative of the European Food Law Association in the stakeholder meetings organized by the Commission on this revision.

FDA to Extend Compliance Date for Certain Vending Machine Calorie Disclosures
On July 8, 2016, the FDA announced that it is extending the compliance date for final calorie declaration requirements for certain food products sold from vending machines from December 1, 2016, to July 26, 2018. The final rule, which appeared in the December 1, 2014, *Federal Register*, applies to certain food from vending machines operated by operators with 20 or more machines and requires information to be displayed so prospective purchasers can examine an item's calorie content before purchasing it. The FDA granted the extension for glass-front vending machines after several trade associations requested it, arguing it would be helpful to have a compliance date that aligns with the recently published nutrition facts label final rule. The extension will allow companies to make all changes to their food labels, including front-of-pack ("FOP") calorie information, at one time. FDA is also extending the compliance date for certain gums, mints, and roll candy sold in vending machines in response to industry requests to provide flexibility for labeling these products.

The extension applies only to foods sold from glass-front vending machines that have visible FOP labeling. If packaged food sold in glass-front vending machines does not have visible FOP labeling, the calorie disclosures will have to appear in, on, or adjacent to the vending machine consistent with the requirements in the final rule by December 1, 2016. The December 2016 compliance date also still applies to vending machines that use electronic displays or sell unpackaged products.

Other News
Federal Appeals Panel Approves Three-Month Sentences for Corporate Officers Over Egg-Related *Salmonella* Outbreak

FDA, in Collaboration with AMA, Releases Continuing Medical Education Video about Nutrition Facts Label

Effective October 1, 2016, Dermal Exposure from Solid Materials of Bisphenol A will be

Limited to 3 mcg/day in California

EFSA Update on BPA: Experts Start Immunotoxicity Review

Regulatory Updates

FDA Extends Comment Period for Risk Assessment of Foodborne Illness
In the June 30, 2016, *Federal Register*, the FDA announced the extension of the comment period for a notice titled "Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments." The notice was originally published on March 4, 2016. (FDA had previously extended the comment period in a notice published on April 22, 2016). The current extension is due to maintenance of the Federal eRulemaking Portal. ***Comments are due July 19, 2016***.

FDA Extends Comment Period for Inorganic Arsenic in Rice Cereals for Infants
In the June 30, 2016, *Federal Register*, the FDA announced the extension of the comment period for a draft guidance titled "Inorganic Arsenic in Rice Cereals for Infants: Action Level," which was originally published on April 6, 2016. The extension is due to maintenance of the Federal eRulemaking Portal. ***Comments are due July 19, 2016*.**

FDA Announces Newer Version of Imported Food Guidance
In the June 16, 2016, *Federal Register*, the FDA released a final industry guidance titled "Prior Notice of Imported Food Questions and Answers (Edition 3)." Before publishing Edition 3, FDA had issued two rules. First, a final rule in 2008 requires the submission to FDA of prior notice of food, including animal feed, imported or offered for import into the United States. Second, a final rule in 2013, in accordance with the Food Safety Modernization Act ("FSMA"), requires disclosure in the "prior notice" of the name of any country to which an article had been refused entry. The third edition addresses industry questions, clarifies previous responses, updates previous responses to reflect the 2008 rule, and includes information about FSMA's new prior notice requirement. The final guidance largely resembles the draft guidance released by the Agency on March 31, 2014.

FDA Finalizes Guidance on Nutrition Labeling
In the July 1, 2016, *Federal Register*, the FDA released a final industry guidance titled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels." The guidance addresses manufacturers of conventional foods and dietary supplements, and explains FDA's policy on determining the amount to declare on the nutrition label for certain nutrients and dietary supplements that are present in a small amount. The final guidance largely resembles the draft guidance released by the Agency on July 30, 2015. FDA has made only editorial changes to the guidance, which include updates to the list of nutrients consistent with the final rule titled "Food Labeling; Revision of the Nutrition and Supplement Facts Labels," which appeared in the *Federal Register* on May 27, 2016.

FDA Proposes Rule to Establish Requirements for the Electronic Filing of Entries
In the July 1, 2016, *Federal Register*, the FDA released a proposed rule that would require certain data elements be submitted in the Automated Commercial Environment or any other CBP-authorized electronic data interchange system. The requirement would apply to information material to the admissibility determination for FDA-regulated products being imported or offered for import. This proposed action would facilitate automated "may proceed" determinations for low-risk FDA-regulated products, and it would allow the Agency to focus its resources on products that may be associated with a greater public health risk. ***Comments are due August 30, 2016***.

FDA Extends Comment Period for Chromium Propionate Permitted in Feed and Drinking Water of Animals

In the June 27, 2016, *Federal Register*, the FDA announced the extension of the comment period for a final rule, published on June 3, 2016, regarding the safe use of chromium propionate as a source of chromium in broiler chicken feed. The comment period extension is due to the filing with the FDA of a food additive petition. ***Comments are due July 19, 2016***.

FDA Files Food Additive Petition
In the June 15, 2016, *Federal Register*, the FDA announced that it filed a food additive petition submitted by the Styrene Information and Research Center. The petition proposes to amend the food additive regulations "to no longer provide for the use of styrene as a synthetic flavoring substance and adjuvant in food because those uses of styrene have been permanently abandoned." The petition asserts that regulatory authorization is unnecessary because styrene is no longer manufactured, imported, or otherwise marketed as a food additive in the United States or abroad. ***Comments are due August 15, 2016***.

FDA Files Food Additive Petition
In the June 30, 2016, *Federal Register*, the FDA announced that it filed a petition submitted by Keller and Heckman LLP on behalf of the Society of the Plastics Industry ("SPI"). The petition proposes to amend the food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure sealing gaskets for food containers. SPI asserts in its petition that regulation is no longer authorized because the use has been intentionally and permanently abandoned. ***Comments are due August 29, 2016***.

APHIS Extends Comment Period for Importation of Lemons from Northwest Argentina
In the July 11, 2016, *Federal Register*, USDA's Animal Plant Health Inspection Service ("APHIS") announced the extension of the comment period for a proposed rule, published on May 10, 2016, regarding the importation of lemons from northwest Argentina. The comment period extension will allow interested persons additional time to submit comments. ***Comments are due August 10, 2016***.

USDA Announces the Re-Establishment of the Council for Native American Farming and Ranching
In the July 6, 2016, *Federal Register*, the USDA re-established the advisory Council for Native American Farming and Ranching ("Council"). The Council "discusses issues related to the participation of Native American farmers and ranchers in USDA programs and transmits recommendations concerning any changes to regulations or internal guidance or other measure." The USDA is seeking candidates to be considered for membership on the Council. ***Nominations are due August 22, 2016***.

AMS Issues Final Rule for Spearmint Oil
In the June 15, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") implemented recommendations from the Far West Spearmint Oil Administrative Committee in a final rule regarding the handling of spearmint oil produced in the Far West. The Far West includes Washington, Idaho, and Oregon, and certain parts of Nevada and Utah. The rule established "salable quantities and allotment percentages for Class 1 (Scotch) spearmint oil of 958,711 pounds and 45 percent, respectively, and for Class 3 (Native) spearmint oil of 1,209,546 pounds and 50 percent, respectively."

AMS Revises Cotton Board Regulations for *De Minimis* Cotton Imports
In the June 15, 2016, *Federal Register*, AMS amended the Cotton Board Rules and Regulations to remove the cotton import *de minimis* provision. The provision exempted U.S. cotton producers and importers of cotton and cotton-containing products from paying an import assessment if a line item on the U.S. Customs and Border Protection ("CBP") documentation was $2.00 or less. As a result of technological developments in the CBP documentation, transaction costs associated with collecting import assessments no longer exceed $2.00, and hence the provision is no longer necessary. ***The rule is***

effective July 15, 2016.

AMS Proposes Rule for Tart Cherries and Establishes Free and Restricted Percentages
In the June 15, 2016, *Federal Register*, AMS proposed to implement recommendations from the Cherry Industry Administrative Board regarding cherries grown in the states of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. The proposed action would establish inventory release procedures and "increase the maximum carry-out volume available when calculating optimum supply from 20 million pounds to 10 million pounds" under Marketing Order No. 930. ***Comments are due July 15, 2016***.

In addition, in the June 16, 2016, *Federal Register*, AMS established free and restricted percentages for the 2015–16 crop year under the Order per recommendations from the Board.

APHIS Amends Asian Longhorned Beetle Regulations
In the June 16, 2016, *Federal Register*, APHIS removed plants of the genus *Celtis* from the list of regulated articles for the Asian longhorned beetle ("ALB"). APHIS determined that because plants of the genus *Celtis* are not a host plant of ALB, there was no need to restrict the movement of *Celtis* plants from ALB quarantined areas. ***The Rule is effective June 16, 2016, and comments are due August 15, 2016***.

AMS Proposes to Revise U.S. Standards for Grades of Canned Vegetables
In the June 17, 2016, *Federal Register*, AMS proposed to revise the U.S. standards for grades of canned vegetables with language reflective of current canned vegetable industry practices. The proposed action would replace the two-term grading system (dual nomenclature) with a single term to describe each quality level for 18 standards covering various canned vegetables. The proposed changes would increase the grade standards' usefulness in the industry. ***Comments are due August 16, 2016***.

FCIC Amends Common Crop Insurance Regulations
In the June 22, 2016, *Federal Register*, the Federal Crop Insurance Corporation ("FCIC") amended the Common Crop Insurance Regulations to provide policy changes and to clarify existing policy provisions to better meet the needs of policyholders. Specifically, the amendments: (i) revise the definition of "practical to replant" to provide a clear, known deadline for when replanting of the crop is considered to be practical, with certain exceptions; (ii) allow the allocation of comingled first and second crop production to the associated crop acreage in proportion to the liability for the acreage that was and was not double cropped; and (iii) revise the qualifications for double cropping acres to adequately account for changes in growing farm operations or for added land. ***The rule was effective June 22, 2016; comments are due August 22, 2016***.

APHIS Amends Animal Import/Export Regulations
In the June 21, 2016, *Federal Register*, APHIS amended its regulations regarding the importation and exportation of animals, plants, and animal and plant products to address instances where the current regulations require the use of a hard-copy form or specify that a particular document must be submitted in writing. The rule amends the regulations to provide the flexibility needed for persons to take advantage of electronic systems when a regulation has a limiting requirement. The amendments do not mandate the use of electronic systems or preclude the use of paper documents; rather, they address those instances where regulations specify a submission method to the exclusion of other methods. ***The rule was effective June 21, 2016***.

FNS Makes Technical Amendment to Rule on Donated Foods
In the June 20, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") made corrections to the final rule "Requirements for the Distribution and Control of Donated Foods—The Emergency Food Assistance Program: Implementation of the Agricultural Act of 2014," published on April 19, 2016. The final rule revised and clarified requirements to

ensure that USDA donated foods are distributed, stored, and managed in a safe, efficient, and cost-effective manner at state and recipient agency levels. The final rule was published with some spelling and technical errors. This document corrects those errors. ***The amendments were effective June 20, 2016***.

FSIS Revises Meat and Poultry Regulations
In the June 29, 2016, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") amended the meat and poultry inspection regulations to provide for an electronic export application and certification system in order to enhance the Agency's Public Health Information System. The rule makes available the export application and certification system as an alternative to the paper-based application. ***The rule is effective August 29, 2016***.

AMS Withdraws Proposed Amendment to the Beef Promotion and Research Rules and Regulations
In the June 30, 2016, *Federal Register*, AMS withdrew its proposed rule published on March 16, 2016, regarding the Beef Promotion and Research Rules and Regulations. The proposed rule is being withdrawn because of an error noted in the formula determining the assessment rate on imported veal carcass weight and to provide the calculation to establish the assessment rate on imported veal and veal products.

APHIS Proposes to Revise Phytosanitary Treatment Regulations
In the June 30, 2016, *Federal Register*, APHIS proposed to amend the phytosanitary treatment regulations criteria to establish generic criteria. The proposed action would allow for the approval of cold treatment and irradiation facilities in the southern and western Unites States. The proposed rule would amend cold treatment regulations regarding fruit cutting and inspection requirements and would also add requirements for the establishment of fumigation compliance agreements. ***Comments are due August 29, 2016***.

APHIS Proposes to Revise Regulations for Bone-In Ovine Meat from Uruguay
In the July 1, 2016, *Federal Register*, APHIS proposed to amend the regulations for importation of certain animals, meat, and other animal products to allow the importation of ovine meat from Uruguay. The Agency determined that this meat can be safely imported under certain conditions to prevent the introduction of foot-and-mouth disease to the United States. The proposed action specifies the additional conditions that must be met to qualify for importation. ***Comments are due August 30, 2016***.

AMS Issues Final Rule for Avocados Grown in South Florida
In the June 15, 2016, *Federal Register*, AMS implemented the recommendations from the Avocado Administrative Committee in a final rule regarding an increase in the 2016–17 assessment rate of avocados grown in South Florida that are handled under Marketing Order No. 915. The final rule increases the assessment rate established for 2016–17 from $0.30 to $0.35 per 55-pound bushel of avocados.

AMS Issues Final Rule for Raisins Produced from Grapes Grown in California
In the July 11, 2016, *Federal Register*, AMS amended Marketing Order No. 989, which regulates the handling of raisins produced from grapes grown in California. The amendments, first proposed on October 16, 2015, will allow the Raisin Administrative Committee ("Committee") to utilize customary business practices. The Committee is composed of producers and handlers of raisins grown from grapes in California. ***The rule is effective July 12, 2016***.

AMS Implements Increased Assessment Rate for Grapes in Southeastern California
In the June 23, 2016, *Federal Register*, AMS implemented a recommendation from the California Desert Grape Administrative Committee to increase the assessment rate for grapes grown in designated areas of southeastern California. Under the rule, the established rate for the 2016 and subsequent fiscal periods was raised from $0.0250 to

$0.0300 per 18-pound lug of grapes. Assessments upon grape handlers are used by the Committee to fund reasonable and necessary expenses of the federal marketing order program. ***The rule was effective June 24, 2016***.

In addition, in the July 11, 2016, *Federal Register*, AMS amended Marketing Agreement and Order No. 925, which regulates the handling of table grapes.

AMS Amends U.S. Standards for Grades of Processed Raisins
In the June 23, 2016, *Federal Register*, AMS revised the U.S. Standards for Grades of Processed Raisins by removing five references to the term "midget" throughout the standards. These changes attempt to modernize and clarify the standards by removing dual terminology for the same requirement. ***The rule is effective July 25, 2016***.

EU Regulatory Updates

The European Commission Publishes Scientific Criteria for Identification of Endocrine Disruptors
The Commission has published its long-awaited scientific criteria to identify endocrine-disrupting chemicals in food. The criteria will be used to amend Regulation 1107/2009 on plant protection products and Regulation 528/2012 on biocidal products. The established criteria are relevant for the potential identification as endocrine disruptors of several chemicals that are used, for example, in food contact materials, such as Bisphenol A ("BPA"). The Commission shied away from establishing a safe threshold for endocrine disruptors. The Commission stated that including considerations of how "potent" an endocrine disruptor may be is not necessary, as "potency" is a question to be asked only when a substance has been identified as an endocrine disruptor.

EFSA Issues Statement on Presence of Microplastics and Nanoplastics in Food
On June 23, 2016, EFSA issued a statement regarding the presence of microplastics and nanoplastics as contaminants in food, with a particular focus on seafood (due to marine pollution). EFSA's statement is considered to be a first step in future assessments of potential risks to consumers from microplastics and nanoplastics in food.

Upcoming Meetings, Workshops, and Conferences

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 FNS's National Advisory Council on Maternal, Infant, and Fetal Nutrition, **July 12–14, 2016**, in Arlington, VA.

Public Meeting of USDA's Plant Valley Protection Board to discuss work and outreach plans, subcommittee activities, and proposals for procedure changes, **July 27, 2015**, in Washington, D.C.

Public Meeting of the Council for Native American Farming and Ranching to hear public comments, share USDA program updates, and discuss committee priorities, **July 27–28, 2016**, in Fort Hall, ID.

Public Meeting of Secretary for Food Safety, USDA, and AMS, to provide information and receive comments on agenda items and positions to be discussed at the upcoming September Meeting of the Codex Committee on Processed Fruits and Vegetables, **August 1, 2016**, in Washington, D.C.

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