

Food, Dietary Supplement & Cosmetics Regulatory Update Vol. III | Issue 12 | September 2016

JONES DAY



### FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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#### FDA Issues Final Rule on Food Ingredients that May Be "Generally Recognized as Safe"

On August 12, 2016, FDA finalized a long-awaited proposed rule, "Substances Generally Recognized as Safe." The final rule sets forth the mandatory criteria and scientific evidence that can be used to demonstrate the use of a substance in human or animal food is "generally recognized as safe" ("GRAS"). FDA's Center for Food Safety and Applied Nutrition and FDA's Center for Veterinary Medicine ("CVM") have been using the voluntary GRAS notification procedure as opposed to the former voluntary GRAS affirmation petition since 1997 and 2010, respectively. The final rule officially confirms the use of the GRAS notification procedure.

The voluntary notification procedure helps the agency monitor food safety efforts. Under the final rule, this procedure will be accompanied by a response by the agency within 180 days of a GRAS notice, with a potential to extend its response by another 90 days.

FDA will issue additional guidance on the GRAS regulation, which will become effective on October 17, 2016. Additionally, FDA will accept public comments until September 16, 2016.

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#### FDA Updates Draft Guidance on Premarket Safety Notifications of New Dietary Ingredients in Dietary Supplements

On August 11, 2016, FDA issued a revised draft guidance replacing the original draft guidance of 2011, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," and requesting comments to issue a final guidance on the notification of

new dietary ingredients ("NDI") in dietary supplements. Under the Dietary Supplement Health and Education Act, a manufacturer or distributor must notify FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (one that was not marketed in the United States before October 15, 1994), unless the NDI is used in the food supply without chemical alteration. The revised guidance addresses topics such as: (i) what qualifies as an NDI; (ii) when an NDI notification is required; (iii) what are the procedures for submitting an NDI notification; (iv) what types of data and information FDA recommends industry consider when evaluating the safety of NDIs and dietary supplements containing an NDI; and (v) what FDA recommends industry include in an NDI notification. In addition, the guidance contains questions and answers about the definitions of "dietary supplement," "chemical alteration," "NDI," and "grandfathered" ingredients. These definitions can affect whether a particular substance may be marketed as a dietary ingredient in a dietary supplement. FDA is accepting comments until October 11, 2016.

#### **USDA Allows Negative Claims on GMOs**

Following the July 2016 enactment of the National Bioengineered Food Disclosure Standard, which sets a mandatory uniform national standard for biotechnology labeling of food, USDA's Food Safety Inspection Service ("FSIS") issued a compliance guidance regarding "Statements that Bioengineered or Genetically Modified ("GM") Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products." In the past, FSIS has not allowed the use of terms like "non-GMO" unless the claims were in compliance with standards established by a third-party certifying organization. The new regulation provides that "a food may not be considered to be 'not bioengineered' or 'non-GMO,' or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered." However, FSIS announced it will begin approving "genetically modified organism" or "GMO" terms in "negative claims" for meat, poultry, and egg products provided that the label or labeling is otherwise truthful and not misleading. FSIS still requires that the claims comply with third-party certification organization standards, including the identification of the third party's website on the label. The guidance, which is effective immediately, provides examples on how to use such claims and information regarding the labeling approval procedure.

#### FDA Releases Small Entity Compliance Guide and Draft Guidance on Calorie Labeling of Articles of Food Sold in Vending Machines

On August 15, 2016, FDA issued the "Draft Guidance, Calorie Labeling of Articles of Food in Vending Machines" and the "Small Entity Compliance Guide, Calorie Labeling of Articles of Food in Vending Machines" ("Guide") to help vending machine operators ("VMOs") and industry comply with the December 1, 2014, final rule, which requires operators with 20 or more machines to display the food products' calorie content at the point of purchase.

The draft guidance clarifies, among other things, that: (i) food manufacturers are not required to place calorie information on the articles of foods sold from vending machines; (ii) VMOs are not required to register with FDA to be subject to the rule but can do so voluntarily; (iii) owners or operators of less than 20 vending machines are not considered VMOs unless they voluntarily register to follow the rule; (iv) state and local licensing requirements for vending machine operations are not affected by the rule; and (v) when an owner of vending machines contracts their operation to a third party, such that the owner does not control or direct the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, the third party, and not the owner, would be responsible for posting the calorie information. The guidance also mentions methods for displaying the calorie information, such as the use of images, stickers, or signs, and the format that can be used to display the required information.

In addition, the Guide directed to small operators provides information and examples beneficial to both small and regular VMOs. For instance, the Guide explains how and

where the calorie declarations have to be placed, what and where contact information should be provided, and how to determine the calorie content for vending machine foods.

For compliance dates, please see our previous Jones Day Update.

# FDA Bans Sale of OTC Antiseptic Wash Products Containing Certain Active Ingredients

On September 2, 2016, FDA issued a final rule prohibiting the sale of antiseptic wash products (including liquid, foam, gel hand soap, bar soaps, and body washes) that contain one or more of 19 specific active ingredients, including two of the most common used ingredients—triclosan and triclocarban. When issuing the proposed rule in 2013, FDA requested safety and efficacy data regarding use of certain active ingredients in antibacterial products. Those ingredients are added to consumer products with the intent of reducing or preventing bacterial infection. FDA concluded that "antibacterial hand and body wash manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infection." In fact, Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research, said that "... some data suggests that antibacterial ingredients may do more harm than good over the long-term." Some of the potential health risks that are under study include bacterial resistance or hormonal effects. FDA issued a proposed rule in June 29, 2016, requesting information to address data gaps on safety and efficacy of consumer hand "sanitizers" or wipes (used when no water is available as opposed to antiseptic wash products that are intended for use with water and are rinsed off after use). For now, these products are not affected by the final rule. Likewise, antibacterial products used in health care settings, such as hospitals and nursing homes, have not been prohibited. In addition, FDA will allow the use of three active ingredients—benzalkonium chloride, benzethonium chloride, and chloroxylenol (PCMX)—in antibacterial products for one more year, pending the collection by the agency of new safety and effectiveness data regarding the use of such ingredients. Industry has one year to comply with the rule, which will become effective on September 6, 2017.

#### FDA Issues Infant Formula Draft Guidance

On September 8, 2016, FDA issued draft guidance "Substantiation for Structure/Function Claims in Infant Formula Labels and Labeling." The guidance describes the type and quality of evidence that is appropriate to substantiate claims about effects on the structure or function of the body (i.e., supports digestion) made on the label and in other labeling of nonexempt and exempt infant formulas, which are defined as "a food which purports to be or is represented for special dietary use solely as a food for infants [a person not more than 12 months old] by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." FDA does not preapprove structure/function claims in the labeling of infant formulas. However, FDA stated these claims need to be substantiated by "competent and reliable scientific evidence" as "this vulnerable population is entirely dependent upon caregivers who must be able to trust that the information on the label is truthful and scientifically supported."

## FDA Extends Compliance Dates for Food Safety Modernization Act Implementing Rules

Effective August 24, 2016, FDA issued a final rule extending the compliance dates for four of the seven foundational rules that are part of FDA's implementation of the Food Safety Modernization Act ("FSMA"). Specifically, FDA is extending the compliance dates for the rules titled, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food"; "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals"; "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals"; and "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." FDA is extending the compliance dates to address concerns about the practicality of compliance with certain provisions, to consider changes to the regulatory text, and to better align compliance dates across the rules. To see the new compliance dates, please see a chart created by Jones Day here.

#### **Other News**

FDA Releases Report on Regional FSMA Import Safety Meetings of June 2016

FDA Provides \$21.8 Million to States for FSMA Produce Safety Rule Implementation

In Light of July 2016 Preempting GMO Labeling Law, the State of Vermont and the Grocery Manufacturers Association Agreed to Drop GMO Labeling Suit

FDA Announces Award of Cooperative Agreements to Develop Training Options for Local Food Producers and Tribal Operations to Enhance Food Safety Compliance Under FSMA

China Extends for Five More Years Anti-Dumping Duties on U.S. Chicken Meat

### **Regulatory Updates**

#### FDA Extends Comment Period for Draft Sodium Guidance

In the August 30, 2016, *Federal Register*, FDA announced an extension on the comment periods for the Draft Guidance, "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods," which originally appeared in the June 2, 2016, *Federal Register*. The draft guidance, when finalized, will seek to help Americans achieve the Dietary Guidelines-recommended sodium levels by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in processed, packaged, and prepared foods. FDA has requested comments on developing the sodium targets and for implementation of the guidance document, and it is now extending the comment deadline. For more information regarding the final guidance, see our previous Jones Day *Update. Comments on issues primarily related to the draft short-term (two-year)* sodium reduction target (Issues 1-4 of Section IV) are due October 17, 2016. Comments on issues primarily related to the draft long-term (10-year) sodium reduction target (Issues 5-8 of Section IV) are due December 2, 2016.

#### FDA Announces Three Draft Guidance Documents Under FSMA

In the August 25, 2016, Federal Register, see here, here, and here, FDA announced the availability of three draft guidance documents under FSMA. Two of the draft guidances, "Human Food By-Products for Use as Animal Food," and "Current Good Manufacturing Practice Requirements for Food for Animals," are meant to assist domestic and foreign companies in complying with human food by-product requirements under the FSMA Preventive Controls for Animal Food Rule, and with Current Good Manufacturing Practice ("CGMP") requirements. The third draft guidance "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities," is aimed at helping food businesses determine which of the FSMA rules apply to their operations. Once finalized, this draft quidance will help food establishments determine whether the activities they perform are within the "farm" definition established in regulations for the registration of food facilities. Determining whether activities are within the "farm" definition plays a key role in determining whether a business is exempt from regulations for the registration of food facilities and from certain CGMP requirements and requirements for hazard analysis and risk-based preventive controls for human and animal food. The guidance includes several hypothetical operations as examples to assist businesses in evaluating their own operations. Comments are due November 23, 2016, for the two first draft guidance document, and February 21, 2017, for the third draft guidance.

## FDA Announces Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food

In the August 24, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry, "Hazard Analysis and Risk-Based Preventive Controls for Human

Food." This draft guidance includes the first five chapters of a multi-chapter guidance intended to explain how to comply with the requirements for hazard analysis and risk-based preventive controls for human food. Specifically, the document provides guidance on understanding: (i) the biological, chemical, and physical hazards in manufacturing, processing, packing, and holding of FDA-regulated food products; (ii) the components of a food safety plan; (iii) how to conduct a hazard analysis and develop a food safety plan; (iv) how to identify control measures for common biological, chemical, and physical hazards associated with processed foods; (v) how to identify and apply the preventive control management components; and (vi) the recordkeeping requirements associated with the food safety plan. *Comments are due February 21, 2017*.

#### FSIS Releases Compliance Guidance on "Negative" GM Labeling Claims

As discussed above, in the August 24, 2016, *Federal Register*, USDA's FSIS announced the availability of a compliance guidance for companies seeking to make "negative" label or labeling claims, or claims that bioengineered or GM ingredients were not used in a meat, poultry, or egg product. The guidance also provides information on how companies can make label or labeling claims that a product was produced from livestock or poultry that were not fed bioengineered or GM feed. *Comment are due October 24, 2016*.

#### AMS Removes Program to Assess Organic Certifying Agencies

In the August 9, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") issued a final rule informing the public it was removing the 1999 Program to Assess Organic Certifying Agencies from Title 7 Code of Federal Regulations ("CFR") Part 37. This action removes unnecessary regulations from the CFR. After the publication of the organic regulations in 2000, the Program to Assess Organic Certifying Agencies has no longer been applicable or necessary. *The rule is effective November 7, 2018*.

## AMS Announces Interim Instructions on Material Review under the National Organic Program

In the August 30, 2016, *Federal Register*, USDA's AMS announced the availability of an interim instruction document intended for use by accredited organic certifying agents. Specifically, the instruction document details the criteria and process that accredited certifying agents must follow when approving substances for use in organic production and handling. The instruction is directed specifically at certifying agents, who must meet certain terms and conditions as part of their accreditation. *Comments are due October* **31, 2016**.

#### AMS Implements the Livestock Mandatory Reporting Program

In the August 11, 2016, *Federal Register*, USDA's AMS implemented the Livestock Mandatory Reporting ("LMR") program as required by the Livestock Mandatory Reporting Act of 1999. The LMR program was reauthorized in October 2006 and September 2010. On September 30, 2015, the Agriculture Reauthorizations Act of 2015 ("2015 Reauthorization Act") reauthorized the LMR program for an additional five years until September 30, 2020, and directed the Secretary of Agriculture to amend the LMR swine reporting requirements. This final rule incorporates the swine reporting revisions contained within the 2015 Reauthorization Act and a minor revision to the lamb reporting requirements under the Agricultural Marketing Act of 1946, USDA Livestock Mandatory Reporting regulations. **The rule is effective October 11, 2016**.

#### **APHIS Amends the National Poultry Improvement Plan and Auxiliary Provisions**

In the August 12, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") issued a final rule amending the National Poultry Improvement Plan ("NPIP"), its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza. Specifically, the rule clarifies who may participate in the NPIP, amends participation requirements, amends definitions for poultry and breeding stock, amends the approval process for new diagnostic tests, and amends slaughter plant inspection and laboratory inspection and testing requirements. These changes will align the regulations with international standards. The changes in this final rule were voted on and approved by the voting delegates at the Plan's 2014 National Plan Conference. **The** 

#### rule was effective September 12, 2016.

#### **APHIS Amends the National Dairy Promotion and Research Program**

In the August 12, 2016, *Federal Register*, USDA's APHIS amended the Dairy Promotion and Research Order ("Dairy Order"). The amendment modifies the total number of importer members, which would be reduced from two members to one member, and the domestic Dairy Board members, which would remain the same at 36. The Dairy Order requires that at least once every three years, after the initial appointment of importer members on the Dairy Board, the secretary will review the average volume of domestic production of dairy products compared to the average volume of imports of dairy products into the United States during the previous three years, and, on the basis of that review, if warranted, reapportion the importer representation on the Dairy Board to reflect the proportional shares of the U.S. market served by domestic production and imported dairy products. **The rule was effective August 12, 2016**.

#### AMS Announces Draft Guidance on Treated Lumber at Organic Farms

In the August 31, 2016, *Federal Register*, USDA's AMS announced the availability of a draft guidance document on treated lumber at organic farms. Current USDA regulations provide that organic producers may not use lumber treated with arsenate or other prohibited synthetic materials on organic farms if the lumber is in contact with crops, soil, or livestock. Accordingly, the draft guidance provides information for organic producers and certifying agents to ensure consistent interpretation and enforcement of USDA organic regulations by clarifying how treated lumber installed by producers prior to certification affects certification eligibility, providing information about using treated lumber outside of organic production areas, and describing the role of buffers and barriers in preventing contact between prohibited materials in treated lumber and organic production. *Comments are due October 31, 2016*.

#### **CCC Revises Food for Progress Program Regulations**

In the September 12, 2016, *Federal Register*, USDA's Commodity Credit Corporation ("CCC") reviewed the regulations governing the award of agricultural commodities to recipients under the Food for Progress Program. CCC stated the revision is necessary to clarify requirements for applicants for, and recipients of, awards under the Food for Progress Program and to inform interested parties that the Office of Management and Budget ("OMB") guidance on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, as supplemented by USDA regulations, applies to awards under the Food for Progress Program other than awards to foreign public entities. The revised regulations will enable applicants and recipients to better understand program requirements and USDA's Foreign Agricultural Service ("FAS"), on behalf of CCC, to more effectively implement the Food for Progress Program. *Comments are due October 12, 2016*.

#### **NIFA Revises Competitive Grant Program Guidelines**

In the August 26, 2016, *Federal Register*, USDA's National Institute for Food and Agriculture ("NIFA") issued a final rule revising the general administrative guidelines applicable to the Agriculture and Food Research Initiative competitive grant program. Specifically, the final rule implements the Agriculture and Food Research Initiative commodity board provisions added by section 7404 of the Agricultural Act of 2014, which amended the general administration, special considerations, and eligible entities subsections for the program, and added a special contributions requirement making it necessary to modify the program's administrative provisions. *The rule was effective August 26, 2016*.

#### FAS Revises McGovern-Dole International Food for Education and Child Nutrition Program

In the September 12, 2016, *Federal Register*, USDA's FAS reviewed the regulations governing the award of agricultural commodities and financial and technical assistance to recipients under the McGovern-Dole International Food for Education and Child Nutrition ("McGovern-Dole") Program. FAS stated the revision is necessary to clarify requirements

for applicants for, and recipients of, awards under the McGovern-Dole Program and to inform interested parties that the OMB guidance on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, as supplemented by USDA regulations, applies to awards under the McGovern-Dole Program other than awards to foreign public entities. The revised regulations will enable applicants and recipients to better understand program requirements and FAS to more effectively implement the McGovern-Dole Program. *Comments are due October 12, 2016*.

#### AMS Proposes to Amend Beef Promotion and Research Order

In the August 23, 2016, *Federal Register*, USDA's AMS proposed to amend the Beef Promotion and Research Order established under the Beef Promotion and Research Act of 1985. Specifically, the proposed rule would add six Harmonized Tariff System codes for imported veal and veal products and update assessment levels for imported veal and veal products based on revised determinations of live animal equivalencies. *Comments are due October 24, 2016*.

#### APHIS Proposes the Import of Orchids from the Republic of Korea

In the August 12, 2016, *Federal Register*, USDA's APHIS proposed to amend the regulations governing the importation of plants for planting to add orchid plants of the genera *Phalaenopsis* and *Cymbidium* from the Republic of Korea to the list of plants that may be imported into the continental United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. APHIS is taking this action in response to a request from the Republic of Korea and after determining that the plants could be imported under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed. *Comments are due October 11, 2016*.

#### AMS Amends Quality Control Requirements for Almonds Grown in California

In the August 17, 2016, *Federal Register*, USDA's AMS implemented a recommendation from the Almond Board of California to change the quality control requirements currently prescribed under the California almond marketing order. The order regulates the handling of almonds grown in California. The Board locally administers the order and comprises growers and handlers operating within California. This rule relaxes incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers' disposition obligation. This change also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order's requirements. *Comments are due October 17, 2016*.

## AMS Reopens Comment Period to Increase Assessment Rate of Almonds Grown in California

In the September 12, 2016, *Federal Register*, USDA's AMS announced that the comment period on the proposed rule to increase the assessment rate for California almonds under Marketing Order No. 981 is reopened until October 12, 2016. The proposed rule would implement a recommendation from the Almond Board of California 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. *Comments are due October 12, 2016*.

## **APHIS Proposes Rule to Allow Importation of Persimmons with Calyxes from Japan**

In the August 30, 2016, *Federal Register*, APHIS proposed to amend its regulations to allow the importation of fresh persimmons with calyxes from Japan into the United States. As a condition of entry, the persimmons must be produced in accordance with a systems approach that would include requirements for orchard certification, orchard pest control, post-harvest safeguards, fruit culling, traceback, and sampling. In addition, the persimmons must be accompanied by a phytosanitary certificate with an additional

declaration stating that they were produced under, and meet all the components of, the agreed-upon systems approach and were inspected and found to be free of quarantine pests in accordance with the proposed requirements. *Comments are due October 31, 2016*.

**APHIS Reopens Comment Period for Proposed Rule on Lemons from Chile** 

In the August 26, 2016, *Federal Register*, APHIS announced the reopening of the comment period for its proposed rule that would list lemons from Chile as eligible for importation into the continental United States subject to a systems approach. In reviewing information supporting the safe importation of fresh lemons from Chile, APHIS considered a pathway-initiated risk assessment, which, although made available for review and comment on the APHIS webpage in 2014, was not made available with the proposed rule for further review and comment. Accordingly, APHIS is reopening the comment period for an additional 30 days to give interested parties additional time to review the pathway-initiative risk assessment. *Comments are due September 26, 2016*.

**APHIS Proposes Rule to Allow Importation of Raspberries from Morocco** 

In the August 26, 2016, *Federal Register*, APHIS proposed to amend its regulations to allow the importation of fresh raspberry fruit from Morocco into the continental United States. As a condition of entry, the raspberries must be produced under a systems approach to mitigate for the fungus *Monilinia fructigena* and must be inspected prior to exportation from Morocco and found free of this pest. In addition, the raspberries must be imported in commercial consignments only, produced at registered places of production, and field inspected for signs of *M. fructigena* infection no more than 30 days prior to harvest in registered packinghouses. The raspberries must be accompanied by a phytosanitary certificate with an additional declaration stating that the conditions for importation have been met. *Comments are due October 25, 2016*.

**APHIS Proposes Rule to Allow Importation of Persimmons from New Zealand** In the August 26, 2016, *Federal Register*, APHIS proposed to amend its regulations to allow the importation of fresh persimmons from New Zealand into the United States. As a condition of entry, the persimmons must produced in accordance with a systems approach that would include requirements for orchard certification, orchard pest control, post-harvest safeguards, fruit culling, traceback, sampling, and treatment with either hot water or modified atmosphere treatment. In addition, the persimmons must be accompanied by a phytosanitary certificate with an additional declaration stating that they were produced under, and meet all the components of, the systems approach and were inspected and found to be free of quarantine pests in accordance with the proposed requirements. *Comments are due October 25, 2016*.

#### AMS Requests Comments on U.S. Standards for Grades of Carcass Beef

In the August 24, 2016, *Federal Register*, AMS announced a request for public comments on a petition requesting revision to U.S. standards for grades of carcass beef. Specifically, the petition requests that the beef standards be amended to include dentition and documentation of actual age as an additional determination of maturity grouping for official quality grading. Currently, the standards include only skeletal and muscular evidence as a determination of maturity grouping for the purposes of official quality grading. *Comments are due October 24, 2016*.

#### AMS Proposes to Increase Assessment Rate for Apricots in Washington

In the August 23, 2016, *Federal Register*, AMS proposed to increase the assessment rate for Washington apricots from \$.75 to \$1.40 per ton for the 2016–17 and subsequent fiscal periods. The proposed rule would implement a recommendation from the Washington Apricot Marketing Committee, which is composed of growers and handlers who locally administer Marketing Agreement and Order No. 922 to regulate the handling of apricots grown in designated counties in Washington. *Comments are due September 22, 2016*.

### **EU Regulatory Updates**

#### France to Introduce Tax on High-Calorie Foods

On September 6, 2016, Euractiv reported that France is planning to introduce an additional nutrition tax, under which products may be taxed if they contain more than a certain amount of calories. This tax is an attempt to tackle the increasing overweight problem. A draft decree is under preparation. France currently has two nutritional taxes, applied to well-defined products. One tax applies to sugary and sweetened drinks and the other to energy drinks.

#### Denmark Wants EU Limits for Fluorinated Substances in Food Packaging

On September 5, 2016, Denmark's environment and food minister called on the European Commission to set maximum levels for fluorinated substances in food packaging, in particular in paper and cardboard. Food contact materials such as paper and cardboard are not yet harmonized at the EU level.

Fluorinated compounds constitute a large group of chemical substances containing organic fluorine that is persistent and bioaccumulative. In addition, several of these substances are suspected to be carcinogenic, immunotoxic, and endocrine disruptors. Denmark has already adopted a recommendation setting out a limit for the total content of organic fluorine in paper and board food contact materials at 0.35 microgram of organic fluorine per square decimeter of paper.

The press release on the Danish strategy on fluorinated substances in food packaging is available here.

### **Upcoming Meetings, Workshops, and Conferences**

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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