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

Top News

FDA Announces Intention to Not Enforce Certain FSMA Final Rules Provisions

On January 4, 2018, the U.S. Food and Drug Administration ("FDA") issued a guidance announcing that it does not intend to enforce certain provisions of four final rules implementing the FDA Food Safety Modernization Act ("FSMA"). Although FDA had already extended the compliance dates for many of the affected provisions, FDA suspended enforcement of these provisions to allow the Agency to reevaluate the rulemaking after receiving comments from producers and farmers.

"We're actively working to pursue permanent fixes to some of these remaining issues through rulemaking or other means, but this will take time," Dr. Scott Gottlieb recently said. Specifically, FDA will exercise enforcement discretion (not enforce) the following:

- The requirement to request written assurance from customers that the food will be processed to control for hazards before the food reaches consumers. This requirement is imposed by the Current Good Manufacturing Practice ("cGMP"), Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal food rules ("Preventive Controls rules"), Foreign Supplier Verification Programs rule ("FSVP"), and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule ("Produce Safety rule"). Nonetheless, FDA stated manufacturers, processors, importers, and farmers are still required to disclose to their customers when a relevant hazard has not been controlled.
- The requirement for facilities that do not fall under the "farm" definition but conduct activities that are also typically conducted in a farm to comply with preventive controls and cGMP requirements covered by the Preventive Controls Rules. Certain exceptions apply with the enforcement discretion of compliance with cGMP procedures.
- The obligation of importers of food contact substances to comply with FSVP.
- The animal food Preventive Controls rule requirements for certain manufacturing/processing activities performed on human food by-products used as animal food.

FDA has issued a fact sheet identifying the entities and activities covered by the enforcement discretion. Additionally, consistent with the Agency's goal of assisting industry with the implementation of FSMA, FDA has launched a new webpage publicizing the FSMA Collaborative Training Forum. This webpage provides links to various resources that provide FSMA training to industry.
[Go to Top]

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When Is An Action Considered a Refusal to Inspect a Foreign Food Establishment?

On December 11, 2017, FDA issued a draft guidance explaining when the Agency considers a foreign food establishment's or foreign government's action to be a refusal to permit entry to inspect a food facility. In the guidance, FDA states that not only actions but statements and passive behaviors that prevent or delay FDA investigators from scheduling or fully conducting an inspection, or that are intended to avoid inspection or to mislead or deceive would be considered a refusal to inspect. For example, FDA would so classify not responding within 24 hours after FDA issues a written inspection request. Similarly, FDA could make such a finding when the owner, operator, or agent in charge of a facility stops communicating with FDA at any time after he or she initially responds to FDA's request to schedule an inspection, provides an incomplete or inaccurate response (e.g., an owner, operator, or agent in charge falsely claims the establishment is not operating or does not ship food to the United States), rejects (without a reasonable explanation) FDA's attempt to schedule an inspection by not agreeing to an inspection start date, or agrees to an inspection start date and then requests a later date without giving a reasonable explanation. Other examples are when FDA is directly prevented from entering the establishment, is barred from entering a specific area, is asked to not take photographs or collect samples for analysis, or when a foreign government bars access to the country.

Under FSMA, to ensure the imported products meet U.S. standards and are safe for consumers, FDA can deny entry of food products if the Agency has been prevented from inspecting the facility where such products have been manufactured, processed, packed, or held. If FDA is denied entry to a foreign food establishment—either by the facility or the foreign government—FDA will place the food establishment(s) on the Red List of "Import Alert 99-32 Detention Without Physical Examination of Products From Firms Refusing FDA Foreign Establishment Inspection," and food products will not be able to enter into the United States.

[Go to Top]

FDA Releases Guide on FSMA Sanitary Transportation of Human and Animal Food

On November 21, 2017, FDA announced the availability of a guidance for industry titled "Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation—Small Entity Compliance Guide." The guide is intended to help small entities comply with the final rule titled Sanitary Transportation of Human and Animal Food Rule ("Sanitary Transportation Rule"). This rule requires rail and motor vehicle carriers covered by the rule to provide food safety training to their personnel engaged in transportation operations when the carrier is responsible, in whole or in part, for the sanitary conditions during transportation. The 23-page guide describes in a Q&A format who must comply with the rule, when compliance is required, and what requirements apply to vehicles and transportation. It also answers other questions related to transportation operations, training, records, and waivers to comply with the Sanitary Transportation Rule. Small businesses have until April 6, 2018, to comply with the rule.

[Go to Top]

European Commission Renews Approval of Glyphosate

On December 12, 2017, the European Commission adopted Implementing Regulation (EU) 2017/2324 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 ("Commission Renewal Decision").

The European Commission renewed the approval of glyphosate for use as an herbicide as of December 16, 2017, for a period of five years (i.e., until December 15, 2022) on the basis of the opinion of the Committee for Risk Assessment of the European Chemicals Agency ("ECHA") on the harmonized classification as regards to the carcinogenicity of glyphosate. The ECHA Committee concluded that, on the basis of the information currently available, a classification of glyphosate as carcinogenic is not justified. In parallel, the European Food Safety Authority ("EFSA"), supported by experts from EU Member States national authorities, assessed the potential endocrine disrupting properties of glyphosate and found that glyphosate does not have endocrine-disrupting properties through estrogen, androgen, thyroid, or steroidogenesis mode of action.

The Commission Renewal Decision for glyphosate was adopted despite the adoption by the European Parliament on October 24, 2017, of a nonbinding Resolution opposing the European Commission's proposal to renew the authorization of glyphosate and requesting a phase-out of the substance by 2022 as well as the submission on October 6, 2017, of a European Citizens' Initiative titled "Ban Glyphosate and Protect People and the Environment from Toxic Pesticides" in accordance with Article 11(4) of the Treaty on the European Union (see the Commission Communication of December 12, 2017, on this matter). In the Commission Communication of December 12, 2017, the European Commission clarifies that in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, even after an active substance is authorized at the EU level, separate authorization is required at the national level for plant protection products containing such active substance. Therefore, individual EU Member States may still decide to refuse or restrict the placing on the market of some or all of the glyphosate-containing plant protection products where this is warranted on the basis of evidence related to the particular agricultural and environmental circumstances

in their territories.
[Go to Top]

EU Institutions and Industry Associations Recommend Actions to Help SME Registrants with 2018 REACH Registrations

Under Regulation (EC) No 1907/2006, concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH Regulation"), companies manufacturing phase-in substances or importing them from outside of the European Union above one tons per year but not above 100 tons per year must successfully register such substance(s) before June 1, 2018 (i.e., by May 31, 2018) in order to place them on the EU market following that date.

On December 20, 2017, the Directors' Contact Group, a platform of the European Commission, European Chemicals Agency ("ECHA") and industry associations, published a Recommendation to help small-volume and SME registrants in registering for the 2018 REACH registration deadline in which it recommended the four following actions:

- Reducing the costs of data for 1-10 tons registrants by exploring data waiving arguments;
- Addressing situations caused by late data-sharing negotiations or pending dispute decisions;
- Reducing the cost burden on SMEs by allowing payment in installments; and
- Offering a low-cost affordable lump sum payment option for 1-10 tons registrants.

According to the ECHA press release on this matter, the ECHA will hold its REACH 2018 Stakeholders' Day on January 31, 2018, when first-time registrants can get advice from ECHA and industry experts, and can ask questions of ECHA staff.
[Go to Top]

Other News

FDA Issues Guidance Advising on the Use of Terms "Brown King Crab" and "Golden King Crab" in the Labeling of Crabmeat Products Derived from Species Known as Lithodes Aequispina

The Interagency Food Safety Analytics Collaboration Issues Report on Foodborne Illness Source Attribution Estimates for 2013. The report found that: *Salmonella* illnesses came from a wide variety of foods; *E. coli* O157 illnesses were most often linked to vegetable row crops (such as leafy greens) and beef; *Listeria monocytogenes* illnesses were most often linked to fruits and dairy products; and non-dairy *Campylobacter* illnesses were most often linked to chicken.

FDA Creates the Produce Safety Network to Support Growers and Regulators in Implementing the Produce Safety Rule

APHIS Proposes Flat-Rate Payment Reimbursement as Opposed to Per-Bird Payment to Meat Poultry Facilities to Eliminate Avian Influenza Outbreaks

FDA Releases Input Related to Protecting the Food Supply from Intentional Adulteration and the Benefits of the Voluntary Qualified Importer Program
[Go to Top]

Regulatory Updates

FDA Announces Termination of Food Advisory Committee

In the December 13, 2017, *Federal Register,* FDA announced the termination of the Food Advisory Committee, established on March 6, 1992. The Agency has communicated that any relevant food issues in the future can be addressed by FDA's Science Board and/or FDA's Risk Communication Advisory Committee, with additional augmentation of expertise by appropriate subject-matter experts serving as temporary members on either of those committees. In addition, CFSAN will continue to hold workshops, meetings, conferences, and webinars to engage with its stakeholders. ***The rule was effective December 13, 2017.***
[Go to Top]

FDA Issues Guidance "Best Practices for Convening a GRAS Panel"

In the November 16, 2017, *Federal Register,* FDA announced the availability of a draft guidance for industry titled "Best Practices for Convening a GRAS Panel." This draft guidance document is intended for any person who convenes a panel of experts ("GRAS panel") to determine whether a substance may be used in food on the basis of the generally recognized as safe ("GRAS") provision of the Federal Food, Drug, and Cosmetic Act. A GRAS Panel is tasked with independently evaluating whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. The draft guidance provides FDA's current thinking on best

practices to identify GRAS panel members who have appropriate and balanced expertise, to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of the GRAS panel's report (including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest), and to limit the data and information provided to a GRAS panel to public information (e.g., by not providing the GRAS panel with information such as trade secret information). ***Comments are due May 15, 2018, except for the collection of information provisions in the draft guidance, which are due January 16, 2018.***
[Go to Top]

FDA Amends Food Additive Regulations

In the November 13, 2017, and January 2, 2018, *Federal Register,* FDA amended the food additive regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formic acid and ammonium formate, and of formic acid as a feed acidifying agent in complete poultry feeds. ***The rules became effective immediately.***
[Go to Top]

FDA Amends Listing of Color Additives Exempt from Certification

In the November 7, 2017, *Federal Register*, FDA amended the color additive regulations to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. ***The rule was effective December 8, 2017.***
[Go to Top]

AMS Withdraws Organic Livestock and Poultry Practices Final Rule

In the December 18, 2017, *Federal Register,* USDA proposed to withdraw the Organic Livestock and Poultry Practices ("OLPP") final rule published on January 19, 2017, by USDA's Agricultural Marketing Service ("AMS"). The OLPP final rule amends the organic livestock and poultry production requirements in the USDA organic regulations by adding new provisions for livestock handling and transport for slaughter and avian living conditions. It also expands and clarifies existing requirements covering livestock care and production practices and mammalian living conditions. USDA proposed withdrawing the OLPP rule based on its interpretation of 7 U.S.C. 6905, under which the OLPP final rule would exceed USDA's statutory authority, and upon USDA's revised assessments of its benefits and burdens and USDA's view of regulatory policy. If this withdrawal is finalized, the existing organic livestock and poultry regulations now published at 7 CFR Part 205 would remain effective. The OLPP final rule was originally set to take effect on March 20, 2017, but extended to May 14, 2018. ***Comments are due January 17, 2018.***
[Go to Top]

USDA Announces Withdrawal of Certain Proposed Rules and Other Proposed Actions

In the January 4, 2018, *Federal Register,* USDA announced its withdrawal of certain advance notice of proposed rulemakings and proposed rules that were either published in the *Federal Register* more than four years ago without subsequent action or determined to no longer be candidates for final action. USDA stated it is taking this action to reduce its regulatory backlog and focus its resources on higher priority actions. Some of the proposed rules that have been withdrawn are: the Foreign Agricultural Service's ("FAS") Quality Samples Program (71 FR 43992); FAS's Export Sales Reporting Program (78 FR 16819); APHIS's Viruses, Serums, Toxins, and Analogous Products, Detection of Avian Lymphoid Leukosis Virus (72 FR 4467); APHIS's Tuberculosis: Require Approved Herd Plans Prior to Payment of Indemnity (73 FR 43171); APHIS's Forfeiture Procedures Under the Endangered Species Act and the Lacey Act Amendments (78 FR 29659); AMS's Farmers' Market Promotion Program (76 FR 3046); AMS's Hardwood Lumber and Hardwood Plywood Research and Promotion Program (78 FR 68297); AMS's Soybean Promotion, Research, and Consumer Information; Beef Promotion and Research; Amendments to Allow Redirection of State Assessments to the National Program; Technical Amendments (81 FR 45984); or USDA's Food and Nutrition Service ("FNS") National School Lunch Program: Reimbursement for snacks in after-school care programs (65 FR 60502).
[Go to Top]

USDA Amends Regulation on Highly Erodible Land Conservation and Wetland Conservation

In the December 12, 2017, *Federal Register,* USDA amended the Highly Erodible Land Conservation and Wetland Conservation provisions to conform to changes regarding conservation compliance made by the Federal Crop Insurance Corporation to regulations in Catastrophic Risk Protection Endorsement, the Area Risk Protection Insurance Basic Provisions, and the Common Crop Insurance Policy Basic Provisions. The changes are aimed at providing more flexibility for conservation compliance determinations, reducing burdens on policyholders, and allowing the conservation compliance certification process for crop insurance to be administered more consistently with the practices of the Farm Service Agency ("FSA"). ***The rule was effective December 12, 2017.***
[Go to Top]

AMS Amends Definition of "Judge" in the Rules of Practice and Procedure

In the December 11, 2017, *Federal Register,* USDA's AMS adopted a final rule to amend the definition of "judge" in the rules of practice and procedure to formulate or amend a marketing agreement, marketing

order, or certain research and promotion orders under 7 CFR Parts 900 and 1200. The new definition adds a presiding official appointed by the Secretary, as well as an administrative law judge, as an official who may preside over the rulemaking hearing. ***The rule was effective December 11, 2017.***
[Go to Top]

AMS Proposes Temporary Supplemental Charge on Class I Milk

In the December 11, 2017, *Federal Register,* USDA's AMS announced a public hearing that was finally held on December 14, 2017, to consider a proposal submitted by Southeast Milk, Inc., Dairy Farmers of America, Inc., Premier Milk, Inc., Maryland and Virginia Milk Producers Cooperative Association, Inc., and Lone Star Milk Producers, L.C. The proposal sought a temporary supplemental charge on Class I milk to provide emergency reimbursement to handlers and producers for costs incurred as a result of market disruptions stemming from Hurricane Irma in September 2017, which caused extensive damage in the United States.
[Go to Top]

FNS Announces Flexibilities for Milk, Whole Grains, and Sodium Requirements in Child Nutrition Programs

In the November 30, 2017, *Federal Register,* USDA's FNS issued an interim final rule extending through school year 2018-2019 three menu-planning flexibilities currently available to many Child Nutrition Program operators, giving them near-term certainty about Program requirements and more local control to serve meals to children nationwide. These flexibilities include: providing operators the option to offer flavored, low-fat (1 percent fat) milk in the Child Nutrition Programs; extending the state agencies' option to allow individual school food authorities to include grains that are not whole grain-rich in the weekly menu offered under the National School Lunch Program ("NSLP") and School Breakfast Program ("SBP"); and retaining Sodium Target 1 in the NSLP and SBP. The comments from the public on the long-term availability of these three flexibilities will help inform the development of a final rule, which is expected to be published in fall 2018 and implemented in school year 2019-2020. ***Comments are due January 29, 2018, and the rule is effective July 1, 2018***.
[Go to Top]

EU Regulatory Updates

European Commission Issues New Regulation on Acrylamide in Food

On November 20, 2017, the European Commission adopted Commission Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food ("Acrylamide Regulation"). As described in the Acrylamide Regulation, acrylamide is a chemical substance formed by a reaction between asparagine and sugars. It typically occurs when certain carbohydrate-rich foods are cooked at high temperatures (over 120°C) in a process of frying, roasting, or baking. The Acrylamide Regulation is based on the European Food Safety Authority's ("EFSA") scientific opinion of 2015, in which the EFSA concluded that the presence of this contaminant in food can potentially have toxic effects, including genotoxicity and carcinogenicity, in human beings.

The new Acrylamide Regulation will apply on or by April 11, 2018. Once the new rules become applicable, food business operators will, *inter alia*, be required to adopt the acrylamide mitigation measures as part of their food safety management procedures. Guidelines providing clarification on the enforcement of the new Regulation are expected to become available in 2018.

European Commission Adopts Implementing Acts for Regulation (EU) 2015/2283 on Novel Foods

On December 20, 2017, the European Commission adopted three Implementing Regulations to Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods ("Novel Foods Regulation"), namely:

- Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with the Novel Foods Regulation;
- Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of the Novel Foods Regulation; and
- Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with the Novel Foods Regulation.

The Novel Foods Regulation, applicable to "novel foods" defined as any foods not used for human consumption to a significant degree in the European Union before May 15, 1997, comes into force on January 1, 2018. Novel food can be newly developed, innovative food, food produced using new technologies and production processes, as well as food that is or has been traditionally eaten outside of the European Union. This Regulation establishes a centralized approval system for novel foods, with applications submitted to the European Commission rather than individual EU Member States.
[Go to Top]

European Food Safety Authority Publishes the Hazard Assessment Protocol to Start Re-Evaluation of the Toxicity of Bisphenol A in 2018

On December 21, 2017, the EFSA published the Bisphenol A ("BPA") hazard assessment protocol, setting out the EFSA strategy for the re-evaluation of the toxicity of BPA in 2018. The hazard assessment protocol establishes *a priori* the approach and methodology for performing BPA hazard identification and characterization. It details the scope, methodology, and information needed before the assessment starts.

The hazard assessment protocol was made subject to an external consultation from June 30 to September 3, 2017. The EFSA published the outcome of the public consultation in a Report dated December 21, 2017. According to the protocol, the general aim of the hazard assessment of BPA will be to assess whether the new scientific evidence (published from 2013 onward and not previously appraised by EFSA) still supports the current temporary Tolerable Daily Intake for BPA of 4 µg/kg bw per day. In accordance with the EFSA press release of December 14, 2017, the EFSA will set up a new working group in 2018 and start collecting scientific papers and data, including available results of newly performed studies by the Consortium Linking Academic and Regulatory Insights on BPA Toxicity.
[Go to Top]

Meetings, Workshops, and Conferences

Public Meeting of FDA, USDA, and DHHS to provide information and receive public comments on agenda items and draft U.S. positions to be discussed at the 50th Session of the Codex Committee on Food of the Codex Alimentarius Commission, taking place in Xiamen, Fujian, Province China, **March 26-30, 2018**; **February 13, 2018**, in College Park, MD.

Public Meeting of FDA, USDA, and DHHS to provide information and receive public comments on agenda items and draft U.S. positions to be discussed at the 12th Session of the Codex Committee on Contaminants in Food of the Codex Alimentarius Commission, taking place in the Netherlands, **March 12-16, 2018**; **February 22, 2018**, in College Park, MD.
[Go to Top]