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

Trump Administration Announces Temporary Regulatory Freeze
On January 20, 2017, the Trump Administration issued a memorandum "for the Heads of Executive Departments and Agencies" requesting the "regulatory freeze" of almost all pending regulations and policies drafted by the Obama Administration. The memorandum requests that no regulation be sent to the Office of the Federal Register ("OFR") until "a department or agency head appointed or designated by the President … reviews and approves the regulation." Regulations that were sent to the OFR but not published to the *Federal Register* by the date the memorandum was published must be withdrawn for review and approval. In addition, regulations that had been published in the OFR but are not yet in effect must have their effective date delayed for at least 60 days "for the purpose of reviewing questions of fact, law, and policy they raise."

There are only two exceptions to the freeze: (i) regulations subject to statutory or judicial deadlines, and (ii) regulations issued for or affecting "emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters, or otherwise."

The memorandum states that the "freeze" applies to "'any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking,' and also covers any agency statement of general applicability and future effect 'that sets forth a policy on

CONTACTS

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Françoise S. Labrousse
Paris

Katherine M. Llewellyn
Brussels

Ales Bartl
Brussels

Laura E. Koman and Marina E. Moreno of the Washington Office assisted in the preparation of this Update.

Detailed Contact Information

RELATED PRACTICES

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a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.'" Guidance documents are also included.

Recently, three proposed rules issued by USDA's Grain Inspection, Packers and Stockyards Administration issued an extension of comment period "consistent with the memorandum of January 20, 2017." *See* the delay notices here, here, and here.

FDA Revises Control of *Listeria Monocytogenes* in Ready-To-Eat Foods
On January 17, 2017, FDA announced the availability of a revised draft guidance for industry titled, "Control of *Listeria monocytogenes* in Ready-To-Eat Foods." The revised draft guidance is intended for any person who is subject to FDA's "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" regulation, and who manufactures, processes, packs, or holds ready-to-eat ("RTE") foods. The guidance is intended to help industry comply with the requirements of that regulation with respect to measures that can significantly minimize or prevent the contamination of RTE food with *Listeria*. The guidance includes recommendations for controls involving personnel, cleaning and maintenance of equipment, and sanitation, as well as for treatments that kill *Listeria* and formulations to prevent it from growing during storage of the food between production and consumption. Industry best practices and the "seek and destroy" approach used by the Food Safety and Inspection Service ("FSIS") have also been incorporated into the draft guidance. Comments are due July 26, 2017.

FDA Issues Two Draft Guidance Documents on Nutrition Facts Label and Serving Sizes
Last month, FDA issued a draft guidance in the form of questions and answers that addresses questions related to the compliance date, added sugars, and declaration of quantitative amounts of vitamins and minerals set forth in the 2016 final rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels."

The draft guidance discusses the available methods to calculate the amount of added sugars in a fruit juice blend that has not been reconstituted to 100 percent, or to calculate the added sugars when a non-enzymatic browning or fermentation process is added to the product or when a concentration process is added during the processing of the product. The guidance also includes a chart with recommendations for declaration of quantitative amounts of vitamins and minerals on the Nutrition and Supplement Facts labels using RDIs for adults and children four years of age or older. FDA confirms it will refrain from taking regulatory action or compliance actions with respect to mandatory and dual column nutrition labeling for "bottled water products and coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors that would have been exempt under §101.9(j)(4)."

FDA issued a second draft guidance to provide examples of products that belong in each of the product categories included in the tables of Reference Amounts Customarily Consumed ("RACCs") per Eating Occasion established in 21 CFR §101.12(b). The RACCs were updated or modified by the 2016 final rule "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments."

FDA Receives Citizen Petition on Foods with Added Sugars
A citizen petition from the Union of Concerned Scientists asks FDA to amend regulations regarding health and nutrient content claims for packaged foods to include a disqualifying level for added sugar. In the 2016 final rule mentioned above, FDA required disclosure of added sugars in food products. FDA also published updated dietary guidelines advising that consumers not take in more than 10 percent of daily calories from added sugars. The petition states that "food companies should not be able to label or advertise foods as healthy or nutritious if the amount of added sugar exceeds an FDA-determined percent of calories per serving." The petition supports its request, stating "scientific research

continues to generate a body of evidence for a causal relationship between sugar consumption and weight gain and between sugar consumption and the rise in the incidence of the major chronic metabolic diseases (i.e. type 2 diabetes, cardiovascular disease, high triglycerides, and hypertension)." FDA has acknowledged receipt of the petition.

EFSA Issues Positive Opinion on Health Claims Related to Vitamin C in Infant Foods
On January 27, 2017, the European Food Safety Authority ("EFSA") issued a positive opinion on the health claims regarding Vitamin C in infant foods as it relates to protection of DNA, proteins, and lipids from oxidative damage. This is a strong indication that these claims will likely be authorized by the European Commission and included in the EU list of approved health claims. As background information, no health claims on foods (other than botanicals) can be used in the EU unless they have been included in the list. Infant food is "food used by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding." Infant food is a specific category for which the health claims must be authorized specifically.

EFSA Updates Guidance on How to Prepare a Health Claims Application
EFSA has updated its Guidance for applicants on how to prepare and present a health claim application (for inclusion into the EU list of approved health claims, *see* the previous article). The guidance presents a standardized format for a well-structured application. It also details the kind of information and data applicants need to submit in support of their claim.

European Commission Recommends Monitoring Mineral Residues in Foods
The European Commission has adopted a nonbinding recommendation for Member States to monitor mineral oil hydrocarbons ("MOHs") in food and in materials and articles intended to come into contact with food. According to EFSA, MOHs are suspected of causing cancer and altering the human genome, with children being particularly susceptible. Where MOHs are detected in food, further investigations should be carried out in the food business establishments to determine the possible sources. The monitoring data should be supplied to EFSA.

Other News
FDA Updates Strategy for FSMA Training

FDA and Partnership for Food Safety Education Create New Toolbox and Guide for Consumer Food Safety Educators

FoodDrinkEurope Challenges France's Meat and Dairy COOL Two-Year Mandatory Labeling

WTO Rules Indonesian Food Import Restrictions Violate GATT

Regulatory Updates

FDA Issues Draft Guidance on Use of Lead in Cosmetics
In the December 22, 2016, *Federal Register*, FDA announced a draft guidance titled, "Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level." This draft guidance provides a recommended maximum level of 10 parts per million ("ppm") for lead as an impurity in cosmetic lip products (such as lipsticks, lip glosses, and lip liners) and externally applied cosmetics (such as eye shadows, blushes, shampoos, and body lotions) marketed in the United States. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices and consistent with the 10 ppm maximum lead level for similar products recommended by other countries. FDA has concluded that the recommended maximum lead level would not pose a health risk. ***Comments are due February 21,***

2017.

FDA Updates Guidance on Food Facility Registration
In the December 27, 2016, *Federal Register*, FDA announced a draft guidance titled, "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." It supersedes the version of the food facility registration draft guidance announced on November 8, 2016. When finalized, this guidance is intended to provide updated information relating to the food facility registration requirements in the Federal Food, Drug, and Cosmetic Act. ***Comments are due March 27, 2017***.

FDA Extends Request for Comments on Term "Healthy" in Food Products
In the December 30, 2016, *Federal Register*, FDA extended the comment period for a docket to receive information and comments on the use of the term "healthy" in the labeling of human food products. In the notice, FDA requested comments on the term "healthy" generally, and as a nutrient content claim in the context of food labeling. FDA also requested comments on specific questions contained in the notice. FDA is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. ***Comments are now due April 26, 2017***.

FDA Clarifies Compliance Date for Nutrition Labeling Regulations
In the December 30, 2016, *Federal Register*, FDA extended the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule was published on December 1, 2014, and on May 5, 2016, FDA stated the enforcement date would be May 5, 2017. *See* the Docket. FDA clarifies and confirms that the compliance date for the final rule is May 5, 2017. ***The final rule was effective December 30, 2016***.

FDA Announces Draft Guidance on Nutrition Labeling Regulations
As discussed above, in the January 5, 2017, *Federal Register*, FDA announced the availability of a draft guidance for industry titled, "Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals." The draft guidance, when finalized, will provide questions and answers on topics related to compliance, labeling of added sugars, declaration of quantitative amounts of vitamins and minerals, and format for Nutrition and Supplement Facts labels. ***Comments are due March 6, 2017***.

FDA Issues Draft Guidance Related to the Produce Safety Rule
In the January 23, 2017, *Federal Register*, FDA announced the availability of the draft guidance "Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations." The guidance primarily focuses on assisting sprout operations subject to FDA's Produce Safety Rule in complying with the sprout-specific requirements in Subpart M (Sprouts). The draft guidance also includes limited discussion of certain other applicable requirements of the Produce Safety Rule. ***Comments are due July 24, 2017***.

FDA Approves Food Additive
In the December 27, 2016, *Federal Register*, FDA amended the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of feed-grade sodium formate as a feed acidifying agent in complete poultry feeds. This action is in response to a food additive petition filed by BASF Corp. ***Objections and requests for a hearing were due January 26, 2017***.

AMS Proposes Organic Program
In the January 18, 2017, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") proposed establishing an industry-funded promotion, research, and information program for certified organic products to strengthen their position in the marketplace, support research to benefit the organic industry, and improve access to information and

data across the organic sector. The proposed program, which was submitted by the Organic Trade Association ("OTA"), would require certified producers and certified handlers with gross sales in excess of $250,000 to pay an assessment of one-tenth of one percent of net organic sales. Importers importing greater than $250,000 in transaction value of organic products for the previous marketing year would pay an assessment of one-tenth of one percent of the transaction value of certified organic products reported to the U.S. Customs and Border Protection. Producers, handlers, and importers that fall below these thresholds could choose to pay assessments into the program as a "voluntarily assessed" entity.

An initial referendum would be held among mandatorily and voluntarily assessed entities to determine whether they favor implementation of the program prior to its going into effect. ***Comments are due March 10, 2017***.

AMS Proposes Adding Mandatory COOL Requirements for Venison
In the January 13, 2017, *Federal Register*, USDA's AMS proposed to amend the country of origin labeling ("COOL") regulation to add muscle cuts of venison and ground venison to mandatory COOL requirements as mandated by the Agricultural Act of 2014. ***Comments are due March 14, 2017***.

APHIS Proposes Importation, Interstate Movement, and Environmental Release of Certain GMOs
In the January 19, 2017, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to revise its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms ("GMOs") in order to update the regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by GMOs, thereby reducing the burden for regulated entities whose organisms pose no plant pest or noxious weed risks. APHIS also proposed to revise its regulation regarding the movement of plant pests and soil, and proposed criteria regarding the movement and environmental release of biological control organisms. ***Comments are due May 19, 2017, and March 20, 2017 respectively***.

FSIS Proposes Revision of the Nutrition Facts Labels for Meat and Poultry Products
In the January 19, 2017, *Federal Register*, USDA's FSIS proposed, consistent with the recent changes that FDA finalized, to amend the nutrition labeling requirements for meat (including fish of the order *Siluriformes*) and poultry products to better reflect the most recent scientific research and dietary recommendations and to improve the presentation of nutrition information to assist consumers in maintaining healthy dietary practices. FSIS is proposing to: (i) update the list of nutrients that are required or permitted to be declared; (ii) provide updated Daily Reference Values and Reference Daily Intake values; and (iii) amend the labeling requirements for foods represented or purported to be specifically for children under the age of four years and pregnant women and lactating women and to establish nutrient reference values specifically for these population subgroups. FSIS is also proposing to: (iv) revise the format and appearance of the Nutrition Facts label; (v) amend the definition of a "single-serving container"; (vi) require dual-column labeling for certain containers; and (vii) update and modify several reference amounts customarily consumed. Finally, FSIS is proposing to consolidate the nutrition labeling regulations for meat and poultry products into a new Code of Federal Regulations part. ***Comments are due March 20, 2017***.

AMS Issues Final Rule on Organic Livestock and Poultry Practices
In the January 19, 2017, *Federal Register*, USDA's AMS amended the organic livestock and poultry production requirements by adding new provisions for livestock handling and transport for slaughter and avian living conditions. AMS also expanded and clarified existing requirements covering livestock care and production practices and mammalian living conditions. ***The rule is effective March 20, 2017, and will be fully implemented (some exceptions apply) March 20, 2018***.

FNS Proposes Clarifying Requirements for the Processing of Donated Foods
In the January 5, 2017, *Federal Register*, USDA's Food and Nutrition Service ("FNS") proposed to revise and clarify requirements for the processing of donated foods in order to incorporate successful processing options tested in demonstration projects, ensure accountability for donated foods provided for processing, and increase program efficiency. The rule would require multistate processors to enter into National Processing Agreements to process donated foods into end products, permit processors to substitute commercially purchased beef and pork of U.S. origin and of equal or better quality for donated beef and pork, and increase oversight of inventories of donated foods at processors. The rule also revises regulatory provisions in plain language to make them easier to read and understand. ***Comments are due March 6, 2017***.

USDA Proposes to Amend Product Categories for Federal Procurement
In the January 13, 2017, *Federal Register*, USDA proposed to amend the Guidelines for Designating Biobased Products for Federal Procurement to add 12 sections of product categories composed of intermediate ingredient and feedstock materials within which biobased products would be afforded procurement preference by federal agencies and their contractors. USDA also proposed minimum biobased contents for each of these product categories. ***Comments are due March 14, 2017***.

AMS Proposes Removing 11 Substances from National List
In the January 18, 2017, *Federal Register*, USDA's AMS issued a proposed rule to address recommendations submitted to the Secretary of Agriculture by the National Organic Standards Board ("NOSB") following their October 2015 meeting. These recommendations pertain to the 2017 Sunset Review of substances on the USDA National List of Allowed and Prohibited Substances. Consistent with the recommendations from the NOSB, the proposed rule would remove 11 substances from the National List for use in organic production and handling. ***Comments are due March 20, 2017***.

APHIS Reviews Select Agent and Toxin List
In the January 19, 2017, *Federal Register*, USDA's APHIS amended and republished the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products, adding provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety and clarifying regulatory language concerning security, training, incident response, and records. APHIS has decided not to finalize the proposed changes to the contents of the list of select agents and toxins at this time. ***The rule is effective February 21, 2017***.

EU Regulatory Updates

EFSA Consults on Follow-on Formulae
EFSA has launched a public consultation on its draft scientific opinion on the safety and suitability of "follow-on formulae" with a protein content of at least 1.6 g/100 kcal, which is lower than the levels permitted under current EU legislation. Follow-on formulae are "food[s] used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants." EFSA considered follow-on formulae made from various protein sources and concluded that follow-on formulae made from cow's milk protein or goat's milk protein with a protein content of at least 1.6 g/100 kcal, but otherwise complying with relevant EU legislation, is safe and suitable for infants living in Europe. The available data did not allow EFSA to establish the safety and suitability of follow-on formulae with a similar protein content made from soy protein isolates or protein hydrolysates.

In parallel, EFSA has also launched a public consultation on its draft guidance for the preparation and presentation of applications for authorization of infant or follow-on formulae manufactured from protein hydrolysates. The guidance document specifies what kind of information and data applicants need to submit. It covers applications for

the assessment of the safety and suitability of the specific formula and applications on the formula's efficacy in reducing the risk of infants becoming allergic to milk proteins. ***Written comments are due March 3, 2017***.

UK Evaluates Two Novel Foods
Two companies have applied to the Food Standards Agency ("FSA") for approval to market their novel food products in the EU under the Novel Food Regulation (EC) 258/97. Before any new food product can be introduced into the European market, it must be rigorously assessed for safety. In the United Kingdom, the assessment of novel foods is carried out by the Advisory Committee on Novel Foods and Processes, an independent committee of scientists appointed by the FSA.

The first application is seeking to extend the food categories to which oils rich in fatty acids (docosahexaenoic acid or "DHA") extracted from microalgae can be used. The second is seeking authorization to sell their phytosterol ester on the basis that it is substantially equivalent to the phytosterol ester ingredients that are already authorized to be marketed in the European Union. ***Comments were due February 2, 2017***.

Titanium Dioxide in Food Potentially Linked to Gut Health Effects
Titanium dioxide (E 171) is a food additive that is widely used in foods and confectionery as a whitening agent. A French proposal has been issued to set a mandatory EU classification of titanium dioxide as a 1B inhalation carcinogen. If adopted, such classification would heavily impact further use of titanium dioxide. On February 2, 2017, the Chemical Watch reported that in addition to the ongoing classification proposal, new findings conducted by the French National Institute of Agricultural Research revealed that titanium dioxide particles crossed the rat gut barrier and reached the liver. They were also found in the lymphoid tissue of the small intestine, where they upset the immune system by altering the number of dendritic cells and triggering imbalances in immune responses.

Upcoming Meetings, Workshops, and Conferences

Public meeting of the FDA, USDA, and HHS on food additives, **February 21, 2017**, in College Park, MD.

Public meeting of the FDA on use of the term "healthy," **March 9, 2017**, in Rockville, MD.

Public Meeting of the National Organic Standards Board to assist the USDA in the development of standards for substances to be used in organic production and to advise the Secretary of Agriculture on any other aspects of the implementation of the Organic Foods Production Act, **April 13, 2017**, via webinar, and **April 19–21, 2017**, in Denver, CO.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Françoise S. Labrousse
Paris
+33.1.56.59.39.48
flabrousse@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Ales Bartl
Brussels
+32.2.645.14.52
abartl@jonesday.com

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