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

Food, Dietary Supplement & Cosmetics Regulatory Update

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Top News

FDA Delays Compliance Dates for the New Nutrition Labeling Regulations

On June 13, 2017, FDA delayed the compliance date for the Nutrition Facts and Supplement Facts Label and Serving Size final rules, providing additional time for implementation. The rules were finalized in May 2016 and (originally) required compliance on July 26, 2018 (July 26, 2019, for companies with less than $10 million in annual food sales). The rules, which are intended to reflect new knowledge of nutritional science and to help consumers achieve nutrition and weight-loss goals, change the format and appearance of the Nutrition Facts label. Among other changes, the new rules would require printing calorie count and serving size information in larger typeface, and declaring the gram amount and percent Daily Intake values of "added sugars" in a serving of a product. See our previous Jones Day *Update* for more information.

FDA stated it had decided to extend the compliance date after receiving feedback from industry and consumer groups, determining that "additional time would provide manufacturers covered by the rule with necessary guidance from FDA, and would help them be able to complete and print updated nutrition facts panels for their products before they are expected to be in compliance." The Grocery Manufacturers Association applauded FDA's decision, stating companies are still waiting on FDA for "vitally important" and "essential" final guidance on added sugars and dietary fibers. Other nonprofit organizations, like the Natural Products Association, filed a June 20, 2017, citizen petition with FDA to "shelve" the final rule on Nutrition and Supplement Facts Labeling, citing the Trump Administration's policy to freeze pending new regulations and to withdraw those it deems overly burdensome or unnecessary.

FDA did not provide a new compliance date but stated it will provide details through a *Federal Register* Notice at a later time.
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Two Consumer Advocacy Groups Sue FDA for Postponing the Menu Labeling Rule

As reported in our previous Jones Day *Update*, FDA published an interim final rule extending the compliance date of the menu labeling final rule a day before restaurants and other retail food establishments would have been required to list calorie information on their menus and menu boards. This was not the first time the compliance date for this rule was postponed; FDA has repeatedly delayed it since December 1, 2015, when it was initially set to go into effect.

As a result of FDA's most recent postponement of the rule, two nonprofit consumer advocacy groups, the Center for Science in the Public Interest and the National Consumers League, sued FDA on June 7, 2017. The groups claimed the interim final rule violated the Administrative Procedure Act because it did not rationally explain (i) why it was changing its interpretation of the requirements set forth in the Affordable Care Act, which directed FDA to promulgate the rule, or (ii) why it was changing its conclusions about the importance of mandating nutrition labeling to protect public health, as incorporated in the rule. The groups also claimed FDA failed to provide interested persons an opportunity to comment on the interim final rule. For these reasons, the groups claimed the interim final rule was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and requested the court to vacate the interim final rule and declare a certain date for compliance with the rule.
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FDA Launches Site for the Application of Accredited Third-Party Bodies

On June 21, 2017, FDA launched a website where organizations can apply to be recognized as a Third-Party Accreditation body. FDA's voluntary Accredited Third-Party Certification program was established under the FDA Food Safety Modernization Act and recognizes accreditation bodies that will have the authority to accredit third-party "certification bodies," otherwise known as third-party auditors. In turn, the certification bodies (i) conduct consultative and/or regulatory food safety audits and (ii) issue certifications to eligible entities that produce food for humans and animals, such as to help establish eligibility for participation in the Voluntary Qualified Importer Program, which offers expedited review and entry of food for eligible participants.

Foreign governments and agencies or private third-parties may apply to be recognized as an accreditation body. As explained by FDA, the process includes a web-based application and a user fee.
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Food Color Titanium Dioxide Proposed for Harmonized Classification as Suspected of Causing Cancer

On June 9, 2017, the European Chemicals Agency announced that the Committee for Risk Assessment ("RAC") proposed to classify the food color titanium dioxide (E 171) as suspected of causing cancer when inhaled (Category 2 Carcinogen). Although France originally proposed to classify titanium dioxide as presumed to cause cancer (Category 1B Carcinogen), the RAC disagreed with this more severe classification, which likely would have led to a marketing ban of titanium dioxide in the European Union. The RAC opinion will be sent to the European Commission ("EC") for final adoption.
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EFSA Offers Pre-Submission Checks For Novel Food Applications

On June 6, 2017, the European Food Safety Authority ("EFSA") launched a new support initiative for small and medium-sized enterprises ("SMEs") to submit applications for EFSA's approval of novel foods (excluding traditional foods) or feed additives. In accordance with this initiative, SMEs are allowed to ask EFSA to carry out a pre-submission check on their dossier from June to December 2017.

This pre-submission check, which will consist of a teleconference organized between EFSA's staff and an individual from the SME, is intended to provide SMEs with preliminary feedback on the format and administrative completeness of their applications, as well as to provide dedicated support to SMEs to speed up the transfer of such applications to the risk assessment phase.

This initiative is particularly relevant for novel food applications, which will be subject to new requirements as the new Novel Foods Regulation enters into force in January 2018.
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Other News

What to Know and What's Ahead Regarding Compliance with the Foreign Supplier Verification Programs, by Sharon Mayl, FDA

FDA Sampling of Gluten-Free Products Results in 99.5% Compliance

The European Court of Justice Rules that Unless Exceptions Apply, Purely Plant-Based Products, Such as Soya and Tofu, May Not Be Marketed With Designations Like "Milk," "Cream," "Butter," "Cheese," or "Yogurt"

As part of the European Union Observatory for Nanomaterials' Initiative, the European Chemicals Agency Launches a Website in 23 Languages with Information on the Use of Nanomaterials and the Health and Safety Issues Linked to their Use
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Regulatory Updates

FDA Announces Food Additive Petition

In the May 30, 2017, *Federal Register*, FDA announced that BASF Corporation filed a petition on February 10, 2017, proposing that the food additive regulations be amended to provide for the safe use of formic acid as a feed-acidifying agent in complete poultry feeds.
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FSIS Proposes to Amend Poultry Products Inspections Regulations

In the June 16, 2017, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") proposed to amend the poultry products inspection regulations to list the People's Republic of China ("PRC") as eligible to export to the United States poultry products from birds slaughtered in the PRC. The PRC is currently eligible to export processed poultry products to the United States if the products are derived from poultry slaughtered in the United States or in other countries eligible to slaughter and export poultry to the United States. FSIS is proposing this action because the Agency has reviewed the PRC's laws, regulations, and poultry slaughter inspection system as implemented and has determined that the PRC's poultry slaughter inspection system is equivalent to the system that the United States has established under the Poultry Products Inspection Act and its implementing regulations.

Although the PRC may be listed in FSIS's regulations as eligible to export poultry products to the United States, the products also must comply with all other applicable U.S. requirements, including those of USDA's Animal and Plant Health Inspection Service ("APHIS"). All such products are subject to reinspection at U.S. ports-of-entry by FSIS inspectors. ***Comments are due August 15, 2017***.
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GIPSA Suspends Supervision Fee Assessment

In the June 12, 2017, *Federal Register*, USDA's Grain Inspection Packers and Stockyards Administration ("GIPSA") announced the suspension of fees charged for the supervision of official inspection and weighing services of domestic grain and land carriers to Canada and Mexico performed by delegated states and/or designated agencies under the United States Grain Standards Act ("USGSA"). GIPSA has determined that suspending the supervision fees will not impair the objectives of the USGSA because the current operating reserve far exceeds that needed to maintain the service without additional funds. ***This document is effective July 1, 2017, and remains in effect through June 30, 2018***.
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AMS Issues Beef Promotion and Research Rules and Regulations

In the May 30, 2017, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") amended the Beef Promotion and Research Order established under the Beef Promotion and Research Act of 1985 by adding six Harmonized Tariff Schedule codes for imported veal and veal products and updating assessment levels based on revised determinations of live animal equivalencies. In addition, AMS is amending the Order's definition of "imported beef or beef products" by deleting its reference to tariff numbers that are no longer in use and are obsolete. ***The rule is effective June 29, 2017***.
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APHIS Updates List of Regulated Articles for the Asian Longhorned Beetle

In the May 25, 2017, *Federal Register*, USDA's APHIS adopted as a final rule, without change, an interim rule that amended the Asian longhorned beetle ("ALB") regulations by removing plants of the genus Celtis, which APHIS determined not to be a host plant of ALB, from the list of regulated articles. As a result of the interim rule, there are no longer any restrictions on the movement of Celtis spp. plants from areas quarantined for ALB. ***The rule was effective May 25, 2017***.
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AMS Changes Reporting and Notification Requirements for Imported Fruits, Vegetables, and Specialty Crops

In the May 25, 2017, *Federal Register,* USDA's AMS adopted without change, as a final rule, an interim rule that updated reporting and notification requirements associated with the fruit, vegetable, and specialty crop import regulations for certain commodities regulated under section 608(e) ("8e regulations") of the Agricultural Marketing Agreement Act of 1937. The interim rule also made clarifying changes. The interim rule shifted the exempt reporting requirement for imported tomatoes destined for noncommercial outlets for experimental purposes from the tomato import regulations to the safeguard procedures section of the vegetable import regulations. In addition, the pistachio import regulations were updated by removing reference to a paper-based notification of entry process. Other administrative changes were made to several of the 8e regulations to replace outdated information. These changes to the import regulations support the International Trade Data System, a system that streamlines and automates the filing of import and export information by the trade. ***The rule was effective May 30, 2017***.
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AMS Proposes Change to Quality and Handling Standards for Domestic and Imported Peanuts

In the May 25, 2017, *Federal Register*, USDA's AMS proposed to implement a recommendation from the Peanut Standards Board to revise the minimum quality and handling standards for domestic and imported peanuts marketed in the United States. AMS stated this action would relax the allowance for damaged kernels in farmers' stock peanuts when determining segregation and would increase the allowance for damaged kernels under Segregation 1 from not more than 2.49 percent to not more than 3.49 percent. The requirements for Segregation 2 also would be adjusted to reflect this change. The Board recommended this change to align the incoming standards with recent changes to the outgoing quality standards and to help increase returns to producers. ***Comments are due June 26, 2017***.
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FSIS Requests Comments on Inspection Practices for Fish Slaughtering Facilities

In the May 17, 2017, *Federal Register*, USDA's FSIS announced and requested comments on its plan under the final rule "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish" to adjust inspection coverage at official establishments that slaughter fish of the order Siluriformes, which includes catfish, from all hours of operation to once per production shift. ***Comments were due June 16, 2017.*** In the June 15, 2017, Federal Register, FSIS also announced two educational meetings to discuss the enforcement and implementation of the final rule, where FSIS will present information on the upcoming full implementation of the regulatory requirements, as well as information on entry procedures and reinspection at official import inspection establishments. FSIS stated it is particularly interested in soliciting participation from representatives from domestic wild-caught operations that process Siluriformes fish and fish products. ***The meetings are scheduled June 27, 2017, in Richmond, VA, and July 20, 2017, in Linthicum Heights, MD***.
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European Updates

EFSA Confirms Safety Levels of Nitrites and Nitrates Added to Food but Recommends Conducting Further Risk Assessments

In June 2017, as part of the European Food Safety Authority ("EFSA") reevaluation program of all food additives authorized in the European Union before 2009, the EFSA reassessed the safety of food additives nitrites and nitrates, confirming the previously set acceptable daily intakes ("ADIs") are sufficiently protective of public health.

The ADI for nitrates is 3.7 milligrams per kilogram of body weight per day ("mg/kg bw/day"), and the ADI for nitrites is 0.06 and 0.07 mg/kg bw/day. Sodium and potassium salts of nitrite and nitrate (E 249-252) are used in meat, fish, and cheese products to hinder microbial growth, as well as to keep meat red and enhance its flavor. Nitrate is also found naturally in high concentrations in certain vegetables, and it can enter the food chain as an environmental contaminant, mainly in water.

With respect to nitrates, EFSA experts estimated that consumer exposure solely from food additives was less than 5 percent of the overall exposure to nitrate in food and did not exceed the safety levels. However, if all sources of dietary nitrate were considered (food additive, natural presence in foods, and environmental contaminants), the safe level may be exceeded for individuals of all age groups with medium to high exposure. With respect to nitrites used as food additives, experts estimated exposure to be within safe levels for all population groups, except for highly exposed children, who might slightly exceed the ADI. Exposure from all dietary sources may exceed the ADI for infants, toddlers, and children with medium exposure, and for highly exposed individuals of all age groups. The EFSA therefore recommended conducting further studies and collecting additional epidemiological evidence in humans, as well as better data on exposure to nitrites/nitrates from other food sources than additives (including from contaminants in vegetables), in order to refine future risk assessments.
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Toxicologist Challenges Scientific Basis for Authorization of Glyphosate

On May 31, 2017, leading toxicologist and environmental engineer Christopher Portier sent a letter to the EC denouncing the poor scientific quality of the European Union's research into glyphosate. Last month, the EC decided to reauthorize glyphosate for 10 more years after the EFSA and the European Chemicals Agency found that exposure to glyphosate in food products was not harmful to human health. Glyphosate is the most widespread herbicide in the world. In particular, Portier argued that the EU agencies did not take into account observations of increased cancer rates after exposure to glyphosate. To his letter, he attached a complete list of all the data not previously reviewed by EFSA and asked the Agencies to examine them and correct their conclusions.

The EC restated its position that there was currently no reason to doubt the evaluation of the EU Agencies but announced the Agencies would respond to Portier's letter.
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EC Consults Printing Ink Food Industry on Food Contact Materials

This June, the EC started consulting with members of the food packaging industry on a harmonized EU measure on printed food contact materials ("FCMs"). The EC, which recently announced the results of a study that it had conducted to describe the current situation concerning FCMs for which there are no specific measures at the EU level, is assessing the suitability of the current EU framework, regulated under the Commission Regulation (EC) No 1935/2004, both for the harmonized and nonharmonized sectors. For more information, click here.

To this end, industry players were invited to provide input via a joint taskforce, the European Printing Inks Association. This initiative follows the EC's announcements last year that it would adopt a harmonized law on printed FCMs as early as mid-2018.
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Upcoming Meetings, Workshops, and Conferences

Public Meetings of FSIS to discuss the enforcement and implementation of the Final Rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish," **June 27, 2017**, in Richmond, VA, and **July 20, 2017**, in Linthicum Heights, MD.

Public Meeting of AMS's 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 Organic Foods Production Act, **October 24, 2017**, via webinar, and **October 31–November 2, 2017**, in Jacksonville, FL.
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