



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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Top News

Senate Confirms Califf as New FDA Commissioner

After weeks of opposition, on February 24, 2016, the [Senate confirmed](#) Dr. Robert Califf, [President Obama's nominee for FDA Commissioner](#). Although his nomination was not expected to be controversial, several lawmakers had blocked his nomination due to what they claimed was FDA's poor record regarding controlling abuse of prescription painkillers, particularly opioids. Califf, a prominent cardiologist and medical researcher at Duke University, has been a consultant to drug companies and has run a research institute at Duke primarily funded by the pharmaceutical industry, raising concerns among some lawmakers that he was too close to the industry he will be tasked with regulating. In response to the pressure to curb painkiller abuse, Califf along with other FDA leaders [launched a plan](#) in early February 2016 calling for a "sweeping review of agency opioids policies."

USDA Establishes Faster Way to Approve GM Crops

Last week, [USDA issued](#) a new, accelerated process for extending deregulation status for certain genetically modified ("GM") crops in a [guidance document](#).

Under its current policy, USDA's Animal and Plant Health Inspection Service ("APHIS") deregulates GM products after determining they do not pose a plant pest risk. The document lays out how APHIS will decide which GM crops are eligible to go through the new process. If a crop qualifies for the accelerated process, the agency could reach a determination within as little as eight months, compared to a current average of a year

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and a half. To qualify for the deregulation by extension, crops must contain genetic traits that are the same or similar to ones APHIS has already approved. If similarity between crops decreases, APHIS review might become longer. The guidance document provides an example of GM apples modified to resist browning. Under the new process, only one company would need to go through the agency's full GM crop screening, and any subsequent apple varieties would qualify for the accelerated process.

Senate Republican Unveils New Bill to Block State GMO Label Laws

Senator Pat Roberts (R-Kan) has [unveiled legislation](#) that would preempt states from issuing mandatory labeling laws for foods that contain genetically modified organisms ("GMOs"). The bill would require the USDA Secretary to establish a national voluntary labeling standard for GM foods. The bill is similar to parallel legislation passed by the House in July 2015, called the [Safe and Accurate Food Labeling Act](#), as discussed in a previous issue of this [newsletter](#).

FDA to Hold Public Meeting on FSMA Import System Regulations

[FDA announced](#) last week that it will hold a public meeting, titled "FDA Food Safety Modernization Act: Prevention-Oriented Import System Regulations and Implementation," to provide importers and other stakeholders a chance to discuss import safety regulations and programs, including final rules for foreign supplier verification programs for importers of food for humans and animals, and accreditation of third-party certification bodies. [The meeting will be held March 21, 2016.](#)

Obama's FY 2017 Budget Requests Funds for FSMA Implementation

President Obama has proposed additional funding resources that include an increase of \$25.3M of new budget authority to implement FSMA. FDA will use the funds to focus on two key areas: (i) a nationally integrated food safety system (\$11.3M); and (ii) new import safety systems (\$14.0M). For the first key area, the funding will be used mainly to support state capacity to implement the [produce safety rule](#) by educating and assisting farmers and providing ongoing compliance support and oversight. Funding for the second key priority will be used to implement the [Food Supplier Verification Program rule](#), which makes importers responsible for ensuring foods they import are produced in a manner consistent with U.S. food safety standards.

House Votes to Weaken, but Not Kill, FDA Menu Labeling Rule

[The House recently voted](#) to approve a law that would relieve fast food chains and other establishments from complying with the [new government rules on listing calories on menus](#). The rule was originally set to go into effect in December 2015, but implementation was [delayed until at least December 2016](#) amid complaints the rule was too broad and inflexible. The menu labeling rule will require restaurants and other establishments that sell prepared foods and have 20 more locations to post the calorie content of food on menus, menu boards, and displays. House Republicans argue that the rule is too burdensome and inflexible for businesses. The House's proposal, called the Common Sense Nutrition Disclosure Act, will leave the rules in place but give restaurants discretion to inform customers about calorie counts by posting information online or in a smartphone app, as opposed to on menu boards in stores. According to the White House, "[i]f enacted, [the law] would reduce consumers' access to nutrition information and likely create consumer confusion by introducing a great deal of variability into how calories are declared." The legislation will head to the Senate.

FDA Issues Compliance Guide on Omega-3 Fatty Acids Final Rule

[FDA announced](#) the availability of a [Small Entity Compliance Guide](#) to help food companies comply with [FDA's final rule](#) addressing specific nutrient content claims for omega-3 fatty acids. The final rule, published on April 28, 2014, became effective as of January 1, 2016, and prohibits claims that a food is "high in" specific omega-3 fatty acids docosahexaenoic acid ("DHA") or eicosapentaenoic acid ("EPA"), along with synonyms like "rich in" and "excellent source of." Among other issues, the compliance guide addresses requirements for submitting a notification for a prospective nutrient content claim, types of nutrient content claims prohibited by the rule, and why nutrient content

claims for DHA and EPA are prohibited.

Other News

[NY Appeals Court Stays NYC Menu Salt Warning Rule](#)

[FDA Posts Questions and Answers on Spice Safety](#)

[FDA Announces Grant Award to Establish Regional Food Safety Training Centers](#)

[USDA Expands Insurance Program for Farmers Transitioning to Organic Crops](#)

Regulatory Updates

FDA Reopens Comment Period on Gluten-Free Labeling of Fermented or Hydrolyzed Foods

In the [February 23, 2016, Federal Register](#), FDA announced it is [reopening the comment period](#) to allow interested parties to comment on its [proposed rule of November 18, 2015](#), titled "Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods." The proposed rule would establish requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. **Comments are due April 25, 2016.**

FDA Extends Comment Period on Food Additive Petitions

In the [February 23, 2016, Federal Register](#), FDA announced an extension of the comment period for the notice that appeared in the [Federal Register of January 4, 2016](#), wherein FDA requested comments on a food additive petition (FAP 5A4810), submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, and other interested groups proposing that the food additive regulations be amended to no longer authorize the use of seven listed synthetic flavoring food additives and to establish zero tolerances for the additives. **Comments are due May 3, 2016.**

FDA Issues Guidance on Omega-3 Fatty Acids

In the [February 23, 2016, Federal Register](#), FDA announced the availability of a guidance for industry titled "Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids—Small Entity Compliance Guide." The small entity compliance guide is intended to help small entities comply with the final rule titled "[Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids](#)." Final rule prohibits certain nutrient content claims for foods, including conventional foods and dietary supplements that contain omega-3 fatty acids based on the determination that such nutrient content claims do not meet the requirements of the Federal Food, Drug, and Cosmetics Act. **Final rule was effective January 1, 2016.**

AMS Issues Final Rule to Revise Lamb and Swine Reporting Requirements

In the [February 29, 2016, Federal Register](#), [here](#) and [here](#), USDA's Agricultural Marketing Service ("AMS") issued final rules to implement the Livestock Mandatory Reporting ("LMR") program of 2001. The LMR program was reauthorized in October 2006 and again in September 2010. On September 30, 2015, the Agriculture Reauthorizations Act of 2015 ("2015 Reauthorizations Act") reauthorized the LMR program for an additional five years and directed the Secretary of Agriculture to amend the LMR lamb reporting requirements by redefining terms within the Code of Federal Regulations not later than 180 days after enactment. This direct final rule incorporates the lamb and swine reporting changes contained within the 2015 Reauthorizations Act under the USDA LMR regulations. **Comments are due April 29, 2016.**

APHIS Announces Final Environmental Assessment and Finding of No Significant Impact Relative to Control of Highly Pathogenic Avian Influenza Outbreaks

In the [February 9, 2016, Federal Register](#), USDA's APHIS announced it had prepared a

final environmental assessment ("EA") and finding of no significant impact relative to the control of highly pathogenic avian influenza ("HPAI") outbreaks, which is a significant and often fatal zoonotic disease of poultry. The final EA recommends an approach in which APHIS uses its centralized management of carcass disposal activities to ensure consistency in responses to HPAI outbreaks throughout the United States. Under this approach, APHIS helps state and local authorities determine which depopulation, disposal, and cleaning and disinfection methods are most appropriate for the situation.

APHIS Amends Regulations Specifying Conditions for Payment of Indemnity Claims for HPAI

In the [February 9, 2016, Federal Register](#), USDA's APHIS issued an interim rule amending regulations pertaining to certain diseases of livestock and poultry to specify conditions for payment of indemnity claims for HPAI. Specifically, APHIS is providing a formula to split such payments between poultry and egg owners and parties with which the owners enter into contracts to raise or care for the eggs or poultry based on the proportion of the production cycle completed. This action is intended to appropriately compensate contractors. For example, APHIS will provide for payment of indemnity for eggs required to be destroyed due to HPAI. Additionally, APHIS will require owners and contractors, unless specifically exempted, to provide a statement that at the time of detection of HPAI in their facilities, they had in place and were following a biosecurity plan aimed at keeping HPAI from spreading to commercial premises. **Comments are due April 11, 2016.**

AMS Amends Classification of Foreign-Growth Cotton

In the [February 10, 2016, Federal Register](#), USDA's AMS announced a final rule that amends regulations pertaining to administrative and operational procedures for the classification of foreign-growth cotton. AMS clarifies the existing language, updates the terms and practices described to comply with today's industry norms and current cotton classification technologies, and establishes procedural safeguards to the classification process for foreign-growth cotton that promote accuracy. **Comments are due March 11, 2016.**

FSIS Assesses Certain Pathogen Reduction Performance Standards

In the [February 11, 2016, Federal Register](#), USDA's Food Safety and Inspection Service ("FSIS") announced that it will begin assessing whether establishments meet the pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat ("NRTE") comminuted chicken and turkey products. It will also begin posting, based on FSIS sampling results and depending on the standard for the particular product, whether an establishment meets the FSIS pathogen reduction performance standards, or what category an establishment is in. FSIS's notice also responds to comments received on the January 2015 *Federal Register* notice that proposed the standards and announced changes to FSIS's verification sampling program. **FSIS will start the assessment on May 11, 2016.**

USDA Issues Final Rule to Amend the Agriculture Acquisition Regulation

In the [February 12, 2016, Federal Register](#), USDA's Office of Procurement and Property Management amended the Agriculture Acquisition Regulation ("AGAR") by adding a new clause titled "Fire Suppression and Liability." Section 8205 of the Agricultural Act of 2014 provided the USDA Forest Service with permanent authority for Stewardship End Result Contracting, requiring the agency to use a fire liability provision in all stewardship contracts and agreements that is in substantially the same form as the fire liability provisions contained in the integrated resource timber contract in Forest Service Contract Numbered 2400-13, Part H, Section H.4. This final rule establishes a new clause in the AGAR, the USDA supplement to the Federal Acquisition Regulation ("FAR"), for use in Integrated Resource Service Contracts subject to the FAR. **Final rule is effective March 14, 2016.**

NIFA Announces Initiation of an Interagency Special Report Titled "2nd State of the Carbon Cycle Report"

In the [February 12, 2016, Federal Register](#), USDA's National Institute of Food and

Agriculture ("NIFA") announced that the U.S. Carbon Cycle Science Program and the Carbon Cycle Interagency Working Group, under the auspices of the U.S. Global Change Research Program, are initiating an Interagency Special Report titled "2nd State of the Carbon Cycle Report." The focus of this report will be on U.S. and North American carbon cycle processes, stocks, and flows in the context of and interactions with global-scale budgets and climate change impacts in managed and unmanaged systems. **Comments, scientific/technical information, and nomination of technical contributors are due March 14, 2016.**

USDA Issues Final Rule on Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

In the [February 16, 2016, Federal Register](#), USDA's Office of the Chief Financial Officer, Farm Service Agency, Commodity Credit Corporation, National Institute of Food and Agriculture, Rural Utilities Service, Rural Business-Cooperative Service, and Rural Housing Service finalized their portion of the uniform federal assistance rule and amended specific regulations on administrative requirements, cost principles, and audit requirements for federal awards to reference the conforming changes published by the Office of Management and Budget in the [Federal Register on December 19, 2014](#). **Final rule is effective February 16, 2016.**

FNS Proposes Amending Regulations Pertaining to Eligibility of SNAP Retail Food Stores

In the [February 17, 2016, Federal Register](#), USDA's Food and Nutrition Service ("FNS") proposed changes to the Supplemental Nutrition Assistance Program ("SNAP") regulations pertaining to the eligibility of SNAP retail food stores. These proposed changes (i) address depth of stock, (ii) amend the definition of "staple foods," and (iii) amend the definition of "retail food store" to clarify when a retailer is a restaurant rather than a retail food store. The rulemaking also proposes that FNS begin disclosing to the public specific information about retailers who have violated SNAP rules. **Comments are due April 18, 2016.**

AMS National Organic Program Amends National List

In the [February 23, 2016, Federal Register](#), USDA's AMS National Organic Program announced the need for renewal of five synthetic substances (malic acid, microorganisms, activated charcoal, peracetic acid/ peroxyacetic acid, and sodium acid pyrophosphate) and two nonsynthetic substances (ferric phosphate and hydrogen chloride) on the USDA National List of Allowed and Prohibited Substances ("National List"), along with any restrictive annotations. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. This document completes the 2016 National List Sunset Process. **Document is effective September 12, 2016.**

GIPSA Extends Comment Period to Address Grain Standards Act

In the [February 24, 2016, Federal Register](#), USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA") announced the extension of the comment period for its [proposed rule](#) addressing changes to the United States Grain Standards Act ("USGSA"), as amended, in order to comply with amendments to the USGSA made by the Agriculture Reauthorizations Act of 2015. This rulemaking proposes to (i) eliminate mandatory barge weighing, (ii) remove the discretion for emergency waivers of inspection and weighing, (iii) revise GIPSA's fee structure, (iv) revise exceptions to official agency geographic boundaries, (v) extend the length of licenses and designations, and (vi) impose new requirements for delegated states. **Comments are due April 25, 2016.**

Other USDA Announcements

- APHIS Authorizes Importation of *Phalaenopsis* Spp. Plants for Planting from China in Approved Growing Media into the Continental United States
- APHIS Extends Nonregulated Status of Pioneer Corn Event DP-004114-3 to Syngenta's Genetically Engineered Corn Event MZIR098

- APHIS Makes a Preliminary Determination of Nonregulated Status of Genetically Engineered Maize Designated as Event MON 87419
- APHIS Adopts Final Rule Amending Golden Nematode Regulations by Removing Areas in Orleans, Nassau, and Suffolk Counties in the State of New York from the List of Generally Infested Areas
- APHIS Adds the European Union ("EU") to APHIS' List of Regions Affected with African Swine Fever
- AMS Directs a Referendum Be Conducted Among Eligible Domestic Manufacturers and Importers of Softwood Lumber to Determine Whether They Favor Continuance of the Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order
- AMS Directs a Referendum Be Conducted Among Eligible Producers and Importers of Highbush Blueberries to Determine Whether They Favor Continuance of the Blueberry Promotion, Research, and Information Order
- AMS Increases Assessment Rate for the 2015–16 and Subsequent Production Years for Pistachios Handled Under the Marketing Order for Pistachios Grown in CA, AZ, and NM
- AMS Decreases Assessment Rate for the 2015–16 and Subsequent Crop Years for Dates Grown or Packed in Riverside County, California
- AMS Proposes Rule to Collect Industry Data and Conduct Research and Promotion Activities of Pecans Grown in AL, AK, AZ, CA, FL, GA, KS, LA, MS, MO, NC, NM, OK, SC, and TX

FDA Announced the Opportunity for Public Comment on the Following Proposed Information Collections:

- Manufactured Food Regulatory Program Standard
- Substances Generally Recognized as Safe; Notification Procedure
- Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water
- Food Additive Petitions and Investigational Food Additive Exemptions

FDA Announced the Following Information Collection Activities Have Been Approved by OMB:

- Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

USDA Announced the Following Requests for Information:

- Request for Release of Lien and/or Approval of Sale, RUS Form 793
- Generic Clearance to Conduct Formative Research for Development of Nutrition Education and Promotion Materials and Related Tools for FNS Population Groups
- 7 CFR part 235—State Administrative Expense Funds

USDA Announced Its Intent to Reinstate, Revise, Renew, or Extend the Following Previously Approved Information Collections:

- Specimen Submission
- USDA Local and Regional Food Aid Procurement Program
- Swine Contract Library
- Livestock Mandatory Reporting Act of 1999
- Reporting Requirements for Research, Education, and Extension Project Online Reporting Tool
- Horse Protection Regulations

USDA Announced the Following Information Collections Have Been Submitted to OMB:

- Food Program Reporting System
- Child Nutrition Program Operations Study II
- Agricultural Foreign Investment Disclosure Act Report
- National School Lunch Program
- Quality Control Review Schedule

European Regulatory Updates

European Parliament Opposes Stripping Organic Certification From Products Contaminated with GMOs or Pesticides

On February 8, 2016, the Committee of the European Parliament ("EP") adopted a [report](#) including a set of proposed revisions to EU organic farming standards [published](#) by the European Commission ("EC") on March 24, 2014. In particular, the EP disagreed with the EC's proposal to eliminate the organic certificate from farming products that have been contaminated with GMOs or pesticides. The EC's proposal applies even when products have been contaminated by GMOs or pesticides that have previously been authorized for use in foods within the EU. The rejection by the EP was a result of concerns raised by Germany and France over the possibility that the proposed rule might hold back the expansion of the agro-ecology in Europe, as accidental contamination by chemicals or by approved GMOs (e.g., during transport or storage) cannot be avoided.

Other EU Regulatory Updates

[EFSA Scientific Network for Risk Assessment of GMO Publishes 2015 Annual Report](#)

[EC Says It's Ready to Back Livestock Farmers](#)

Upcoming Meetings, Workshops, and Conferences

[Public Meeting of FSIS on Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, **March 3, 2016**](#), in Newark, NJ.

[Public Meeting of the Codex Alimentarius Commission Committee on Contaminants in Food, **March 7, 2016**](#), in College Park, MD.

[Public Meeting of FSIS on Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, **March 17, 2016**](#), in Los Angeles, CA.

[Public Meeting of the FDA Titled "FDA Food Safety Modernization Act: Prevention-Oriented Import System Regulations and Implementation," **March 21, 2016**](#), in College Park, MD.

[Public Meeting of the National Advisory Committee on Meat and Poultry Inspection to Review and Determine Better *Listeria Monocytogenes* Control at Retail, **March 29–30, 2016**](#), in Washington, D.C.

[Public Meeting of FSIS on Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish, **March 24, 2016**](#), in Houston, TX.

[Public Meeting of the FDA on Food Labeling, **April 13, 2016**](#), in College Park, MD. *This meeting is to receive comments on agenda items and draft U.S. positions to be discussed at the 43rd Session of the Codex Committee on Food Labeling Commission, taking place on May 9–13, 2016, in Ottawa, Canada.*

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