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MEMORANDUM

From: Joseph A. Levitt
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Date: June 20, 2019

Re: **OMB Releases Spring 2019 Unified Agenda of Regulatory Actions**

The Office of Management and Budget (OMB) recently released the Spring 2019 Unified Agenda of Regulatory Actions, which outlines the rulemaking actions currently under development in each federal agency. This memorandum summarizes the major actions that may be of particular interest to the food industry that are being planned by the U.S. Food and Drug Administration (FDA) and the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service (APHIS), Food and Nutrition Service (FNS), and Agricultural Marketing Service (AMS). After highlighting the most significant priorities, we provide charts for each agency that provide additional details on their plans. More information can be found by clicking on the blue link next to each item, which will take you to a specific page about each agenda item on OMB's website.

We want to caution that the dates included in the Unified Agenda are not commitments to act on or by the date shown and simply indicate the agencies' aspirations. Rather than focusing on projected dates, the Unified Agenda is a valuable tool to identify the substantive issues the agencies consider to be priorities for rulemaking.

FDA's current priorities include the following:

- FDA has completed the seven major rulemakings under the FDA Food Safety Modernization Act (FSMA) and the agency has turned its efforts to more discrete actions to fine tune the regulations. FDA's agenda for future FSMA-related rulemakings includes:
 1. Streamlining the written assurance requirements that apply when a manufacturer/processor or importer of food identifies a hazard requiring a preventive control, but does not control the hazard (e.g., 21 CFR § 117.136) (May 2019). FDA plans to conduct parallel rulemakings for the Preventive Controls for Human Food, Preventive Controls for Animal Food, and Foreign Supplier Verification Programs rules, but the Unified Agenda does not include similar plans for the Produce Safety rule;
 2. Clarifying changes to the food facility registration requirements, including revising the definition of "farm" (November 2019);

3. Proposing a regulation on laboratory accreditation, which will enable FDA to recognize accreditation bodies that will accredit laboratories performing analyses of food under certain circumstances (May 2019); and
 4. Proposing a regulation to revise certain requirements that currently apply to produce that satisfies criteria for an exemption from the Produce Safety rule because that produce will receive commercial processing to adequately reduce the presence of microorganisms of public health significance (October 2019).
- FDA plans to issue a proposed rule to update the agency's regulations to remove all mention of partially hydrogenated oils (PHOs) and to revoke all prior sanctioned uses. This action follows FDA's declaratory order in June 2015 announcing the agency's determination that there no longer is a consensus among qualified experts that PHOs are Generally Recognized as Safe (GRAS) for any use in human food and FDA's denial of a food additive petition in May 2018 requesting that the regulations be amended to provide for the safe use of PHOs in certain food applications (November 2019).
 - FDA will issue a proposed rule to update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines (May 2019).
 - FDA also plans to propose a rule to add a second methodology for the analysis of sulfites in foods, which FDA states will improve the speed and efficiency in FDA testing for sulfites in food for enforcement activities (May 2019).
 - FDA will reopen the comment period for a proposed rule relating to modernizing food standards of identity (September 2019). The agency also will promulgate proposed rules to revoke the current standards of identity for French dressing and frozen cherry pie (November and December 2019). FDA plans to finalize a rule amending the standard for yogurt and revoking the standards for lowfat and nonfat yogurt (September 2019).
 - FDA will issue a final rule on fluoride levels in bottled water (April 2020). The comment period for the proposed rule ended earlier this month. The proposed rule revises the quality standard for bottled water to specify that bottled water to which fluoride is added by the manufacturer may not contain fluoride that exceeds 0.7 milligrams per liter (mg/L).
 - FDA plans on finalizing several other proposed regulations, including:
 1. An amendment to FDA's regulation authorizing the use of health claims regarding the relationship between soy protein and coronary heart disease (December 2019); and
 2. A rule that would establish requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients (September 2019).
 - FDA intends to finalize its proposed rule to amend its regulations on the type size requirement for calorie declarations for Front of Pack (FOP) labeling in glass front vending machines (October 2019).

The priorities for agencies within USDA include the following:

- FSIS currently is finalizing initiatives to modernize inspection systems and to eliminate or streamline regulations. FSIS plans to finalize a proposal to modernize swine slaughter inspection (July 2019), and it intends to finalize a rule to transition egg products manufacturing from a “command and control” system to a Hazard Analysis and Critical Control Point (HACCP) program (August 2019). The swine slaughter modernization rule follows on the Agency’s modernized poultry slaughter inspection rule from several years ago.
- FSIS will issue a proposed rule expanding the categories of meat and poultry products that can be approved through the generic labeling approval process. FSIS is proposing to make these changes by revising its labeling regulations in 9 CFR Part 412. (October 2019).
- FSIS will issue a proposed rule amending the Federal meat inspection regulations to clarify that official establishments that transport adulterated or misbranded product under establishment or FSIS controls to another official establishment for appropriate disposition are not required to notify or obtain permission from FSIS prior to transporting the product (October 2019).
- FSIS pushed back its estimate for issuing a final rule that would allow China to export to the U.S. poultry products from birds slaughtered in China from October 2018 to May 2019. Currently, China only may export to the U.S. poultry products processed in China but slaughtered in the U.S. or other eligible countries.
- FSIS’s proposed nutrition labeling update, which in large part would harmonize FSIS nutrition labeling regulations with FDA’s updated regulations, remains as a “long term action,” which indicates FSIS is unlikely to prioritize finalizing the changes this fiscal year. FSIS currently is letting companies follow either the existing FSIS nutrition labeling rules or the updated FDA nutrition labeling rules.
- FSIS plans to propose rules establishing limitations on the time periods in which establishments may appeal inspectional decisions. Currently, FSIS encourages timely appeals but does not have regulations limiting when appeals may be made. (October 2019).
- AMS plans to publish an interim final rule initiating a new part 990 establishing rules and regulations for a domestic hemp production program (August 2019). This action is required to implement provisions of the 2018 Farm Bill.
- AMS is proposing to revise its regulations under the Packers and Stockyards Act (P&S Act) to specify criteria the Secretary could consider in determining whether conduct or action by packers, swine contractors, or live poultry dealers constitutes an undue or unreasonable preference or advantage and a violation of the P&S Act (June 2019). This proposal is part of a long-running and contentious rulemaking effort initiated in response to the 2008 Farm Bill.

- APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms in order to update the regulations in response to advances in genetic engineering and APHIS' understanding of the plant health risk posed by genetically engineered organisms to reduce the burden for regulated entities whose organisms pose no plant health risks (April 2019).

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We will continue to monitor the *Federal Register* for agency actions and will keep you notified of items of interest. Please contact us if you have any questions.

**Fall 2018 Regulatory Agendas:
Summary of Selected Items Relating to Food Regulation**

FDA FSMA:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Laboratory Accreditation for Analyses of Foods	NPRM 05/2019	0910-AH31	NPRM Changed from Nov. 2018 to May 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to Commercial Customers and Receipt of Written Assurances From Commercial Customer is in Current Good Manufacturing Practice and Preventative Control Human Food	NPRM 05/2019	0910-AH77	NPRM Changed from Dec. 2018 to May 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to Commercial Customers and Receipt of Written Assurance from Commercial Customers in the Current Good Manufacturing Practice and Preventive Control Animal	NPRM 08/2019	0910-AI24	NPRM Changed from Dec. 2018 to Aug. 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to Commercial Customers and Receipt of Written Assurances from Commercial Customers in the Foreign Supplier Verification Programs	NPRM 10/2019	0910-AI23	NPRM Changed from Dec. 2018 to Oct. 2019
Proposed Rule Stage	The FDA Food Safety Modernization Act: Amendments to Exemption Provisions in the Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption Regulation	NPRM 10/2019	0910-AI25	NPRM Changed from Dec. 2018 to Oct. 2019
Proposed Rule Stage	Amendments to Registration of Food Facilities	NPRM 11/2019	0910-AH82	NPRM Changed from Apr. 2019 to Nov. 2019

FDA Non-FSMA:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	NPRM 05/2019	0910-AI13	NPRM Changed from Mar. 2019 to May 2019

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Beverages: Bottled Water	NPRM Comment Period end 06/09/2019; Final Rule 04/2020	0910-AI03	Title changed; NPRM Comment Period End June 2019; Final Rule Apr. 2020
Proposed Rule Stage	Amendment to Add a New Method for the Analysis of Sulfites in Foods	NPRM 05/2019	0910-AI02	NPRM Changed from Mar. 2019 to May 2019
Proposed Rule Stage	Investigational New Drug Applications Requirements for Conventional Foods, Dietary Supplements, and Cosmetics	NPRM 07/2019	0910-AH07	NPRM Changed from Apr. 2019 to Jul. 2019
Proposed Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	NPRM 09/2019	0910-AI01	NPRM Changed from Mar. 2019 to Sept. 2019
Proposed Rule Stage	Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period)	NPRM Comment Period Reopened 09/2019	0910-AC54	NPRM Reopening Changed from June 2019 to Sept. 2019
Proposed Rule Stage	Frozen Cherry Pie; Proposed Revocation of Standards of Identity	NPRM 11/2019	0910-AI17	NPRM Changed from May 2019 to Nov. 2019
Proposed Rule Stage	Revocation of Uses of Partially Hydrogenated Oils in Foods	NPRM 11/2019	0910-AI15	NPRM Changed from Jun. 2019 to Nov. 2019
Proposed Rule Stage	French Dressing; Proposed Revocation of Standards of Identity	NPRM 12/2019	0910-AI16	NPRM Changed from May 2019 to Dec. 2019
Proposed Rule Stage	Permanent Listing of Color Additive Lakes	NPRM 12/2019	0910-AH80	NPRM Changed from Jan. 2019 to Dec. 2019

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Final Rule Stage	New Animal Drugs: Updating Tolerances for Residues of New Animal Drugs in Food	Final Rule 05/2019	0910-AG17	Final Rule Changed from Apr. 2019 to May 2019
Final Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	Final Rule 09/2019	0910-AH00	Final Rule Changed from Dec. 2019 to Sept. 2019
Final Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	Final Rule 09/2019	0910-AF78	Final Rule Changed from May 2019 to Sept. 2019
Final Rule Stage	Milk and Cream Product and Yogurt Products; Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat and to Amend the Standard for Yogurt	Final Action 09/2019	0910-AI40	NPRM Comment Period End Apr. 2009; Final Rule Sept. 2019
Final Rule Stage	Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements	Final Rule 11/2019	0910-AH51	No
Final Rule Stage	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	Final Action 12/2019	0910-AH43	Final Rule Changed from Sept. 2019 to Dec. 2019
Long-Term Actions	Food Labeling: Calorie Labeling of Food Sold from Certain Vending Machines; Front of Package Type Size	Final Action 10/2019	0910-AH83	No

FSIS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Changes to Accreditation of Non-Federal Laboratories for Analytical Testing of Meat, Poultry, and Processed Egg Products	NPRM 08/2019	0583-AD70	First Time in Unified Agenda
Proposed Rule Stage	Publication Method for Lists of Foreign Countries Eligible to Export Meat, Poultry, and Egg Products to the United States	NPRM Comment end 06/2019	0583-AD72	First Time in Unified Agenda
Proposed Rule Stage	Elimination of Dual Weight Labeling Regulations for Certain Meat and Poultry Products	NPRM Comment end 06/2019	0583-AD71	NPRM issued; NRP Comment end June 2019

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Prior Label Approval System: Expansion of Generic Label Approval	NRPM 10/2019	0583-AD78	First Time in Unified Agenda
Proposed Rule Stage	Movement of Adulterated and Misbranded Product	NRPM 10/2019	0583-AD79	First Time in Unified Agenda
Proposed Rule Stage	To Establish a Uniform Time Period Requirement and Clarify Related Procedures for Filing Appeals of Agency Inspection Actions	NPRM 10/2019	0584-AD76	NPRM Changed from Apr. 2019 to Oct. 2019
Final Rule Stage	Eligibility of the People's Republic of China (PRC) for the Importation Into the United States of Poultry Products From Birds Slaughtered in the PRC	Final Action 05/2019	0583-AD64	Final Action Changed from Oct. 2018 to May 2019
Final Rule Stage	Modernization of Swine Slaughter Inspection	Final Rule 07/2019	0583-AD62	Final Rule Changed from Apr. 2019 to Jul. 2019
Final Rule Stage	Egg Products Inspection Regulations	Final Action 08/2019	0583-AC58	Final Rule Changed from May 2019 to Aug. 2019
Final Rule Stage	Preparation of Uninspected Products Outside of the Hours of Inspectional Supervision	Final Rule 08/2019	0583-AD66	Final Rule Changed from Dec. 2018 to Aug. 2019
Final Rule Stage	Eligibility of the People's Republic of China to Export Siluriformes Fish and Fish Products to the United States	Final Action 09/2019	0583-AD73	Final Rule Sept. 2019
Final Rule Stage	Eligibility of the Socialist Republic of Vietnam to Export Siluriformes Fish and Fish Products to the United States	Final Action 09/2019	0583-AD74	Final Rule Sept. 2019
Final Rule Stage	Eligibility of Thailand to Export Siluriformes Fish and Fish Products to the United States	Final Action 09/2019	0583-AD75	Final Rule Sept. 2019
Long-Term Actions	Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed	Next Action Undetermined	0583-AD56	No

APHIS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms	NPRM 05/2019	0579-AE47	NPRM Moved from Apr. 2019 to May 2019
Proposed Rule Stage	Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments	NPRM Comment Period End 06/2019	0579-AE43	NPRM Comment Period End Jun. 2019
Proposed Rule Stage	National Poultry Improvement Plan and Auxiliary Provisions	NPRM 09/2019	0579-AE49	First Time in Unified Agenda
Proposed Rule Stage	Swine Health Protection Act: Amendments to Garbage Feeding Regulations	NPRM 07/2019	0579-AE50	First Time in Unified Agenda
Final Rule Stage	Plant Pest Regulations; Update of General Provisions	Final Rule 06/2019	0579-AC98	Final Rule Moved from Nov. 2018 to Jun. 2019
Long Term Action	National List of Reportable Animal Diseases	NPRM 09/2020	0579-AE39	NPRM Moved from Apr. 2019 to Sept. 2020

FNS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Providing Regulatory Flexibility for Retailers in the Supplemental Nutrition Assistance Program (SNAP)	NPRM Comment Period End 06/2019	0584-AE61	NPRM Comment Period End Jun 2019
Proposed Rule Stage	Streamlining Program Requirements and Improving Integrity in the Summer Food Service Program	NPRM 09/2019	0584-AE72	First Time in Unified Agenda
Proposed Rule Stage	Child and Adult Care Food Program: Meal Pattern Revisions; Grains Ounce Equivalents: Delayed Implementation	NPRM 11/2019	0584-AE65	First Time in Unified Agenda
Proposed Rule Stage	Simplifying Meal Service and Monitoring Requirements in the National School Lunch and School Breakfast Programs	NPRM 11/2019	0584-AE67	First Time in Unified Agenda
Proposed Rule Stage	Strengthening Integrity and Reducing Retailer Fraud in the Supplemental Nutrition Assistance Program (SNAP)	NPRM 11/2019	0584-AE71	First Time in Unified Agenda

AMS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyards Act	NPRM 06/2019	0581-AD81	First Time in Unified Agenda
Proposed Rule Stage	NOP; Proposed Amendments to the National List of Allowed and Prohibited Substances for 2018 NOSB Recommendations	NPRM 07/2019	0581-AD80	NPRM Moved from Oct. 2018 to Jul. 2019
Proposed Rule Stage	Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2018 Recommendations (Crops and Handling)	NPRM 07/2019	0581-AD83	First Time in Unified Agenda
Proposed Rule Stage	Establishment of a Domestic Hemp Production Program	Interim Final Rule 08/2019	0581-AD82	First Time in Unified Agenda
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	NPRM 09/2019	0581-AD09	NPRM Moved from Mar. 2019 to Sept. 2019