

MEMORANDUM

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Re: OMB Releases Spring 2018 Unified Agenda of Regulatory Actions

The Office of Management and Budget (OMB) recently released the Spring 2018 Unified Agenda of Regulatory Actions for federal agencies, 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), 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 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. Extending the compliance dates for the agricultural water provisions of the Produce Safety rule for covered produce other than sprouts;
 2. Removing 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);
 3. Clarifying changes to the food facility registration requirements, including revising the definition of "farm;" and
 4. 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.
- FDA will reopen the comment period for a proposed rule relating to modernizing food standards of identities.

- FDA plans to issue a 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.
- FDA also plans on finalizing several other 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; 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.

The priorities for agencies within the U.S. Department of Agriculture (USDA) include the following:

- AMS plans to finalize the proposed rule issued earlier this month to establish the national mandatory bioengineered food disclosure standard. The Unified Agenda states that the agency plans to finalize the proposal in July 2018, the statutory deadline for finalizing the rulemaking, but this timing is unlikely given that comments on the proposal are not due until July 3, 2018.
- FSIS has announced several initiatives to modernize inspection systems and to eliminate or streamline regulations. For example, FSIS is currently accepting comments (due June 13, 2018) on a proposed rule to transition egg products manufacturing from a command and control system to a Hazard Analysis and Critical Control Point (HACCP) program. FSIS plans to finalize in 2019 a proposal to modernize swine slaughter inspection.
- FSIS estimates it will issue a final rule in September 2018 that would allow China to export to the U.S. poultry products from birds slaughtered in China. Currently, China only may export to the U.S. poultry products manufactured in China but slaughtered in the U.S. or other eligible countries.
- In November 2017, FNS issued an interim final rule extending flexibilities for certain requirements for milk, whole grains, and sodium under FNS Child Nutrition Programs through school year 2018-2019. FNS plans to finalize the regulation in December 2018.

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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.

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

FDA:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size	NPRM 05/2018	0910-AH83	NPRM Changed from Mar. to May 2018
Proposed Rule Stage	Proposed Rule to Revise the Allowable Level of Fluoride Added to Bottled Water	NPRM 06/2018	0910-AI03	First Time in Unified Agenda
Proposed Rule Stage	Laboratory Accreditation for Analyses of Foods	NPRM 09/2018	0910-AH31	No
Proposed Rule Stage	The Food and Drug Administration Food Safety Modernization Act; Removing Written Assurance Requirements From the Customer Provisions in Certain Implementing Rules	NPRM 11/2018	0910-AH77	NPRM Changed from Aug. to Nov. 2018
Proposed Rule Stage	Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period)	NPRM Comment Period Reopened 12/2018	0910-AC54	Moved from LTA List to Proposed Rule Stage
Proposed Rule Stage	Permanent Listing of Color Additive Lakes	NPRM 12/2018	0910-AH80	NPRM Changed from Aug. to Dec. 2018
Proposed Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	NPRM 12/2018	0910-AI01	First Time in Unified Agenda
Proposed Rule Stage	Investigational New Drug Applications Requirements for Conventional Foods, Dietary Supplements, and Cosmetics	NPRM 04/2019	0910-AH07	Moved from LTA List to Proposed Rule Stage
Proposed Rule Stage	Amendments to Registration of Food Facilities	NPRM 04/2019	0910-AH82	Moved from LTA List to Proposed Rule Stage
Final Rule Stage	Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods	Final Rule 05/2018	0910-AH92	Moved from Proposed Rule Stage to Final Rule Stage
Final Rule Stage	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Extension of Compliance Dates for Subpart E	Final Action 06/2018	0910-AH93	No

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Final Rule Stage	Label Requirement for Food That Has Been Refused Admission Into the United States	NPRM Withdrawal 08/2018	0910-AF61	Final Action July 2018 Changed to Withdrawal of NPRM Aug. 2018
Final Rule Stage	Crabmeat; Amendment of Common or Usual Name	Direct Final Rule 11/2018	0910-AI04	First Time in Unified Agenda
Final Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	Final Rule 12/2018	0910-AF78	Final Rule Changed from Aug. to Dec. 2018
Final Rule Stage	New Animal Drugs: Updating Tolerances for Residues of New Animal Drugs in Food	Final Action 12/2018	0910-AG17	Final Action Changed from Aug. to Dec. 2018
Final Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	Final Rule 12/2018	0910-AH00	Final Rule Changed from Oct. to Dec. 2018
Final Rule Stage	Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements	Final Action 02/2019	0910-AH51	Moved from Proposed Rule Stage to Final Rule Stage
Final Rule Stage	Amendment to Add a New Method for the Analysis of Sulfites in Foods	Direct Final Rule 03/2019	0910-AI02	First Time in Unified Agenda
Long-Term Actions	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	Final Action 09/2019	0910-AH43	Moved from Proposed Rule Stage to LTA List

FSIS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Allowing Pet Food and Other Uninspected Articles to be Prepared in an Official Establishment Outside the Hours of Operation Under Inspection	NPRM 05/2018	0583-AD66	NPRM Changed from Mar. to May 2018
Proposed Rule Stage	Eliminating Unnecessary Requirements for Hog Carcass Cleaning	NPRM 05/2018	0583-AD68	No
Proposed Rule Stage	Eliminating the Requirement That Livestock Carcasses be Marked "U.S. Inspected and Passed" at the Time of Inspection When Carcasses Are to be Further Processed Within the Same Establishment	NPRM 05/2018	0583-AD69	No

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Egg Products Inspection Regulations	NPRM Comment Period End 06/13/2018	0583-AC58	NPRM Issued Feb. 2018
Proposed Rule Stage	Publication Method for Lists of Foreign Countries Eligible to Export Meat, Poultry, and Egg Products to the United States	NPRM 08/2018	0583-AD72	First Time in Unified Agenda
Proposed Rule Stage	Changes to Accreditation of Non-Federal Laboratories for Analytical Testing of Meat, Poultry, and Processed Egg Products	NPRM 09/2018	0583-AD70	First Time in Unified Agenda
Final Rule Stage	Elimination of Trichina Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations	Final Action 05/2018	0583-AD59	Final Rule Dec. 2017 Changed to Final Action May 2018
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 09/2018	0583-AD64	Final Action Changed from Mar. to Sep. 2018
Final Rule Stage	Modernization of Swine Slaughter Inspection	Final Rule 04/2019	0583-AD62	Moved from Proposed Rule Stage to Final Rule Stage
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	National Poultry Improvement Plan and Auxiliary Provisions	NPRM 04/09/2018; NPRM Comment Period End 05/09/2018	0579-AE37	First Time in Unified Agenda
Proposed Rule Stage	Branding Requirements for Bovines Imported Into the United States From Mexico	NPRM 04/12/2018; NPRM Comment Period End 06/11/2018	0579-AE38	First Time in Unified Agenda
Proposed Rule Stage	National List of Reportable Animal Diseases	NPRM 11/2018	0579-AE39	First Time in Unified Agenda

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments	NPRM 11/2018	0579-AE43	First Time in Unified Agenda
Final Rule Stage	Bovine Spongiform Encephalopathy and Scrapie; Importation of Small Ruminants and Their Germplasm, Products, and Byproducts	Final Rule 07/2018	0579-AD10	Final Rule Changed from Feb. to July 2018
Final Rule Stage	Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables	Final Rule 07/2018	0579-AD71	Final Rule Changed from Dec. 2017 to July 2018
Final Rule Stage	Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims	Final Rule 10/2018	0579-AE14	Moved from LTA List to Final Rule Stage

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 09/2018	0584-AE61	NPRM Changed from Jan. to Sep. 2018
Final Rule Stage	Revisions and Clarifications in Requirements for the Processing of Donated Foods	Final Action 05/2018	0584-AE38	No
Final Rule Stage	Child Nutrition Programs: Flexibilities for Milk, Whole Grains, and Sodium Requirements	Interim Final Rule Effective 07/01/2018; Final Action 12/2018	0584-AE53	No

AMS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	NOP; Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2017 Recommendations (Livestock and Handling)	NPRM 04/2018	0581-AD78	First Time in Unified Agenda
Proposed Rule Stage	National Bioengineered Food Disclosure Standard	NPRM 05/2018; Final Action 07/2018	0581-AD54	NPRM Changed from Dec. 2017 to May 2018

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	NOP; Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2017 Recommendations (Livestock and Handling)	NPRM 04/2018	0581-AD78	First Time in Unified Agenda
Proposed Rule Stage	NOP; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)	NPRM Comment Period Reopened End 05/14/2018; Final Rule 07/2018	0581-AD60	No
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	NPRM 03/2019	0581-AD09	NPRM Changed from Sep. 2014 to Mar. 2019