

MEMORANDUM

From: Steven B. Steinborn
Joseph A. Levitt
Leigh G. Barcham

Date: November 12, 2018

Re: OMB Releases Fall 2018 Unified Agenda of Regulatory Actions

The Office of Management and Budget (OMB) recently released the Fall 2018 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. Finalizing the extension of the compliance dates for the agricultural water provisions of the Produce Safety rule for covered produce other than sprouts (November 2018);
 2. 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) (December 2018). 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;
 3. Clarifying changes to the food facility registration requirements, including revising the definition of "farm" (April 2019);

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 (November 2018); and
 5. 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 (December 2018).
- 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 (June 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 (March 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 (March 2019).
 - FDA will reopen the comment period for a proposed rule relating to modernizing food standards of identities (June 2019). The agency also will promulgate proposed rules to revoke the current standards of identity for French dressing and frozen cherry pie (May 2019).
 - 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 (September 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 (December 2018).
 - 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); however, this action has been moved to FDA's Long-Term Actions list as it extends beyond the current fiscal year, which ends September 30, 2019.

The priorities for agencies within USDA include the following:

- AMS plans to finalize the proposed rule issued earlier this year to establish the national mandatory bioengineered food disclosure standard (November 2018).

- 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 (April 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 (May 2019).
- FSIS's estimate for issuing a final rule that would allow China to export to the U.S. poultry products from birds slaughtered in China was pushed back from September to October 2018 (a date which appears to have been missed). Currently, China only may export to the U.S. poultry products manufactured in China but slaughtered in the U.S. or other eligible countries.
- FSIS's proposed nutrition labeling update, which in large part would have harmonized 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.
- In November 2017, FNS issued an interim final rule extending flexibility for certain requirements for milk, whole grains, and sodium under FNS Child Nutrition Programs through school year 2018-2019. The rule provided Child Nutrition Program operators with flexibility in their menu planning, including providing operators the option to offer flavored, low-fat (1 percent fat) milk in the Child Nutrition Programs; extending the state agencies' option to allow individual school food authorities to include grains that are not whole grain-rich in the weekly menu offered under the National School Lunch Program (NSLP) and School Breakfast Program (SBP); and retaining Sodium Target 1 in the NSLP and SBP. FNS plans to finalize the regulation in December 2018.
- 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).

* * *

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 11/2018	0910-AH31	NPRM Changed from Sept. to Nov. 2018
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	NPRM 12/2018	0910-AH77	Rule Title Changed from "Removing Written Assurance Requirements From the Customer Provisions in Certain Implementing Rules"; NPRM Changed from Nov. to Dec. 2018
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 12/2018	0910-AI25	First Time in Unified Agenda
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 12/2018	0910-AI23	First Time in Unified Agenda
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 12/2018	0910-AI24	First Time in Unified Agenda
Proposed Rule Stage	Amendments to Registration of Food Facilities	NPRM 04/2019	0910-AH82	No
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 11/2018	0910-AH93	Final Action Changed from June to Nov. 2018

FDA Non-FSMA:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Proposed Rule to Revise the Allowable Level of Fluoride Added to Bottled Water	NPRM 11/2018	0910-AI03	NPRM Changed from June to Nov. 2018
Proposed Rule Stage	Permanent Listing of Color Additive Lakes	NPRM 01/2019	0910-AH80	NPRM Changed from Dec. 2018 to Jan. 2019
Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	NPRM 03/2019	0910-AI13	First Time in Unified Agenda
Proposed Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	NPRM 03/2019	0910-AI01	NPRM Changed from Dec. 2018 to Mar. 2019
Proposed Rule Stage	Amendment to Add a New Method for the Analysis of Sulfites in Foods	NPRM 03/2019	0910-AI02	Changed from Direct Final Rule to NPRM
Proposed Rule Stage	Investigational New Drug Applications Requirements for Conventional Foods, Dietary Supplements, and Cosmetics	NPRM 04/2019	0910-AH07	No
Proposed Rule Stage	French Dressing; Proposed Revocation of Standards of Identity	NPRM 05/2019	0910-AI16	First Time in Unified Agenda
Proposed Rule Stage	Frozen Cherry Pie; Proposed Revocation of Standards of Identity	NPRM 05/2019	0910-AI17	First Time in Unified Agenda
Proposed Rule Stage	Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period)	NPRM Comment Period Reopened 06/2019	0910-AC54	NPRM Reopening Changed from Dec. 2018 to June 2019
Proposed Rule Stage	Rule to Revoke Uses of Partially Hydrogenated Oils in Foods	NPRM 06/2019	0910-AI15	First Time in Unified Agenda
Final Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	Final Rule 12/2018	0910-AH00	No
Final Rule Stage	Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements	Final Rule 02/2019	0910-AH51	Final Rule Changed from Feb. to Nov. 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 04/2019	0910-AG17	Final Rule Changed from Dec. 2018 to Apr. 2019
Final Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	Final Rule 05/2019	0910-AF78	Final Rule Changed from Dec. 2018 to May 2019
Final Rule Stage	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	Final Action 09/2019	0910-AH43	Moved from to LTA List to Final Rule Stage
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	NPRM Issued May 2018; Moved to Long-Term Action

FSIS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Elimination of Dual Weight Labeling Regulations for Certain Meat and Poultry Products	NPRM 10/2018	0583-AD71	NPRM changed from Aug. to Oct. 2018
Proposed Rule Stage	To Establish a Uniform Time Period Requirement and Clarify Related Procedures for Filing Appeals of Agency Inspection Actions	NPRM 04/2019	0584-AD76	First Time in Unified Agenda
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 10/2018	0583-AD64	Final Action Changed from Sept. to Oct. 2018
Final Rule Stage	Preparation of Uninspected Products Outside of the Hours of Inspectional Supervision	Final Rule 12/2018	0583-AD66	Moved from Proposed to Final Rule Stage
Final Rule Stage	Modernization of Swine Slaughter Inspection	Final Rule 04/2019	0583-AD62	No
Final Rule Stage	Egg Products Inspection Regulations	Final Action 05/2019	0583-AC58	Moved from Proposed to Final Rule Stage

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
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	Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments	NPRM 11/2018	0579-AE43	No
Proposed Rule Stage	National List of Reportable Animal Diseases	NPRM 04/2019	0579-AE39	NPRM Moved from Nov. 2018 to Apr. 2019
Proposed Rule Stage	Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms	NPRM 04/2019	0579-AE47	First Time in Unified Agenda
Final Rule Stage	Plant Pest Regulations; Update of General Provisions	Final Rule 11/2018	0579-AC98	No

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 11/2018	0584-AE61	NPRM Changed from Sept. to Nov. 2018
Final Rule Stage	Child Nutrition Programs: Flexibilities for Milk, Whole Grains, and Sodium Requirements	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 2018 NOSB Recommendations	NPRM 10/2018	0581-AD80	First Time in Unified Agenda
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	NPRM 03/2019	0581-AD09	No
Final Rule Stage	NOP; Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2017 Recommendations (Livestock and Handling)	Final Rule 10/2018	0581-AD78	Moved from Proposed to Final Rule Stage

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 2018 NOSB Recommendations	NPRM 10/2018	0581-AD80	First Time in Unified Agenda
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	NPRM 03/2019	0581-AD09	No
Final Rule Stage	NOP; Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2017 Recommendations (Livestock and Handling)	Final Rule 10/2018	0581-AD78	Moved from Proposed to Final Rule Stage
Final Rule Stage	NOP; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)	Final Rule 10/2018	0581-AD60	Final Rule Changed from July to Oct. 2018
Final Rule Stage	National Bioengineered Food Disclosure Standard	Final Action 11/2018	0581-AD54	Final Action Changed from July to November 2018