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MEMORANDUM

From: Joseph A. Levitt
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Date: December 19, 2019

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

The Office of Management and Budget (OMB) recently released the Fall 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 (note, for example, that dates for some planned actions have already passed). 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). FDA plans to conduct parallel rulemakings for the Preventive Controls for Human Food (November 2019), Preventive Controls for Animal Food (July 2020), and Foreign Supplier Verification Programs (November 2019) rules, but the Unified Agenda does not include similar plans for the Produce Safety rule;

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2. Clarifying changes to the food facility registration requirements, including revising the definition of “farm” (April 2020);
 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. This proposed rule was published on November 4, 2019; see Hogan Lovells Memorandum dated November 12, 2019;
 4. Proposing a regulation to revise certain requirements currently applying 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 (March 2020); and
 5. Enhancing traceability requirements by proposing additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk foods, as required by consent decree (September 2020).
- FDA plans to reopen the comment period for a proposed rule to provide for the use of fluid ultrafiltered milk in the manufacturer of standardized cheeses and related cheese products (November 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 (March 2020).
 - FDA plans to 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 (November 2019).
 - FDA plans to issue a final 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 (October 2020).
 - FDA pushed back the reopening of the comment period for a proposed rule relating to modernizing food standards of identity (January 2020). The agency also plans to promulgate proposed rules to revoke the current standards of identity for French dressing and frozen cherry pie (May 2020 for both rules). FDA plans to finalize a rule amending the standard for yogurt and revoking the standards for lowfat and nonfat yogurt (May 2020).
 - FDA plans to issue a final rule on fluoride levels in bottled water (April 2020). The proposed rule would revise 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 to propose a rule broadening the regulatory criteria for studies exempt from Investigational New Drug requirements and provide clarity and consistency regarding when studies evaluating drug uses of products lawfully marketed as conventional foods, dietary supplements, or cosmetics are subject to IND review (November 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 (May 2020); 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 2019).

The priorities for agencies within USDA include the following:

- FSIS has a small number of rulemaking actions on its agenda.
- FSIS currently is finalizing initiatives to modernize inspection systems and to eliminate or streamline regulations. FSIS plans 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 (March 2020).
- FSIS plans to issue a proposed rule expanding the categories of meat and poultry products that are eligible for generic label approval. FSIS is proposing to make these changes by revising its labeling regulations in 9 CFR Part 412 (February 2020).
- FSIS has moved its proposal to eliminate certain restrictions on the movement of adulterated or misbranded product onto its "long term action" list, which indicates that FSIS is unlikely to prioritize proposing the rule. The rule would consolidate certain regulations and clarify or eliminate others regarding the transportation of adulterated or misbranded product between official establishments.
- FSIS's proposed nutrition labeling update, which in large part would harmonize FSIS nutrition labeling regulations with FDA's updated regulations, remains a "long term action," which indicates FSIS is unlikely to prioritize finalizing the changes this fiscal year. FSIS currently allows establishments to follow either the existing FSIS nutrition labeling rules or the updated FDA nutrition labeling rules.
- FSIS has moved its proposal to establish time limits for appealing inspection decisions to its "long term action" list, signaling this rulemaking will not be an Agency priority. Currently, FSIS encourages timely appeals but does not have regulations limiting when appeals may be made.

- AMS's comment period for the interim final rule initiating a new part 990 establishing rules and regulations for a domestic hemp production program was scheduled to close in December but has been extended to January 29, 2020 (December 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 (November 2019). This proposal is part of a long-running and contentious rulemaking effort initiated in response to the 2008 Farm Bill.
- AMS plans to propose rules that would limit the types of operations in the organic supply chain that are not required to obtain organic certification (January 2020). The proposed rules would also require imported organic products to be accompanied by an electronic import certificate to validate organic status and import certificates to be submitted to the U.S. Customs and Border Protection. Certifying agents would be required to notify USDA within 90 days of the opening of any new office conducting certification activities. The rule would allow for the suspension of entities acting on behalf of certifying agents when there is noncompliant activity.
- APHIS plans to publish a final rule 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's 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 2020).

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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 2019 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 11/2019	0910-AH31	NPRM Changed from May 2019 to Nov. 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurance From Commercial Customers in the Preventative Controls for Human Food Rule	NPRM 11/2019	0910-AH77	Title changed; NPRM Changed from May 2019 to Nov. 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurance from Commercial Customers in the Preventive Controls for Animal Food Rule	NPRM 11/2019	0910-AI24	Title changed; NPRM Changed from Aug. 2019 to Nov. 2019
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurances from Commercial Customers in the Foreign Supplier Verification Programs Rule	NPRM 07/2020	0910-AI23	Title changed; NPRM Changed from Oct. 2019 to July 2020
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 03/2020	0910-AI25	NPRM Changed from Oct. 2019 to Mar. 2020
Proposed Rule Stage	Amendments to Registration of Food Facilities	NPRM 04/2020	0910-AH82	NPRM Changed from Nov. 2019 to Apr. 2020

FDA Non-FSMA:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	NPRM 11/2019	0910-AI13	NPRM Changed from May

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
				2019 to Nov. 2019
Proposed Rule Stage	Investigational New Drug Applications Requirements for Drug Studies of Conventional Foods, Dietary Supplements, and Cosmetics	NPRM 11/2019	0910-AH07	Title changed; NPRM Changed from July 2019 to Nov. 2019
Proposed Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	NPRM 05/2020	0910-AI01	NPRM Changed from Sept. 2019 to May 2020
Proposed Rule Stage	Food Standards: General Principles and Food Standards Modernization (Reopening of Comment Period)	NPRM Comment Period Reopened 01/2020	0910-AC54	NPRM Reopening Changed from Sept. 2019 to Jan. 2020
Proposed Rule Stage	Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality	NPRM 05/2020	0910-AI17	Title changed; NPRM Changed from Nov. 2019 to May 2020
Proposed Rule Stage	Revocation of Uses of Partially Hydrogenated Oils in Foods	NPRM 03/2020	0910-AI15	NPRM Changed from Nov. 2019 to Mar. 2020
Proposed Rule Stage	French Dressing; Proposed Revocation of a Standard of Identity	NPRM 05/2020	0910-AI16	Title changed; NPRM Changed from Dec. 2019 to May 2020
Proposed Rule Stage	Permanent Listing of Color Additive Lakes	NPRM 04/2020	0910-AH80	NPRM Changed from Dec. 2019 to Apr. 2020
Proposed Rule Stage	Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; Reopening of Comment Period	NPRM Comment Period Reopened 11/2019	0910-AI42	First Time in Unified Agenda

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Enhanced Traceability Record Requirements for Certain Foods	NPRM 09/2020	0910-A144	First Time in Unified Agenda
Final Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed	Final Rule 12/2019	0910-AH00	Title changed; Final Rule Changed from Sept. 2019 to Dec. 2019
Final Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	Final Rule 04/2020	0910-AF78	Final Rule Changed from Sept. 2019 to Apr. 2020
Final Rule Stage	Milk and Cream Product and Yogurt Products, Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt	Final Rule 05/2020	0910-A140	NPRM Comment Period End Apr. 2009; Final Rule May 2020
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 Rule 05/2020	0910-AH43	Final Rule Changed from Dec. 2019 to May 2020
Final Rule Stage	Amendment to Add a New Method for the Analysis of Sulfites in Foods	Final Rule 10/2020	0910-A102	NPRM Comment Period End Oct. 2019; Final Rule Oct. 2020
Final Rule Stage	Beverages: Bottled Water	Final Rule 04/2020	0910-A103	NPRM Comment Period End June 2019; Final Rule Apr. 2020

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,	NPRM 12/2019	0583-AD70	NPRM Changed from

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
	Poultry, and Processed Egg Products			Aug. 2019 to Dec. 2019
Proposed Rule Stage	Prior Label Approval System: Expansion of Generic Label Approval	NRPM 02/2020	0583-AD78	NPRM Changed from Oct. 2019 to Feb. 2020
Final Rule Stage	Egg Products Inspection Regulations	Final Action 03/2020	0583-AC58	Final Action Changed from Aug. 2019 to Mar. 2020
Final Rule Stage	Publication Method for Lists of Foreign Countries Eligible to Export Meat, Poultry, and Egg Products to the United States	Final Action 02/2020	0583-AD72	NPRM Comment Period End 06/2019; Final Rule 02/2020
Final Rule Stage	Elimination of Dual Weight Labeling Regulations for Certain Meat and Poultry Products	Final Action 02/2020	0583-AD71	NPRM Comment Period End June 2019; Final Action Feb. 2020
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
Long-Term Actions	Movement of Adulterated and Misbranded Product	Next Action Undetermined	0583-AD79	NPRM Changed from Oct. 2019 to Next Action Undetermined
Long Term Actions	To Establish a Uniform Time Period Requirement and Clarify Related Procedures for Filing Appeals of Agency Inspection Actions	Next Action Undetermined	0583-AD76	NPRM Changed from Oct. 2019 to Next Action Undetermined

APHIS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	National Poultry Improvement Plan and Auxiliary Provisions	NPRM 11/2019	0579-AE49	NPRM Changed from Sept. 2019 to Nov. 2019
Final Rule Stage	Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms	Final Rule 04/2020	0579-AE47	NPRM Comment Period End Aug. 2019; Final Rule Apr. 2020
Final Rule Stage	Establishment of Regulations for the Evaluation and Recognition of the Animal Health Status of Compartments	Final Rule 01/2020	0579-AE43	NPRM Comment Period End Jun. 2019; Final Rule Jan. 2020
Final Rule Stage	Swine Health Protection Act: Amendments to Garbage Feeding Regulations	Final Rule 11/2019	0579-AE50	NPRM Comment Period End Aug. 2019; Final Rule Nov. 2019
Long Term Actions	National List of Reportable Animal Diseases	NPRM 10/2020	0579-AE39	NPRM Moved from Sept. 2020 to Oct. 2020

FNS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Streamlining Program Requirements and Improving Integrity in the Summer Food Service Program	Final Action 06/2020	0584-AE72	NPRM changed from Sept. 2019 to Nov. 2019; Final Action June 2020
Proposed Rule Stage	Simplifying Meal Service and Monitoring Requirements in the National School Lunch and School Breakfast Programs	Final Action 05/2020	0584-AE67	NPRM issued Nov. 2019; Final Action May 2020
Proposed Rule Stage	Strengthening Integrity and Reducing Retailer Fraud in the Supplemental Nutrition Assistance Program (SNAP)	NPRM 02/2020	0584-AE71	NPRM Changed from Nov. 2019 to Feb. 2020
Long Term	Providing Regulatory Flexibility for	Next Action	0584-	NPRM

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Actions	Retailers in the Supplemental Nutrition Assistance Program (SNAP)	Undetermined	AE61	Comment Period End Jun 2019; Next Action Undetermined

AMS:

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Origin of Livestock; Final Rule	Final Rule 06/2020	0581-AD89	First Time in Unified Agenda
Proposed Rule Stage	Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyards Act	NPRM 11/2019	0581-AD81	NPRM Changed from June 2019 to Nov. 2019
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 Comment Period End 12/2019	0581-AD83	NPRM Comment Period End Dec. 2019
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	NPRM 01/2020	0581-AD09	NPRM Moved from Sept. 2019 to Jan. 2020
Final Rule Stage	Establishment of a Domestic Hemp Production Program	Interim Final Rule Comment Period End 12/2019	0581-AD82	Interim Final Rule Comment Period End Changed from Aug. 2019 to Dec. 2019