

MEMORANDUM

FROM Joseph A. Levitt
Brian D. Eyink
Anneke Baran Altieri

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RE: OMB Releases Spring 2020 Unified Agenda of Regulatory Actions

The Office of Management and Budget (OMB) recently released the Spring 2020 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 Plant Health Inspection Service (APHIS), Food and Nutrition Service (FNS), and Agricultural Marketing Service (AMS).

After highlighting the most significant priorities, we provide charts that enumerate other relevant rules included on each agency's agenda. More information can be found by clicking on the blue "RIN" link, which will direct you to a page on OMB's website dedicated to each agenda item.

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 Priorities

FDA's regulatory priorities largely mirror those that were included in the Fall 2019 Unified Agenda. ^{1/} The vast majority of the rules remain in the same stage, but with new estimated dates of completion. As noted above, the projected dates are not themselves agency commitments, but rather aspirations. Two entries on rulemaking under the FDA Food Safety Modernization Act (FSMA) are worth highlighting:

^{1/} See HL Memo, *OMB Releases Fall 2019 Unified Agenda of Regulatory Actions*, (December 19, 2019), available at <https://www.hoganlovells.com/en/publications/omb-releases-fall-2019-unified-agenda-of-regulatory-actions>.

- *Requirements for Additional Traceability Records For Certain Foods*: FDA must issue its Notice of Proposed Rulemaking on *Requirements for Additional Traceability Records for Certain Foods* by September 2020 as required by a court-ordered consent decree as part of a lawsuit brought by consumer groups, Center for Food Safety (CFS) and Center for Environmental Health (CEH). ^{2/} (September 2020).
- *Laboratory Accreditation for Analysis of Foods*: The comment period for the proposed rule on the *Laboratory Accreditation for Analysis of Foods* closed in July 2020. FDA is required to issue the final rule by February 4, 2022, pursuant to a consent decree as part of a different lawsuit brought by CFS and CEH. ^{3/} With this court-imposed deadline set for 2022, promulgation of a final rule is now considered a “long term action.” (February 2022).

Additionally, there are two rules appearing for the first time in the FDA Unified Agenda that may be of general interest:

- *Amendments to Good Guidance Practices Regulation*: FDA seeks to develop a proposed rule that would amend its current Good Guidance Practices (GGP) regulation (21 CFR § 10.115). GGP regulations outline the processes through which agencies issue guidance documents. This action is intended to implement Executive Order 13891, "Promoting the Rule of Law Through Improved Agency Guidance Documents." The Executive Order requires that agency regulations address certain issues related to guidance documents by 8/27/2020. This proposed action would apply to all FDA-regulated product categories. (June 2020).
- *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*: This proposed rulemaking would revise certain requirements for agricultural water in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation for covered produce other than sprouts. (November 2020).

USDA Priorities

FSIS and AMS have a handful of regulatory priorities that are of particular interest.

FSIS

- *Prior Label Approval System: Expansion of Generic Label Approval*: FSIS plans to issue a proposed rule expanding the scope of meat and poultry products that are eligible for generic label approval. FSIS last expanded the scope for generic approval in 2013. (July 2020).

^{2/} See HL Memo, *Settlement Reached in Lawsuit to Compel FDA to Implement FSMA Traceability Provisions* (June 12, 2019), available at <https://www.hoganlovells.com/en/publications/settlement-reached-in-lawsuit-to-compel-fda-to-implement-fsma-traceability-provisions>

^{3/} See *Center for Food Safety v. Azar*, No.: 3:19-cv-05168-VC (N.D. Cal. Feb. 2, 2020). The Consent Decree is available at https://www.centerforfoodsafety.org/files/2020-02-11--doc-31-order-consent-decree_70062.pdf.

- *Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed:* FSIS has moved its proposed nutrition labeling update from “long term action” to the final rule stage. The update would in large part harmonize FSIS nutrition labeling regulations with FDA’s updated regulations. Currently, FSIS policy allows establishments to follow either existing FSIS nutrition labeling regulations or FDA’s updated labeling regulations. (September 2020).
- *Egg Products Inspection Regulations:* FSIS is finalizing a rule that will extend mandatory Hazard Analysis and Critical Control Point (HACCP) Systems to egg products plants regulated under the Egg Products Inspection Act. In addition, the rule would allow plants to be eligible for generic approval and includes changes to certain labeling requirements. (July 2020).
- *Maximum Line Speed under the New Poultry Inspection System:* FSIS is proposing to amend the poultry products inspection regulations to permit young chicken slaughter establishments operating under NPIS to increase the line speed from 140 bpm to 175 bpm if certain criteria are met. (August 2020).

AMS

- *Establishment of a Domestic Hemp Production Program:* In January 2020, AMS closed the comment period for the interim final rule initiating a new part 990 establishing rules and regulations for domestic hemp production. AMS has been implementing the provisions of the Agriculture Improvement Act of 2018 (Farm Bill) under the interim final rule since November 2019; however, promulgation of a final rule is now considered a “long term action,” and AMS plans to issue a final rule in October 2021. (October 2021).
- *Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyards Act:* AMS plans to issue a final rule that would revise its regulations under the Packers and Stockyards Act (P&S Act) to specify the 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. (August 2020). This final rule is part of a long-running and contentious rulemaking effort initiated in response to the 2008 Farm Bill.
- *Origin of Livestock:* AMS is issuing a final rule that clarifies the requirements for transitioning nonorganic dairy animals to organic production. (August 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.

**Spring 2020 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	Requirements For Additional Traceability Records For Certain Foods	NPRM 09/2020	0910-A144	Title Changed.
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurance From Commercial Customers in the Preventive Controls for Human Food Rule	NPRM 06/2020	0910-AH77	NPRM Changed from Nov. 2019 to June 2020
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 06/2020	0910-A124	NPRM Changed from Nov. 2019 to June 2020
Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurances From Commercial Customers in the Foreign Supplier Verification Programs Rule	NPRM 04/2021	0910-A123	NPRM changed from July 2020 to April 2021
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 11/2020	0910-A125	NPRM Changed from Mar. 2020 to Nov. 2020
Proposed Rule Stage	Amendments to Registration of Food Facilities	NPRM 12/2020	0910-AH82	NPRM changed from Apr. 2020 to Dec. 2020
Long-Term Actions	Laboratory Accreditation for Analyses of Foods	Final Rule 02/2022	0910-AH31	Status Changed from Proposed Rule Stage to Long Term Actions; Final Rule Feb. 2022

FDA Non-FSMA

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Amendments to Good Guidance Practices Regulation	NPRM 06/2020	0910-A148	First Time in Unified Agenda
Proposed Rule Stage	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	NPRM 11/2020	0910-A149	First Time in Unified Agenda
Proposed Rule Stage	Permanent Listing of Color Additive Lakes	NPRM 09/2020	0910-AH80	NPRM Changed from Apr. 2020 to Sept. 2020
Proposed Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	NPRM 09/2020	0910-A101	NPRM Changed from May 2020 to Sept. 2020

Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	NPRM 06/2020	0910-AI13	NPRM Changed from Nov. 2019 to June 2020
Proposed Rule Stage	Revocation of Uses of Partially Hydrogenated Oils in Foods	NPRM Aug. 2020	0910-AI15	NPRM Changed from Mar. 2020 to Aug. 2020
Proposed Rule Stage	French Dressing; Proposed Revocation of a Standard of Identity	NPRM Aug. 2020	0910-AI16	NPRM Changed from May 2020 to Aug. 2020
Proposed Rule Stage	Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality	NPRM Aug. 2020	0910-AI17	NPRM Changed from May 2020 to Aug. 2020
Final Rule Stage	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	Final Rule 06/2020	0910-AF78	Final Rule changed from Apr. 2020 to June 2020
Final Rule Stage	Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods	Final Rule 06/2020	0910-AH00	Final Rule Changed from Dec. 2019 to June 2020
Final Rule Stage	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	Final Rule 02/2021	0910-AH43	Final Rule changed from May 2020 to Feb. 2021
Final Rule Stage	Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements	Final Rule 06/2020	0910-AH51	Final Rule Changed from Nov. 2019 to June 2020.
Final Rule Stage	Beverages: Bottled Water	Final Rule 08/2020	0910-AI03	Final Rule Changed from Apr. 2020 to Aug. 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 08/2020	0910-AI40	Final Rule Changed from May 2020 to Aug. 2020
Final Rule Stage	Amendment to Add a New Method for the Analysis of Sulfites in Foods	Final Rule 10/2020	0910-AI02	No change.
Final Rule Stage	Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; Reopening of Comment Period	Final Rule 04/2021	0910-AI42	NPRM Comment Period Ended Mar. 2020

USDA / 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 06/2020	0583-AD70	NPRM Changed from Dec. 2019 to June 2020
Proposed Rule Stage	To Establish a Uniform Time Period Requirement and Clarify Related Procedures for Filing Appeals of Agency Inspection Actions	NPRM 07/2020	0583-AD76	NPRM Moved from Long Term Action List to July 2020
Proposed Rule Stage	Prior Label Approval System: Expansion of Generic Label Approval	NPRM 07/2020	0583-AD78	NPRM Changed from Feb. 2020 to July 2020

Proposed Rule Stage	Movement of Adulterated and Misbranded Product	NPRM 08/2020	0583-AD79	NPRM moved from Long Term Actions List to Aug. 2020
Proposed Rule Stage	Avian Visceral Leukosis: Poultry Carcasses Affected by any of the Forms of Avian Leukosis Complex	NPRM 08/2020	0583-AD84	First Time in Unified Agenda
Proposed Rule Stage	Maximum Line Speed under the New Poultry Inspection System	NPRM 08/2020	0583-AD85	First Time in Unified Agenda
Final Rule Stage	Egg Products Inspection Regulations	Final Rule 07/2020	0583-AC58	Final Action Changed from Mar. 2020 to July 2020
Final Rule Stage	Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed	Final Rule 09/2020	0583-AD56	Final Action moved from Long-Term Actions List to Sept. 2020
Final Rule Stage	Elimination of Dual Weight Labeling Requirements for Certain Meat and Poultry Products	Final Rule 07/2020	0583-AD71	Final Action Changed from Feb. 2020 to July 2020

USDA / APHIS

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	National List of Reportable Animal Diseases	Next Action Undetermined	0579-AE39	Moved from Long Term Actions to Proposed Rule Stage; NPRM comment period ended June 2020
Proposed Rule Stage	Web Listing of Quarantined Areas and Regulated Articles	NPRM 08/2020	0579-AE53	Previously Published in the Unified Agenda, but additional information not available on Rule Page
Final Rule Stage	Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms	Final Rule Effective 08/17/2020	0579-AE47	Final Rule Issued May 2020; Final Rule effective Aug. 2020
Final Rule Stage	National Poultry Improvement Plan and Auxiliary Provisions	Final Rule 07/2020	0579-AE49	NPRM Comment Period End Feb. 2020; Final Rule July 2020

USDA / AMS

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	NOP; Strengthening Organic Enforcement	Final Rule 10/2020	0581-AD09	NPRM Issued June 2020; Final Rule Oct. 2020

Proposed Rule Stage	Annual Updates to List of Bioengineered Foods	NPRM 07/2020	0581-AD95	First Time in Unified Agenda
Final Rule Stage	Undue and Unreasonable Preferences and Advantages Under the Packers and Stockyards Act	Final Rule 08/2020	0581-AD81	NPRM Comment Period Ended Mar. 2020; Final Rule Aug. 2020
Final Rule Stage	Proposed Amendments to the National List of Allowed and Prohibited Substances for October 2018 Recommendations (Crops and Handling)	Final Rule 07/2020	0581-AD83	Final Rule proposed for July 2020
Final Rule Stage	Origin of Livestock; Final Rule	Final Action 08/2020	0581-AD89	Final Rule Changed from June 2020 to Aug. 2020
Final Rule Stage	Revisions to the Federal Seed Act Regulations	Final Rule 06/2020	0581-AD91	First time published in Unified Agenda; NPRM Comment Period Ended Mar. 2020
Long-Term Actions	Establishment of a Domestic Hemp Production Program	Final Rule 10/2021	0581-AD82	NPRM Comment Period ended Jan. 2020; Final Rule Oct. 2021

USDA / FNS

Stage of Rulemaking	Subject	Estimated Date	RIN	Change in Status?
Proposed Rule Stage	Strengthening Integrity and Reducing Retailer Fraud in the Supplemental Nutrition Assistance Program (SNAP)	NPRM 10/2020	0584-AE71	NPRM changed from Feb. 2020 to Oct. 2020
Proposed Rule Stage	Strengthening Integrity and Reducing Retailer Fraud in the Supplemental Nutrition Assistance Program (SNAP)	NPRM 10/2020	0584-AE71	NPRM changed from June 2020 to Aug. 2020
Final Rule Stage	Simplifying Meal Service and Monitoring Requirements in the National School Lunch and School Breakfast Programs	Final Action 08/2020	0584-AE67	Final Action changed from June 2020 to Aug. 2020
Final Rule Stage	Streamlining Program Requirements and Improving Integrity in the Summer Food Service Program (SFSP)	Final Action 06/2020	0584-AE72	Final Rule Stage
Long-Term Actions	Providing Regulatory Flexibility for Retailers in the Supplemental Nutrition Assistance Program (SNAP)	Final Action Date to be Determined	0584-AE61	No Change
Long-Term Actions	Providing Regulatory Flexibility for Retailers in the Supplemental Nutrition Assistance Program (SNAP)	Final Action Date to be Determined	0584-AE61	Change from NPRM to Long-Term Actions