On October 30, 2024, the U.S. Food and Drug Administration's (FDA) newly minted Human Foods Program (HFP) published a list of priority deliverables for Fiscal Year 2025.

By way of brief background, FDA designed the HFP to facilitate a consistent, systematic, and intentional risk management approach to the agency's regulatory responsibilities. To achieve the HFP's public health mission and vision more effectively and efficiently, FDA has centralized its food regulatory risk management activities into three main areas. For FY 2025, these food regulatory activities are:

- **Microbiological food safety.** To focus on food traceability and produce safety, including to advance strategies to prevent pathogen-related foodborne illness in close collaboration with other regulatory agencies, states, industry, and other stakeholders.

- **Food chemical safety.** To focus on both pre- and post-market assessments of chemicals, including additives and contaminants, that occur in foods.
- **Nutrition.** To focus on infant formula safety and on updating labeling requirements to help consumers make more informed choices about the food they eat.

Below, we highlight FDA deliverables intended to strengthen regulatory oversight. In general, the enumerated priorities align with the agency's Foods Program Guidance Under Development and the most recent Unified Agenda of Regulatory and Deregulatory Actions. See our Updates on each, here and here. It remains to be seen how the identified FY 2025 priorities will fare post-election, though we currently view many of these items as issues of continued bipartisan interest.

Microbiological Safety

- **Pre-harvest agricultural water.** Finalize an implementation plan and execute key actions related to FDA's FSMA Final Rule on Pre-harvest Agricultural Water. On November 4, 2024, FDA and the U.S. Environmental Protection Agency announced the successful registration of the first antimicrobial product using the revised efficacy protocol for pre-harvest agricultural water.
- **Food traceability.** Work toward implementation of the FDA Food Traceability Final Rule by advancing traceability tools and other resources to educate and engage with industry.
- **Food Safety Modernization Act (FSMA) guidance for industry.** Issue final guidance for FSMA's Produce Safety Rule and prioritize development resources to support FSMA requirements.

Food Chemical Safety

- **Pre-market review.** Complete a review to identify efficiencies in FDA's current pre-market review processes for manufacturer submissions for food and color additives, food contact substances, and generally recognized as safe (GRAS) substances and ensure operational alignment under the new HFP organizational structure.
- **Post-market assessment of chemicals in food.** Update the agency's assessment framework based on feedback from the recent public meeting on a systematic approach for post-market assessments of chemicals in food and publish an updated list of substances prioritized for re-assessment with projected timelines.
- **Closer to Zero action levels.** Continue to advance work under Closer to Zero by targeting issuance of a guidance to establish action levels for environmental contaminants in foods intended for infants and young children, including a final guidance on action levels for lead.
- **New dietary ingredient notification (NDIN) guidance.** Continue work to release additional sections of final guidance on how and when to submit new dietary ingredient notifications.
- **FSMA guidance for industry.** Target issuance of draft guidance for Preventive Controls for Human Food specific to Chemical Hazards.

Nutrition

- **Update FDA's nutrient content claim "healthy."** Issue a final rule on "healthy" claims and continue working on a proposed design for a voluntary "healthy" symbol. FDA's proposed rule is available here.
- **Propose front-of-package nutrition labeling.** Issue a proposed rule on a mandatory front-of-package (FOP) nutrition labeling scheme.
- **Sodium in the food supply.** The HFP also intends to work to finalize the draft rule on the use of sodium through finalizing draft Phase II targets, among other actions. On November 1, 2024, FDA extended the comment period for the Voluntary Sodium Reduction Goals (Edition 2): Draft Guidance for Industry by an

additional 60 days.
- **U.S. infant formula market.** Increase resiliency of U.S. infant formula market through publication of a long-term national strategy to help facilitate entry of new infant formula manufacturers to increase supply and mitigate future shortages.

Looking Ahead

With HFP's recent launch on October 1, 2024, we anticipate that FDA will work steadily through FY 2025 to fully operationalize the program. In addition to hiring permanent leadership for the HFP offices, HFP plans to develop and release a multiyear strategic plan.

Operationally, FDA plans to (1) utilize enhanced risk modeling to inform how the agency allocates field resources going forward, (2) improve the reach and clarity of its recall communications, and (3) develop a coordinated performance management framework utilizing the existing Food Safety Dashboard. Importantly, the agency also intends to establish a Human Foods Advisory Committee of external experts with an aim to hold meetings in FY 2026. The HFP would leverage the expertise of the advisory committee to obtain external advice on "challenging and emerging" issues concerning food safety, nutrition, new and innovative food technologies, and other foods-related scientific, technical, and policy matters.

Perkins Coie's Food Regulatory team actively monitors developments at FDA and would be happy to provide additional insights on the newly announced FY 2025 priority deliverables and related issues.

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