

# Health Policy and Legislation Alert

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## Food for Thought: FDA Proposes New Vision for the Human Foods Program

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On January 31, 2023, the U.S. Food and Drug Administration (FDA) announced a proposal to restructure the agency's human foods program. FDA regulates almost 80 percent of the nation's food supply and this work is a cornerstone of the agency's mission to protect and promote public health, spanning a broad range of products and the entities involved in bringing them forward for consumers. The agency's announcement also marks an inflection point in FDA's continual efforts to modernize and carry out their public health charge in an evolving regulatory landscape. While this much anticipated announcement lays out an updated vision and some initial details, it also makes clear that moving forward with the proposed redesign will be an iterative process, leaving much to digest for stakeholders and Congress alike in the coming weeks and months. In particular, certain aspects of FDA's proposal may require congressional approval or formal notification. This alert outlines key takeaways from FDA's announcement.

### Key Takeaways

FDA's plan for the human foods program is for the functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR), as well as certain functions of the Office of Regulatory Affairs (ORA), to be unified into a newly envisioned organization called the Human Foods Program (the "Program") led by a Deputy Commissioner for Human Foods. As outlined by FDA, the Deputy Commissioner for Human Foods will oversee the Program, report directly to the Commissioner of Food and Drugs and will have decision-making authority over policy, strategy and regulatory program activities within the Human Foods Program, including resource allocation and risk-prioritization. FDA plans to conduct a competitive national search for this new Deputy Commissioner position.

FDA also outlines additional elements for the Program in its proposal:

- The creation of a Center for Excellence in Nutrition within the Agency and within which the agency would further establish an Office of Critical Foods, as directed by the 2023 Consolidated Appropriations Act, within this center.

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- The establishment of an Office of Integrated Food Safety System Partnerships that will focus on elevating, coordinating and integrating FDA's food safety and response activities with state and local regulatory partners.

Stakeholders may be particularly interested in FDA's call for the establishment of a Human Foods Advisory Committee, which will enable the agency to obtain independent expert advice on various issues, including issues in food safety, nutrition and innovative food technologies.

As part of the proposal for the human foods program, FDA is also calling for a realignment of ORA's operating structure into an enterprise-wide organization that supports the Human Foods Program and all other FDA regulatory programs, including programs governing drugs, biologics and medical devices. As a result, these proposed changes will have potential impacts well beyond just the Program. In the announcement, FDA lays out that this realignment will allow ORA to focus on its core mission (inspections, laboratory testing, import and investigative operations), but that other ORA functions will be aligned in other parts of FDA. These proposed changes will be closely watched by a much broader range of stakeholders than just those focused specifically on food and nutrition.

The plan notes that FDA's Center for Veterinary Medicine (CVM) will continue to operate as a stand-alone center with the relevant food safety activities closely coordinated between the CVM Center Director and Deputy Commissioner for Human Foods. However, FDA's proposal includes the creation of an Office of Animal Biotechnology Innovation in CVM to advance FDA's regulation of animal biotechnology. Also notable is the proposed expansion of the CVM Director's role to include the duties of Chief Veterinary Officer (CVO) to strengthen the center's One Health role and connection to the Human Foods Program as CVM continues to collaborate across the agency on issues that have implications for human, environmental and animal health.

## What's Next?

Stakeholders hungry for more details on how FDA will move forward with their proposed reforms will be closely watching for additional agency action. In unveiling the proposal, FDA highlighted that it recently formed an Implementation and Change Management Group that will be charged with developing a detailed plan to execute this announcement. The agency also outlined that it will need to develop a concrete reorganizational proposal, but noted that as details of this proposal continue to be developed, CFSAN, ORA and OFPR will continue to operate under their current structures. FDA also committed to providing additional public updates by the end of February on their progress, organizational design and timelines.

Beyond these agency-focused actions, stakeholders will also be watching to see what if any appetite Congress has for FDA's proposal and wondering whether members of Congress are satiated on this policy front. It also remains to be seen if Congress will seek to legislate on these policy fronts in the 118th Congress and/or focus on oversight of the [implementation of the FDA food reforms enacted](#) at the end of last year. While uncertainty remains on how FDA's proposed reforms will play out, given the far reaching implications of the agency's work in the food space for consumers, industry, public health and a broad range of stakeholders, it is certain that this is an area of FDA's work that will continue to be closely followed.

