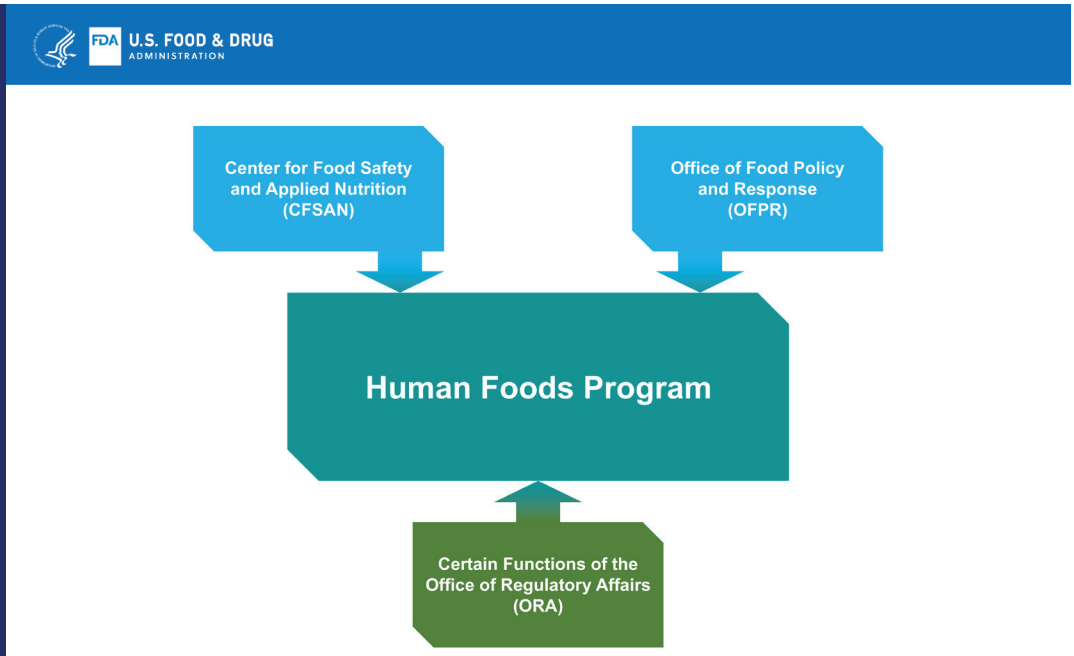
Vision for a Reimagined FDA Human Foods Program

KEY ELEMENTS OF A UNIFIED HUMAN FOODS PROGRAM

On January 31, 2023, the FDA provided an update on the agency's new vision for the FDA's Human Foods Program following evaluations released last year. The agency will continue to collaborate with federal partners on a whole-of-government approach to food safety and nutrition. This fact sheet summarizes key components of Commissioner Califf's vision for a unified and reimagined Human Foods Program. These include:

- **A unified Human Foods Program** will be created by combining the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR) and certain functions of the Office of Regulatory Affairs (ORA) under one leader.

Vision: How a Unified Human Foods Program will be Formed

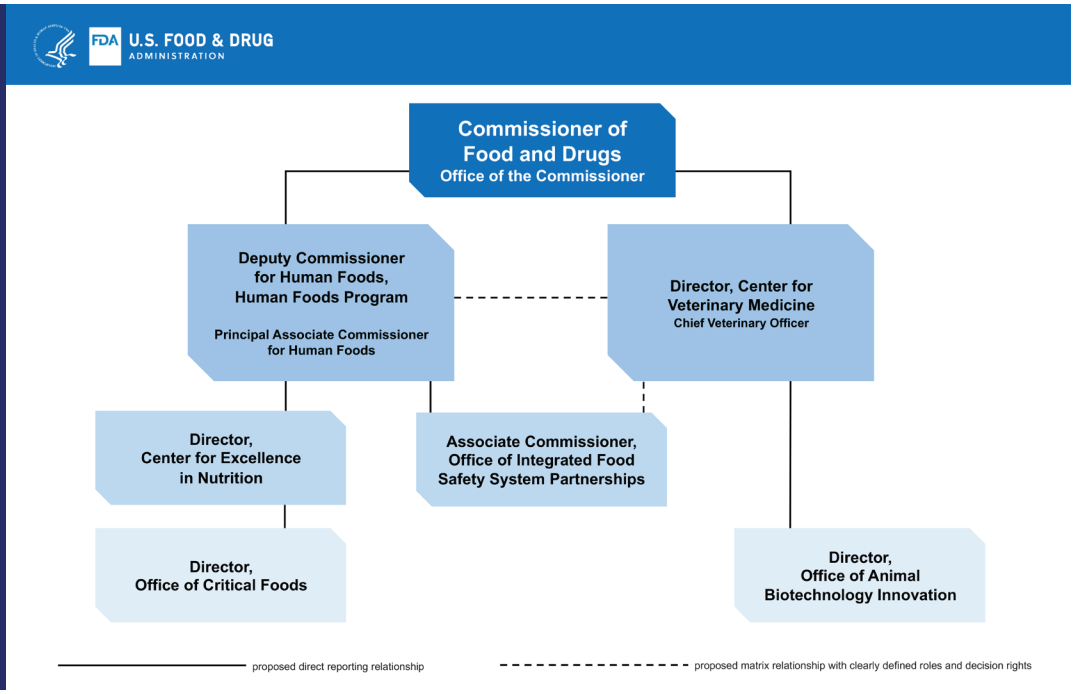


- **An empowered Deputy Commissioner for Human Foods** will be established to provide executive leadership and strategic direction over the entire portfolio, including resource allocation strategy, risk prioritization, integrated food safety partnership programs, communications, policy initiatives, and cultural transformation.
- **A larger executive team for the Human Foods Program** will be put in place with clearly defined lines of authority to ensure decisive leadership over the program's vast responsibilities. This includes a Principal Associate Commissioner for Human Foods position, reporting to the Deputy Commissioner, to provide strong, effective operational management of the program's day-to-day operations. In addition, a team of executives for the program's major areas of responsibility will be created to provide the necessary management infrastructure.

Vision: Key Executive Responsibilities of Deputy Commissioner for Human Foods

- **A Center for Excellence in Nutrition** will be created to elevate and empower action on nutrition science, policy, and initiatives to reduce diet-related chronic diseases and improve health equity. An Office of Critical Foods will be included within this center to manage the regulation of infant formula and medical foods.
- **An Office of Integrated Food Safety System Partnerships** will be formed to prioritize and unify the FDA's work with state and local regulators and strengthen the nation's Integrated Food Safety System as envisioned in the FDA Food Safety Modernization Act.
- **A Human Foods Advisory Committee** of external experts will be set up to advise the FDA on challenging or emerging issues in food safety, nutrition, and innovative food technologies.
- **These changes will allow for improved communication, efficiency and workflow** with better information technology, digitization and algorithms as envisioned in the New Era of Smarter Food Safety.

Vision: Key Structures of the Human Foods Program



- **An Office of Animal Biotechnology Innovation in the Center for Veterinary Medicine (CVM)** will be created to advance the FDA's ongoing smart regulation of animal biotechnology. There will be a robust cross collaboration between CVM and the Human Foods Program on agricultural biotechnology innovation.
- **An expansion of the CVM Director's role to include duties of Chief Veterinary Officer (CVO)** to strengthen the center's One Health role and connection to the Human Foods Program as it continues to collaborate across the agency on issues that have implications for human, environmental, and animal health. In cases where the CVM Director is not a veterinarian, the duties will be held by a senior veterinarian in CVM leadership.

REIMAGINING THE OFFICE OF REGULATORY AFFAIRS

Vision: An Integrated ORA Supporting the Entire FDA Portfolio

A new model for ORA will focus on its core activities – setting the global gold standard in inspections, investigations, laboratory analysis, and import operations. This model will better integrate ORA with all FDA regulatory programs by:

- **Improving the risk prioritization and public health impact of the FDA's field activities**. ORA's goals will be set by the regulatory programs and take a more prevention-based approach to food safety inspections as envisioned in the FDA Food Safety Modernization Act.
- **Modernizing the FDA's field activities**. ORA will focus on strengthening and modernizing its core operations and increase its specialization in concert with the regulatory programs.
- **Creating operational efficiencies**. Certain ORA functions will be realigned into the Human Foods Program and other regulatory programs or with agency-wide services to create a more streamlined organization. For example, state and local food safety partnership functions will be unified into the Human Foods Program.