

SMG 1122A.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Human Food Inspectorate

Effective Date: May 13, 2024

1. Office of Human Food Inspectorate. (DCSK).

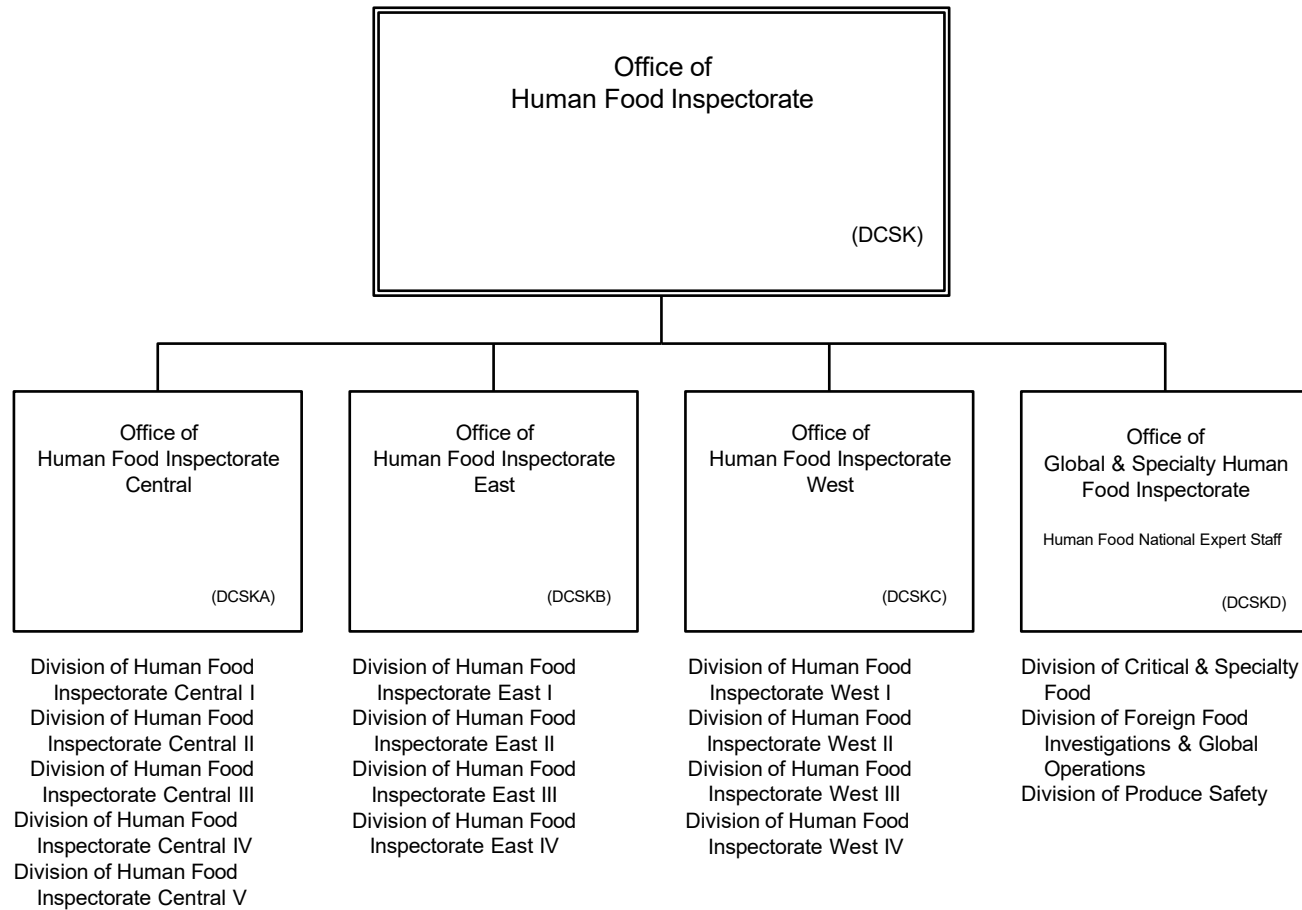
- A. Leads Office Directors in the coordination, interpretation, and evaluation of the Food and Drug Administration's (FDA) overall field inspections efforts in the areas of domestic and foreign human food and other products regulated by the Human Foods Program (HFP).
- B. Provides direction and guidance to the Office of Inspections and Investigations (OII) leaders and other senior FDA leaders on human food inspection and other field activities.
- C. Coordinates human food operations with the Deputy Commissioner for Human Foods and HFP Offices.
- D. Supports human food partnerships and inspectorate policy through collaboration with the Integrated Food Safety Systems Partnerships office in the HFP.
- E. Evaluates the overall management and capabilities of the FDA's human food field organization and initiates action to improve the management of global human food field activities.
- F. In collaboration with the FDA HFP, Centers, and offices, establishes inspection goals that align with the resource capacity of OII.
- G. Coordinates human food quality system activities and coordinates work planning and maintenance of the official establishment inventory with HFP.
- H. Develops, issues, and approves proposals and instructions affecting global human food field operations.

- I. Develops, clears, issues, and maintains guidance to the field in the investigation's operations manual relative to human food.
- J. Promotes the need for prompt and positive action within the FDA to assure safe human food products.
- K. Coordinates with the Office of Emergency Response to support HFP for emergency preparedness and response activities relative to human food.
- L. Participates, where appropriate, in international cooperation activities relative to human food.
- M. Review responses to FDA Form 483 and issues FMD-145s for NAI inspections, and a portion of VAI inspections, in coordination with the HFP, Centers, and offices.

2. Authority and Effective Date.

The functional statements for the Office of Human Food Inspectorate were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Human Food Inspectorate**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Human Food Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Office of Human Food Inspectorate Central (DCSKA)
Office of Human Food Inspectorate East (DCSKB)
Office of Human Food Inspectorate West (DCSKC)
Office of Global and Specialty Human Food Inspectorate (DCSKD)

These organizations report to the Office of Human Food Inspectorate Central (DCSKA):

Division of Human Food Inspectorate Central I
Division of Human Food Inspectorate Central II
Division of Human Food Inspectorate Central III
Division of Human Food Inspectorate Central IV
Division of Human Food Inspectorate Central V

These organizations report to the Office of Human Food Inspectorate East (DCSKB):

Division of Human Food Inspectorate East I
Division of Human Food Inspectorate East II
Division of Human Food Inspectorate East III
Division of Human Food Inspectorate East IV

These organizations report to the Office of Human Food Inspectorate West (DCSKC):

Division of Human Food Inspectorate West I
Division of Human Food Inspectorate West II
Division of Human Food Inspectorate West III
Division of Human Food Inspectorate West IV

These organizations report to the Office of Global and Specialty Human Food Inspectorate (DCSKD):

Human Food National Expert Staff
Division of Critical and Specialty Food
Division of Foreign Food Investigations and Global Operations
Division of Produce Safety