

**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**

**Office of Global and Specialty Human Food Inspectorate**

**Division of Critical and Specialty Food**

Effective Date: May 13, 2024

**1. Division of Critical and Specialty Food (DCSKDA).**

- A. Coordinates and supports specialty food field operations in the Office of Global and Specialty Human Food Inspectorate in collaboration with Food and Drug Administration (FDA) Centers and Offices.
- B. Serves as subject matter experts on specialty human food operations such as, but not limited to Critical Foods, Food Defense, and emerging food technologies.
- C. Supports foodborne outbreak and emergency preparedness and response activities relative to specialty food.
- D. Provides inspectional and investigational support to other human and animal food offices.
- E. Provides technical and programmatic expertise to the field, the Human Foods Program (HFP), and the Center for Veterinary Medicine (CVM) through program experts.
- F. Monitors emerging issues and advancements in human and animal food technology.

**2. Critical Food Investigations Branch (DCSKDA1).**

- A. Serves as subject matter experts in Infant Formula and Medical Foods in the field.

- B. Plans, conducts, and directs highly technical, complex, and multi-faceted inspections and in-depth investigations of critical foods manufacturers and related facilities in coordination with FDA Centers and Offices.
- C. Collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.
- D. Refers inspections and investigations with 483 observations to HFP for consideration of appropriate follow-up of firms involved in infant formula, medical foods, or other FDA regulated product manufacturing facilities.
- E. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to FDA Centers and Offices.
- F. Works collaboratively with the Office of Critical Foods in the HFP to ensure FDA oversight.

**3. Food Defense Branch (DCSKDA2).**

- A. Inspects human food establishments for which the HFP has regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.
- B. Serves as field subject matter experts on intentional adulteration investigational activities.
- C. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to FDA Centers and Offices.
- D. Coordinates and participates in outbreak and emergency preparedness and response activities relative to specialty food.
- E. Works collaboratively with the HFP to evaluate and educate facilities to reduce the risks of intentional contamination in the nation's food supply.

**4. Human Food Program Expert Branch (DCSKDA3).**

- A. Serves as a focal point within the FDA, furnishing authoritative guidance and consultative services to Office of Inspections and Investigations (OI) headquarters and field offices on inspectional and investigate methods and procedures necessary to carry out effective foodborne illness investigations and food related emergencies.
- B. Develops human and animal food related procedures and OI-wide procedures to create uniform development of evidence.
- C. Provides guidance and procedures for personal safety, and other cross programmatic needs related to investigative operations.

- D. Monitor and assist with technical guidance to divisions regarding special assignments from the HFP and CVM.
- E. Collaborate with the HFP and CVM to develop special assignments to investigate new and emerging food safety issues.

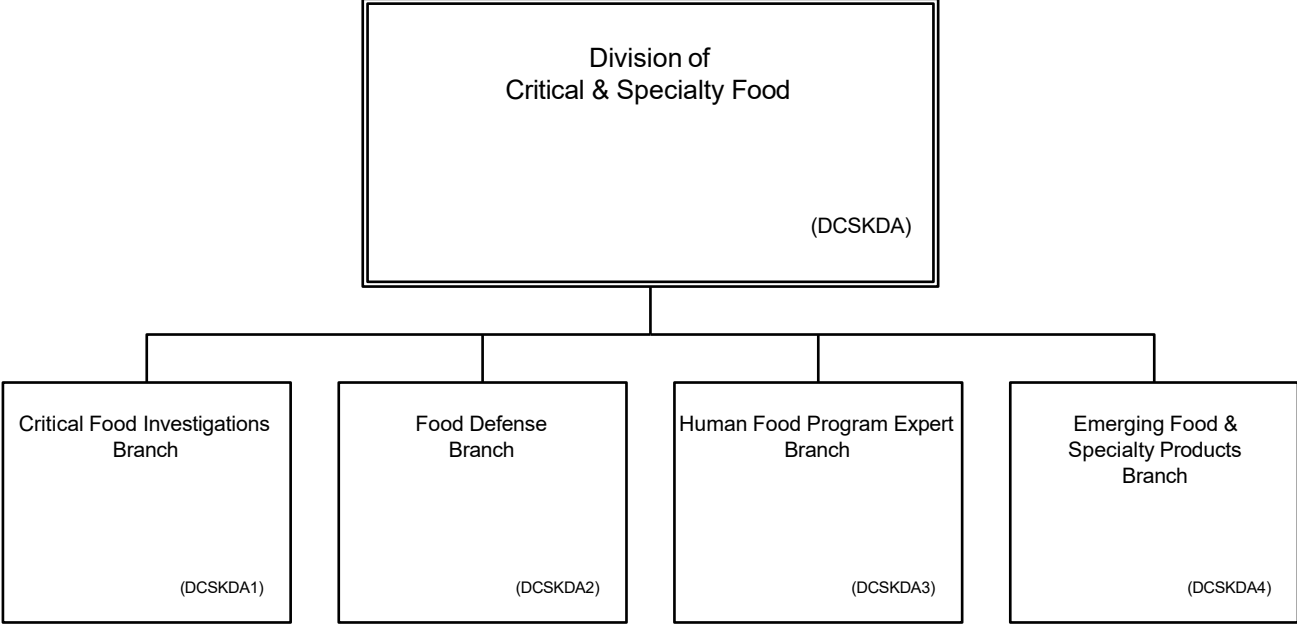
**5. Emerging Food and Specialty Products Branch (DCSKDA4).**

- A. Serves as Subject Matter Experts in specialty and emerging food manufacturing operations such as dietary supplement manufacturing and cell-cultivated food.
- B. Plans, conducts, and directs highly technical, complex, and multi-faceted inspections and in-depth investigations of specialty food products and related facilities in coordination with FDA Centers and Offices.
- C. Collects samples for analysis, performs field examinations, and prepares reports for FDA Centers and Offices.
- D. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to FDA Centers and Offices.
- E. Provides inspectional and investigational support to other human and animal food offices.
- F. Supports foodborne outbreak and emergency preparedness and response activities relative to specialty food.
- G. Monitors and investigates emerging issues and advancements in human and animal food technology.
- H. Advises the Office Director on new or emerging problems and trends, future program needs and priorities.

**6. Authority and Effective Date.**

The functional statements for the Division of Critical and Specialty Food 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  
Office of Global and Specialty Human Food Inspectorate  
Division of Critical and Specialty Food**



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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, Office of Global and Specialty Human Food Inspectorate, Division of Critical and Specialty Food organization structure depicting all the organizational structures reporting to the Director:

Critical Food Investigations Branch (DCSKDA1)

Food Defense Branch (DCSKDA2)

Human Food Program Expert Branch (DCSKDA3)

Emerging Food and Specialty Products Branch (DCSKDA4)