

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 Human Food Inspectorate East

Division of Human Food Inspectorate East II

Effective Date: May 13, 2024

- 1. Division of Human Food Inspectorate East II (DCSKBB).**
 - A. Manages field inspection within the associated division and other products regulated by the Human Foods Program (HFP) in coordination with the HFP.
 - B. Manages and evaluates resource use in support of the Human Food Inspectorate in coordination with the HFP.
 - C. Conducts and monitors investigations and inspections related to products for which HFP has regulatory responsibility.
 - D. Refers inspections to the HFP, Office of Compliance and Enforcement for consideration of regulatory and enforcement action and assists in implementing approved action, including liaising with U.S. attorneys and U.S. Marshals, and ensures court-ordered actions are completed on time and in total fulfillment of the court's order.
 - E. Manages and evaluates Human Food Inspectorate activities and manages a Quality Assurance Program in coordination with the HFP.
 - F. Develops short and long-term work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.
 - G. Advises the Office of Human Food Inspectorate East Director of emerging problems, trends, program needs and any local or state issues.

- H. Manages program and operational activities, including all phases of personnel management, financial management, and supplies for the Division.

2. Human Food Investigations Branch 1 (DCSKBB1).

- A. Inspects human food establishments for which the HFP have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports for the HFP.
- B. Refers inspections and investigations with 483 observations to the HFP for consideration of appropriate follow-up.
- C. Evaluates the corrective actions taken by establishments and provides feedback such that the HFP may determine effectiveness.
- D. Prepares and provides evidence of investigational findings.
- E. Performs special investigations, including foodborne outbreaks.
- F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- G. Provides inspectional and investigational support to the Office of Inspections and Investigations (OII) headquarters, HFP, and other divisions, as needed.
- H. Plans, schedules, and monitors inspectional operations related to products regulated by the HFP.
- I. Supports the development and implementation of domestic and foreign inspectional work plans in coordination with the HFP.
- J. Works with the HFP to provide guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry, as appropriate.
- K. Supports the HFP in managing, evaluating, and auditing the program aspects of federal-state contracts.

3. Human Food Investigations Branch 2 (DCSKBB2).

- A. Inspects human food establishments for which the HFP have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports for the HFP.
- B. Refers inspections and investigations with 483 observations to the HFP for consideration of appropriate follow-up.

- C. Evaluates the corrective actions taken by establishments and provides feedback such that the HFP may determine effectiveness.
- D. Prepares and provides evidence of investigational findings.
- E. Performs special investigations, including foodborne outbreaks.
- F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- G. Provides inspectional and investigational support to OII headquarters, HFP, and other divisions, as needed.
- H. Plans, schedules, and monitors inspectional operations related to products regulated by the HFP.
- I. Supports the development and implementation of domestic and foreign inspectional work plans in coordination with the HFP.
- J. Works with the HFP to provide guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry, as appropriate.
- K. Supports the HFP in managing, evaluating, and auditing the program aspects of federal-state contracts.

4. Human Food Investigations Branch 3 (DCSKBB3).

- A. Inspects human food establishments for which the HFP have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports for the HFP.
- B. Refers inspections and investigations with 483 observations to the HFP for consideration of appropriate follow-up.
- C. Evaluates the corrective actions taken by establishments and provides feedback such that the HFP may determine effectiveness.
- D. Prepares and provides evidence of investigational findings.
- E. Performs special investigations, including foodborne outbreaks.
- F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- G. Provides inspectional and investigational support to OII headquarters, HFP, and other divisions, as needed.

- H. Plans, schedules, and monitors inspectional operations related to products regulated by the HFP.
- I. Supports the development and implementation of domestic and foreign inspectional work plans in coordination with the HFP.
- J. Works with the HFP to provide guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry, as appropriate.
- K. Supports the HFP in managing, evaluating, and auditing the program aspects of federal-state contracts.

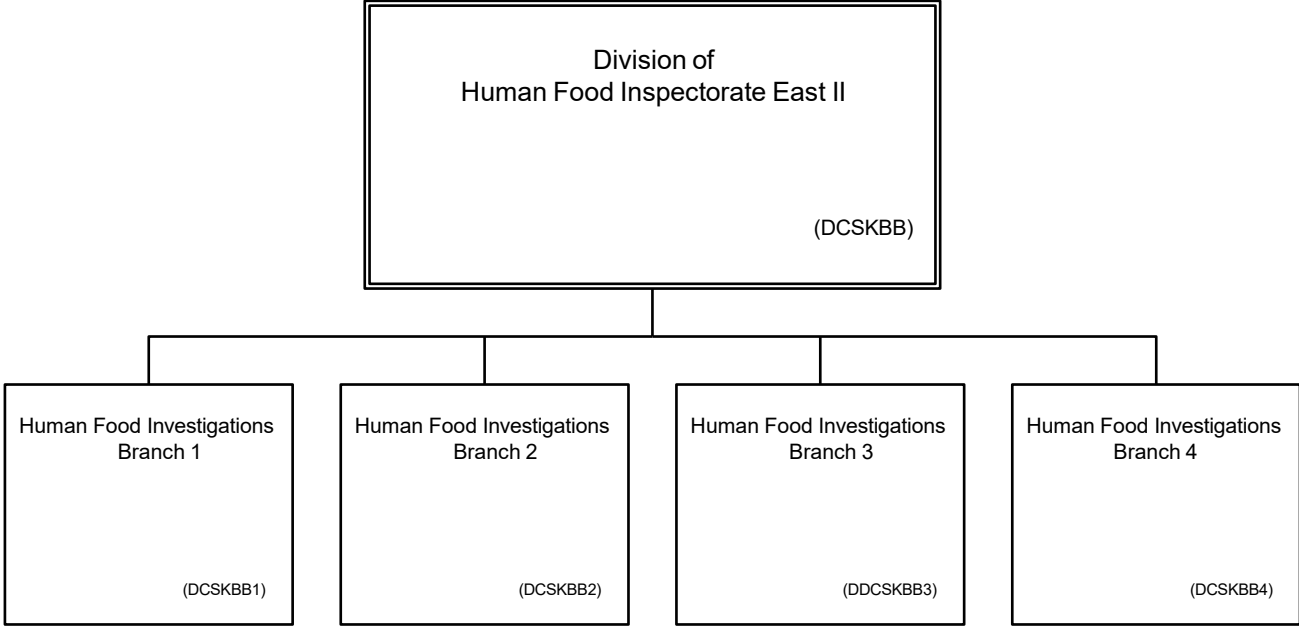
5. Human Food Investigations Branch 4 (DCSKBB4).

- A. Inspects human food establishments for which the HFP have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports for the HFP.
- B. Refers inspections and investigations with 483 observations to the HFP for consideration of appropriate follow-up.
- C. Evaluates the corrective actions taken by establishments and provides feedback such that the HFP may determine effectiveness.
- D. Prepares and provides evidence of investigational findings.
- E. Performs special investigations, including foodborne outbreaks.
- F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- G. Provides inspectional and investigational support to OII headquarters, HFP, and other divisions, as needed.
- H. Plans, schedules, and monitors inspectional operations related to products regulated by the HFP.
- I. Supports the development and implementation of domestic and foreign inspectional work plans in coordination with the HFP.
- J. Works with the HFP to provide guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry, as appropriate.
- K. Supports the HFP in managing, evaluating, and auditing the program aspects of federal-state contracts.

6. Authority and Effective Date.

The functional statements for the Division of Human Food Inspectorate East II 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 Human Food Inspectorate East
Division of Human Food Inspectorate East II**



Staff Manual Guide 1122A.222

Organizations and Functions

Effective Date: May 13, 2024

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 Human Food Inspectorate East, Division of Human Food Inspectorate East II organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Human Food Inspectorate East II (DCSKBB):

Human Food Investigations Branch 1 (DCSKBB1)

Human Food Investigations Branch 2 (DCSKBB2)

Human Food Investigations Branch 3 (DDCSKBB3)

Human Food Investigations Branch 4 (DCSKBB4)