

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Science

Office of Food and Feed Laboratory Operations

Southeast Food and Feed Laboratory

Effective Date: December 14, 2018

1. Southeast Food and Feed Laboratory (DCIFCG).

- A. Plans, schedules, and controls Regional laboratory operations; and formulates, implements, and coordinates analytical workplans for field offices being served.
- B. Performs laboratory analysis of samples for the Office of Regulatory Affairs (ORA) field offices, as requested to:
 - 1. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA).
 - 2. Determine the extent to which findings provide evidence of violative conditions and practices.
 - 3. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides evidence regarding analytical findings as requested.
- D. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- E. Serves as a national resource in scientific knowledge, laboratory methodology, and techniques applicable to animal use.
- F. Conducts reviews of data provided from contract, state, and private laboratories in support of ORA's regulatory mission.

- G. Provides assistance to districts in the conduct of complex food and feed inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- H. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.
- I. Implements an effective internal quality assurance program.

2. Microbiology Branch (DCIFCG1).

- A. Performs microbiological analyses of samples for field offices, as requested, in order to assess each sample's compliance with applicable laws and regulations enforced by the FDA.
- B. Conducts research to develop and refine methodology used in the analyses of microbiological samples and to explore new techniques and systems of analysis.
- C. Provides court testimony regarding analytical findings, as requested.
- D. Plans, schedules, and controls Branch operations; and formulates, implements, and coordinates workplans for field offices serviced as these operations relate to the Branch.
- E. Maintains liaison with scientists and scientific bodies with interests pertinent to its particular scientific specialty.
- F. Implements an effective internal quality assurance program.
- G. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies; to State, local, and foreign counterpart agencies; and to industry.
- H. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in microbiologically contaminated products.

3. Nutrient Analysis Branch (DCIFCG2).

- A. Serves as a national resource in scientific knowledge, laboratory methodology, and techniques applicable to solving Field problems pertinent to nutritional analyses.

- B. Performs laboratory analyses of samples for all FDA field offices throughout the FDA's Regions in order to assess each sample's compliance with applicable laws and regulations enforced by the FDA.
- C. Conducts research to develop, modify and/or validate methodology for the assay of nutrients in foods and to explore new systems and analyses.
- D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies; to State, local, and foreign counterpart agencies; and to industry.
- E. Plans, schedules, and controls Center operations; implements and coordinates workplans for all field offices throughout the FDA's Regions, as these operations relate to nutrient analysis.
- F. Performs laboratory analyses of samples for nutrient content for all Districts throughout the FDA in order to:
 - 1. Assess each sample's compliance with applicable laws and regulations enforced by the FDA.
 - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- G. Implements an effective internal quality assurance program.
- H. Provides court testimony regarding analytical findings as requested.
- I. Maintains liaison with scientists and scientific bodies with interests pertinent to nutritional analyses.

4. Chemistry Branch (DCIFCG3).

- A. Performs laboratory analyses for filth and decomposition, chemotherapeutics, mycotoxins, pesticides, colors and food additives. and examines samples of longer veterinary drugs, collected field offices to assess each sample's compliance with applicable laws and regulations enforced by the FDA; and to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.
- B. Conducts research to develop and refine methodology used in the analysis of filth and decomposition, chemotherapeutics, mycotoxins, pesticides, colors and food additives samples which includes developing analytical methodology, developing sample and sample preparation procedures, analytical methods validation and collaborative studies,

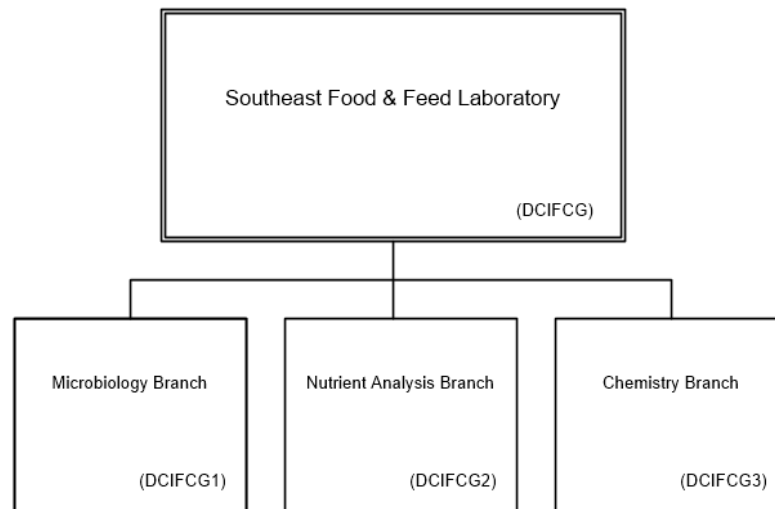
extension of existing analytical methods to additional commodities and exploring new systems of analysis.

- C. Provides court testimony regarding analytical findings as requested.
- D. Plans, schedules, and controls Branch operations; and formulates, implements, and coordinates workplans for field offices serviced as these operations relate to the Branch.
- E. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- F. Implements an effective internal quality assurance program.
- G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food and feed products.

5. Authority and Effective Date.

The functional statements for the Southeast Food and Feed Laboratory were approved by The Secretary for Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Regulatory Science
Office of Food and Feed Laboratory Operations
Southeast Food and Feed Laboratory**



Staff Manual Guide 1121.937
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Food and Feed Laboratory Operations, Southeast Food & Feed Laboratory organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Southeast Food & Feed Laboratory (DCIFCG):

Microbiology Branch (DCIFCG1)

Nutrient Analysis Branch (DCIFCG2)

Chemistry Branch (DCIFCG3)