

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

Pacific Southwest Food and Feed Laboratory

Effective Date: December 14, 2018

1. Pacific Southwest Food and Feed Laboratory (DCIFCH)

- A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates domestic and import analytical laboratory work plans and schedules with the Office of Regulatory Science (ORS).
- B. Conducts laboratory analysis of samples to:
- C. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA);
 - 1. Determines the extent to which findings provide evidence of violative conditions and practices; and
 - 2. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- D. Provides evidence regarding analytical findings as requested.
- E. Conducts research to develop and refine methodology used in the analysis of samples and explore new techniques and systems of analysis.
- F. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to products regulated by the FDA.
- G. Serves as a resource in scientific knowledge and provides expert-advice and training regarding laboratory techniques and technological

developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.

- H. Provides assistance to the ORS, as requested, in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.
- I. Serves as national resource for analyses requiring complex electronic spectrophotometric, mass spectroscopic and other instrumental analyses.
- J. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- K. Conducts reviews of data provided from contract, state, and private laboratories in support of the Office of Regulatory Affairs (ORA) regulatory mission.
- L. Implements an effective internal quality assurance program.
- M. Maintains working liaison with other Federal offices-providing support services to the FDA.
- N. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

2. Chemistry Branch (DCIFCH1).

- A. Performs laboratory analyses and examinations of samples of food, feed and ceramic-ware 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 samples and to explore new techniques and systems of analysis.
- C. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to food chemistry analyses. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry. Provides court testimony regarding analytical findings as requested.
- D. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for the ORS.

- E. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed and ceramic-ware.
- F. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- G. Maintains an effective internal quality assurance program.

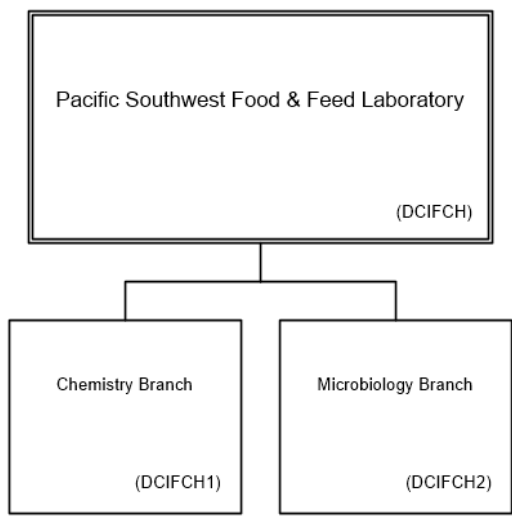
3. Microbiology Branch (DCIFCH2).

- A. Performs laboratory analyses and examinations of samples 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 analysis of samples and to explore new techniques and systems of analysis.
- C. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to microbiology analyses.
- D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry.
- E. Provides court testimony regarding analytical findings as requested
- F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for the ORS.
- G. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- H. Assists investigational staff in conducting inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed and drugs.
- I. Maintains an effective internal quality assurance program.

4. Authority and Effective Date.

The functional statements for the Pacific Southwest Food and Feed Laboratory were approved by the Secretary for Health and Human Services and effective 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
Pacific Southwest Food and Feed Laboratory**



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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, Pacific Southwest Food & Feed Laboratory organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Pacific Southwest Food & Feed Laboratory (DCIFCH):

Chemistry Branch (DCIFCH1)

Microbiology Branch (DCIFCH2)