

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Laboratory Operations and Applied Science

Office of Chemistry and Toxicology

Division of Bioanalytical Chemistry

Effective Date: May 13, 2024

1. Division of Bioanalytical Chemistry (DCRMCB).

- A. Develops, extends, refines, and validates analytical chemistry methods for toxic and nutrient elements, including radionuclides, gluten and allergens, chemical contaminants and nutrients in food and ingredients and contaminants in dietary supplements.
- B. Performs laboratory analysis of samples and provides technical support and expert advice in cooperation with other Human Foods Program (HFP) and Food and Drug Administration (FDA) components to support policy and regulation development.
- C. Recommends analytical methods to, and collaborates with, HFP regulatory labs to identify and multi-lab validate methods for use in monitoring and enforcement programs.
- D. Reviews regulatory actions for adequacy of evidence in support of HFP and FDA compliance programs.
- E. Assists other HFP organizations in review and evaluation of chemistry information and data provided in New Dietary Ingredient Notifications and Infant Formula Notifications; and maintains the HFP's analytical capability for food labeling compliance.

2. Bioanalytical Methods Branch (DCRMCB1).

- A. Conducts laboratory investigations in the broad areas of natural constituents and contaminants in dietary supplements, as well as chemical contaminants, natural toxins, and nutrients in food.

- B. Develops analytical methods and provides expert technical advice in support of regulations and related policy developments in areas of Branch expertise.
- C. Reviews regulatory actions for adequacy of evidence in support of HFP compliance programs in areas of Branch expertise.
- D. Serves as the HFP focal point for expertise in the development and dissemination of methods of analysis and technical review of data for HFP regulatory laboratories for constituents and contaminants in dietary supplements, as well as chemical contaminants, natural toxins, and nutrients in food.
- E. Conducts sampling surveys in the broad areas of natural constituents and contaminants in dietary supplements, as well as chemical contaminants, natural toxins, and nutrients in food to gather information in support of policy/regulation development and risk assessment.

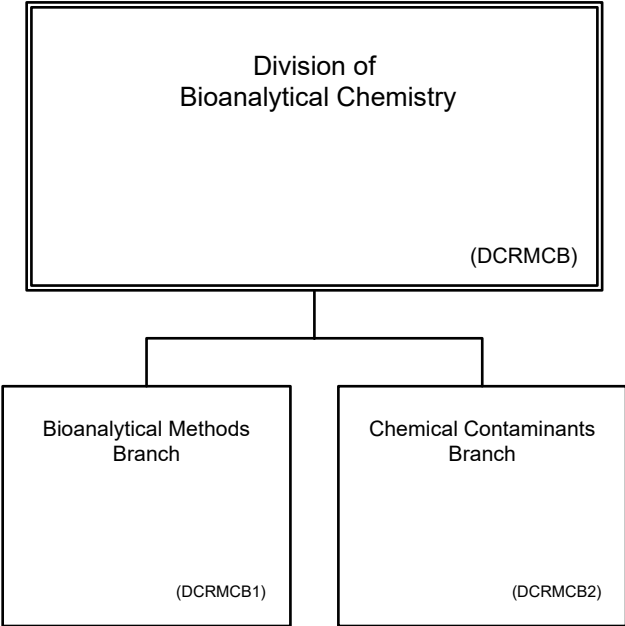
3. Chemical Contaminants Branch (DCRMCB2).

- A. Conducts laboratory investigations in the broad areas of elemental analysis, as well as allergens and gluten in food, food ingredients, and dietary supplements.
- B. Develops analytical methods and provides expert technical advice in support of regulations and related policy developments in areas of Branch expertise.
- C. Reviews regulatory actions for adequacy of evidence in support of FDA compliance programs in areas of Branch expertise.
- D. Serves as the focal point for expertise in the development and dissemination of methods of analysis and technical review of data for HFP regulatory laboratories for elements and radionuclides in foods and dietary supplements, as well as allergens and gluten in foods, food ingredients, and dietary supplements.
- E. Conducts sampling surveys in the broad areas of elemental analysis, as well as allergens and gluten in food, food ingredients, and dietary supplements to gather information in support of policy/regulation development and risk assessment.

4. Authority and Effective Date.

The functional statements for the Division of Bioanalytical Chemistry 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
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Division of Bioanalytical Chemistry**



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Chemistry and Toxicology, Division of Bioanalytical Chemistry organization structure depicting all the organizational structures reporting to the Director:

Bioanalytical Methods Branch (DCRMCB1)

Chemical Contaminants Branch (DCRMCB2)