

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Regulatory Science

Division of Bioanalytical Chemistry

Effective Date: December 14, 2018

1. Division of Bioanalytical Chemistry (DCEFC).

- A. Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and components of cosmetics.
- B. Develops analytical methods and provides technical support in support of regulations and related policy developments in areas of Division expertise.
- C. Reviews regulatory actions for adequacy of evidence in support of Food and Drug Administration (FDA) compliance programs.
- D. Serves as the focal point for expertise in the development and dissemination of methods of analysis for elements and radionuclides in foods, including dietary supplements.
- E. Identifies substances and issues of safety concern for cosmetic products and their raw materials and contaminants; develops and evaluates methods to identify and quantify potentially harmful ingredients and contaminants.
- F. Provides expert scientific and technical advice and assistance to the Center Director and other key officials on the conduct of international seafood activities, including the development and implementation of bilateral agreements; and develops technical content for and participates in programs designed to improve compliance by industry through problem prevention.
- G. Originates, plans, and conducts laboratory research related to the scope of responsibilities of the Office; develops appropriate methods for analysis of

nutrients in food and ingredients in dietary supplements; reviews and evaluates chemistry information and data provided in New Dietary Ingredient Notifications and Infant Formula Notifications; and maintains the Center's analytical capability for food labeling compliance.

2. Chemical Contaminants Branch (DCEFC1)

- A. Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins in foods, and allergens in food and food ingredients.
- B. Develops analytical methods and provides technical support in support of regulations and related policy developments in areas of Division expertise.
- C. Reviews regulatory actions for adequacy of evidence in support of FDA compliance programs.
- D. Serves as the focal point for expertise in the development and dissemination of methods of analysis for elements and radionuclides in foods and dietary supplements, for natural toxins in foods and seafoods, and allergens in foods and food ingredients.
- E. Provides expert scientific and technical advice and assistance to the Center Director and other key officials on the conduct of international seafood activities, including the development and implementation of bilateral agreements; and develops technical content for and participates in programs designed to improve compliance by industry through problem prevention.
- F. Originates, plans, and conducts laboratory research related to the scope of responsibilities of the Office. Develops appropriate methods for analysis of elements (including radionuclides) in food and ingredients and in dietary supplements; reviews and evaluates chemistry information and data provided in New Dietary Ingredient Notifications and Infant Formula Notifications; maintains the Center's analytical capability for food labeling compliance.

3. Bioanalytical Methods Branch (DCEFC2)

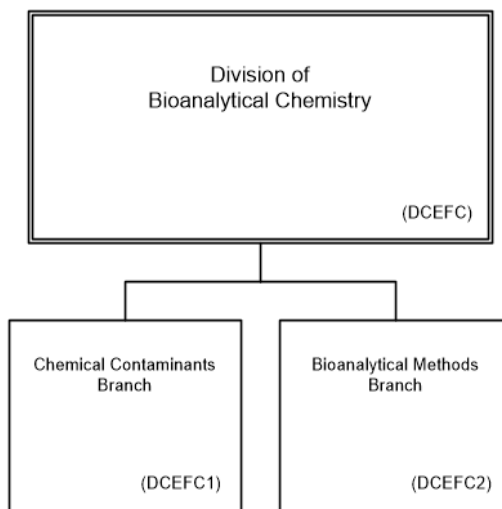
- A. Conducts laboratory investigations in the broad areas of natural constituents in dietary supplements, natural toxins, nutrients in food, and components of cosmetics.
- B. Develops analytical methods and provides technical support in support of regulations and related policy developments in areas of Division expertise.

- C. Reviews regulatory actions for adequacy of evidence in support of FDA compliance programs.
- D. Serves as the Center focal point for expertise in the development and dissemination of methods of analysis for specific nutrients in foods and constituents in dietary supplements and constituents in cosmetics.
- E. Identifies substances and issues of safety concern for cosmetic products and their raw materials and contaminants; develops and evaluates methods to identify and quantify potentially harmful ingredients and contaminants.
- F. Serves as the Center focal point for expertise in chemistry information and data provided in New Dietary Ingredient Notifications, Infant Formula Notifications and food labeling compliance.

4. Authority and Effective Date.

The functional statements for the Division of Bioanalytical Chemistry were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Science
Division of Bioanalytical Chemistry**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Regulatory Science, Division of Bioanalytical Chemistry organization structure depicting all the organizational structures in the immediate office reporting to the Director.

These branches report to the Division of Bioanalytical Chemistry (DCEFC)

- Chemical Contaminants Branch
- Bioanalytical Methods Branch