SMG 1231.151

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 Analytical Chemistry

Effective Date: December 14, 2018

1. Division of Analytical Chemistry (DCEFA).

A. Performs laboratory analysis of samples and provides technical support and expert advice in cooperation with other Center and Food and Drug Administration (FDA) components to support research and policy development and assess sample compliance with laws and regulations enforced by the FDA.

B. Develops, extends, refines, and validates analytical chemistry based methods for food defense threat agents, food additives, pesticides, allergens, dietary supplements, seafood toxins, and industrial chemicals that may be present in or contaminate Center for Food Safety and Applied Nutrition (CFSAN)-regulated food and cosmetic products; recommends analytical methods for field use in monitoring and enforcement programs for these chemicals.

C. Provides specialized infrared, near-infrared, Raman, surface Plasmon resonance, nuclear magnetic resonance and electron spin resonance spectroscopy, and mass spectrometry support to the FDA.

D. Provides specialized protein analysis and proteomics support to the FDA.

E. Conducts research to develop and refine the application of specialized and field portable instrumentation to FDA problems.

F. Originates, plans, and documents research to ascertain the nature and magnitude of chemical additives, seafood toxins, pesticides, allergens or chemical contamination of CFSAN-regulated food and cosmetic products via environmental and other routes for risk assessment and policy development purposes.

G. Develops analytical testing protocols for evaluating the migration of food packaging components to foods or food stimulants in order to facilitate submission and safety evaluation of indirect food additive petitions and notifications.

H. Supports food defense measures through special research projects and scientific support during threat situations.

I. Supports food safety through the development of DNA-based methods for plant and animal species identification.

2. Methods Development Branch (DCEFA1)

A. Performs laboratory analysis of samples to support research and policy development and assess their compliance with laws and regulations enforced by the FDA.

B. Develops and evaluates analytical methods to determine the presence and concentration of food defense threat agents, pesticides, contaminants or additives in foods and/or dietary supplements; provides scientific expertise and technical support for policy development and enforcement of FDA regulations.

C. Originates, plans, and documents research to ascertain the nature and magnitude of chemical additives or contamination in food via environmental and other routes for risk assessment and policy development purposes.

D. Develops analytical testing protocols for evaluating the migration of food packaging components to foods or food stimulants in order to facilitate submission and safety evaluation of indirect food additive petitions and notifications.

E. Supports food defense measures through special research projects and scientific support during threat situations.

3. Spectroscopy and MASS Spectrometry Branch (DCEFA2)

A. Provides specialized infrared, near-infrared, Raman, surface Plasmon resonance, nuclear magnetic resonance and electron spin resonance spectroscopy, and mass spectrometry support to the FDA.

B. Conducts research to develop and refine the application of specialized and field portable instrumentation to FDA problems.

C. Conducts research to develop and refine the application of proteomics methods to FDA problems.

D. Performs laboratory analysis of samples, in cooperation with other Center and FDA components, to support research and assess their compliance with laws and regulations enforced by the FDA.

E. Develops and evaluates methods to determine the presence and concentration of contaminants in foods, dietary supplements, seafood and/or harvest waters.

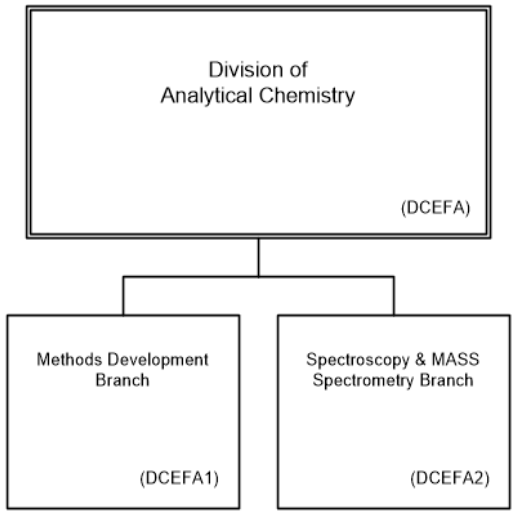
F. Originates, plans, and conducts research on seafood toxins, protein allergens and toxins, bacterial proteins, dietary supplements, food defense threat agents and other chemicals of potential food safety concern.

G. Originates, plans, and conducts research on seafood toxins, allergens, dietary supplements, food defense threat agents and other chemicals of potential food safety concern.

4. Authority and Effective Date.

The functional statements for the Division of Analytical 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 Analytical 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 Analytical Chemistry organization structure depicting all the organizational structures in the immediate office reporting to the Director.

These branches report to the Division of Analytical Chemistry (DCEFA)

- Methods Development Branch
- Spectroscopy and MASS Spectrometry Branch

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