SMG 1232A.431

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 Analytical Chemistry

Effective Date: May 13, 2024

1. Division of Analytical Chemistry (DCRMCA).

A. Develops, extends, refines, and validates analytical chemistry methods for chemicals that may be present in or contaminate food and food contact materials including methods for fish species identification and food authenticity.

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. Provides specialized expertise in infrared, near-infrared, Raman, surface Plasmon resonance, nuclear magnetic resonance and electron spin resonance spectroscopy, and mass spectrometry and in specialized protein analysis and proteomics support to the HFP and FDA.

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

2. Method Development Branch (DCRMCA1).

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 marine toxins chemical contaminants, adulterants 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. Develops genomic methods for species identification of seafood species to support for policy development and enforcement of FDA regulations.

3. Spectroscopy and Mass Spectrometry Branch (DCRMCA2).

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 organizations in the HFP 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 protein allergens and toxins, bacterial proteins, dietary supplements, genetically modified foods and other chemicals of potential food safety concern.

G. Conducts research to develop non-targeted mass spectrometric workflows for the determination of chemical compounds in foods, including food additives, packaging, environmental contaminants, adulterants and unknowns. Develop databases for identification of plant proteins.

H. Develops and evaluates methods for the characterization of nanoparticles.

4. Authority and Effective Date.

The functional statements for the Division of Analytical Chemistry were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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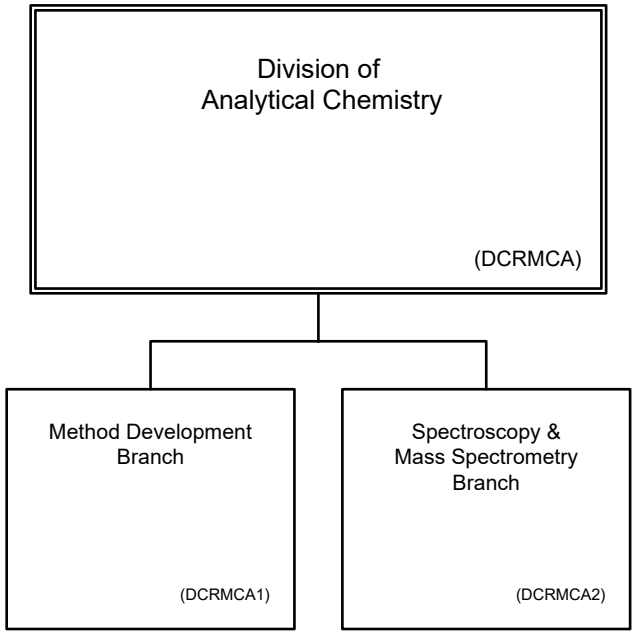

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Chemistry and Toxicology, Division of Analytical Chemistry organization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

Method Development Branch (DCRMCA1)

Spectroscopy and Mass Spectrometry Branch (DCRMCA2)