SMG 1232A.421

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 Applied Microbiology and Technology

Division of Food and Environmental Safety

Effective Date: May 13, 2024

1. Division of Food and Environmental Safety (DCRMBA).

A. Develops advanced bioinformatic methods to identify DNA biomarker sequences for the identification and subtyping of bacterial foodborne pathogens to aid epidemiological source tracking and attribution to illness.

B. Develops and validates new/improved and more rapid methods for detection and characterization of emerging and re-emerging microbial foodborne pathogens (including bacteria, viruses, and parasites) and understanding the survival and growth of those pathogens in foods and environment, including impact of environmental microbial foodborne pathogens.

C. Conducts critical longitudinal field, farm, and phytotron-based microbiological studies to guide standards in support of Food and Drug Administration’s (FDA's) produce safety mission and to improve and enhance Good Agricultural Practices (GAPs) for produce safety, providing the scientific knowledge and unique environmental testing methodologies that underpin FDA's guidance, rules, and regulations focused on the priority of ensuring a safe and wholesome produce supply.

D. Conducts microbiological, cultural, and molecular methods development, evaluation, and validation, providing accurate diagnostic approaches and technologies for detection of foodborne bacterial pathogens and toxins from FDA regulated food commodities and their production environment for use by FDA’s Foods Regulatory Program, labs and other food safety stakeholders worldwide.

E. Conducts studies and establishes collaborations with internal and external research partners to explore the role of the environment on foodborne pathogen persistence and transfer and the movement of emerging chemicals of concerns throughout the agricultural environment, including impact of environmental microbiomes to support development of prevention strategies.

F. Conducts studies in plant growth chambers and growing rooms that is critical to answering regulatory and scientific questions related to identifying risk factors, intervention or mitigation strategies in the environment (soil, water) that impact food safety (produce), including needed applied research studies involving the survival, persistence and transmission of microbial foodborne pathogens in the environment and food and their interaction with emerging chemicals of concern.

G. Conducts scientific studies in growth chambers on emerging chemicals of concern to determine their presence in agricultural soils and water, their uptake by plants and potential interaction with the environmental microbiome and/or microbial pathogen.

H. Conducts scientific studies to further determine impact of post-harvest practices for development of control and intervention strategies.

I. Critically manages the FDA-Bacterial Analytical Manual (FDA-BAM), the FDA-STEC Advisory Committee (FSAC) and other critical food safety programs including HFP outbreak response and compliance efforts surrounding contamination of foods and facilities with enteric bacterial pathogens.

J. Supports and actively promotes through expert scientific representation, standardization and harmonization of microbial food safety methods with the International Organization for Standardization (ISO), the World Health Organization (WHO), MicroVal, the European Food Safety Authority (EFSA), the Association of Official Agricultural Chemists (AOAC), and others as appropriate.

2. Environmental Microbiology Branch (DCRMBA1).

A. Conducts research on the identification and characterization of foodborne pathogens and their virulence factors.

B. Conducts research to assess bacterial growth and survival in high priority food matrices.

C. Develops and validates molecular methods for the detection of foodborne pathogens in contaminated foods

D. Performs community analyses (metagenomics and quasi-metagenomics) of foods, food production environments, and food processing environments

E. Conducts studies in plant growth chambers and growing rooms that is critical to answering regulatory and scientific questions related to identifying risk factors, intervention or mitigation strategies in the environment (soil, water) that impact food safety (produce)

F. Conducts critical longitudinal field, farm, and phytotron-based microbiological studies to guide standards in support of FDA's produce safety mission and to improve and enhance Good Agricultural Practices (GAPs) for produce safety

G. Trains other federal and state laboratory personnel in the methods devised for microbial pathogens.

H. Provides scientific and technical expertise on bacterial pathogens to Center management.

3. Virology and Parasitology Branch (DCRMBA2).

A. Develops improved extraction and detection methods for enteric viruses from food matrices including improved cell culture methods for their enrichment.

B. Evaluates novel culture dependent methods for virus enrichment and analysis of virus infectivity are enabling better infectivity assessment for certain viruses.

C. Develops improved extraction and detection methods for protozoan parasites in food matrices.

D. Provides scientific and technical expertise on viral and protozoan pathogens to HFP management.

E. Conducts genomic sequencing of foodborne viruses and Cyclospora cayetanensis for expansion of the virus (ViroTrakr) and Cyclospora (Cyclotrakr) databases.

4. Microbial Methods Development Branch (DCRMBA3).

A. Develops, optimizes, and validates cultural and molecular biologic methods for surveillance, recovery, detection, identification, and quantization of pathogens and/or toxins from foods and cosmetics including the food processing environment, and evaluates new technologies developed by industry, academia, and other local and international government entities for efficacy, sensitivity, utility, and application to food safety testing for the FDA Foods program.

B. Accomplishes the standardization and general acceptance of FDA-developed foodborne pathogen surveillance and screening methodologies by field personnel in their use and application.

C. Reviews FDA regulatory microbiology worksheets and provides subject matter expertise to FDA field laboratories and compliance programs in matters related to detection and identification methodologies for high-risk enteric foodborne pathogens.

D. Supports HFP and FDA program missions with subject matter expertise and support related to the biology, ecology, phenotype, surveillance, and detection of Salmonella enterica, hemorrhagic E. coli, Listeria monocytogenes, Shigella spp., and other significant foodborne pathogens, and provides expertise at the national and international levels for the harmonization and standardization of food screening and detection methodologies.

E. Oversees and leads the addition, modification, or amending of specific test methods and protocols for the FDA-BAM compendium.

F. Conducts methods development research for improvement of surveillance and detection of dangerous enterotoxins in the food supply.

5. Authority and Effective Date.

The functional statements for the Division of Food and Environmental Safety 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
Food and Drug Administration
Human Foods Program
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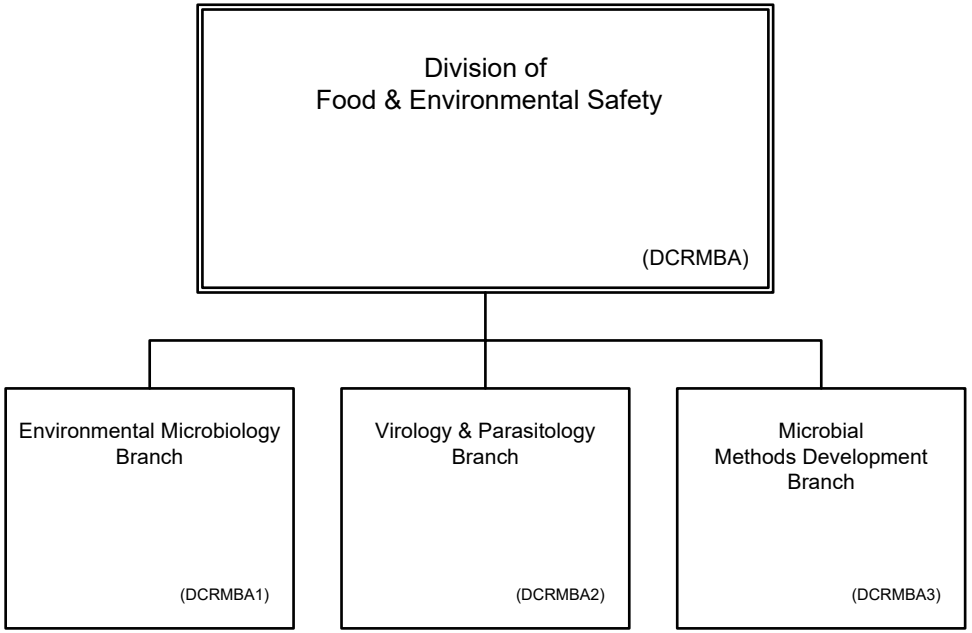

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Applied Microbiology and Technology, Division of Food and Environmental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

Environmental Microbiology Branch (DCRMBA1)

Virology and Parasitology Branch (DCRMBA2)

Microbial Methods Development Branch (DCRMBA3)