SMG 1232A.422

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 Safety Genomics

Effective Date: May 13, 2024

1. Division of Food Safety Genomics (DCRMBB).

A. Develops, optimizes, and validates genomic methods for enhanced whole genome sequence-based outbreak strain source tracking, root cause analysis, and subtyping in support of the Human Foods Program (HFP) outbreak response, compliance, and risk assessment activities.

B. Evaluates, implements, and standardizes new genomic platforms for open data analysis, metadata curation that allows users to leverage ontological data and use the data to develop modern visualization dashboards for data tracking.

C. Applies and advances precision food safety by using whole genome sequencing strategies to map and characterize unique adaptive changes among foodborne pathogenic strains and develop informative genomic diagnostics to identify critical pathogen adaptations such as biocide resistance, persistence, and biofilm formation.

D. Develops and applies metagenomic sequencing approaches to advance Food and Drug Administration's (FDA’s) goals toward culture independent and direct detection, identification, and subtyping of foodborne bacterial pathogens directly from a wide array of readily-consumed-raw and long-term shelf-life foods as well as complex environmental matrices associated with pre-harvest food production.

E. Conducts molecular, genotypic, phenotypic and genomic 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 HFP and other food safety stakeholders worldwide.

F. Develops, optimizes, and validates genomic methods for use directly in the field during ecological traceback studies, in facilities for root cause analysis, and advanced biological understanding of specific pathogens (i.e., long read sequencing for better characterization of STEC/EHEC virulence determinants and pathogenicity.

G. Develops and implements sequencing methods to detect, identify, and quantitate agents associated with filth.

H. Expands chloroplast sequencing methods to authenticate botanical and plant-derived dietary supplements.

I. Evaluates, implements, and standardizes new genomic platforms for open data analysis, metadata curation that allows users to leverage ontological data, and use the data to develop modern visualization dashboards for data tracking.

J. Enhances international coordination and data-sharing with food safety genomics program counterparts (e.g., European Food Safety Authority (EFSA) whole genome sequence (WGS) cluster) to identify technical solutions for sharing non-public gene-based epistasis (GenEpi) data between countries; Global Microbial Identifier (GMI) liaisons, and FDA international affairs projects including Asia-Pacific Economic Cooperation (APEC), German Federal Institute for Risk Assessment (BfR), the United Kingdom (UK) Food Standards Agency (FSA), Costa Rica, and Brazil's National Institute for Quality Control in Health (INCQS).

K. Serves as general molecular biology expertise for the HFP in the support, development, and transfer of technologies to other intra-center research organizations and field components.

L. Provides expertise, advice, and research assessment in areas of new and emerging molecular biotechnologies and disciplines such as genomics, transcriptomics, and proteomics with an applied forward-thinking vision.

2. Genomics Development and Applications Branch (DCRMBB1).

A. Develops, optimizes, and validates genomic methods for enhanced whole genome sequence-based outbreak strain source tracking, root cause analysis, and subtyping in support of HFP outbreak response, compliance, surveillance assignments, and risk assessment activities.

B. Advances precision food safety and enhanced preventive controls by using whole genome sequencing strategies to map and characterize unique

adaptive changes among foodborne pathogens such as biocide resistance, persistence, and biofilm formation.

C. Develops new genomic methods for ecological traceback studies, for facility root cause and persistence studies, and for advanced biological understanding of specific pathogens and their phenotypes.

D. Evaluates, implements, and standardizes new genomic platforms for open data analysis and metadata curation that allows users to leverage ontological data and use the data to develop modern visualization dashboards for data tracking.

E. Enhances and advances national and international coordination and data-sharing in support of FDA's GenomeTrakr Network with food safety genomics program counterparts and stakeholders (e.g. CDA, FSIS, NCBI, EFSA, Public Health England, CFIA, Public Health Canada, SENASICA, WHO, FAO).

F. Evaluates, assesses, and adapts newly emerging commercial whole genome sequencing technologies for utility and potential application in FDA's whole genome sequencing program.

G. Develops and/or evaluates and optimizes analytical pipelines and dashboard applications for the analysis of whole genome sequencing data from microbiological organisms.

H. Provides mission critical whole genome sequencing laboratory support to the HFP.

3. Metagenomic Diversity and Ecology Branch (DCRMBB2).

A. Develops and applies metagenomic sequencing approaches to advance FDA's goals toward culture independent and direct detection, identification, and subtyping of foodborne bacterial pathogens directly from a wide array of foods as well as complex environmental matrices associated with pre-harvest food production.

B. Develops and validates novel metagenomic sequencing methods and associated analytical data pipelines for use directly in the field during longitudinal microbiology studies and other pathogen ecology studies associated with the pre-harvest produce safety environment.

C. Develops and implements a variety of genome skimming and other metagenomic sequencing methods to detect, identify, and quantitate filth agents associated with food.

D. Develops and expands numerous chloroplast sequencing methods to authenticate botanical and plant-derived dietary supplements.

E. Conducts metagenomic studies on microbiome population diversity and structure associated with high microbiological risk crops and the surrounding production environment.

F. Uses metagenomic sequencing to monitor foodborne microbial pathogens and indicator species in agricultural water, fugitive dust, and other environmental matrices associated with the produce growing environment

G. Evaluates and adapts relevant novel extramural and other commercially and academically available metagenomic sequencing technologies for applications in microbiological food safety and food authenticity and misbranding.

H. Provides mission critical metagenomic sequencing laboratory support and consultative services to the HFP for food safety and authenticity regulatory field activities and outbreak responses

4. Molecular Genetics Methods Branch (DCRMBB3).

A. Provides expertise and research assessment in areas of new and emerging molecular biotechnologies and disciplines such as genomics, transcriptomics, and proteomics and provides general molecular biology expertise for the HFP in the support, development, training, and transfer of technologies to other FDA research organizations and FDA field surveillance and testing components.

B. Develops, optimizes, and validates and bioinformatic methods to identify DNA biomarker sequences for the identification and subtyping of foodborne pathogens and viruses to aid in molecular epidemiological source tracking and other characterizations of pathogens.

C. Develops, optimizes, and validates molecular biologic methods (e.g., quantitative polymerase chain reaction (qPCR)) for pathogen detection from food and environmental samples, including the food processing environment

D. Develops, oversees and implements the addition, modification, or amendment of specific molecular and genomic-based test methods and protocols for the FDA Bacterial Analytical Methods (BAM) for foodborne pathogenic bacteria and viruses.

E. Investigates the molecular etiologies and functional genomics of foodborne pathogenic bacteria including underlying phenotypes, observed mutations, and adaptation by gene regulation in response to external environmental signals and during stages of infection

F. Reviews regulatory documents and actions, in support of program offices, relating to genetically modified organisms (GMOs) or New Dietary Ingredient (NDI) notifications for live microbials.

G. Conducts molecular evolutionary and genomic research on the genetic and phenotypic diversity of foodborne pathogens including acquisition of virulence and other deleterious pathogen phenotypes known to exist in the food supply.

H. Accomplishes validation, standardization, and general acceptance of FDA-developed foodborne pathogen rapid molecular surveillance and screening methodologies by FDA field personnel and State food safety partners in their use and application.

5. Authority and Effective Date.

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

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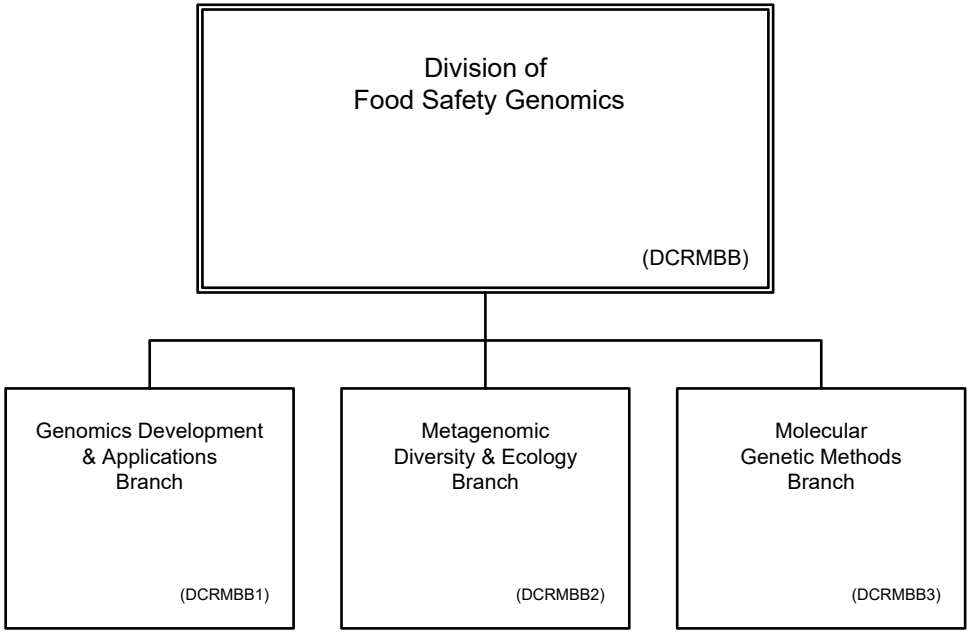

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Applied Microbiology and Technology, Division of Food Safety Genomics organization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

Genomics Development and Application Branch (DCRMBB1)

Metagenomic Diversity and Ecology Branch (DCRMBB2)

Molecular Genetic Methods Branch (DCRMBB3)