

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF FOODS AND VETERINARY MEDICINE**

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**

**OFFICE OF REGULATORY SCIENCE**

**DIVISION OF MICROBIOLOGY**

Effective Date: October 1, 2012

**1. DIVISION OF MICROBIOLOGY (DJJHFB).**

- A. Develops, optimizes, and validates methods for recovery, detection, identification, and quantization of pathogens and/or toxins from foods and cosmetics, and the processing environment.
- B. Accomplishes the standardization and general acceptance of FDA-developed methodology by field personnel in their use and application, and supports compliance where questions of microbial methodology arise.
- C. Maintains FDA's food-related gateway to the PulseNet System; develops and applies subtyping methods to further enhance data generated for PulseNet, strain identification, and molecular epidemiological investigations.
- D. Supports food defense measures through special research projects and scientific support during threat situations.

**2. MICROBIAL METHODS AND DEVELOPMENT BRANCH (DJJHFB1).**

- 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 Center and Agency 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. toxigenic fungi, 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 Bacterial Analytical Methods (BAM) compendium.
- F. Conducts methods development research for improvement of surveillance and detection of dangerous enterotoxins in the food supply.

### **3. MOLECULAR METHODS AND SUBTYPING BRANCH (DJJHFB2).**

- A. Develops, optimizes, and validates novel molecular, genetic, and phenotypic subtyping methods for the identification, differentiation, and source-tracking of enteric foodborne outbreak strains and provides field transfer of subtyping and identification methods for use in compliance and outbreak situations by FDA field and center laboratorians.
- B. Supports and responds to FDA's Outbreak Response Teams and compliance program officials on laboratory and scientific issues related to pathogen persistence or outbreak events including matters of inclusivity/exclusivity, strain taxonomy, specific strain attribution, and outbreak cluster relatedness.
- C. Serves as the FDA PulseNet gateway by reviewing FDA regulatory pulsed-field gel electrophoresis (PFGE) analyses and related analytical submissions by FDA field laboratories and providing subject matter expertise to FDA field laboratories in subtyping matters related to facilitate detection and identification methodologies as well as matters related to the PulseNet pathogen detection network.
- D. Evaluates and validates new technologies developed by industry, academia, and other local and international government entities for efficacy, sensitivity, utility, and application to pathogen identification and subtyping for the FDA foods program.
- E. Supports Center and Agency program missions with subject matter expertise and support related to the genetic relatedness, genotypes, taxonomy, and molecular diagnostics of *Salmonella enterica*, *E. coli* O157:H7, STEC, *Listeria*

monocytogenes, toxigenic molds, and other significant foodborne pathogens and provides expertise at the national and international levels for the networking and standardization of next-generation pathogen identification and subtyping technologies.

- F. Develops and applies next-generation whole-genome sequencing and DNA biosensor technologies to identifying and resolving complex foodborne outbreaks that emerge from the food supply.
- G. Coordinates and provides consultative expertise to other local, state, and federal partners, including the USDA Food Safety and Inspection Service Home (FSIS) and Centers for Disease Control (CDC), for the application of whole-genome sequence-based strategies to the differentiation and traceback of foodborne outbreaks and provides subject matter expertise to global scientific bodies such as FAO/WHO who are actively engaged in scientific and policy issues surrounding disease cluster detection, pathogen identification, and outbreak swarm differentiation, and strain source attribution.
- H. Supports food defense measures through special research projects and scientific support during threat situations, including the development, validation, and deployment of test methods for detection and differentiation of *C. botulinum* toxin directly from the food supply.

#### **4. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for the Division were approved by the Secretary of Health and Human Services, effective October 1, 2012.