

**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 Applied Research and Safety Assessment**

**Division of Virulence Assessment**

Effective Date: December 14, 2018

**1. Division of Virulence Assessment (DCEIB).**

- A. Performs research to support the Food and Drug Administration's (FDA) regulatory and public health mission. The research is geared towards the development of newer methods for detection and characterization of microbial foodborne pathogens, including select agents, and understanding the survival and growth of microbial pathogens in foods and environment.
- B. Performs validation and improvement of detection methods for food allergens and gluten, characterization of allergenic proteins, identification of critical factors for food allergen detection and the identification of data gaps that could impact food allergen and gluten compliance programs; identifying host immunological biomarkers as indicators of exposure and susceptibility to foodborne pathogens and their products to target risk assessment strategies to susceptible populations who have unique vulnerabilities to foodborne pathogens.

**2. Virulence Mechanisms Branch (DCEIB1)**

- 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. Utilizes and develops animal models and alternate models where necessary for the characterization of virulence potential of foodborne pathogens.
- E. Utilizes animal models to determine the infectious dose of foodborne pathogens.
- F. Devises tests methods for the isolation and identification of microbial threat agents such as *Bacillus anthracis* in foods.
- G. Utilizes animals for the detection of bioterror agents when traditional culture methods are unavailable or not sensitive enough for pathogen detection.
- H. Maintains BSL-3 facility for handling of select agents in foods.
- I. Trains other federal and state laboratory personnel in the methods devised for microbial threat agents.
- J. Participates in Food Emergency Network (FERN) activities and maintains the FERN store room.
- K. Is a member of the Centers for Disease Control Prevention (CDC) Laboratory Response Network.
- L. Provides scientific and technical expertise on bacterial and protozoan pathogens to Center management.

### **3. Immunology Branch (DCEIB2)**

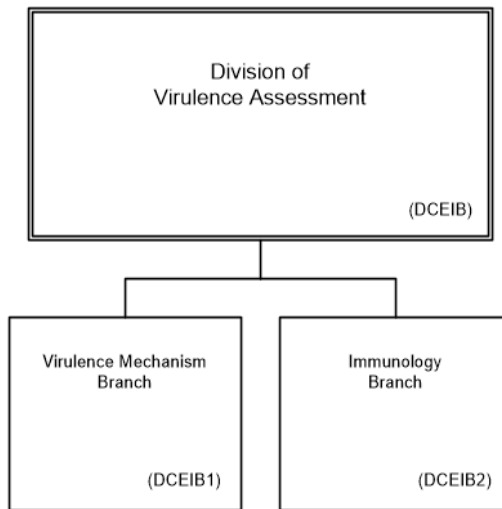
- A. Develop and validate immunochemical methods for the detection and characterization of food allergens, gluten and bioengineered food proteins.
- B. Develop and validate appropriate standard reference materials for detection of food allergens and gluten.
- C. Evaluate effect of food processing on food allergen and gluten detection.
- D. Develop/evaluate appropriate sampling plans and sample preparation methods for detection of food allergens and gluten.
- E. Use of animal models as surrogates for examining food allergen sensitization mechanisms and intervention strategies.
- F. Identification of host factors that increase susceptibility to foodborne pathogens. Develop models to use as surrogates for foodborne disease in susceptible populations.

- G. Identification and analysis of components or metabolic products of foodborne microorganisms that may impact host susceptibility to infection through their effects on the host immune system.
- H. Identify risk factors that can increase post-acute sequelae in susceptible populations following foodborne infection.
- I. Provide advice to risk managers and stakeholders to reduce the incidence and severity of foodborne disease in susceptible populations. Provide information on relevant models of susceptibility for use in probabilistic risk assessment.
- J. Provides immunological expertise to Center management on a variety of issues including allergens, foods derived from biotechnology, microbial immunology, assay development, biomarkers of susceptible populations.
- K. Collaborates with other researchers wishing to incorporate immunological methods into their research.

#### **4. Authority and Effective Date.**

The functional statements for the Division of Virulence Assessment 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 Applied Research and Safety Assessment  
Division of Virulence Assessment**



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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 Applied Research and Safety Assessment, Division of Virulence Assessment organization structure depicting all the organizational structures in the immediate office reporting to the Director.

These branches report to Division of Virulence Assessment (DCEIB)

- Virulence Mechanisms Branch
- Immunology Branch