

**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 Molecular Biology**

Effective Date: December 14, 2018

**1. Division of Molecular Biology (DCEIA).**

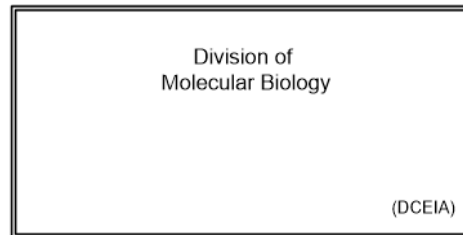
- A. Conducts research to investigate the evolution of foodborne pathogens including the roles and nature of mutation and their emergence in the environment.
- B. Develops improved extraction and detection methods for enteric viruses from food matrices including improved cell culture methods for their enrichment.
- C. 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.
- D. Develops and applies bioinformatic methods to identify DNA biomarker sequences for the identification and subtyping of foodborne pathogens and viruses to aid epidemiological source tracking.
- E. Explores and develops new molecular approaches to support rapid, high-throughput in vitro methods to identify new toxicants and profile complex mixtures and extracts.
- F. Explores and develops new molecular metagenomic approaches to harness the gastrointestinal microbial community as a new measurable human health endpoint.
- G. Investigates functional genomics of foodborne pathogenic bacteria including underlying phenotypes of observed mutations and adaptation by gene regulation in response to external environmental signals and during stages of infection.

- H. Reviews regulatory actions for adequacy of analytical evidence in support of programmatic offices such as the Office of Food Additive Safety (OFAS) [Biotechnology Notification Files (BNFs) for genetically modified organisms (GMOs)], the Office of Nutrition and Food Labeling (ONFL), and the Office of Dietary Supplement Programs (ODSP) [New Dietary Ingredient (NDI) notifications for live microbials].
- I. Serves as general molecular biology expertise for the Center in the support, development, and transfer of technologies to other intracenter research organizations and field components.

## **2. Authority and Effective Date.**

The functional statements for the Division of Molecular Biology were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
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Division of Molecular Biology**



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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 Molecular Biology organization structure depicting all the organizational structures in the immediate office reporting to the Director.

Division of Molecular Biology (DCEIA)