

**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 Coordinated Outbreak Response and Evaluation Network**

Effective Date: December 14, 2018

- 1. Office of Coordinated Outbreak Response and Evaluation Network (DCEN).**
  - A. Provides leadership and direction for Food and Drug Administration (FDA) outbreak activities including preparedness, response, environmental assessments and post response activities associated with FDA-regulated food, dietary supplements, and cosmetics.
  - B. Prioritizes efforts in conjunction with other FDA components, directs resources and provides guidance to the field on investigational activities associated with outbreaks related to FDA-regulated food, dietary supplements, and cosmetics.
  - C. Reviews and analyzes information for the early recognition of outbreaks associated with FDA-regulated food, dietary supplements, and cosmetics. Ensures findings, pertinent data and recommendations are incorporated into prevention-based regulatory efforts.
  - D. Collaborates with federal, state, local, and tribal partners and non-governmental stakeholders to support outbreak preparedness, response, environmental assessments and post response activities as part of an integrated food safety system.
  - E. Develops and coordinates communication materials and outreach activities related to outbreak preparedness, response, environmental assessments and post response activities with federal, state, local tribal partners, non-governmental stakeholders, and the public.

## **2. Signals and Analysis Staff (DCEN1)**

- A. Gathers historical data on pathogens/outbreaks in food, cosmetics, and dietary supplements.
- B. Provide all needed data and background information required to initiate response activities and propose appropriate response strategies.
- C. Directs other FDA units in surveillance and trending activities for both foods, cosmetics and dietary supplements and seeks to leverage assistance from other FDA units.
- D. Partners with Veterinary Medicine (VM) programs to evaluate incoming information to determine whether there are incidents on which Coordinated Outbreak Response and Evaluation (CORE) program should focus.
- E. Partners with Centers for Disease Control and Prevention (CDC) for data gathering needs/requests and trends analysis from the Pulsed-field gel electrophoresis (PFGE) databases and other databases.
- F. Determines whether environmental assessments (EAs), root cause analyses, and other activities will be conducted during or after an outbreak.
- G. Prepares and communicates findings from select outbreaks and incident summary closeout reports for each incident handled by CORE.

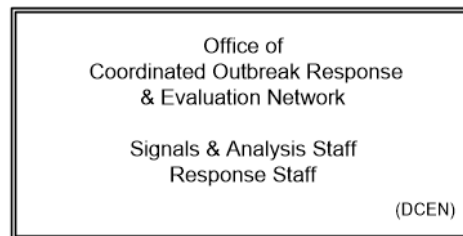
## **3. Response Staff (DCEN2)**

- A. Coordinates outbreak actions with the Centers and the field components. Provides leadership and direction for all outbreaks within its responsibilities.
- B. Coordinates information flow across organizations during response efforts.
- C. Manages communication with the field and initiates assignments in relation to outbreak response, unless the FDA Emergency Operations program (OEO/IMG) is managing the outbreak.
- D. Responsible for preparing strategic incident plans in consultation with regulatory stakeholders.
- E. Coordinates with signals and analysis program, the selection of outbreaks for environmental assessments and other activities.

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

The functional statements for the Office of Coordinated Outbreak Response and Evaluation Network 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 Coordinated Outbreak Response and Evaluation Network**



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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 Coordinated Outbreak Response and Evaluation Network organization structure depicting all the organizational structures in the immediate office reporting to the Director.

These staffs report to the Office of Coordinated Outbreak Response and Evaluation Network (DCEN)

- Signals and Analysis Staff
- Response Staff