FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Surveillance Strategy and Risk Prioritization

Division of Surveillance and Data Integration

Effective Date: May 13, 2024

1. **Division of Surveillance and Data Integration (DCRGA).**

   A. Leads overall surveillance strategy development, oversight, and associated activities through a comprehensive, integrated approach to detect and assess hazards (new and emerging risks), and to assess the overall state of the food supply, including prevalence of various hazards across commodities. Includes leveraging of state partner data.

   B. Develops and facilitates public health analytics and signal detection for the Human Foods Program (HFP), including statistical and epidemiological support for risk managers and the HFP's Laboratory Operations and Applied Science.

   C. Leads the development and maintenance of a data inventory/catalogue from active and passive surveillance systems and manages cross-cutting surveillance systems and programs for the HFP.

   D. Leads and manages HFP access to data and collection of data; includes integrating various sources of available public and non-public data, and ensuring data structure, format, reliability, consistency, integrity, and visualization are sufficiently rigorous, and as possible cleaned, standardized, and integrated with existing applications and platforms. Leads HFP-wide data governance framework and processes, in coordination with the Food and Drug Administration's (FDA) Digital Transformation and Enterprise Transformation operations.

   E. Leads coordination of multi-disciplinary work groups that periodically review signals and emerging hazards.

F. Leads initial assessment and triaging of signals from passive surveillance systems for health hazard assessment and/or immediate response and leads assessment of signals from active surveillance systems (microbial or chemical hazards identified from food samples collected in the field, through inspections or at import) to establish potential causation of or risk for illness or harm.

G. Leads development and deployment of new and enhanced methods to utilize new sources of data and information beyond traditional passive and active surveillance systems to identify potential (new, emerging, or previously unknown) hazards in food that could contribute to public health concerns, illnesses, and diseases. Includes such approaches as horizon scanning, social media analysis, and procurement of novel data streams.

2. Surveillance Design Branch (DCRGA1).

A. Leads overall surveillance strategy development, oversight, and associated activities through a comprehensive, integrated approach to detect and assess hazards (new and emerging risks), and to assess the overall state of the food supply, including prevalence of various hazards across commodities.

B. Ensures regulatory science and research function, laboratory functions, compliance functions, state partnership functions, and others are involved in development of the surveillance strategy and includes leveraging of state partner data.

C. Through consultation with risk managers, designs risk-based targeted sampling and inspectional plans that enable statistical inferences to enable risk identification within commodities, food groups, or individual foods.

3. Signal Detection and Bioinformatics Branch (DCRGA2).

A. Develops sophisticated methods and facilitates public health analytics and signal detection for the Human Foods Program (HFP), including statistical and epidemiological support for risk managers and laboratory programs.

B. Leads initial detection and triaging of signals from passive surveillance systems for health hazard assessment and/or immediate response.

C. Leads identification and triaging of signals from active surveillance systems (microbial or chemical hazards identified from food samples collected in the field, through inspections or at import) to establish potential causation of or risk for illness or harm.

D. Leads identification and triaging of signals from passive surveillance systems (e.g., adverse event reports, reportable foods registry, Whole Genome Sequencing (WGS) clinical data) for identifying hazards, triaging hazards for

additional assessment or treatment, and establishing potential causation of hazard and an adverse event or illness.

    E. Leads coordination of multi-disciplinary work groups that periodically review signals and emerging hazards.

4. Surveillance Systems Operations Branch (DCRGA3).

    A. Develops and maintains systems, technology, and infrastructure for collection of data from passive surveillance systems (e.g., adverse event reports, reportable food registry).

    B. Leads the development and maintenance of a data inventory/catalogue of food facility registration to inform active surveillance systems and programs for the HFP.

    C. Provides data analyses, summaries and reports of data collected through passive surveillance to inform broader surveillance and prioritization efforts.
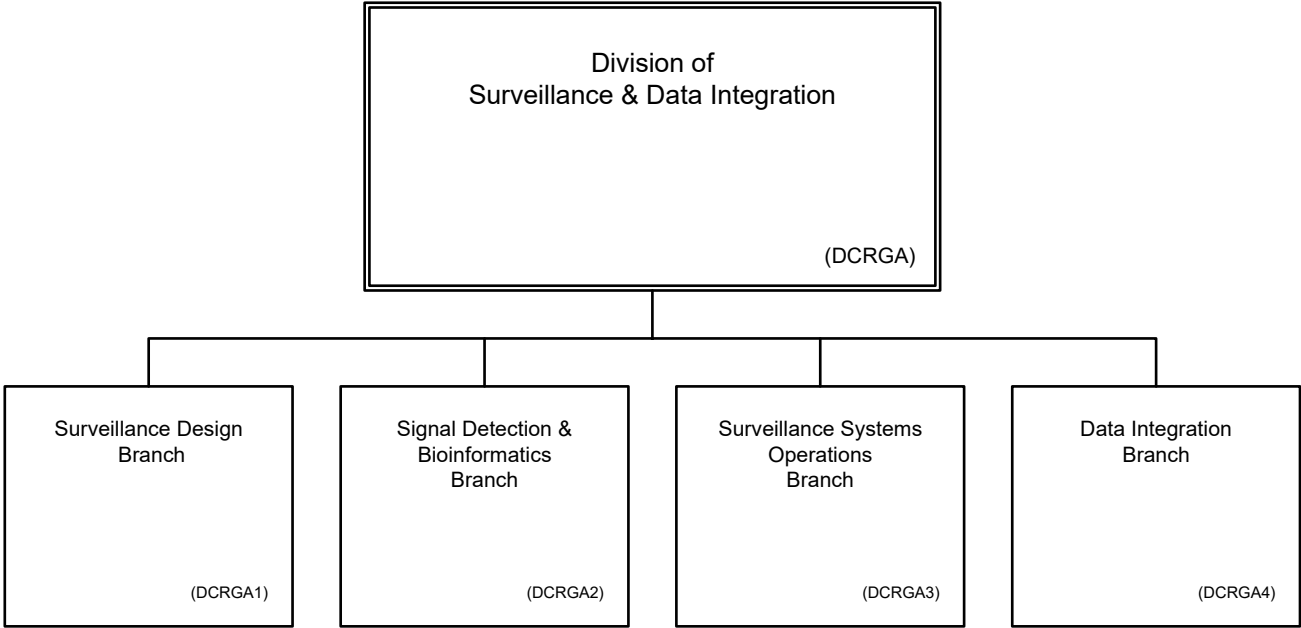
5. Data Integration Branch (DCRGA4).

    A. Manages data collected from systems to ensure data integrity and to promote and facilitate analysis for various purposes, such as signal detection or data inquiries.

    B. Leads, manages, and advises on HFP access to data and collection of data and provision of new or updated tools and platforms; integrates various sources of available public and non-public data and ensuring data structure, format, reliability, consistency, integrity, and visualization are sufficiently rigorous; and as possible, that data are cleaned, standardized, and integrated with existing applications and platforms.

6. Authority and Effective Date.

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

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Division of
Surveillance & Data Integration

(DCRGA)

Surveillance Design Branch	Signal Detection & Bioinformatics Branch	Surveillance Systems Operations Branch	Data Integration Branch
(DCRGA1)	(DCRGA2)	(DCRGA3)	(DCRGA4)

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office Surveillance Strategy and Risk Prioritization, Division of Surveillance and Data Integration organization structure depicting all the organizational structures reporting to the Director:

Surveillance Design Branch (DCRGA1)

Signal Detection and Bioinformatics Branch (DCRGA2)

Surveillance Systems Operations Branch (DCRGA3)

Data Integration Branch (DCRGA4)