

**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 Evaluation and Population Health Science**

Effective Date: May 13, 2024

**1. Division of Evaluation and Population Health Science (DCRGC).**

- A. Regularly leads, convenes, and coordinates the Human Foods Program's (HFP) multi-year approach to evidence-based evaluations and scientific studies utilizing biostatistics, epidemiology, social sciences, and other disciplines and practice orientations to supporting the HFP and other HFP Surveillance Strategy and Risk Prioritization organizations.
- B. Leads and coordinates HFP's research and methods design for evaluations and certain scientific studies, primarily those that assess the efficacy and impact of risk management strategies; includes implementing cross-cutting evaluation teams that ensure data collection for such purposes have sufficient statistical rigor.
- C. Leads behavioral and social science research on how consumers and other stakeholders perceive, understand, and react to HFP policies, messages, and regulatory actions.
- D. Leads the application of epidemiologic methods to better understand how food and nutrition-related hazards impact population-level human health and evaluate health risks and interventions.
- E. Partners with risk managers in providing expertise to design effective, targeted surveillance strategies to complement and support risk management strategies.
- F. Regularly partners with risk communicators for developing potential strategies for addressing or influencing consumer behaviors through labeling, education, and other strategies, and on assessing and evaluating their ability to reduce risks and improve safety of foods regulated by the HFP.

- G. Develops, implements, and manages a tiered HFP prioritization process for research publication planning and review, aligned with overall risk-informed framework and associated rationale for decisions.

## **2. Behavioral and Social Sciences Branch (DCRGC1).**

- A. Leads behavioral and social science research on how consumers and other stakeholders perceive, understand, and react to HFP policies, messages, and regulatory actions.
- B. Informs HFP on emerging and recognized public health issues for policy development, regulatory decision-making, and outreach to consumers and other stakeholders.
- C. Develops and conducts activities with risk communicators and managers on potential strategies, and associated scientific assessment, of potential impacts of communication policies (such as labeling or education), on consumer behaviors (or precursors of behavior, such as perceptions) designed to reduce risks and improve safety of foods regulated by the HFP.
- D. Regularly leads, convenes, and coordinates the HFP's multi-year approach to evidence-based evaluations and scientific studies utilizing biostatistics, epidemiology, social sciences, and other disciplines and practice orientations to supporting the HFP and other OSSRP divisions.
- E. Leads and coordinates HFP's design and associated cross-cutting staffing of evaluations and certain scientific studies, including those that assess the efficacy and impact of risk management strategies and helps determine the HFP's collective positive public health impact as well as identifies gaps, data needs, and short and long-term needs. Also provides broad and area-specific expertise to ensure that all multi-disciplinary analyses, studies, and evaluations conducted in the HFP are in alignment with priorities, are structured to support decision-making, and collect and use data and information appropriately to ensure sufficient rigor and HFP-wide integration.
- F. Ensures sound design of impact and outcome evaluations, with the aim of capturing the complex, and multiple direct and indirect effects of public investments. Makes determinations as to whether evaluations should be quasi-independent (internal evaluator) or independent (external evaluator).
- G. Leads internal evaluations, including research methods and design, logic model development and use, data collection and selection, analytical methods, development and use of outcome and impact metrics, completing qualitative and quantitative data analysis, developing findings, reporting, and participating in appropriate review processes. Includes assessing data for usability in evaluating and re-evaluating risk management strategies and decisions as to their efficacy in achieving priority public health goals.

- H. Manages independent evaluations, which includes developing and prioritizing questions that can provide the evidence needed to inform decision-making, determine funding, develop timelines, advise on methods, select evaluation contractors. including through competitive solicitations, provide appropriate access to data, records, and staff, monitors evaluation projects, ensures internal and external peer review of studies, and reports results.
- I. Provides advice to the Deputy Commissioner, Executive Programs and Strategic Planning function and Resource Management Office on the development and implementation of HFP-wide evaluation strategy and develops frameworks for assessing overall impact of HFP activities and applies investments accordingly.
- J. Supports activities within the Office and across HFP to estimate the impact of risk management decisions or measures (outcomes) to achieve HFP priorities/goals such as changes to nutrition, microbial, and chemical hazards in foods that are associated with PH concerns, disease, illness and/or death.

### **3. Epidemiology and Medical Sciences Branch (DCRGC2).**

- A. Leads assessment of microbial, allergenic and other signals from *active* surveillance systems (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.
- B. Leads assessment of microbial, allergenic and other 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.
- C. Leads the application of epidemiologic methods to better understand how food and nutrition-related hazards impact population-level human health and evaluate health risks and interventions.
- D. 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.
- E. Provides expertise on the design of effective, targeted surveillance strategies to complement and support risk management strategies.
- F. Supports surveillance activities to assess potential signals, particularly through the use of external sources of data from multiple federal and state agencies, as well as novel data sources (and with the Office of Integrated Food Safety System Partnerships).

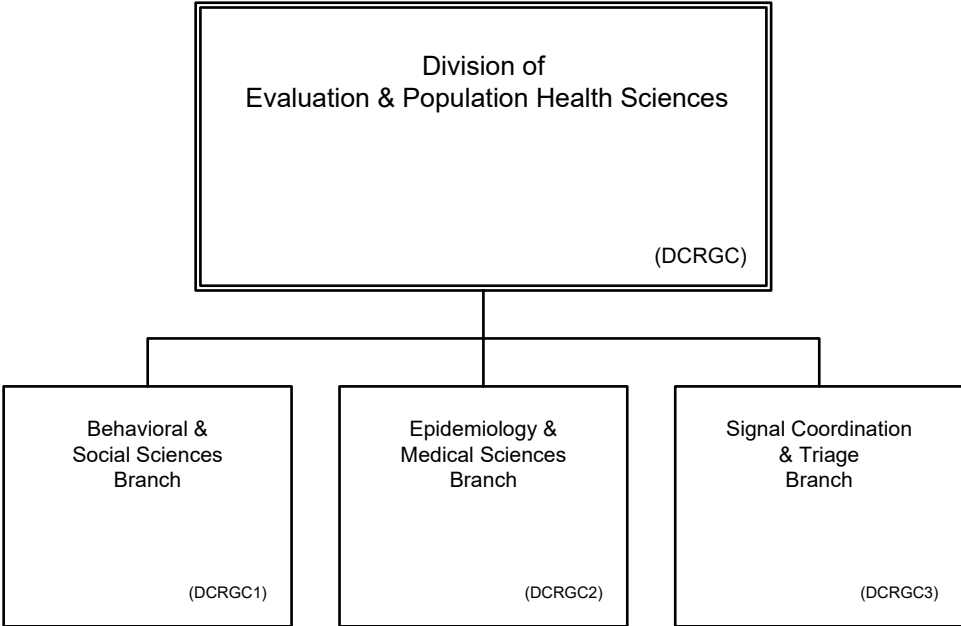
**4. Signal Coordination and Triage Branch (DCRGC3).**

- A. Develops and implements processes to manage signals detected from passive and active surveillance, such as triaging signals for further health and safety assessment and relaying information to risk managers for appropriate response activities.
- B. Ensures coordination and communication across the full array of passive and active surveillance activities.

**5. Authority and Effective Date.**

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

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

Behavioral and Social Sciences Branch (DCRGC1)

Epidemiology and Medical Sciences Branch (DCRGC2)

Signal Coordination and Triage Branch (DCRGC3)