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 Risk Assessment and Prioritization

Effective Date: May 13, 2024

1. **Division of Risk Assessment and Prioritization (DCRGB).**

    A. Leads and conducts highly technical and complex scientific risk studies, assessments, and reviews using internally developed and/or modernized methods, predictive tools and mathematical models, including exposure assessments.

    B. Leads the development of public health risk ranking and the initial application of prioritization criteria for the Human Foods Program (HFP), including the framework for ranking and prioritizing risks.

    C. Provides overall risk-informed framework to inform recommendations and decision-making and ensures application of the criteria and framework to decision-making on a regular basis; includes development of decision support tools and models to inform HFP priorities used for multi-year work planning, and other regulatory activities.

    D. For hazard characterization and evaluation, leads studies to evaluate potential for adverse health impacts, develop benchmarks for exposure, integrates hazard evaluations and exposure assessments to identify potential adulteration, and develops new methods to characterize the potential heath effect of emerging hazards and mixtures of hazards found in foods.

    E. For exposure assessments, leads and conducts population level exposures to hazards from the diet, including among subpopulations of interest and trends across time; develops new methods to characterize exposure to hazards in foods, including mixtures, including the use of data to characterize food intake by different sub-populations. Provides expert advice on the

collection, analysis and use of data relating to food supply, production, and consumption by United States (U.S.) populations.

2. **Hazard Characterization and Assessment Branch (DCRGB1).**

   A. Leads studies to evaluate potential for adverse health impacts, develop benchmarks for exposure, integrates hazard evaluations and exposure assessments to identify potential adulteration, and develops new methods to characterize the potential heath effect of emerging hazards and mixtures of hazards found in foods.

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

   C. Coordinates with risk managers and provides expertise to identify the need for response activities when detected hazards are determined to pose likely health concerns that would render a food adulterated.

   D. Collaborates with other HFP organizational units to facilitate collection and analysis of data and information needed to implement decision support tools that characterize risk associated with hazards in the food supply.

3. **Exposure Assessment Branch (DCRGB2).**

   A. Leads and conducts population-level exposure assessments to hazards from the diet, including among subpopulations of interest and trends across time. Includes providing expert advice on the collection, analysis and use of data relating to food supply, production, and consumption by U.S. populations.

   B. Develops new methods to characterize exposure to hazards in foods, including mixtures, including the use of data to characterize food intake by different sub-populations. Leads the integration of a variety of data sources to estimate intake data and information on the presence and prevalence of hazards in foods to estimate exposure to different subpopulations from specific foods and the total diet.

   C. Collaborates in the development of Human Health Assessments to identify adulterated food, requiring urgent regulatory actions, by providing estimates of potential exposure to US populations.
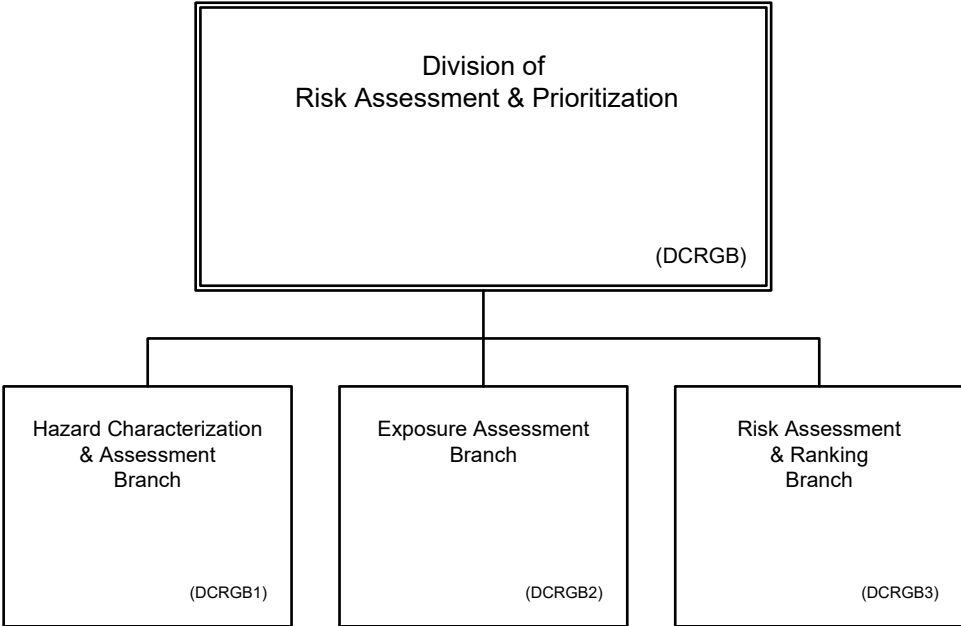
4. **Risk Assessment and Ranking Branch (DCRGB3).**

   A. Leads, develops, and utilizes new methods for innovative application to food safety problems including the development of mathematical models and application of advanced computational approaches, such as machine learning and artificial intelligence.

B. Leads, develops, and implements models and tools to assess the potential impact of new or existing risk management strategies on public health risk and for HFP priority goals.

C. Leads, in consultation with other HFP functions, the inventorying of hazards for subsequent risk ranking and prioritization recommendations to inform HFP strategic priorities and risk management strategies.

D. Provides frameworks for ranking risks to inform recommendations and decision-making and ensures application of the criteria and framework to decision-making on a regular basis; includes development of decision support tools and models to inform HFP priorities used for multi-year work planning, and other regulatory activities.

E. Leads the development of public health risk ranking and the initial application of prioritization criteria for the HFP, including the framework for ranking and prioritizing risks.

5. Authority and Effective Date.

The functional statements for the Division of Risk Assessment and Prioritization 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
Risk Assessment & Prioritization

(DCRGB)

Hazard Characterization
& Assessment
Branch

(DCRGB1)

Exposure Assessment
Branch

(DCRGB2)

Risk Assessment
& Ranking
Branch

(DCRGB3)

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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 Risk Assessment and Prioritization organization structure depicting all the organizational structures reporting to the Director:

Hazard Characterization and Assessment Branch (DCRGB1)

Exposure Assessment Branch (DCRGB2)

Risk Assessment and Ranking Branch (DCRGB3)