SMG 1232A.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Food Chemical Safety, Dietary Supplements, and Innovation

Effective Date: May 13, 2024

1. Office of Food Chemical Safety, Dietary Supplements, and Innovation (DCRK).

A. Serves as the Food and Drug Administration (FDA) lead for scientific, policy, risk management, and regulatory review of food chemical and dietary supplement programs. Including support for the development of FDA initiated regulations as well as stakeholder petitions and notices on matters pertaining to the provisions of the food additive, color additive sections, Generally Recognized As Safe (GRAS) substances, food contact substances, dietary supplements of the Federal Food, Drug, and Cosmetic (FD&C) Act including foods and food ingredients derived from innovative technologies.

B. Serves as the FDA lead for strategic management of the food chemical and dietary supplement program.

C. Provides expert advice and communication throughout the FDA, other Federal organizations, United States (U.S.), and foreign government officials, and external stakeholders including Congress, as well as industry, international and other organizations on food chemical and dietary supplement safety programs and policies.

D. Performs pre- and post-market assessments of food additives, color additives, GRAS ingredients, food contact substances, prior sanctioned substances, dietary supplement ingredients, and contaminants, including prioritizing, evaluating, and communicating findings. Evaluates risk assessments, adverse events, and other sources of signals related to the safety of food additives, color additives, dietary supplements, foods, and food ingredients derived through innovative technologies.

E. Develops position papers, procedural regulations, regulatory guidelines, supports compliance actions, and provides technical advice on issues related to the safe uses of food additives, food contact substances, color additives, GRAS substances, foods derived through innovative technologies, prior sanctioned substances, dietary supplements, and contaminants.

F. Provides relevant subject matter expertise to the FDA and contributes to the FDA's overall safety assessment of food ingredients, dietary supplement ingredients and contaminants. Consults with FDA laboratories regarding research relevant to the regulation of food additives, color additives, food ingredients, dietary supplements, and contaminants.

2. Operations Staff (DCRK1).

A. Manages the Office's administrative management activities, including strategic planning, resource planning, contracts, travel, budget execution, training, and correspondence.

3. Innovative Foods Staff (DCRK2).

A. Provides FDA guidance and coordinates the technical evaluation of regulatory and scientific issues regarding foods derived through innovative technologies including bioengineered plant and human food made with cultured animal cells. Determines when additional or different regulatory pathways are appropriate for products of such technologies.

B. Evaluates toxicological, nutritional, and microbiological data and information, and chemical data (including data on probable human exposure) submitted to the FDA through consultations or notices that pertain to the safety of foods and food ingredients derived through innovative technologies.

C. Consults with stakeholders prior to submission concerning the innovative technology/method of manufacture and uses for food and derived food ingredients and advises on content of submissions and approaches to meet statutory standards. Advises of any inadequacies that may preclude requested action for submissions reviewed by this division.

D. Drafts, finalizes, and amends regulations, guidance, and similar documents related to the relevant provisions of the FD&C Act and provide expertise on to other HFP components for submissions and other documents.

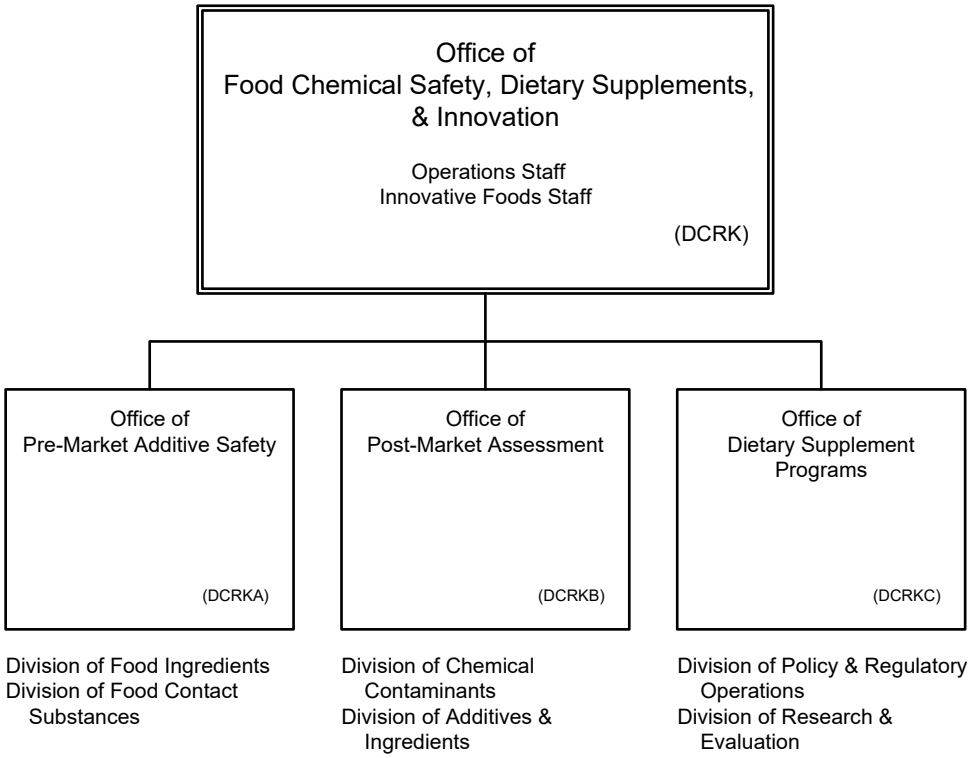
E. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with innovative foods.

F. Develops and maintains information for assessment and monitoring of foods and derived substances. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

4. Authority and Effective Date.

The functional statements for the Office of Food Chemical Safety, Dietary Supplements, and Innovation 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
Human Foods Program
Office of Food Chemical Safety, Dietary Supplements, and Innovation



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Food Chemical Safety, Dietary Supplements, and Innovation organization structure depicting all the organizational structures reporting to the Director:

Operations Staff (DCRK1)

Innovative Foods Staff (DCRK2)

Office of Pre-Market Additive Safety (DCRKA)

Office of Post-Market Assessment (DCRKB)

Office of Dietary Supplement Programs (DCRKC)

These organizations report to the Office of Pre-Market Additive Safety (DCRKA):

Division of Food Ingredients (DCRKAA)

Division of Food Contact Substances (DCRKAB)

These organizations report to the Office of Post-Market Assessment (DCRKB):

Division of Chemical Contaminants (DCRKBA)

Division of Additives and Ingredients (DCRKBB)

These organizations report to the Office of Dietary Supplement Programs (DCRKC):

Division of Policy and Regulatory Operations (DCRKCA)

Division of Research and Evaluation (DCRKCB)