

**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**

**Office of Pre-Market Additive Safety**

**Division of Food Contact Substances**

Effective Date: May 13, 2024

**1. Division of Food Contact Substances (DCRKAB).**

- A. Provides Food and Drug Administration (FDA) guidance and coordinates the technical evaluation of regulatory and scientific issues regarding food contact substances, including industry actions.
- B. Evaluates toxicological data and information, and chemical data and information (including data on probable human exposure), submitted to the FDA by notifiers, petitioners, or from other sources, that pertain to the safety of food contact substances.
- C. Consults with prospective notifiers and petitioners prior to submission concerning proposed new uses of food contact substances, advising on notification or petition content and approaches to meet statutory standards. Advises notifiers, petitioners, and other interested parties of any inadequacies that may preclude requested action on submissions reviewed by this Division.
- D. Develops procedural regulations and guidelines to implement the provisions of food contact substance sections of the Federal Food, Drug, and Cosmetic (FD&C) Act.
- E. Develops current policies, compliance efforts, and research dealing with food contact substance issues.
- F. Develops and maintains information for assessment and monitoring the safety of food contact substances. Responds to stakeholder inquiries and Freedom of Information requests in a timely and efficient manner.

**2. Toxicology Review Branch (DCRKAB1).**

- A. Evaluates toxicological data and information (including data on probable human exposure), submitted to the FDA by notifiers or from other sources that pertain to the safety of food contact substances.
- B. Consults with prospective notifiers prior to submission concerning proposed new uses of food contact substances, advising on notification content and approaches to meet statutory standards. Advises notifiers and other interested parties of any inadequacies that may preclude requested action on submissions reviewed by this Division.

**3. Chemistry Review Branch (DCRKAB2).**

- A. Evaluates chemistry data and information (including probable human exposure estimates), submitted to the FDA by notifiers or from other sources that pertain to the safety of food contact substances.
- B. Consults with prospective notifiers prior to submission concerning proposed new uses of food contact substances, advising on notification content and approaches to meet statutory standards. Advises notifiers and other interested parties of any inadequacies that may preclude requested action on submissions reviewed by this Division.

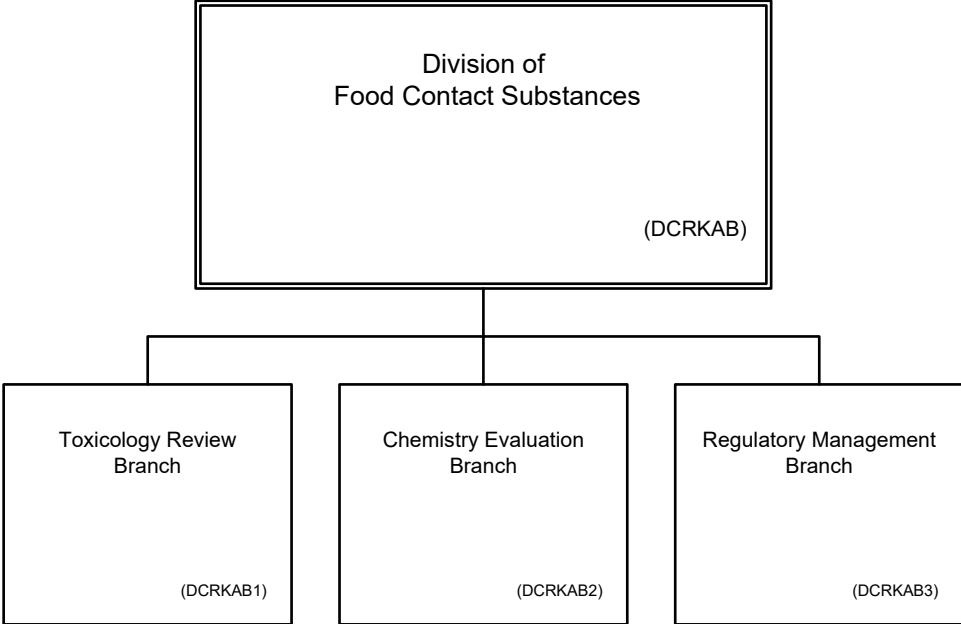
**4. Regulatory Management Branch (DCRKAB3).**

- A. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding food contact substances, including industry actions.
- B. Consults with prospective notifiers and petitioners prior to submission concerning proposed new uses of food contact substances, advising on notification or petition content and approaches to meet statutory standards. Advises notifiers, petitioners, and other interested parties of any inadequacies that may preclude requested action on submissions reviewed by this Division.
- C. Writes and amends, as needed, procedural regulations and guidelines to implement the provisions of food contact substance sections of the FD&C Act.
- D. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with food contact substance issues. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

**5. Authority and Effective Date.**

The functional statements for the Division of Food Contact Substances 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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**Office of Food Chemical Safety, Dietary Supplements, and Innovation**  
**Office of Pre-Market Additive Safety**  
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Effective Date: May 13, 2024

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, Office of Pre-Market Additive Safety, Division of Food Contact Substances organization structure depicting all the organizational structures reporting to the Director:

Toxicology Review Branch (DCRKAB1)

Chemistry Evaluation Branch (DCRKAB2)

Regulatory Management Branch (DCRKAB3)