

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Laboratory Operations and Applied Science

Office of Chemistry and Toxicology

Division of Toxicology

Effective Date: May 13, 2024

1. Division of Toxicology (DCRMCC).

- A. Provides leadership in the areas of new approach methods (NAMS) through the evaluation, development and implementation of NAMS related to Human Foods Program (HFP) activities for cardiotoxicity, developmental neurotoxicology, hepatotoxicity, renal toxicity, and developmental/reproductive toxicology.
- B. Evaluates methodology, conducts research in collaboration with Office of the Chief Scientist and other Food and Drug Administration components and priorities to assess the toxic effects of substances for HFP regulatory responsibilities and investigates mechanisms and toxicogenomics utilizing predictive in vitro cellular models to characterize toxicological effects on cells.
- C. Collaborates with and provides support to external programs in designing appropriate experiments, which assess the toxic effects of substances for which the HFP has regulatory responsibilities.
- D. Develops and/or evaluates systems that may serve to refine, reduce or replace animal models.
- E. Conducts toxicological studies which support the HFP's regulatory responsibilities, including assessing and collecting data applicable to guideline development, the evaluation of petitions and proposals, the review of current tolerances, providing recommendations on toxicological product evaluation criteria, the review of protocols relating to the review and approval process of new substances and for the reaffirmation of marketed substances.

F. Responds to emergencies involving food-related illnesses where potential toxicity has occurred.

2. Predictive Toxicology Branch (DCRMCC1).

A. Develops in vitro screening tools for developmental neurotoxicity (DNT) and cognitive impairments.

B. Serves as leaders in DNT research.

C. Establishes strategic partnerships with external stakeholders.

D. Provides scientific and technical expertise on developmental neurotoxicology to HFP management.

E. Develops in-vitro approaches kidney and liver toxicity.

3. Systems Toxicology Branch (DCRMCC2).

A. Develops and expands a predictive toxicology and concordance program using alternative models.

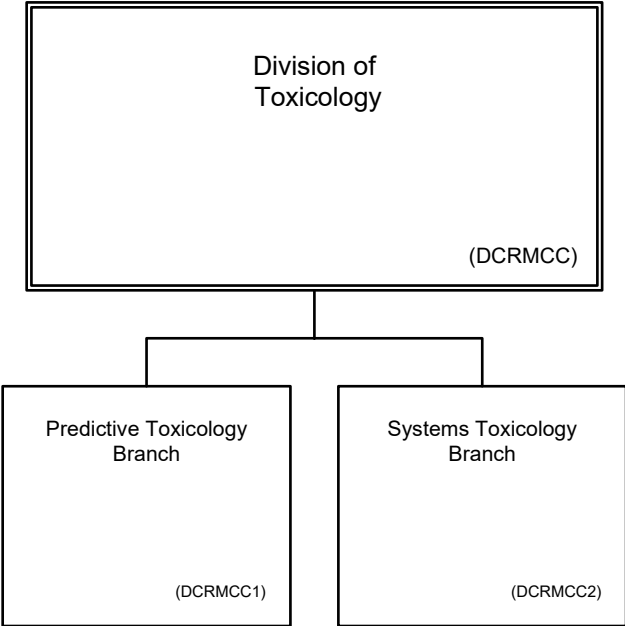
B. Evaluates new alternative animal models for integration and application of modern toxicological approaches to support regulatory and public health decision-making on chemical hazards in foods, dietary supplements, and food additives.

C. Provides more relevant and predictive in vivo and in vitro data for human safety assessment of chemicals of agency interest.

4. Authority and Effective Date.

The functional statements for the Division of Toxicology 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 Laboratory Operations and Applied Science
Office of Chemistry and Toxicology
Division of Toxicology**



Staff Manual Guide 1232A.433

Organizations and Functions

Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Chemistry and Toxicology, Division of Toxicology organization structure depicting all the organizational structures reporting to the Director:

Predictive Toxicology Branch (DCRMCC1)

Systems Toxicology Branch (DCRMCC2)