SMG 1231.163

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Food Additive Safety

Division of Science and Technology

Effective Date: December 14, 2018

1. Division of Science and Technology (DCEGC).

A. Provides scientific expertise, guidance, direction, planning, and management of post-market activities for the Office.

B. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding bioengineered food, including industry actions.

C. Develops guidelines for and monitors newly developed techniques pertaining to the safety assessment of food additives, Generally Recognized As Safe (GRAS) substances, and bioengineered food.

D. Consults with prospective notifiers prior to submission, concerning proposed uses of bioengineered food, advising on content of submissions and approaches to meet statutory standards. Advises notifiers, and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division.

E. Writes and amends, as needed, procedural regulations and guidelines to implement relevant provisions of the Federal Food, Drug, and Cosmetic Act.

F. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with bioengineered food matters.

G. Develops and maintains information for assessment and monitoring of bioengineered food. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

H. Develops and maintains a prioritization scheme to identify and take action to resolve safety concerns associated with marketed substances that are added to food or used in contact with food.

I. Designs and operates post-market monitoring and surveillance programs to identify signals and trends relevant to the safety of marketed substances that are added to food or used in contact with food.

J. Develops and maintains informatics systems to advance the capacity, efficiency, and performance of the premarket and post-market programs. Leverages information from available sources within and outside of the Food and Drug Administration (FDA) (e.g., Environmental Protection Agency (EPA), European Food Safety Authority (EFSA), National Institutes of Health (NIH)) to ensure that all relevant data are reviewed.

K. Reviews environmental data to ensure the environmental safety of substances added to food or used in contact with food and ensures Center and Office compliance with National Environmental Policy Act (NEPA) obligations.

L. Supports FDA enforcement activities regarding food ingredients and food contact substances.

2. Regulatory Review Branch (DCEGC1)

A. Develop and maintain a prioritized list of food additives, color additives, food ingredients, and food contact materials for postmarket safety review.

B. Conduct post-market safety review of food additives, color additives, food ingredients, and food contact materials.

C. Propose and carry out regulatory actions to consolidate and streamline regulations under the purview of the Office.

D. Evaluate current chemical and toxicological science for possible incorporation into premarket safety review paradigms.

E. Ensure that obligations and responsibilities of the Office and Center for Food Safety and Applied Nutrition (CFSAN) pertaining to the NEPA are carried out efficiently and effectively. Provide environmental review support to CFSAN and FDA as needed.

3. Scientific Development Branch (DCEGC2)

A. Develop, operate, and maintain informatics systems to support the Office. Maximize interoperability of Food Additive Safety (FAS) informatics systems with CFSAN and FDA systems.

B. Develop and maintain data entry systems for FAS informatics systems that facilitate automated data entry activities.

C. Maintain cognizance over chemical structure-activity research, incorporating as necessary in FAS review paradigms to maximize review efficiency.

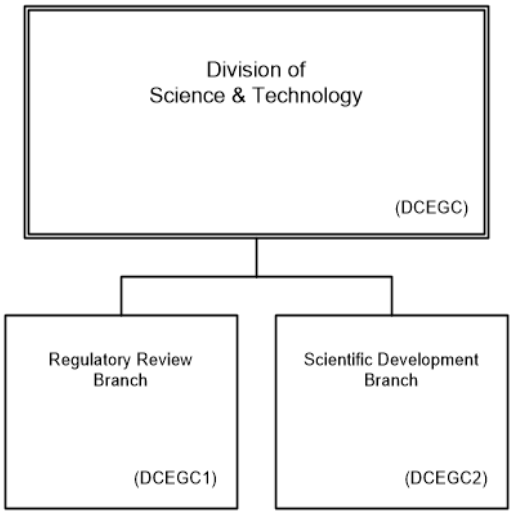
D. Maintain oversight of ongoing dietary sodium reduction activities in the diet.

E. Operate and develop the FAS bioinformatics and chemoinformatics resources on food chemicals.

4. Authority and Effective Date.

The functional statements for the Division of Science and Technology were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Science and Technology



Staff Manual Guide 1231.163
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, Division of Science and Technology organization structure depicting all the organizational structures in the immediate office reporting to the Director.

These branches report to the Division of Science and Technology (DCEGC)

- Regulatory Review Branch
- Scientific Development Branch

Back to Organizations and Functions, Volume I (1000-1300)