

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Microbiological Food Safety

Office of Dairy and Seafood Safety

Division of Seafood Safety

Effective Date: May 13, 2024

1. Division of Seafood Safety (DCROAB).

- A. Provides leadership for development and interpretation of Food and Drug Administration (FDA) regulations, guidance, policy, and programs related to the safety, risk-management, composition and quality of seafood and seafood products.
- B. Advises leadership of novel and emerging food safety challenges and trends and positions the FDA to adopt a preventive stance in ensuring the safety of seafood and seafood products.
- C. Advocates for the adoption, implementation and enforcement of Human Foods Program (HFP) regulatory standards and ordinances related to seafood and seafood products.
- D. Develops and manages seafood and seafood product safety programs designed to manage risks, improve public health, reduce seafood related illness and increase compliance by the industry.
- E. Trains, standardizes, and certifies state regulatory personnel to promote uniformity of inspection and rating activities.

2. Shellfish and Aquaculture Policy Branch (DCROAB1).

- A. Develops regulations, guidance, policy, programs, position papers and advisory opinions, and recommends research priorities for issues related to the safety of seafood and especially those related to shellfish and aquaculture.

- B. Facilitates and examines the implementation of regulations, domestic and foreign programs, and bilateral agreements related to shellfish and aquaculture.
- C. Provides expert review and comment on industry petitions and regulatory activities pertaining to shellfish and aquaculture. Reviews information about proposed shellfish and aquaculture enforcement actions that is provided by the Office of Compliance, to determine if those actions within the Branch's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Branch can provide expert scientific testimony to support the actions. Provides technical review of laboratory analyses supporting proposed enforcement actions.
- D. Provides expert advice to key FDA and government officials, and serves as principal liaison to industry, international, and other organizations on issues related to shellfish, aquaculture, and the Codex Committee on Fish and Fishery Products.
- E. Develops model regulations, and provides scientific/technical support, training, evaluation and certification for State and international shellfish and aquaculture programs.

3. Seafood Processing and Technology Policy Branch (DCROAB2).

- A. Reviews data and information from a variety of sources to develop regulations and guidance and to direct and shape policy and advisory opinions and recommends subsequent research priorities for issues related to safety of seafood.
- B. Facilitates and examines the implementation of the Seafood hazard analysis and critical control points (HACCP) regulations through the foreign and domestic inspectional compliance programs and executes the provisions of established memorandum of understandings (MOU).
- C. Provides expert review and comment on industry petitions and regulatory activities pertaining to seafood; reviews information about proposed general seafood enforcement actions provided by the Office of Compliance to determine if those actions within the Branch's purview are supported by relevant science and established program priorities, policy, and guidance.
- D. Determines where explicit policy or guidance does not exist, whether the Branch can provide expert scientific testimony to support proposed enforcement actions. Provides technical review of laboratory analyses supporting proposed enforcement actions.
- E. Provides expert advice to the Office Director, Deputy Office Director, Division Director and other key FDA and government officials, and serves as principal

HFP liaison to industry, international, and other organizations on issues related to overall seafood safety in accordance with the Seafood HACCP regulations.

4. Shellfish Operations Branch 1 (DCROAB3).

- A. Develops and maintains cooperative relationships with State, international, and other Federal agencies; encourages improved State and local consumer protection programs related to FDA-enforced laws and regulations.
- B. Serves as the primary point of contact for state officials concerning the shellfish sanitation program.
- C. Advises the Seafood Program Director on new or emerging problems and trends, future program needs and priorities; State legislative activities; manpower, equipment, funding needs, and long-range planning.
- D. Provides training, guidance and technical assistance to state, tribal and territorial regulatory personnel.
- E. Promotes the adoption, implementation and enforcement of regulatory standards and ordinances.
- F. Participates in emergency preparedness and response activities associated with national security events, natural and man-made disasters, and illness outbreaks/injuries.
- G. Evaluates state shellfish sanitation programs.
- H. Promotes the effectiveness of shellfish sanitation programs through participation in meetings, seminars, conferences, and committees.
- I. Conducts assessments in conjunction with FDA's international programs and the HFP to evaluate international comparability or equivalency.
- J. Participate within the ISSC where model ordinances, scientific issues and standards are deliberated.

5. Shellfish Operations Branch 2 (DCROAB4).

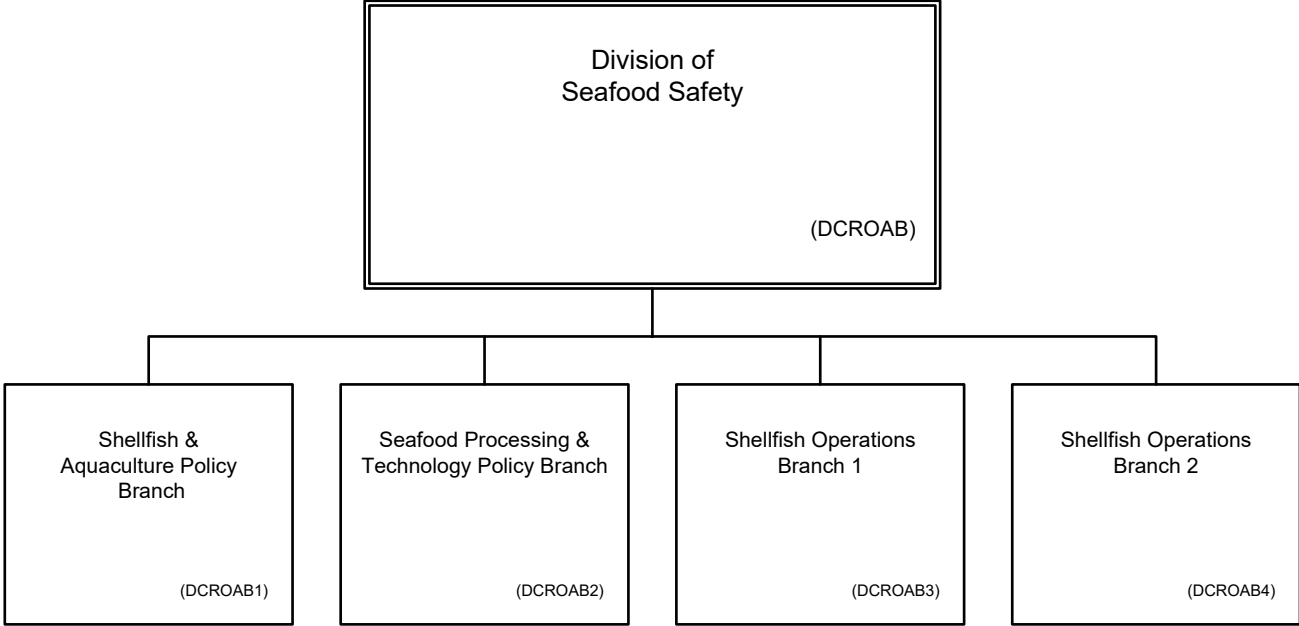
- A. Develops and maintains cooperative relationships with State, international, and other Federal agencies; encourages improved State and local consumer protection programs related to FDA-enforced laws and regulations.
- B. Serves as the primary point of contact for state officials concerning the shellfish sanitation program.

- C. Advises the Seafood Program Director on new or emerging problems and trends, future program needs and priorities; State legislative activities; manpower, equipment, funding needs, and long-range planning.
- D. Provides training, guidance and technical assistance to state, tribal and territorial regulatory personnel.
- E. Promotes the adoption, implementation and enforcement of regulatory standards and ordinances.
- F. Participates in emergency preparedness and response activities associated with national security events, natural and man-made disasters, and illness outbreaks/injuries.
- G. Evaluates state shellfish sanitation programs.
- H. Promotes the effectiveness of shellfish sanitation programs through participation in meetings, seminars, conferences, and committees.
- I. Conducts assessments in conjunction with the FDA's international programs and the HFP to evaluate international comparability or equivalency.
- J. Participate within the ISSC where model ordinances, scientific issues and standards are deliberated.

6. Authority and Effective Date.

The functional statements for the Division of Seafood Safety 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 Microbiological Food Safety
Office of Dairy and Seafood Safety
Division of Seafood Safety**



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Organizations and Functions

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Microbiological Food Safety, Office of Dairy and Seafood Safety, Division of Seafood Safety organization structure depicting all the organizational structures reporting to the Director:

Shellfish and Aquaculture Policy Branch (DCROAB1)

Seafood Processing and Technology Policy Branch (DCROAB2)

Shellfish Operations Branch 1 (DCROAB3)

Shellfish Operations Branch 2 (DCROAB4)