#### SMG 1121.843

# FDA Staff Manual Guides, Volume I – Organizations and Functions

#### **Department of Health and Human Services**

**Food and Drug Administration** 

Office of Regulatory Affairs

Office of Human and Animal Food Operations

Office of State Cooperative Programs

Division of Shellfish Sanitation

Effective Date: December 14, 2018

### 1. Division of Shellfish Sanitation (DCIEAC).

- A. Develops and maintains cooperative relationships with State, international, and other Federal agencies; encourages improved State and local consumer protection programs related to Food and Drug Administration (FDA)-enforced laws and regulations.
- B. Serves as the primary point of contact for state officials concerning the shellfish sanitation program.
- C. Advises the State Cooperative 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. Coordinates Federal interagency matters concerning shellfish sanitation.

- I. Promotes the effectiveness of shellfish sanitation programs through participation in meetings, seminars, conferences, and committees.
- J. Conducts assessments in conjunction with FDA's International Programs and the Center for Food Safety and Applied Nutrition (CFSAN) to evaluate international comparability or equivalency.
- K. Represents the Office of Regulatory Affairs (ORA) with the Interstate Shellfish Shippers Conference (ISSC) where model ordinances, scientific issues and standards are deliberated.

#### 2. Shellfish Sanitation Branch 1 (DCIEAC1)

- 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 State Cooperative 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. Coordinates Federal interagency matters concerning shellfish sanitation.
- I. Promotes the effectiveness of shellfish sanitation programs through participation in meetings, seminars, conferences, and committees.
- J. Conducts assessments in conjunction with FDA's International Programs and the CFSAN to evaluate international comparability or equivalency.

K. Represents the ORA with the ISSC where model ordinances, scientific issues and standards are deliberated.

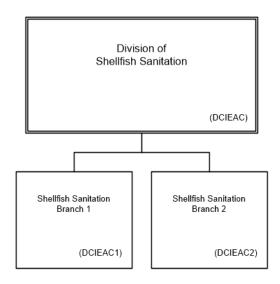
## 3. Shellfish Sanitation Branch 2 (DCIEAC2)

- 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 State Cooperative 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. Coordinates Federal interagency matters concerning shellfish sanitation.
- I. Promotes the effectiveness of shellfish sanitation programs through participation in meetings, seminars, conferences, and committees.
- J. Conducts assessments in conjunction with FDA's International Programs and the CFSAN to evaluate international comparability or equivalency.
- K. Represents the ORA with the ISSC where model ordinances, scientific issues and standards are deliberated.

### 4. Authority and Effective Date.

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

Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Human and Animal Food Operations, Office of State Cooperative Programs, Division of Shellfish Sanitation organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Shellfish Sanitation (DCIEAC):

Shellfish Sanitation Branch 1 (DCIEAC1)

Shellfish Sanitation Branch 2 (DCIEAC2)