

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 Import Operations

Division of Import Operations

Effective Date: February 9, 2022

1. Division of Import Operations (DCIIC).

- A. Serves as the liaison between law enforcement agencies and Food and Drug Administration (FDA) officials regarding intelligence involving food products, including animal feed, which will be imported or offered for import into the United States.
- B. Receives and reviews prior notice and intelligence data on food products, including animal feed, which will be imported or offered for import into the U.S. and directs the field and/or the U.S. Customs and Border Protection (CBP) on the appropriate action to take.
- C. Serves as the liaison with CBP, in the field, providing technical expertise in the inspection, examination and sampling of imported food products, including animal feed, that are held at the ports.
- D. Develops, and reviews guidance documents and recommends policies and procedures regarding the receipt, review, and response to Prior Notice submissions to assure compliance with the Prior Notice regulation and the Federal Food Drug and Cosmetic Act.
- E. Recommends compliance actions based on violations of the Prior Notice regulation.
- F. Serves as a liaison, in conjunction with the Director of the Office of Import Operations, to manage and coordinate the acquisition of equipment needed by CBP to inspect, examine, and sample imported food and animal feed products.

2. Import Operations Branch (DCIIC1).

- A. Provides advice and direction on field import operations, including investigational and sampling activities, in coordination with the ORA program directors.
- B. Supports the development of policies relative to import activities.
- C. Coordinates activities with other Federal agencies and foreign governments through established interagency agreements, memoranda of understanding, and informal working relationships.
- D. Develops and/or reviews FDA import procedures, programs, and assignments, including the development and issuance of operations-related import informational directives in coordination with the Program Directors.
- E. Coordinates FDA import activities with the Customs and Border Protection (CBP), including the development and institution of joint procedures and operations.

3. Import Compliance Branch (DCIIC2).

- A. Provides advice and direction to ORA's field import operations, including compliance and enforcement activities.
- B. Oversees the FDA import filer evaluation program, and associated filer enforcement activities when warranted.
- C. Develops and/or reviews FDA import procedures, programs, and assignments, including the responsibility for the development and issuance of compliance related import informational directives in coordination with the Program Directors.

4. Authority and Effective Date.

The functional statements for the Division of Import Operations were approved by the Deputy Secretary for Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
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Division of
Import Operations

(DCIC)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Import Operations, Division of Food Defense Targeting organization structure depicting all the organizational structures reporting to the Director:

Division of Food Defense Targeting (DCIIE)