SMG 1231A.923

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Compliance and Enforcement

Office of Enforcement

Division of Produce and Imports Enforcement

Effective Date: May 13, 2024

1. Division of Produce and Imports Enforcement (DCRIBC).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges in product.

B. Leads the development of enforcement strategies related to produce products including those for novel, complex, and precedent-setting regulatory problems.

C. Manages engagement between Human Foods Program (HFP) Subject Matter Experts, Food and Drug Administration's (FDA) Field Investigations and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution related to produce.

D. Evaluates firm responses to FDA action and proposed corrective measures related to produce products for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a warning letter closeout, is warranted.

E. Collaborates with FDA Centers and Offices, other Agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions related to produce.

F. Reviews and evaluates foreign and domestic Establishment Inspection Reports (EIRs), inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable regulatory strategy for produce.

G. Establishes final classification for Official Action Indicated (OAI) and select Voluntary Action Indicated (VAI) and/or No Action Indicated (NAI) inspections for produce as agreed upon with FDA's inspections and investigations program.

H. Leads development of produce compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

I. Issues untitled letters, warning letters and other types of compliance and enforcement correspondence to regulated industry related to produce.

J. Leads Regulatory Meetings related to produce with regulated industry.

K. Identifies need and scope for compliance follow up inspection assignments related to produce.

L. Liaises with stakeholders, including the United States (U.S.) Marshalls, FDA's legal counsel, inspections and investigations program, Criminal Investigations, state, and local government, as necessary, to develop and execute enforcement actions related to produce.

M. Provides post-action oversight and monitoring related to matters involving produce by ensuring court-ordered actions and actions required after administrative action are completed.

N. Reviews produce EIRs and develops import detention/refusal and Detention Without Physical Examination (DWPE) letter/Warning Letter (WL) cases based on foreign inspections.

O. Reviews import detention/refusal and DWPE cases (where Direct Reference Authority (DRA) is not authorized). Develops and amends Import Alerts.

P. Serves as liaison for FDA's imports staff and other regulatory partners to consult and assist with imports related compliance and enforcement matters, including serving as the liaison for FDA's imports compliance staff to other HFP components.

Q. Evaluates import case recommendations (e.g., Foreign Supplier Verification Programs (FSVP), Import Alert, admissibility in non-DRA areas) from FDA's imports compliance staff.

2. Imports Enforcement Branch (DCRIBC1).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges related to imported HFP regulated products.

B. Leads the development of enforcement strategies including those for novel, complex, and precedent-setting regulatory problems.

C. Manages engagement between HFP Subject Matter Experts, FDA Field Investigations, FDA inspections and investigations program's Office of Import Operations and other federal agencies and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution.

D. Evaluates firm responses to FDA action and proposed corrective measures for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a FSVP warning letter closeout, is warranted.

E. Collaborates with FDA Centers, other Agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions.

F. Reviews and evaluates FSVP EIRs, inspectional evidence to assess compliance with applicable laws and regulations and determines the most suitable and regulatory strategy.

G. Reviews and evaluates imported product analytical evidence to assess compliance with applicable laws and regulations and determines the most suitable and regulatory strategy.

H. Determines final classification for OAI and VAI inspections, other workload arrangements may be made for VAI inspections by agreement with FDA's inspections and investigations program.

I. Leads development of import related compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

J. Supports detention/refusal cases and issues Warning Letters and other types of compliance and enforcement correspondence to regulated industry.

K. Participates and supports Regulatory Meetings with industry, typically coordinated and led by FDA's inspections and investigations program imports staff.

L. Identifies need and scope for compliance follow up inspection assignments.

M. Liaises with stakeholders, including the US Marshalls, Office of Chief Counsel (OCC), FDA's inspections and investigations program, Office of Criminal Investigations (OCI), state and local officials, as necessary, to develop and execute enforcement actions.

N. Reviews EIRs and develops import detention/refusal and DWPE/WL cases.

O. Reviews import detention/refusal and DWPE cases (where DRA is not available). Develops and amends Import Alerts.

P. Serves as liaison with FDA's inspections and investigations program Imports staff and other regulatory partners to consult and assist with imports related compliance and enforcement matters.

3. Produce Enforcement Branch (DCRIBC2).

A. Implements compliance and enforcement strategies to address regulatory issues or compliance challenges related to produce.

B. Leads the development of enforcement strategies including those for novel, complex, and precedent-setting regulatory problems.

C. Manages engagement between HFP Subject Matter Experts, FDA Field Investigations, the Center for Food Safety and Applied Nutrition (CFSAN) and FDA Produce Safety Network and other federal agencies and state regulatory partners to assist with compliance assessment, efficient evidence collection, and enforcement action execution.

D. Evaluates firm responses to FDA action and proposed corrective measures for adequacy and determines if any additional follow-up actions are necessary or case closeout, such as a warning letter closeout, is warranted.

E. Collaborates with FDA Centers, other Agencies, and other relevant stakeholders concerning multijurisdictional products and/or cross-cutting regulatory or enforcement actions.

F. Reviews and evaluates foreign and domestic EIRs, inspectional evidence and associated analytical findings to assess compliance with applicable laws and regulations and determines the most suitable and regulatory strategy.

G. Determines final classification for OAI and VAI inspections, other workload arrangements may be made for VAI inspections by agreement with FDA’s inspections and investigations program.

H. Leads development of produce related compliance and enforcement cases and manages the development of scientifically and legally supportable advisory, administrative and judicial actions.

I. Issues Untitled Letters, Warning Letters and other types of compliance and enforcement correspondence to regulated industry.

J. Coordinates and leads Regulatory Meetings with regulated industry.

K. Identifies need and scope for compliance follow up inspection assignments.

L. Liaises with stakeholders, including the US Marshalls, OCC, FDA's inspections and investigations program, OCI, state and local officials, as necessary, to develop and execute enforcement actions.

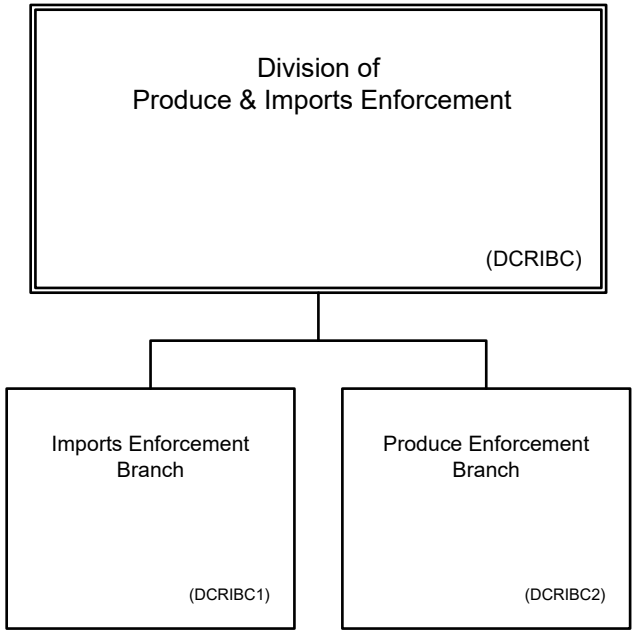
M. Provides post-action oversight and monitoring of required activities for court-ordered judicial actions and administrative actions.

N. Reviews EIRs and develops import detention/refusal and DWPE/WL cases based on foreign inspections.

4. Authority and Effective Date.

The functional statements for the Division of Produce and Imports Enforcement 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 Compliance and Enforcement
Office of Enforcement
Division of Produce and Imports Enforcement



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Compliance and Enforcement, Office of Enforcement, Division of Produce and Imports Enforcement organization structure depicting all the organizational structures reporting to the Director:

Imports Enforcement Branch (DCRIBC1)

Produce Enforcement Branch (DCRIBC2)