U.S. Food and Drug Administration (FDA)
Imports Structure Session
FSVP, VQIP, ITACS

Ruth P. Dixon
District Director, New Orleans District
Program Division Director, Division of Southeast Imports
FDA Office of Regulatory Affairs
Office of Enforcement and Import Operations
November, 2020

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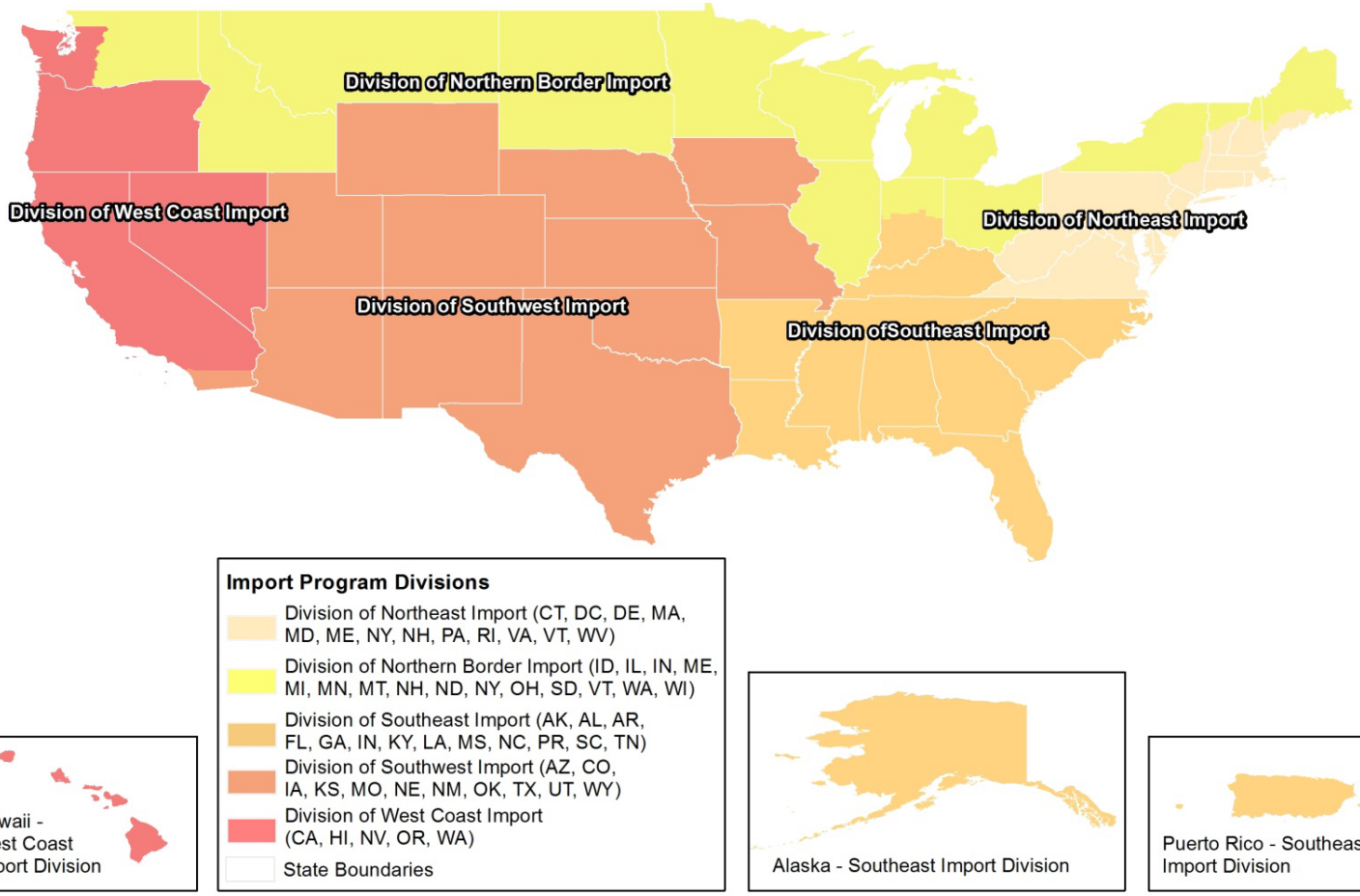
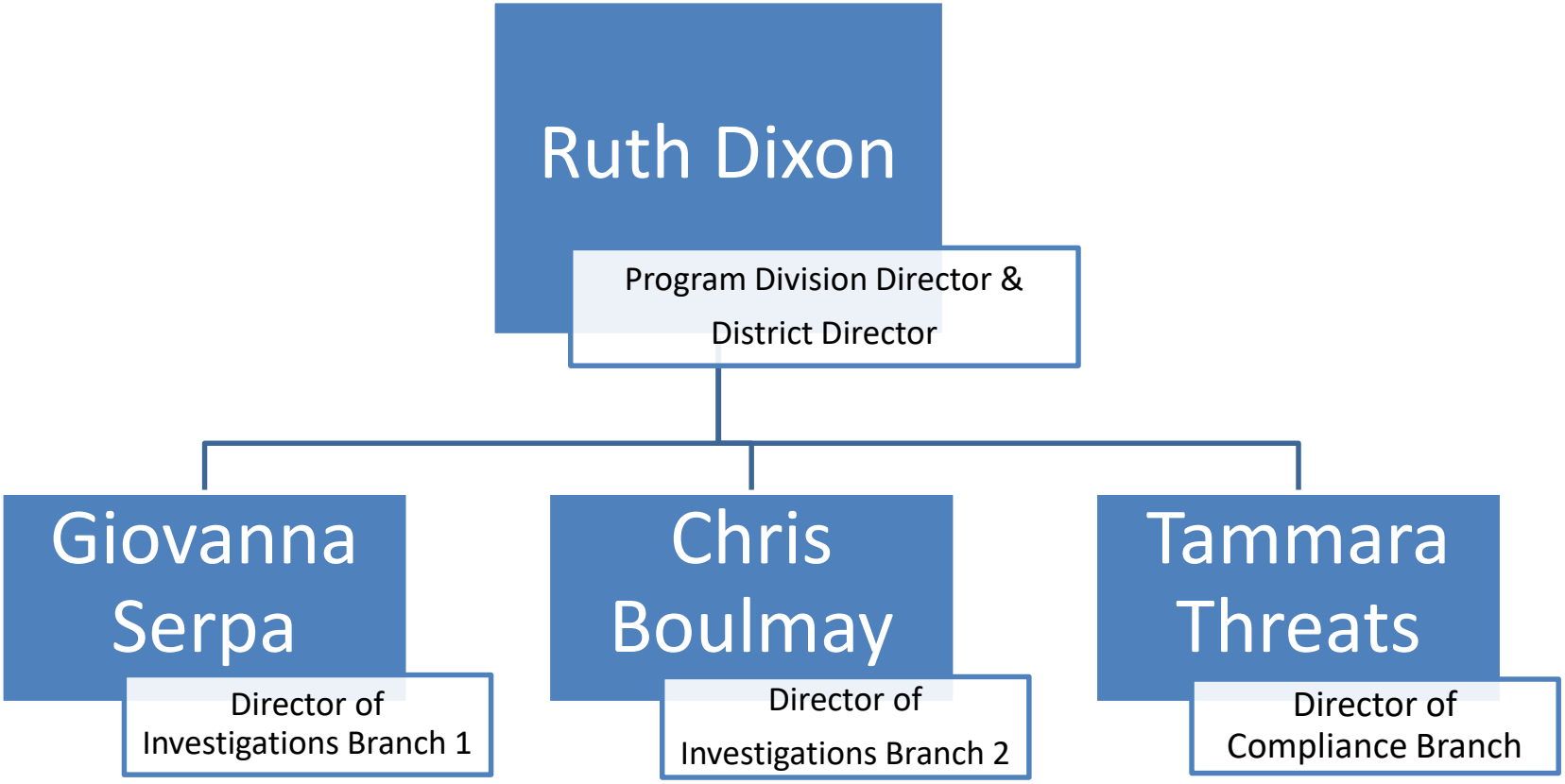
FDA Imports Structure

Office of Enforcement and Import Operations (OEIO)



Division of Southeast Imports Management Team

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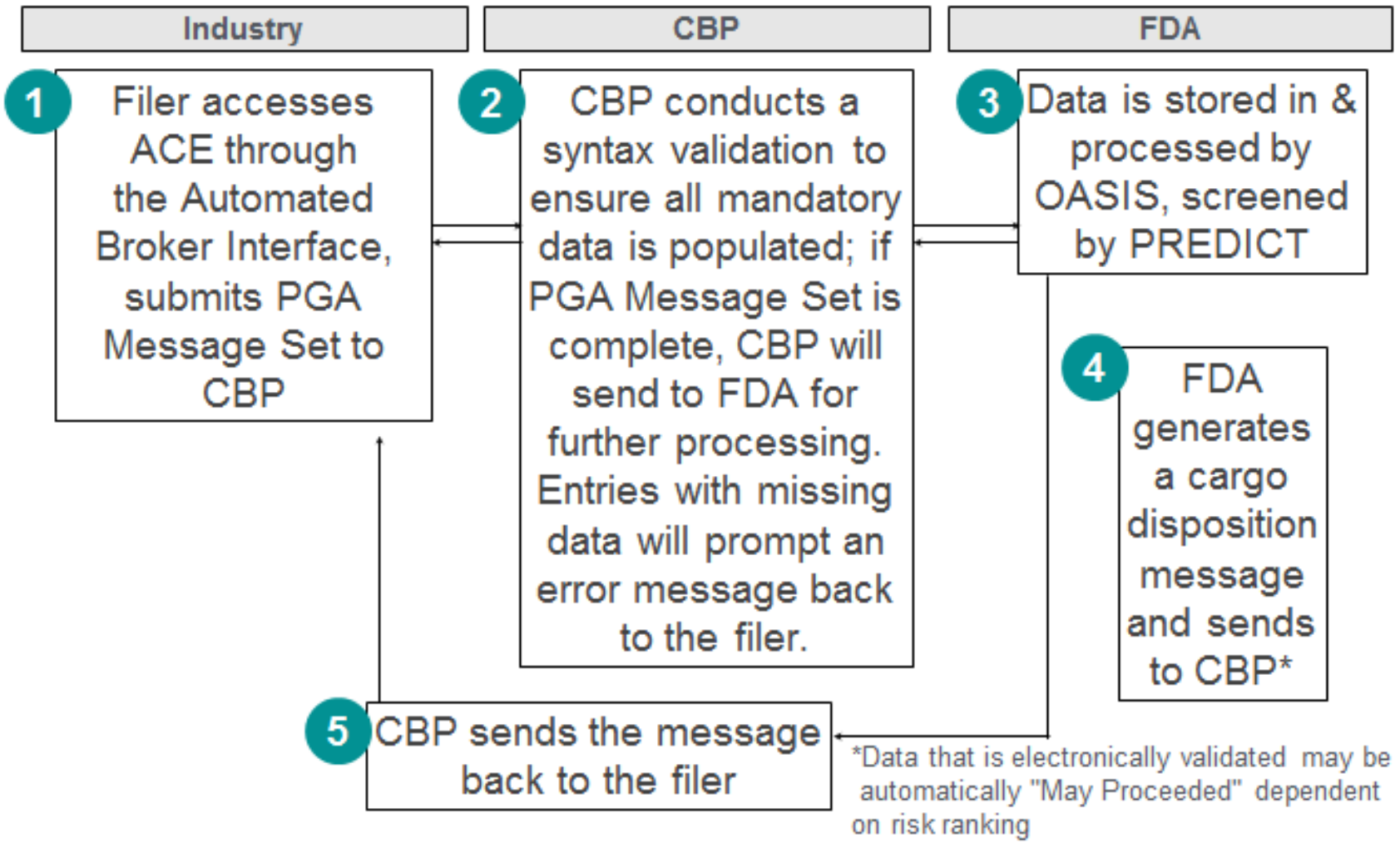
FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)
FDA is working with U.S. Government partners, including CDC, and international partners to address the pandemic.

FDA ACE Process



FDA Import Trade Auxiliary Communication System (ITACS)

- ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at https://www.access.fda.gov/oaa
- Instructions included within the ITACS Account Management Presentation at https://www.fda.gov/industry/import-systems/itacs to request an account.
- ITACS basic functionality can be accessed at https://itacs.fda.gov.

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Foreign Supplier Verification Programs (FSVP)

FDA Authority

- The Foreign Supplier Verification Programs (FSVP) regulation is mandated by the FDA Food Safety Modernization Act (FSMA)
- FDA's inspectional authority for FSVP comes from section 805 of the FD&C Act (21 U.S.C. § 384a)
- Foreign Supplier Verification Programs (FSVP)
  - 21 C.F.R. §§ 1.500-1.514

Purpose of FSVP

- To provide adequate assurances that:
  - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
  - Food is not adulterated or misbranded (as it relates to allergen labeling)
- FSVP creates a level of parity between U.S. food producers and foreign food producers

Standard FSVP requirements

- Develop FSVP
- Use of a qualified individual/auditor
- Conduct Hazard Analysis
- Evaluate Risks Posed by a Food and Performance of the Foreign Supplier for Approval
- Foreign Supplier Verification Activities
- Corrective Actions
- Identification of importer at the time of entry
- Maintenance of Record

Modified Requirements

- Depending on circumstance, certain importers must or may choose to comply with the modified FSVP requirements

- Requirements are modified for specific foods or specific importers; only certain activities must be conducted

- Applies to sections 1.507, 1.511, 1.512, and 1.513

FSVP Implementation

- The Agency will take enforcement action to protect the public health or to address egregious, continued non-compliance
- FSVP inspections began in 2017
- “Educate while we regulate” approach will continue, but enforcement action has been taken
- Additional enforcement steps to ensure compliance include re-inspections and immediate action for deficiencies posing public health risk

FSVP Implementation

- Issuance of 1st FSVP Warning Letter July 30, 2019.
  - caused a *Salmonella* outbreak and recall in May 2019
  - Importer was in violation of the FSVP regulation and placed on Import Alert 99-41
  - identified at time of or post entry, a “for cause” inspection may be initiated
- Beginning to conduct re-inspections
  - To verify if corrective actions have been taken based on issues identified during the previous inspection

Import Alert 99-41

- Import Alert 99-41 was published on July 31, 2019.
  - This is a firm alert and is specific to the importer, foreign supplier, and the food(s) they import
  - As of August 10, 2020, there are four importers subject to detention without physical examination (DWPE)
- The basis of the Import Alert is non- compliance with FSVP
  - Only through demonstration of compliance with their responsibilities under FSVP can an importer gain removal from IA and begin importing foods again

FSVP Remote Inspections

April 3, 2020 –
FDA announced the agency would start remote inspections of FSVP importers.

In rare situations, such as in response to an outbreak of foodborne illness, FDA may still choose to conduct an onsite FSVP inspection.

In these instances, an FDA investigator will make arrangements to conduct the inspection while practicing the social distancing recommendations provided by the Centers for Disease Control and Prevention.

Compliant Importers

- Vast majority of importers want to comply
- The compliance history of these importers and foreign suppliers will be considered to determine entry screening and targeting for inspection
- Compliance helps avoid recalls, product withdrawals, and liability.

Questions

- FDA Imports Inquiries

FDAImportsInquiry@fda.hhs.gov

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Voluntary Qualified Importer Program (VQIP)

What is VQIP?

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants.
- Eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.
- VQIP Importer is “the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”

Elements of the Guidance

- Benefits
- Eligibility Criteria
- Application (e.g., submission, timing, amendments, FDA review)
- User Fees
- Revocation Process
- Reinstatement Process

Benefits of VQIP

- Expedited entry into the U.S.
- Examination and/or sampling generally limited to “for cause” situations
- Any sampling or examination done at location chosen by the importer
- Expedited laboratory analysis if sampled
- VQIP Importers Help Desk
- FDA will post approved VQIP importers, if desired

Should you apply?

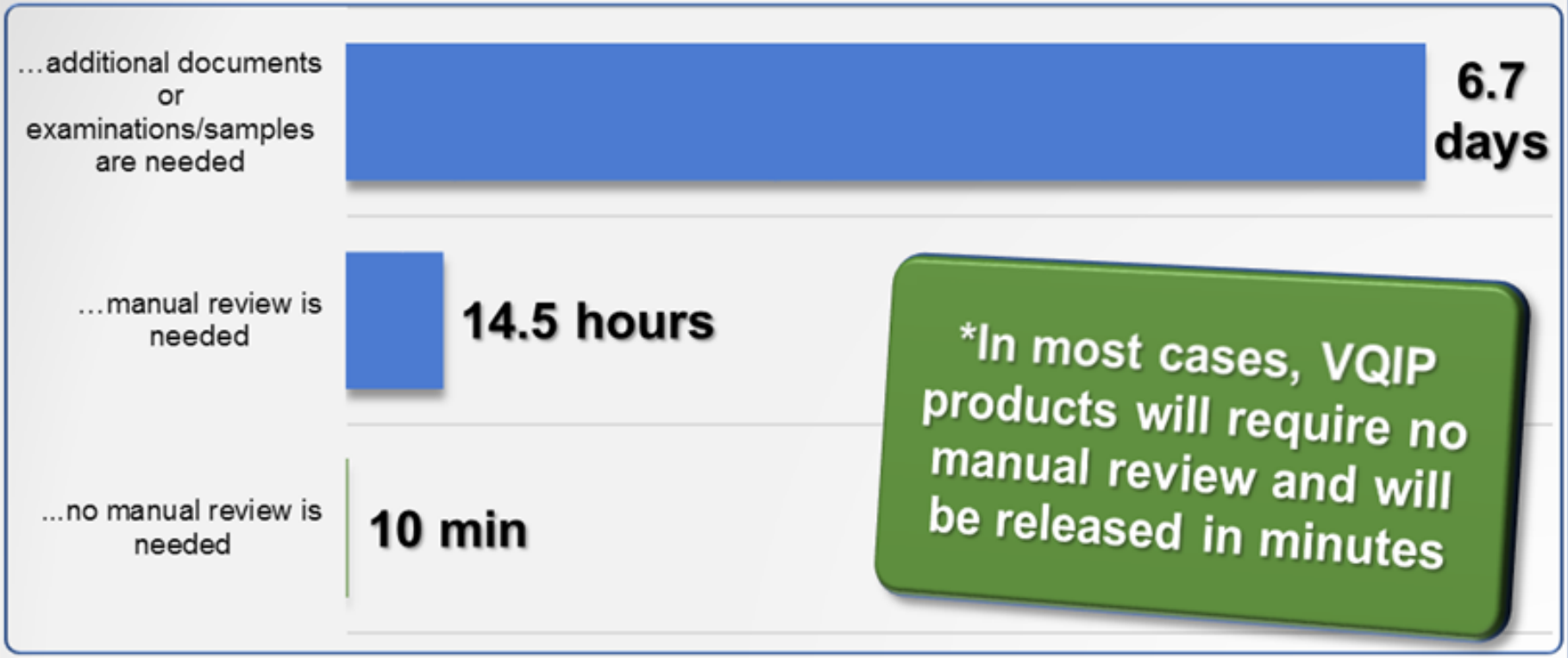
VQIP offers importers speed and predictability when bringing food into the United States. This will help importers meet customer demands, and will be particularly helpful for those importing:

- perishable products
- foods for “just in time” processing, in which ingredients must be at a food facility at a certain time in the manufacturing process

How long can your product wait?

Time for FDA to release a food shipment when...

Data is based on average for all human and animal food shipments submitted to FDA between 10/1/2017 - 05/31/2018



** In limited cases, FDA may need to exam a valid VQIP shipment "for cause", for VQIP auditing, or for statistically necessary risk-based microbiological samples.*

Eligibility Criteria

- 3-year history of importing food into the U.S.
- DUNS Number
- Paperless filers/brokers with acceptable FDA Filer Evaluation results
- Assurance of compliance with FSVP or HACCP regulations
- Current facility certification issued in accordance with FDA's third party accredited certification program for each foreign supplier of food
- Quality Assurance Program (QAP)
- Annual VQIP user fee

Eligibility Criteria, cont.

- No food subject to DWPE under an Import Alert or a Class 1 recall at the time of application
- No ongoing FDA administrative or judicial action, or history of significant non-compliances relating to food safety
- No CBP penalties, forfeitures, or sanctions that are related to the safety or security of any FDA regulated product within the last 3 years

Accredited Third-Party Certification Program

- FDA recognizes “Accreditation Bodies”
- Accreditation Bodies accredit third-party “Certification Bodies”
- Certification Bodies conduct food safety audits & issue certifications of foreign food facilities
- Public Registry, as of 10/30/19
  - 4 Recognized Accreditation Bodies
  - 8 Accredited Third-Party Certification Bodies

Application

- Notice of Intent to Participate
- Applicant & Firm Information
- FSVP and/or HACCP importer information
- Quality Assurance Program (QAP)
- Filer/Broker information
- Foreign Supplier information
- Summary
- E-Signature

How do importers apply for VQIP?

- Importers will be able to apply online at the FDA Industry Systems website January 1st, 2020.
- An account will need to be established and a **Notice of Intent to Participate** in VQIP must be submitted before submitting an application.
- The **VQIP Application User Guide** covers all of this.

VQIP User Fee Status

- User fee rates announced July 24, 2019
- Annual fee finalized at $16,681 for FY20
  - User fee previously estimated to be ~$16,400
  - FY21 fees will be published around August 2020
- Fee assessed after application is approved
- Provides benefits for all foods covered under VQIP

Resources for VQIP

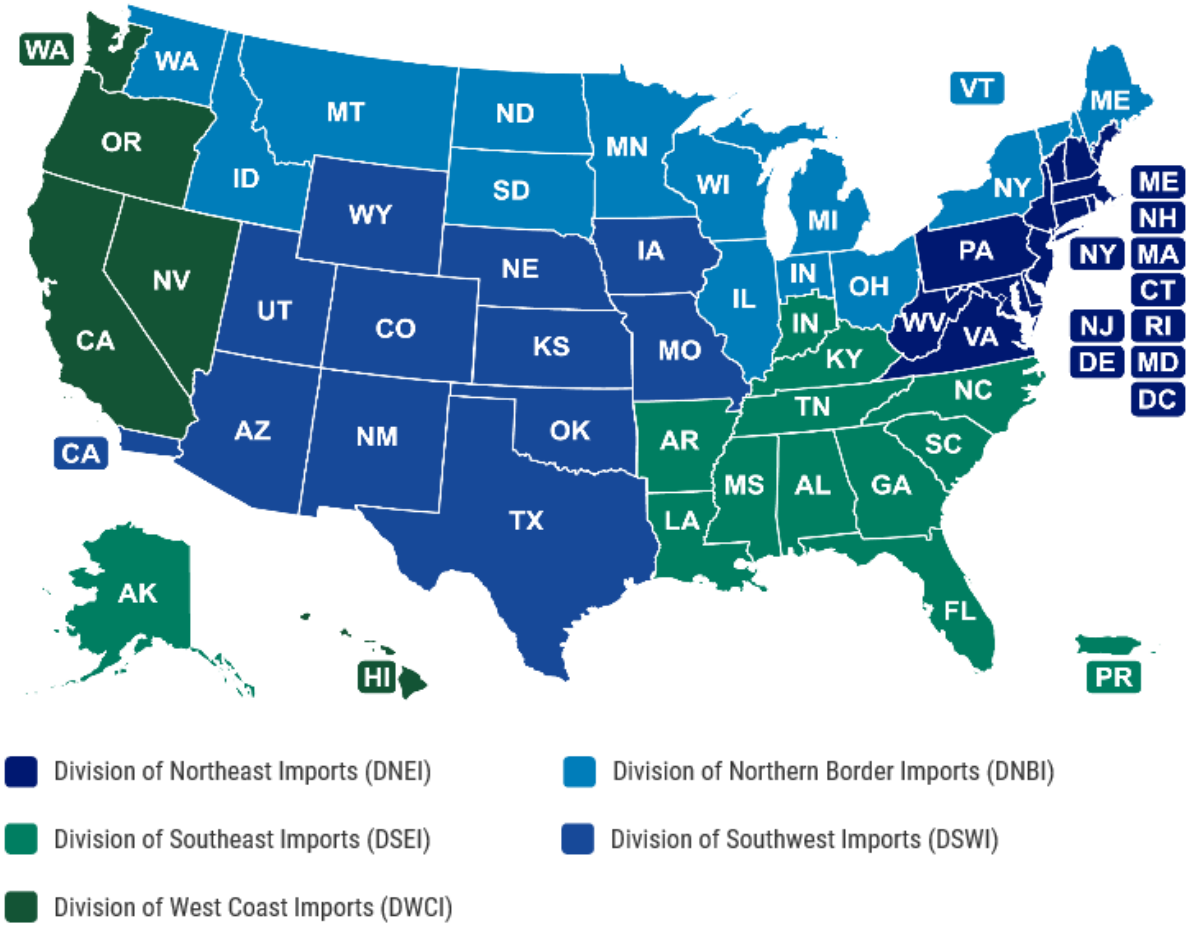
- **VQIP Website**: https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip
- **VQIP Guidance for Industry** (translations available): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program
- **VQIP Fact Sheet** (translations available): https://www.fda.gov/food/food-safety-modernization-act-fsma/fact-sheet-final-guidance-industry-fdas-voluntary-qualified-importer-program
- **Accredited Third-Party Certification Program (TPP) Website:** https://www.fda.gov/food/guidanceregulation/importsexports/importing/ucm558461.htm
- **VQIP Application User Guide**: https://www.fda.gov/media/113346/download

Questions

- VQIP Importer's Help Desk
  - M-F 8am – 8pm EST
  - FSMAVQIP@fda.hhs.gov
  - 1-301-796-8745

"FDA Import Offices and Ports of Entry" link:
https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/import-offices-and-ports-entry

Specific Import Entry inquiries



Thank You

Questions and Discussion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