FDA U.S. FOOD & DRUG ADMINISTRATION

FDA DIVISION OF NORTHEAST IMPORTS:

OVERVIEW OF FDA IMPORT PROCESS FOR CHEESE

NOVEMBER 10, 2022

PRESENTERS:

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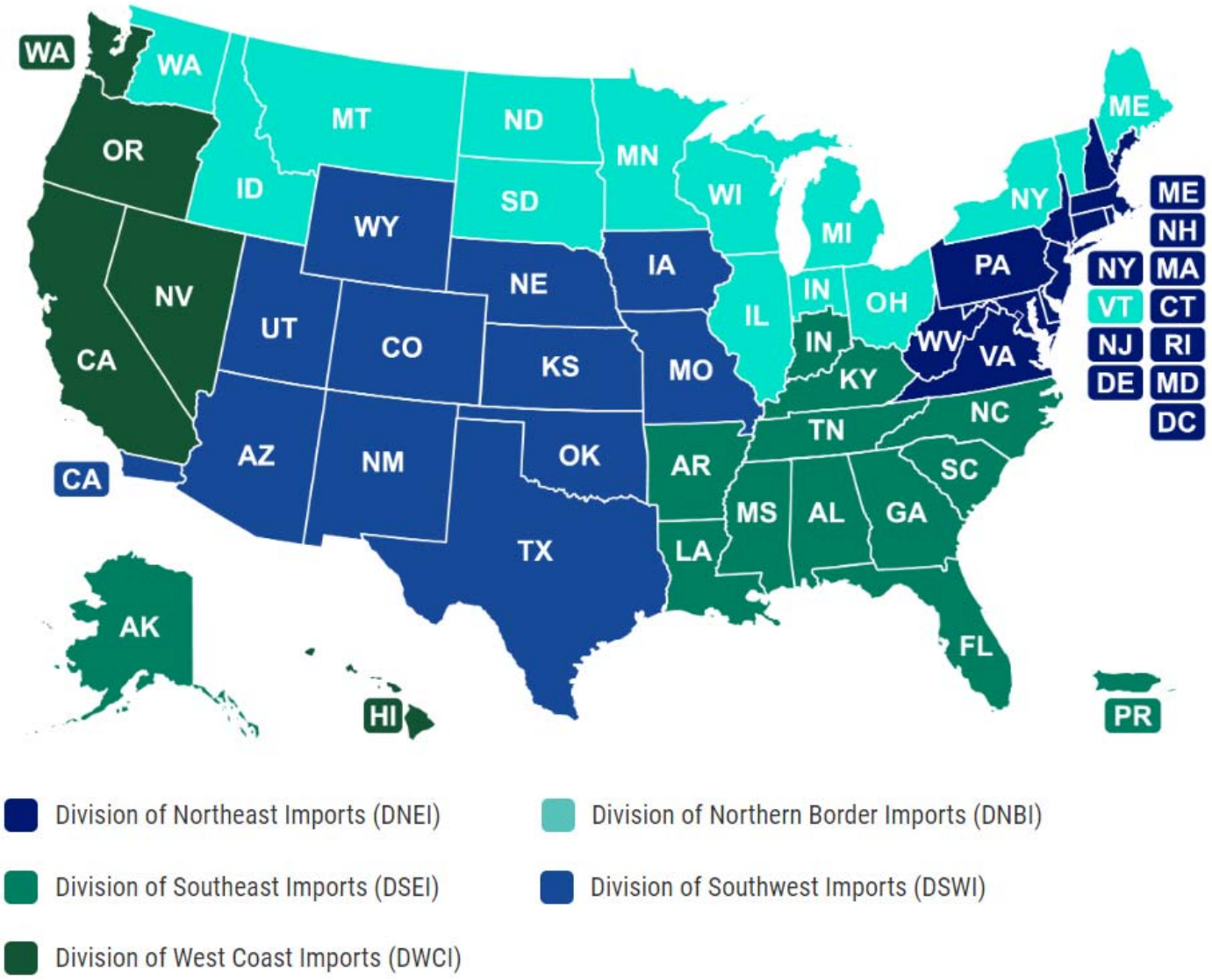
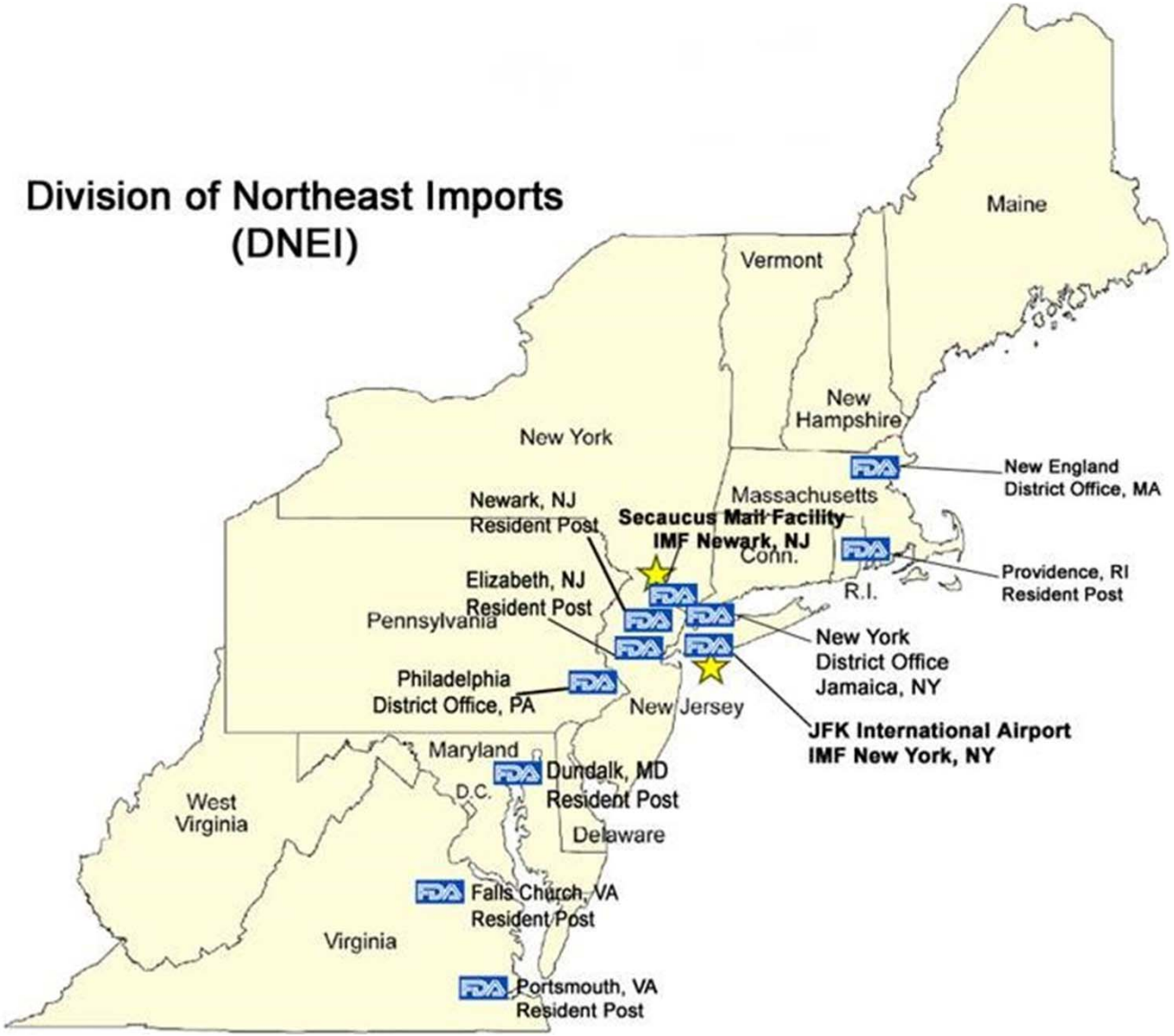
TOPICS OF TODAY'S PRESENTATION

- Division of Northeast Imports (DNEI) management structure
- Communicating with FDA
- Commercial entry review
- Examination and sampling of imported cheese
- Foreign Supplier Verification Program (FSVP)
- Voluntary Qualified Importer Program (VQIP)

FDA Import Offices:
[Import Offices and Ports of Entry | FDA]



Division of Northeast Imports (DNEI)



Division of Northeast Imports: Management Structure

Division of Northeast Imports: NJ/NY Investigations Branch Supervisors

Supervisory Consumer Safety Officer	District	Phone Number
Daniel Green	Jamaica Complex (Queens, NY)	718-662-5569
CDR Joseph Tomao	Jamaica Complex (Queens, NY)	718-662-5698
CAPT Jedeon Virata	JFK International Mail Facility (Queens, NY)	718-662-5467
Kristy Yeaw	Port Elizabeth Resident Post (Elizabeth, NJ)	908-527-2461
Benjamin Bustamante	Newark Resident Post (Newark, NJ)	908-527-2464
Ryan Aguillon	Secaucus International Mail Facility (Newark, NJ)	973-849-9244

Division of Northeast Imports: Investigations Branch Supervisors (cont.)

Supervisory Consumer Safety Officer	District	Phone Number
Frank Boardwick	Dundalk Marine Terminal (Baltimore, MD)	410-631-0322 x113
Myra Reed	Dundalk Marine Terminal (Baltimore, MD)	410-631-0322 x120
Troy Petrillo	New England District Office (Stoneham, MA)	781-587-7478
Bobby Whiddon	Philadelphia District Office (Philadelphia, PA)	215-717-3711

COMMUNICATING WITH FDA

REASON FOR CONTACT	CONTACT
General import Inquiries	FDA Imports Inquiry Desk fdaimportsinquiry@fda.hhs.gov
Problems or issues related to ACE	ACE Support ACE_Support@fda.hhs.gov
Entry Under Review - Initial entry determination - Documents requested - Field examination or sampling	Import Division Status Desk: Import Office and Ports of Entry Use the map to locate applicable port of entry and contact information DNEI Status Desk oraoeioneimpibstatus@fda.hhs.gov
Entry Under Compliance Review	Provide communication through ITACS (preferred): https://itacs.fda.gov *Note: Compliance officer information is included on the FDA Notice of Action.*

www.fda.gov

Import Trade Auxiliary Communications System (ITACS)

- Upload entry documents, entry location, availability status, and email correspondences
- Check up-to-date entry status
- Best platform to communicate with Compliance Branch
  - Including submitting requested information and submitting private lab reports

Entry Review Process

- Dedicated Entry Review Team
  - New Jersey and New York Ports of Entry team headed by Supervisory Consumer Safety Officer Dan Green
- Conduct reviews expeditiously and within specified timeframes
  - Additional time is needed for review when documents are requested
  - Importers and brokers can minimize delays by promptly providing requested documents

Entry Review Considerations

- Sufficient submission of information to make an admissibility decision
  - Documentation or additional information may be requested
- Current FDA examination and sampling requirements
- Review of relevant Import Alerts, including:
  - Import Alert 12-03: "Detention Without Physical Examination of Imported Soft Cheese and Soft Ripened Cheese from France"
  - Import Alert 12-10: "Detention Without Physical Examination of Cheese Due to Microbiological Contamination"
  - Import Alert 12-13: "Detention Without Physical Examination of Dairy Products Manufactured under Insanitary Conditions"

PRODUCT EXAMINATION AND SAMPLING

- Examine products within timeframes to minimize impact on importing community
  - Location needed to schedule appointment for exam
- Sampling reasons: Routine and For-cause
  - Workplan goals developed to ensure public health protection
  - Consumer complaints
  - Response to outbreaks or recalls traced to imported product
- Lab turn-around time: Typically, up to 10 business days
  - Additional time required for initial positive results for confirmation analysis

Compliance Program Guidance Manual 7303.050
Sampling for Foodborne Biological Hazards and Filth – Domestic and Imports

This CPGM provides instructions to prioritize sampling to ensure the U.S. food supply is safe and wholesome.

Link to CPGM 7303.050:
https://www.fda.gov/media/158921/download

Considerations for sampling:

- Risk associated with the product
- Product history (past violations)
- Manufacturer, shipper and importer history (past violations or lack of history)
- Routine surveillance

Microbiological Analytes of Concern

Cheese & Cheese Products (See Note below)	Examples: • Raw Milk Cheese • Soft, Soft-ripened, Smeared Cheese • Semi-Soft Cheese • Brined Cheese • Hard Cheese • Extra Hard Cheese and • Cheese Products (except shelf-stable) • Other cheese (ex. Mexican style cheese, aged gouda, blue cheese)	• *Salmonella* spp. • *Listeria monocytogenes* • EHEC/STEC • *S. aureus* • *Staphylococcus* enterotoxin • Alkaline phosphatase (The methodology for detecting the presence of alkaline phosphatase has been validated for bovine milk and bovine milk products only.)

NOTE: *Cheese and cheese product samples collected under compliance program 7303.050 will generally be analyzed for both microorganisms and alkaline phosphatase.*

FDA's Proactive Approach

1

The FDA Food Safety Modernization Act (FSMA) provides ways to better prevent problems before they occur

2

Communication with international regulatory counterparts for follow-ups related to violative imported products

3

Emerging issues addressed through CFSAN issued assignments and Import Bulletins (internal strategies)

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- Cheese made from unpasteurized milk samples and tested
  - "Raw milk cheese" aged 60 days or less
- Two and a half times as many import samples collected as domestic samples
- FDA refused violative entries of raw milk cheese
- Responsible firms added to Import Alert 12-10
- Worked with regulatory partners in European Union to further follow-up on manufacturing locations abroad.
- *L. monocytogenes* still a concern in semi-soft varieties of cheeses

(*Summary Report Link: https://www.fda.gov/media/99340/download*)

Global and National Concerns Support FDA Action

The Center for Food Safety and Applied Nutrition (CFSAN) looks at various data of public health significance to make informed decisions to implement FDA strategies:

- Large scale studies conducted under FSMA
- Import product sample analysis
- Foreign firm inspections
- Outbreaks related to cheese
- Scientific articles and reports

Foreign Supplier Verification program (FSVP)

IMPORTERS VERIFY THEIR FOREIGN SUPPLIERS

ENSURE FOREIGN SUPPLIERS (FS) MEET APPLICABLE FDA SAFETY STANDARDS

VERIFY FS PROCESSES AND PROCEDURES ARE EQUIVALENT TO PREVENTIVE CONTROLS REQUIREMENTS

VERIFY ADEQUATE IMPLEMENTATION OF CURRENT GOOD MANUFACTURING PRACTICES FOR FOOD

ENSURE FOOD IS NOT ADULTERATED OR MISBRANDED WITH RESPECT TO ALLERGENS

FDA's FSVP Resources

21 CFR Part 1, Subpart L: FSVP for Food Importers

FDA: What Do Importers Need to Know About FSVP

FDA Informational Sheet: Final Rule on Foreign Supplier Verification Programs

FDA's Draft Guidance for Industry: FSVP for Importers of Food for Humans and Animals

FDA Informational Sheet: FSVP Regulation Records Requirements

FDA Data Dashboard

VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP)

For additional info and resources related to VQIP, please visit:

https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip

- Voluntary fee-based program
- Expedited review and import entry
- Ability to import with greater speed and predictability
- Avoid unexpected delays at the point of import entry
- Limited examination and sampling
- Prioritization of FDA laboratory sample processing
- Dedicated help desk:
  - FSMAVQIP@fda.hhs.gov
  - 1-301-796-8745

Additional Resources

- FDA Import Alerts
- FDA Grade "A" Milk Safety Program
- Compliance Policy Guide: Sec. 527.300 Dairy Products – Microbial Contaminants and Alkaline Phosphatase Activity
- Compliance Policy Guide: Sec. 527.200 Cheese and Cheese Products – Adulteration with Filth
- Food Safety Preventive Controls Alliance (FSPCA) Courses:
  - Preventive Controls for Human Foods (PCHF)
  - Foreign Supplier Verification Program (FSVP)


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