Port of NY & NJ Updates
Food and Drug Administration
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Kristy Bonner
Supervisory Investigator
FDA Division of Northeast Imports
Kristy.Bonner@fda.hhs.gov
908-527-2461
Priorities During COVID19

• Sample collection of high risk foods
• Entry Review
• Remote FSVP Inspections
• PPE- hand sanitizer, masks, test kits
• Tobacco products- eCigs
• CBP referrals
• International Mail Facility Operations
• Refusal Verification Activities
• Hiring
FDA Data Dashboard

• In 2019 FDA processed 45,221,776 lines* of products
  • A “line” is a specific product declared within a shipment
  • 13,218 lines were Refused
  • 127,641 lines were Examined
  • 14,462 lines were Sampled

• https://datadashboard.fda.gov/ora/index.htm#summary
FSVP Inspections

• Foreign Supplier Verification Program
  • The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.
  • Importers are responsible for actions that include:
    ◦ Determining known or reasonably foreseeable hazards with each food
    ◦ Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier’s performance
    ◦ Using that evaluation to approve suppliers and determine appropriate supplier verification activities
    ◦ Conducting supplier verification activities
    ◦ Conducting corrective actions
Remote Approach to FSVP

- On April 3rd, the U.S. Food and Drug Administration announced that it will begin requesting that importers send records required under the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule electronically (or through other prompt means) to the Agency as it shifts to conducting these inspections remotely during the COVID-19 public health emergency.
  - Previously conducted in-person.
  - FDA investigators will call importer if selected for inspection, and will explain the process for the remote inspection/make written requests for records.
  - Will issue all forms electronically.
FSVP Updates

• FY20- Nationwide goal of 1325 inspections of human food importers and 75 animal food importers.
  • Initial inspections
  • Cycle re-inspections
  • Re-inspections based on previous violations
  • For-cause (in response to an outbreak)

• Warning Letters

• Import Alert- 99-41 ""Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation"
VQIP

• The Voluntary Qualified Importer Program (VQIP) is a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers.

• Participating importers will be able to import their products to the U.S. with greater speed and predictability, avoiding unexpected delays at the point of import entry. Consumers will also benefit from the importer’s robust management of the safety and security of their supply chains.

• To participate, importers must meet eligibility criteria and pay a user fee that covers cost associated with the FDA’s administration of the program.
FDA Resources

• Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency

• FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

• FDA Data Dashboard
  • [https://datadashboard.fda.gov/ora/index.htm](https://datadashboard.fda.gov/ora/index.htm)

• FSMA Technical Assistance Network (TAN)

• FSMA training - FSPCA, SSA, and PSA