

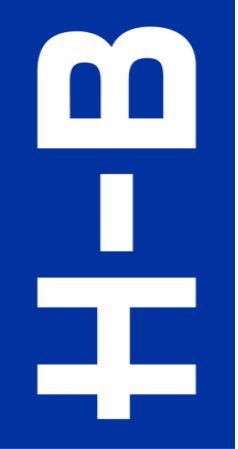


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**Introduction to Food Law and
Regulation:
Imports and International Issues**

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Overview

- FDA Authority over Imports
 - Import Process and Prior Notice
 - Import Alert
- Food Safety Modernization Act and Imported Foods
- USDA Authority over Imports
- Principles of International Harmonization
- Other Considerations



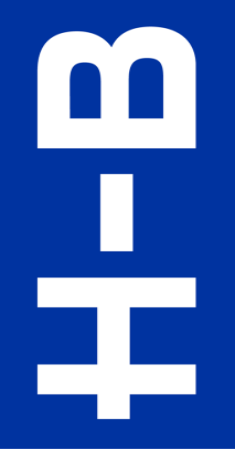
What was the value for food imports into the U.S. in 2021?

A. Between \$50 and \$100 Million

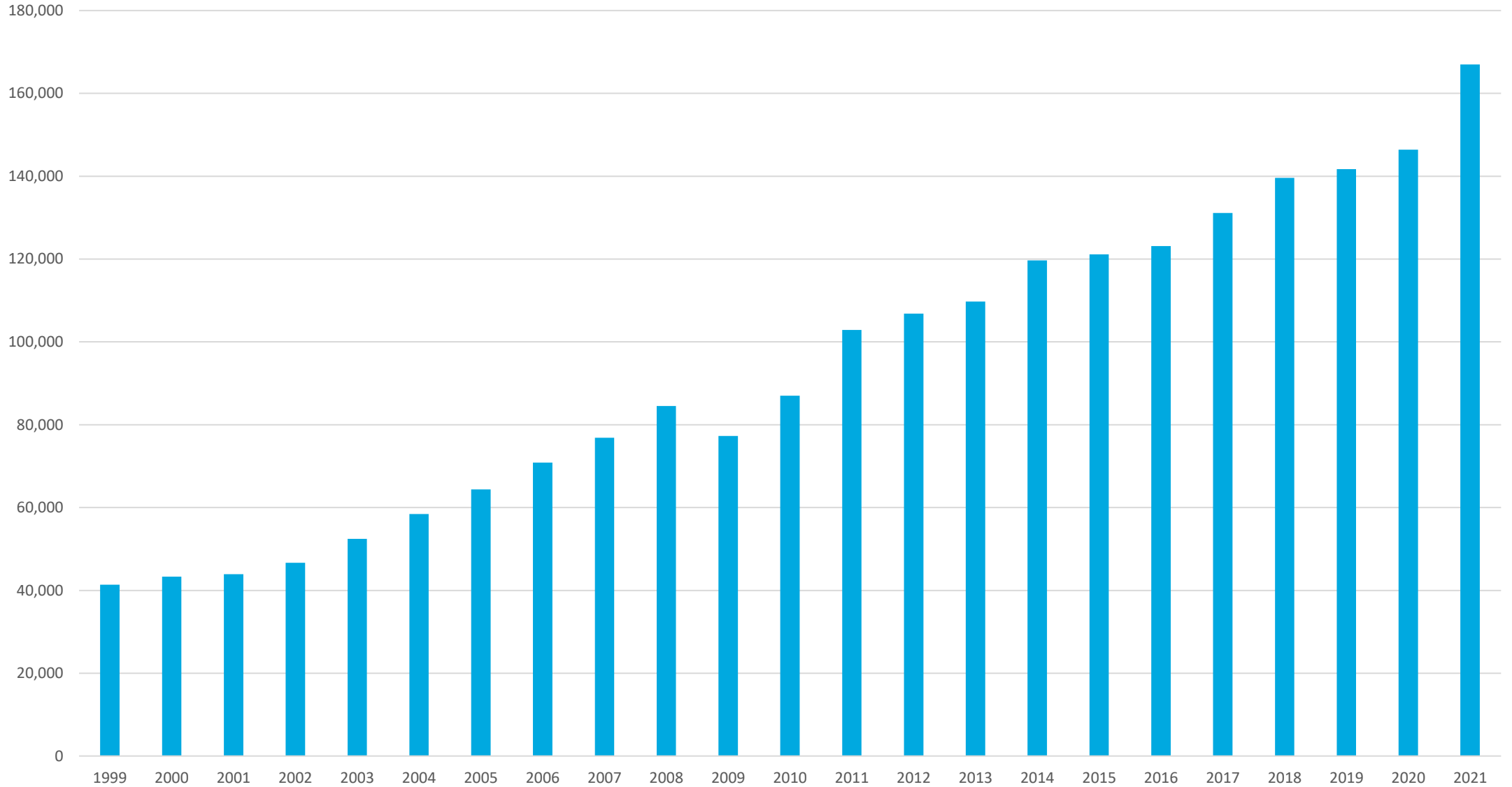
B. Between \$100 and \$150 Million

C. Between \$150 and \$200 Million

D. Between \$200 and \$250 Million



U.S. Food Import Value (in Million (\$))



FDA Authority over Imports



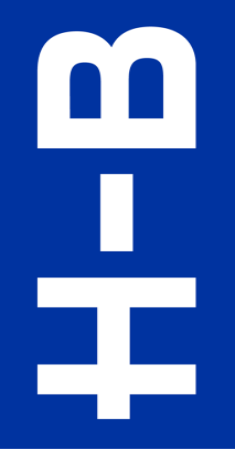
Domestic Enforcement

- Domestic products regulated by the FDA that are adulterated and/or misbranded are subject to seizure and condemnation through the judicial process
- Seizure and condemnation are lengthy and onerous legal processes for the FDA that require a great deal of evidence to prove in a U.S. court of law
- Due to the difficulties, the FDA relies mostly on its administrative powers (Warning Letters, press releases) to obtain compliance from domestic firms



FDA Authority over Imports

- Imports are primarily addressed in FFD&C Act section 801 [21 U.S.C. 381]
- Imports are subject to refusal by FDA “[i]f it appears from the examination of such samples or otherwise that” the food being imported:
 1. has been manufactured, processed, or packed under insanitary conditions
 2. is forbidden or restricted in the country in which it was produced/exported
 3. is adulterated, misbranded, or the importer is in violation of the foreign supplier verification program requirements
 4. is not in compliance with the recordkeeping requirements under 21 U.S.C. 2223 (“Enhancing tracking and tracing of food and recordkeeping”) [which has not been implemented yet]



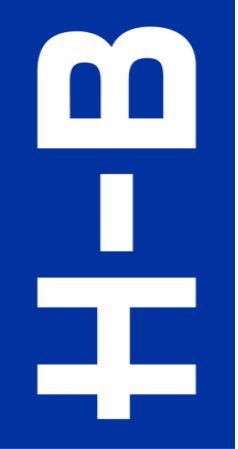
FDA Authority over Imports (cont.)

- There is no provision for judicial review and action by the FDA is committed to agency discretion by law
- The “appearance of” language in sec. 701 provides FDA with a broader authority over imports compared to domestic products
- “or otherwise” is also interpreted to allow the FDA to refuse shipments based only on poor results from foreign inspections
- Import samples are not subject to the reserve sample requirements of section 702(b) [21 U.S.C. 372(b)], although FDA will usually collect an additional sample as part of its policy



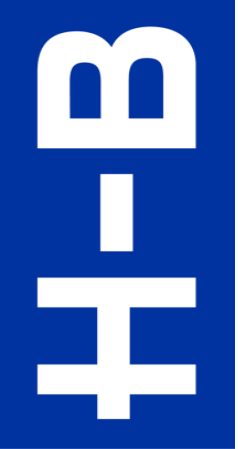
Authority to Inspect Foreign Manufacturers

- FDA asserts that its authority to inspect foreign manufacturing facilities arises from section 704 of the FFD&C Act
- Notwithstanding this position, FDA has a right under section 807(b) of the FFD&C Act to refuse admission of food from a facility that refuses to permit entry by FDA to inspect such establishment
- FDA will consider an inspection refusal to have occurred if the owner, operator, or agent in charge does not permit an inspection during the 24-hour period after FDA submits an inspection request



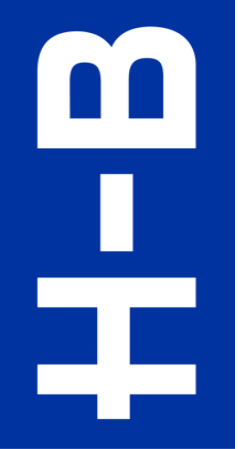
Foreign Inspection Refusals

- FDA will consider an owner, operator, or agent in charge of a foreign food establishment to have not permitted an inspection if they do not respond to FDA during the 24-hour period after FDA submits the initial written inspection request
- FDA also considers an owner, operator, or agent to have not permitted an inspection if they:
 - stop communicating with FDA at any time after they initially respond to FDA's request to schedule an inspection,
 - provide an incomplete or inaccurate response (e.g., falsely claim the establishment is not operating or does not ship food to the United States),
 - reject FDA's attempt to schedule an inspection by not agreeing to an inspection start date and does not give a reasonable explanation for its failure to do so, or
 - agrees to an inspection start date and then requests a later date without giving a reasonable explanation



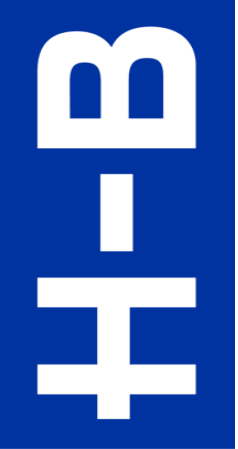
Foreign Inspection Refusals (cont.)

- FDA considers an owner, operator, or agent in charge of a foreign food establishment to have refused an inspection when they:
 - prevent the FDA investigator from entering the establishment,
 - prevent the FDA investigator from conducting the inspection of the establishment, after entry, either by establishing unreasonable preconditions to allowing the inspection or by preventing or interfering with completion of some aspect of the inspection, or
 - delay the FDA investigator from conducting an inspection of the establishment, either before or after entry into the establishment



Prior Notice

- Authority to require prior notice of food imports comes from Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Importers must provide notification to FDA that an article of food (both human food and animal feed) is being imported or offered for import before the food arrives at the U.S. border
- Allows FDA, with the support CBP, to target import inspections more effectively and help protect that nation's food supply against terrorist acts and other public health emergencies
- Prior notice must be filed for all foods and food contact substances entering U.S., with small exceptions, including food samples



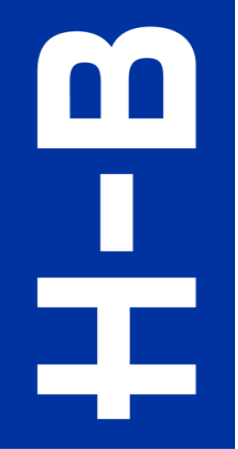
What Is in the Notice?

- Includes information about the shipment and the facility
 - Product identifying information (FDA produce code, product name, estimated quantity, lot code)
 - Name of shipper as well as importer
 - Country of production and from where food is shipped
 - Carrier and mode of transportation
 - Anticipated arrival information (location, date, time)
- Report the name of any country to which the article has been refused entry
- May be filed by exporter, importer, or third party



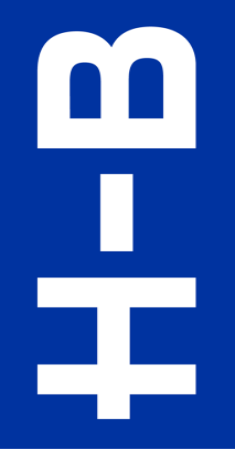
Imported Food Review Process

- U.S. Customs and Border Protection (CBP) has authority for all imported products:
 - Entry is made to CBP
 - If FDA regulated, CBP forwards to FDA
 - FDA then begins its admissibility process
- Field personnel will examine for evidence of:
 - Filth
 - Decomposition
 - Packaging defects
 - Mishandling of products
 - Misbranding



Imported Food Review Process

- Upon review of the product, FDA will either:
 - Release the product
 - Collect samples for further analysis
 - Request additional information or documents
 - Recommend detention of the product
 - Refuse entry of the product
- Prior to refusal, the importer of record may submit an application to FDA requesting permission to re-label or recondition the product in an attempt to bring it into compliance
 - Such reconditioning is subject to FDA's review and approval



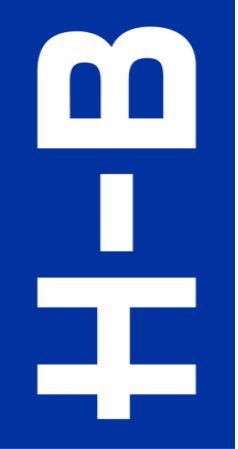
Post-refusal Process

- When a refusal is issued, the importer has the following options:
 - Destroy the product under FDA and CBP supervision
 - Export the product under FDA and CBP supervision
- Reconditioning cannot prevent destruction or export after refusal has occurred



Exports

- Sec. 801(e)(1) provides that: food intended for export shall not be deemed to be adulterated or misbranded if it—
 - A. accords to the specifications of the foreign purchaser,
 - B. is not in conflict with the laws of the country to which it is intended for export,
 - C. is labeled on the outside of the shipping package that it is intended for export, and
 - D. is not sold or offered for sale in domestic commerce



Import Alert

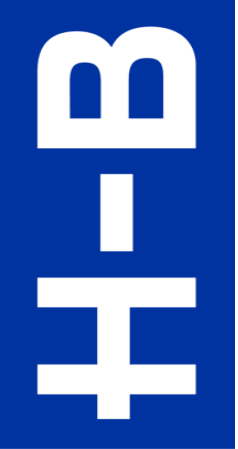
- Also known as “Detention without Physical Examination”
- All shipments from the specified food firm in the alert will be detained by FDA for as long as the company remains on the Import Alert, even after corrective actions have been put in place
- In order to stop the detention process, the firm must submit a petition to FDA that clearly details the corrective actions taken
- For Import Alerts associated with a deficient test result, FDA will generally lift an Import Alert after shipment of three “clean” entries

Food Safety Modernization Act



FSMA Provisions that Address Imports

- Sec. 301. Foreign Supplier Verification Program (Sec. 805 of FD&C Act)
- Sec. 302. Voluntary Qualified Importer program (Sec. 806 of FD&C Act)
- Certification for Food Imports (Sec. 801(q) of FD&C Act)
- Sec. 304. Prior notice of imported food shipments (Sec. 801(m)(1) of FD&C Act)
- Sec. 305. Capacity building
- Sec. 306. Inspection of foreign food facilities (Sec. 807 of FD&C Act)
- Sec. 307. Accreditation of third-party auditors (Sec. 808 of FD&C Act)
- Sec. 308. Foreign Offices of the Food and Drug Administration.
- Sec. 309. Smuggled Food
- Sec. 404. Compliance with International Agreements



Foreign Supplier Verification Program (FSVP)

- Requires importers to share responsibility for ensuring safety of imported food
- Closely aligns with supply-chain provisions of the Preventive Controls rules
- To import food, there must be 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



FSVP Exemptions

- Firms subject to juice or seafood HACCP regulations
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)
- Food transshipped through U.S.
- Food imported for processing and export
- “U.S. food returned” - food that is manufactured/processed, raised, or grown in the U.S., exported, and returned to the U.S. without further manufacturing/processing in a foreign country
- Meat, poultry, and egg products subject to USDA regulation at time of importation



Foreign Supplier Verification

- Key Requirements
- Hazard analysis
- Evaluation of Food and Foreign Supplier
- Verification activities
- Corrective actions
- Importer identification at entry
- Recordkeeping
- Importers subject to PC rules compliant
- Comply with PC supply-chain provisions
- Implement preventive controls under PC regulation for hazards in food they import
- Are not required to implement a preventive control under certain PC provisions
- Will still need to identify themselves at entry under FSVP



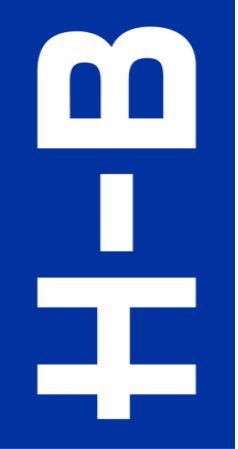
FSVP Compliance Dates

- Compliance Dates
- Importers were required to comply with FSVP by May 30, 2017
- If the foreign supplier is subject to preventive controls or produce safety regulations, importer must comply with FSVP 6 months after supplier must comply with the relevant regulations
- Enforcement Discretion on Certain Provisions
- Written assurance requirements
- Requirements for importers of food contact substances
- Importers of grain Raw Agricultural Commodities requirements
- Importers of live animals that must be slaughtered and processed at establishments regulated by USDA and subject to HACCP requirements



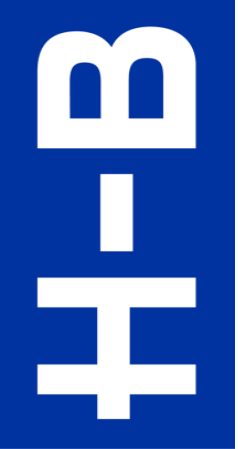
Voluntary Qualified Importer Program (VQIP)

- FDA required to establish a program to provide for the expedited review of food imported by voluntary participants
 - Participation is limited to importers who meet all eligibility criteria, including offering food from a facility certified under FDA's Accredited Third-Party Certification Program
 - Applications accepted between January 1st and May 31st, annually
 - This program is funded by user fees that covers FDA's costs of administering the program
- Eligibility
 - Quality Assurance Program (QAP)
 - Assurance of compliance with the supplier verification and other importer responsibilities under the applicable FSVP or HACCP regulations
 - Current facility certification, including farms, issued under FDA's Accredited Third-Party Certification regulations for each foreign supplier of food in VQIP
 - 3+ year history of importing food to the United States
 - No ongoing FDA administrative or judicial action (e.g., import alert, injunction, recall), or other history of non-compliance with food safety regulations



Accredited Third-Party Certification Program

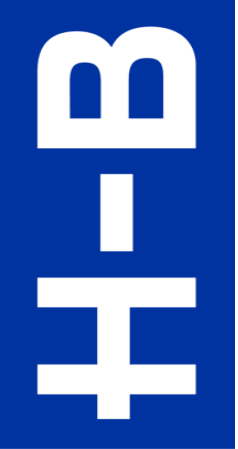
- Establishes a voluntary, fee-based program for the recognition of accreditation bodies that accredit third-party auditors to conduct food safety audits and, where appropriate, to issue certifications to foreign facilities
- Accreditation can be used for:
 - Voluntary Qualified Importer Program
 - Import Certification
- Not required for FSVP or PC rules



Accredited Third-Party Certification Program Process

- FDA recognizes accreditation bodies based on certain criteria such as competency and impartiality – three recognized so far;
 - ANSI-ASQ National Accreditation Board (ANAB)
 - American National Standards Institute (ANSI)
 - National Bureau of Agricultural Commodity and Food Standards (ACFS)
- Accreditation bodies accredit qualified third-party auditors
- Third-party auditors/certification bodies audit and issue certifications for foreign facilities and foods
- Foreign facilities may choose to be audited by an accredited auditor/certification body
- FDA has oversight at all levels of the process

USDA Authority over Food Imports



U.S. Department of Agriculture Authority

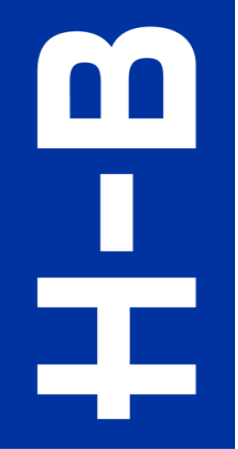




Food Safety Inspection Service

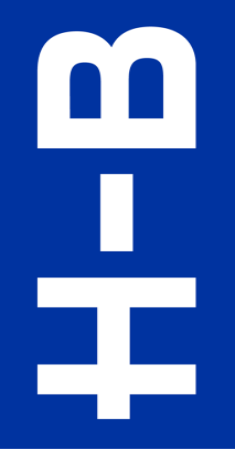
Authorities

- Meat Inspection Act – 21 U.S.C. § 601 et seq.
 - Cattle, sheep, swine, goats, horses, mules, other equine, and catfish products
- Poultry Products Inspection Act – 21 U.S.C. § 451
 - Domesticated chickens, turkeys, ducks, geese, ratites, and squabs.
- Egg Products Inspection Act – 21 U.S.C. § 1031 et seq.
 - Shell eggs of domesticated chickens, turkeys, ducks, geese, and guineas
- Only allow imports from certified countries and foreign establishments
- Countries must have equivalent food safety standards in order to become certified
- Following entry by CBP, meat products must be presented to FSIS for inspection at an official import establishment



Animal and Plant Health Inspection Service

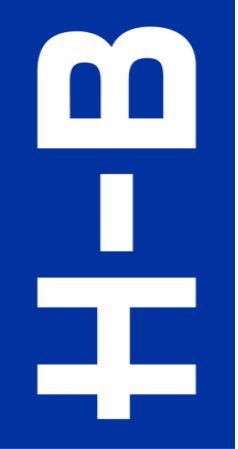
- Food Related Authorities
 - Plant Protection Act – 7 U.S.C. § 7701 et seq.
 - Animal Health Protection Act – 7 U.S.C. § 8301 et seq.
- Intend to prevent the importation of products that would expose the U.S. to plant pests (e.g.,) and animal diseases
- Have specific restrictions on import of animal and plant products and live animals from various countries and regions
- Require import permits for certain animal and plant products.



Agricultural Marketing Service

- Section 8e of the Agricultural Marketing Agreement Act of 1937
 - Applies to specific fruit, vegetable, and specialty crop imports into the United States
 - Restricts imports of various products based upon various Federal Marketing Orders
 - Restrictions can include various minimum quality standards and seasonal restrictions on imports
- Shell egg import quality standards
- Country of Origin Labeling
 - Mandatory for fish, shellfish, lamb, chicken, and goat meat, perishable agricultural commodities, macadamia nuts, pecans, peanuts, and ginseng
- Oversight of enforcement of organic standards for imported foods

International Harmonization



International Harmonization

- FDA works with foreign governments and international standard-setting bodies to harmonize food safety laws, regulations and standards based on science
- Mainly through two mechanisms
 - Systems Recognitions
 - Equivalence
- FDA also works with other federal agencies to represent U.S. interests at the Codex Alimentarius Commission



International Harmonization

Systems Recognition

- FDA reviews a foreign country's food safety regulatory system to determine if it provides a similar set of protections as well as oversight and monitoring to U.S. food safety systems
- These reviews are used to make risk-based decisions regarding foreign inspections, import examination, and responses to food safety incidents
- FDA has systems recognition agreements with New Zealand, Canada, and Australia
- Currently reviewing EU system and implementation by member states

Equivalence

- FDA reviews the sanitary measures included in the exporting country's regulatory system provide the same level of protection as relevant U.S. food safety requirement
- When FDA determines a country's system is equivalent, foods imported are typically permitted entry to the U.S. market without further conditions
- Only one program, EU raw bivalve molluscan shellfish, has equivalence recognition by FDA

Other Considerations



Other Considerations for Imported Foods

Customs and Border Protection

- Assists FDA and USDA in the import and clearance process
- Food production, labeling, marketing can come into play for tariff classification and applicable duty

U.S. Trade Representative

- Recent years, foods are target for additional duties in trade disputes

Made in USA Claims

- Federal Trade Commission has specific requirements for
 - Use of the American flag, images of the country
 - Allows unqualified and qualified claims
 - Can use unqualified claim only on products that are wholly made from US produced and sourced ingredients
- If only selling product in California, the State has its own Made in America standard.



Questions?



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