U.S. Food and Drug Administration

Risk-based Import Procedure for Food
U.S. Food Safety System

President of the United States

Department
- USDA
- HHS
- DoC

Agency
- APHIS
- FSIS
- FDA
- NOAA
- EPA

Center
- CVM
- CFSAN
- NMFS

Biotech
- plant
- pests

plant/animal health
- meat
- feed
- 80% food
- seafood
- agrichemicals

animals
foods
pesticides
U.S. Food Safety System

- **Food and Drug Administration (FDA)**
  - Food (but not meat), dietary supplements, bottled water, seafood, wild game (“exotic” meat), eggs in the shell

- **Food Safety Inspection Service (FSIS)**
  - Meat, poultry, processed eggs

- **Animal and Plant Health Inspection Service (APHIS)**
  - Plant pests and diseases, animal diseases

- **Environmental Protection Agency (EPA)**
  - Pesticide registration, establishment of Maximum Residue Limits (tolerances)
Single Window

- A single, harmonized data set collected electronically by CBP
- Early validation of exporter’s paperwork results in better data quality and quicker admissibility decisions
- Coordinated, consolidated status messaging across agencies
FDA SPS Measures

All food regulated by the U.S. Food and Drug Administration (FDA) must meet the same U.S. food safety requirements, whether imported or produced domestically.
Imported Food Volume

Total Lines* of Products Imported by Fiscal Year


* A line is a distinct product within a shipment. A single shipment may include multiple lines.
All imported food that FDA regulates is electronically screened before it enters the United States.
PREDICT

- **Purpose:** Improve import screening and targeting to prevent entry of adulterated, misbranded, or otherwise violative goods into the United States and expedite the entry of non-violative goods.

- **Method:** Replaced the admissibility portion of FDA’s legacy electronic screening process.
PREDICT Methods Include

- Verification of applicable regulatory requirements, e.g. registration, approval status, etc.
- Automated data mining and pattern discovery
- Automated review of administrative requirements
- Open source intelligence
PREDICT
Methods Continued

• Improved targeting:
  ✓ Evaluate shipments on the basis of risk factors and surveillance requirements
  ✓ Facilitate automated releases, giving border inspectors more time to evaluate higher risk lines.
  ✓ For consignments not automatically admitted, identify risk factors for border inspectors to consider in determining disposition
PREDICT Risk Factors

- Inherent risk of the product
- Results of field exams and analytical testing of previous entries from the same producer or country.
- Results of facility inspections (foreign and domestic)
- Accuracy of import documents
Additional Information

- FDA
  - [https://www.fda.gov/ForIndustry/ImportProgram/default.htm](https://www.fda.gov/ForIndustry/ImportProgram/default.htm)

- FSIS

- APHIS

- EPA
  - [https://www.epa.gov/pesticide-registration](https://www.epa.gov/pesticide-registration)