Food and Drug Administration

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What to Consider Before You Import a Human Food

- Human food is defined as articles for eating or drinking, including for research use and personal use. For product-specific or regulatory questions, please contact FDA's Center for Food Safety and Applied Nutrition (CFSAN).
- Food imported into the United States must meet the same laws and regulations as food produced in the United States.
- Product must be safe and contain no prohibited ingredients, and all labeling and packaging must be informative and truthful.
- It is the importer's responsibility to ensure that the imported food is in compliance and to follow the conditions of their customs bond. Please visit the How to Start a Food Business page for a list of requirements.

What to Consider Before You Import a Human Food

- **Food Facility Registrations(FFR):**
  - Foreign facilities engaged in manufacturing, processing, packing, or holding food products are required to register their food facilities with FDA and given advance notice on shipments of imported food to FDA (Prior Notice).

1. **Ensure product is compliant with all FDA laws, regulations, and policy/guidance.**
   a. Applicable Regulations: 21 CFR Part 1, 100-169
   b. Applicable Guidance
      i. Food Guidance & Regulation (by topic)
      ii. Compliance Policy Guides: Food
      iii. Compliance Policy Manual Guides: Food
      iv. Labeling & Nutrition
      v. Food Good Manufacturing Practices
   c. Labeling Requirements
      i. Human Food: 21 CFR Part 101
      ii. Food Labeling Guide
      iii. Small Business Nutrition Labeling Exemption
   d. Registration Requirements
      i. Food Facility Registration
      ii. FSVP Importer Identifier: D-U-N-S number
   e. Other Requirements
      i. Must submit Prior Notice before goods arrive in the U.S.
      ii. Foreign Supplier Verification Program

What to Consider Before You Import a Human Food

- **Check FDA's Import Alerts** to determine if your product/manufacturer is subject to Detention without Physical Examination (DWPE) and requirements to secure a release of the shipment.

- **Review FDA's Entry Submission and Review Process.**

- **Consider providing the following information to your Customs broker to transmit to FDA.**
  - Complete and accurate information and documentation will help expedite the review process.

    - Product name(s) or descriptions (might be listed on commercial invoice)
    - Intended use of the product(s) in the U.S.
    - Name and address of the physical location of the manufacturer, shipper, importer, and the deliver to party.
      - If any of the entities have an FEI or D-U-N-S number
  - A full list of required data elements can be found in the FDA Supplemental Guide by commodity.
    - Please also see: FDA ACE External Outreach Presentation-Human & Animal Food

What to Consider During the Import Process

- At the time of import, the importer will have to provide information about the shipment, related firms, and products to FDA.
- Once the shipment is transmitted to FDA for review, our systems will conduct an initial evaluation to determine if the product can proceed into commerce or if more information is needed.
- If more information is needed, the shipment information will be sent electronically to the local FDA office where the goods entered the United States for additional review.
- The local FDA office may request documents and/or request a physical examination of the products; If a physical examination is performed, FDA will be evaluating the product and labeling for compliance.
- FDA may collect samples of the products for FDA labs to analyze for known hazards. Depending on the results of the exam and/or sampling, the products will either be **proceeded into commerce** or **held for a compliance review**.
- **Products pending FDA examination or sample collection must be held - should not be distributed into commerce until results are evaluated and the products are released. Failure to hold your products might result in FDA requesting CBP to demand redelivery.**
- The local FDA office also makes the final admissibility decision (release or refuse). This page on FDA's Entry Review Process provides additional information.

What to Consider During the Import Process

- **Stay in contact** with your Customs broker and/or FDA and provide requested information in a timely manner.
  - If FDA requests documents or an inspection, provide the requested information and/or documents via ITACS.
    - Documents might include CBP forms invoices, shipping documents, ingredients list, copies of labels, photos of product, formulations, processing methods, etc.
  - You may provide any information that would help the reviewer determine your product is in compliance with U.S. laws and regulations.
- **Monitor the status** of your entry on ITACS for final admissibility decision.
- **Submit questions** about your shipment to the local FDA office at the port of entry.

What to Consider During the Import Process

- **Entry review**
  - Entry review consists of the examination of any electronic data to make initial admissibility determinations based on the entry documentation received.

- **Entry Review Timeframe**
  - initial entry decision for **perishable** lines is within **one business day of** the electronic submission date.
  - initial entry decision for **nonperishable** lines is within **two business days** of electronic submission date.
  - Document Requested lines entry decision is within **three business days** of receiving entry documents.

- **Field Examination/Sample Collection Timeframe**
  - For entries of a non-perishable product, field work will be conducted within **five business days** of being notified the entry/line is available for examination.

What to Consider During the Import Process

- **Food Labels and Allergens**
  - The FD&C Act requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements.
  - **The laws and regulations requires that food labels identify the food source of all major food allergens used to make the food.**
  - This requirement is met if the common or usual name of an ingredient already identifies that allergen's food source name (for example, buttermilk).

What to Consider During the Import Process

- **Detention & Hearing:**
  - When products in your shipment violate or appear to violate FDA laws and regulations, FDA may detain your product and issue a Notice of FDA Action with the designation of "Detained." This notice is considered the Notice of Detention and Hearing.
  - The Notice of Detention and Hearing provides a "respond by" date for the importer, owner, and/or consignee. The Notice of Detention and Hearing will provide the sections of the laws and regulations that appear to be violated
  - Your product may be detained because it appears to be:
    - adulterated, misbranded, manufactured, processed, or packed under insanitary conditions
  - **If FDA detains your product Submit evidence to overcome the appearance of a violation.**
  - If you are unable to overcome the appearance of a violation, your product will be refused admission - you can work with CBP and FDA to destroy the product or export it from the U.S within 90 days of the refusal.

What to Consider During the Import Process

- **Foreign Supplier Verification Program (FSVP) Requirements**
  - **What is an FSVP?**
    - FSVP requires that importers perform certain risk-based activities to verify that the human and animal food they import into the United States has been produced in a manner that meets applicable U.S. safety standards.
    - Providing assurance that foreign suppliers of food products meet similar requirements to US-based companies.
  - **Who is an FSVP importer?**
    - The FSVP Importer is the U.S. owner or consignee of the food or the U.S. party who has purchased or agreed to purchase the food.
  - **Who is subject to FSVP?**
    - All importers of food, beverages and dietary ingredients
    - A separate FSVP must be developed for each food and each foreign supplier (even if the same food is obtained from different suppliers).
    - Foreign Supplier Verification Program

Additional Resources

Regulations	Guidance	Labeling	Registration	Other	Systems Information
21 CFR Part 1, 100-169	Guidance & Regulation (by topic)	Food Labeling Guide	Food Facility Registration	Prior Notice	FDA Supplemental Guide for ACE
Color Additives: 21 CFR Part 70-82	Compliance Policy Guides: Food		Food Facility Registration Step-by-Step Guide	PNSI Step-by-Step Guide	Product Code Builder
Food Additives: 21 Part 170-189	Compliance Policy Manual Guides		FSVP Importer Identifier: D-U-N-S number	Prior Notice Q & A	Product Code Builder Tutorial
	Labeling & Nutrition			Foreign Supplier Verification Program	
	Food Good Manufacturing Practices			FSVP Q & A	
				Import Alerts	

ACE Transmission Requirements: Human Foods

- The Automated Commercial Environment (ACE) is the system through which the trade community reports imports and exports, and the government determines admissibility

- A full list of data elements can be found in the FDA Supplemental Guide.

- Program Code: FOO
- Processing Code: PRO (processed food) or NSF (natural state food) or ADD (food or color additive)
- Intended Use Code: See the FDA Supplemental Guide for ACE
- Affirmations of Compliance: See the FDA Supplemental Guide for ACE

- Please also see: FDA ACE External Outreach Presentation-Human and Animal Food