Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) Public Law 107-188

U.S. Customs and Border Protection

Presentation Outline

- New working relationship with FDA
- Submitting Prior Notice
- CBP Processing
- Resources

Commissioning CBP Officers

- Memorandum of Understanding (MOU) between FDA and CBP
- Perform Prior Notice initiated Examinations at locations with limited or no FDA presence
- Receive training in FDA examination, sampling, and document review prior to December 12, 2003
- FDA to provide 24x7 hotline 800-number to assist CBP officers

Submitting Prior Notices

How Prior Notices Are Submitted

- Via ABI/ACS
- Via FDA Prior Notice System Interface

Submitting Prior Notice

ACS/ABI/OASIS Changes

- PN submission will be done using several new or enhanced components of FDA's and CBP's existing electronic systems
  - CBP's ACS to FDA's OASIS system will be enhanced to support PN
  - ABI software changes will be required to support PN information
  - New ABI/ACS/OASIS interface, modeled after existing process, will be available to submit PN for entering the U.S. as automated in-bond or FTZ admission

Submitting Prior Notice via ABI / ACS (Entry)

How to Submit PN

- PN information supplied along with ABI entry data
- 80% of entries that require prior notice processed via ABI/ACS
- FDA provides PN confirmation number electronically to CBP and CBP advises filer
- PN results matched to the ABI entry and electronically provided to CBP officers

Submitting PN via ACS (No Entry): "ACS 2-Step"

- Known as 2 step process (about 10%)
  - Electronic transmission through ACS—no consumption entry information.
  - Required information:
    - In-bond number
    - Complete AWB/Master Airway Bill
    - Bill of Lading number
  - Working on a Wanding Bar Code on FDA PN Form

Entries Not Processed Via ABI/ACS

- Any transaction involving a food subject to prior notice requirements can be input through FDA Prior Notice System Interface
- Non-automated and/or paper entries
  - Mail
  - FTZ admissions
- In-bonds unable to be filed through ACS/ABI 2-step process

Submitting PN via FDA Prior Notice System Interface

How to Submit PN

- Filer submits PN information via the FDA PN System Interface and receives PN confirmation number which filer then adds to paper entry submissions
- CBP Inspectors may need to query new database file for PN results
- A paper copy of the PN will be required for release, if requested by CBP

FDA PN System Interface (www.access.FDA.gov)

Submitting PNs: Alternative Methods

How to Submit PN When FDA PN System Interface Is Unavailable

- Use the alternative methods listed below to submit PN:
  - E-mail address: TBD
  - Fax number: TBD

www.access.FDA.gov

(see www.FDA.gov)

Merchandise with Inadequate or No PN is Subject to Refusal

At the CBP Port Director's discretion in consultation with FDA, based on availability of storage and resources merchandise subject to refusal may be:

- Held at the port
  - For seaports, airports, and courier hubs, the terminal facility of the arriving carrier is considered to be within the port of arrival
- Directed to secure facility (must be done under bond)
- Exported

Status of Merchandise with No PN or Inadequate PN

- Legal status is G.O. merchandise
- If carrier has a terminal facility, it will be held in "constructive G.O." at the terminal facility until final disposition (entry, export, sale for export only, or destruction)
- If no terminal facility available, Port Director may send it to nearest G.O. warehouse or suitable facility, which may be inside or outside the port limits

Procedures for Merchandise Retained at Port of Arrival

- Is held under “constructive G.O.”
- The Port Director will make an operational decision if and when a G.O. number should be assigned to the shipment

Procedures for Movement of Goods to a Facility Not Within the Port of Arrival

Documentation Required

- Requires the appropriate CBP control documentation
  - CBP 6043 – Permit to Transfer – for movements within CBP limits
  - CBP 7512 “Restricted in-bond” for movements outside of port entities
  - No documents needed for movement of merchandise to terminal facility of carrier within the port of arrival

Procedures for Merchandise Held in Secure Facility

- Merchandise held under G.O. procedures for each port
- Perishable shipments, or where no suitable G.O. facility exists, will be held under “constructive G.O.” or directed by the Port Director to a suitable facility; will be destroyed or sold for export after 3-days’ public notice
- Carrier will assume cost of destruction. Storage costs are between carrier and importer

Secure Facility Definition

What Is a Secure Facility?

- A bonded facility designated by the CBP Port Director (may include G.O. warehouses or other suitable facilities)
- Facilities must be registered with FDA
- Facilities outside the immediate vicinity of the port, suitable for the storage of food
- May not be the importer's,owner's, or consignee's facility
- Merchandise may be sent to a suitable facility in another port if no other options exist

Procedures for Merchandise Held in Secure Facility (continued)

What Happens to Merchandise

- Merchandise under "constructive G.O." will stay at the carrier's facility until final disposition of the merchandise
- If eventually sold, it will be for:
  - Export only (PN not required) and shipped directly (Immediate Export) out of the port in which it is being held

Registration of Facilities with FDA

Which Facilities Must Register?

- All facilities that hold food for consumption in the United States must be registered with the FDA
  - This includes:
    - Terminal facilities
    - Container freight stations (CFS)
    - Bonded warehouses (includes duty free warehouse)
    - Centralized examination stations (CES)
    - G.O. warehouses
    - Customs approved storage rooms (CASR)

Procedures for Export of Merchandise

- Shipper, importer, or carrier may decide to export with CBP concurrence
- Should be under physical control and custody of CBP
- May be documented using an Immediate Export (IE) in-bond

Procedures for Abandoned Goods

- Abandoned foods, refused for no or inadequate prior notice, will be considered G.O. merchandise and will follow normal G.O. guidelines

Procedures for Segregation of BTA Refused Foods

What Happens to Refused Foods?

- Food refused under 801(m)
  - Commingled foods within same container or truck
  - Commingled goods, e.g., goods that are “PN satisfied” and “PN not satisfied”

Procedures for Segregation of BTA Refused Foods (continued)

What Happens to Refused Foods?

- Goods must be segregated, in accordance with local procedures and in coordination with the secure facility and carrier, so that “PN satisfied” foods may enter
- “PN not satisfied” handled as refused entry and held at port, moved to a secured facility, or exported
- The carrier must bear all costs

Entry Types Impacted by BTA

- BRASS
- Permit Ports
- Customs Form 3461 Entry/Immediate Delivery
- In-bond Filing Trade Requirements
- FTZ admissions
- Express consignment
- Non-automated informal/walk-up
- International mail
- Carnets

BRASS

Entries under BRASS will no longer be permitted for foods subject to prior notice after 12/12/03

Role of Permit Ports

- It is expected that Permit Ports will be able to run ACS/ABI selectivity by effective date of prior notice requirements, 12/12/03, for existing shippers only
- This does not extend "permit" rights to new shippers through permit ports. New shippers wishing to cross at permit ports must still obtain the port director's approval

ABI/ACS Customs Form 3461 Entry/Immediate Delivery

PN Requirements/How to Process

- For merchandise to be released from CBP custody and entered into the commerce of the U.S. or for export (includes warehouse)
- All prior notice and food facility registration requirements must be satisfied prior to release

In-Bond Filing Trade Requirements

PN Requirements/How to Process

- PN submission (through ABI/ACS or FDA PN System Interface) must include in-bond number and bill number (if applicable)
- Transportation (IT) in-bond shipments may be allowed to travel to the port of entry for satisfaction of PN
- Transshipped merchandise (T&E) must satisfy prior notice requirements at port of arrival in the U.S.

In-Bond Filing Trade Requirements (continued)

PN Requirements/How to Process

- In-bond (electronic or paper) must include indicator of PN compliance
- Capability to provide a 6-digit HTS on in-bonds is under development

In-Bond Processing with PN Indicator

PN Requirements/How to Process

- Automated in-bonds will query ACS PN database and return status messages to AMS/ABI
- Paper in-bonds will require manual input by CBP of PN indicator; ACS PN database will be queried automatically and return status messages to CBP officer

Foreign Trade Zones

PN Requirements/How to Process

- No automated system for goods admitted to an FTZ
- PN requirements must be met prior to movement of goods to the FTZ
- Paper copy of PN confirmation number shall be submitted with admission document
- Direct delivery only permitted if PN requirements, including time frames are satisfied
  - 48-hour post arrival reporting time disallowed

Foreign Trade Zones

PN Requirements/How to Process

- All other movement to the FTZ done as follows:
  - Under dray or delivery ticket
  - By CF214
    - FDA PN System Interface used to submit PN
    - In-bond permitted if PN satisfied

Express Consignment

PN Requirements/How to Process

- PN is required for all Express Consignment Courier Facility (ECCF) food shipments subject to prior notice requirements
- This represents fundamental change in business practices
- Consolidated entries for foods subject to prior notice requirements will not be allowed. Separate entries will be required

Express Consignment

PN Requirements/How to Process

- No Section 321 release(on manifest) for foods subject to prior notice requirements. Entry must be made for each item subject to prior notice and food facility registration requirements.

Non-Automated Informal Entries/ Walk-ups

PN Requirements/How to Process

- All foods subject to the prior notice and food facility registration requirements must file PN unless specifically exempted
- There is no De Minimus under the prior notice rule
- Household goods containing items subject to prior notice requirements are not exempt and require PN
- PN must be filed on each item by FDA product code
- Paper copy of PN confirmation number must accompany the shipment
- Failure to have PN confirmation number may result in a refusal of admission

Non-Automated Informal Entries/ Walk-ups

PN Requirements/How to Process

- Inspector will query PN database to determine status
- Most of these will not have a bond and as a result will not be able to move their goods to a secure facility
- Many may not be able to meet PN requirements and shipment will most likely be exported or abandoned

International Mail

PN Requirements/How to Process

- Prior notice requirements apply to food as defined in the interim final regulations imported through international mail
- Food shipment must have PN confirmation number on Postal Declaration Form CN22 or CN23
- Home-made foods sent as gifts are not subject to prior notice requirements

International Mail (continued)

PN Requirements/How to Process

- If there is no PN confirmation number shipment is stamped with Refusal stamp and returned to sender if there is a return address
- If there is no return address, shipment will be destroyed
- Is shipment contains food subject to prior notice requirements and nonfood items or items not subject to prior notice requirements, the shipment will be treated as commingled goods and returned or destroyed

Help Resources

- FDA registration help:
  - U.S. Toll-free: 1-800-216-7331
  - Outside U.S.: 301-575-0156
  - Fax: 301-210-0247
  - Registration tutorial:www.fda.gov/furls
- Federal Register: www.gpoaccess.gov/fr
- Legislation: www.thomas.loc.gov
- CBP web site: www.CBP.gov

Help Resources

- FDA web site: www.FDA.gov
- FDA regional points of contacts
- Each CBP field office will have 2 BTA trained experts
- FDA Publication “What Do I Need To Know About FDA’s New Bioterrorism Rules” will available through trade associations, state agencies,U.S. embassies, and at the FDA website