

FDA and USDA Regulations: Brokers Point of View



Food and Agriculture Border Gateway Summit

Feb. 20, 2014

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A Word About Brokers



Merchandise arriving in the United States by commercial carrier must be entered by the owner, purchaser, consignee his or her authorized regular employee, or by a licensed customs broker designated by the owner, purchaser, or consignee.

US Customs brokers are the only persons who are authorized by the tariff laws of the United States to act as agents for importers in the transaction of their customs business. Customs brokers are private individuals or firms licensed by CBP to prepare and file the necessary customs entries, arrange for the payment of duties found due, take steps to effect the release of the goods in CBP custody, and otherwise represent their principals in customs matters.

Before a customs broker may make entry for their customer, a CBP power of attorney must be completed by the person or firm for whom the customs broker is acting as agent.

In addition to filing import documentation with CBP in proper form, many brokers actively participate trade organizations such as the NCBFAA or joint cooperative government councils such as COAC.

Right to Make Entry

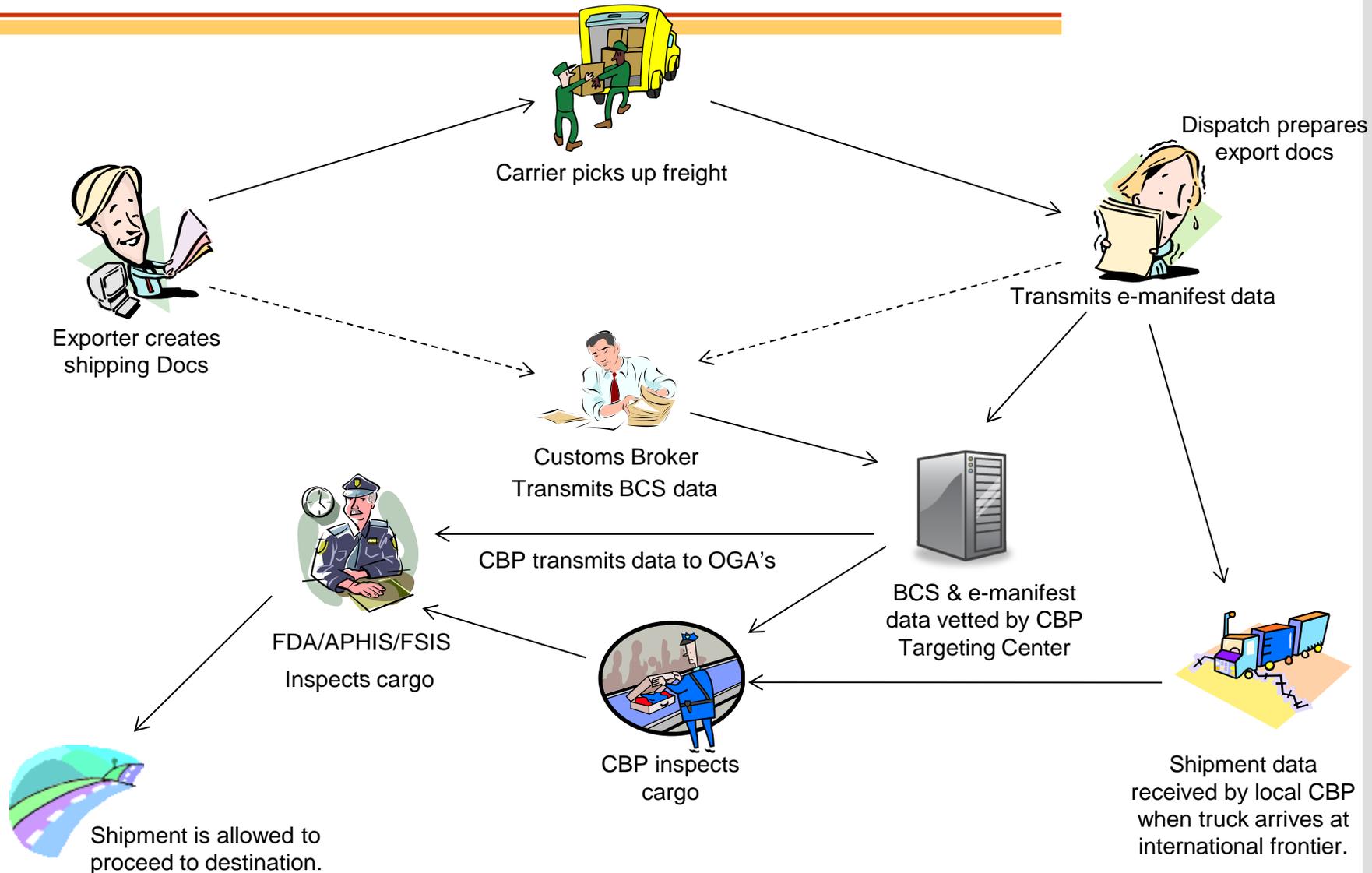


Peace Bridge – Ft Erie/Buffalo

Section 484 (Tariff Act of 1930) provides that only the “importer of record” has the right to make entry.

“Importer of Record” is defined as the owner, purchaser, or consignee of the goods, or when designated by the owner, purchaser, or consignee, a licensed Customs broker.

Basics of Importing to the United States



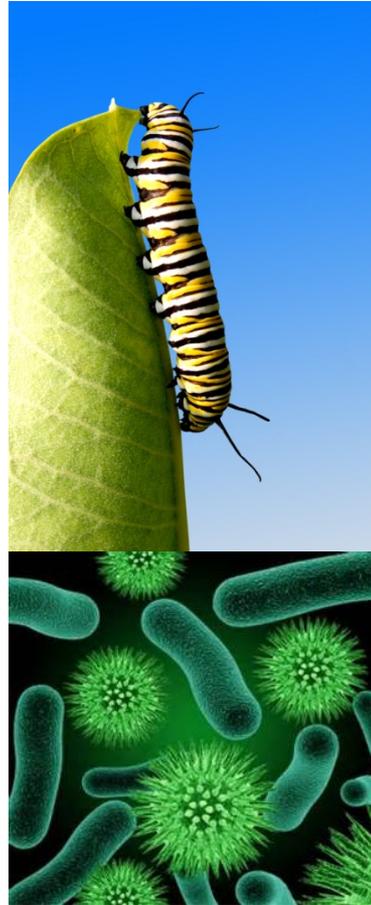
Is it FDA, USDA, APHIS, FWS or What?

- Open-face sandwich
- Closed-face sandwich
- Gravy
- Rabbit
- Eggs
- Soup
- Salmon
- Squid/Octopus
- Pizza
- Pot pies



APHIS – Animal Plant Health Inspection Service

- Agricultural Commodities (phytosanitary certs)
- Plant Materials
- Animal Products
- Biological Agents
- Insects



1. Name and address of exporter: 2. Name, address and telephone number of consignee: 3. Description of commodity: 4. Date of issue: 5. Validity period: 6. Issued at: 7. Issued by: 8. Signature of official:		STATE OF ISRAEL MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT Plant Protection and Quarantine Service PHYTOSANITARY CERTIFICATE No. R. 126/333 - 08 GHC/08/01 A. U.S. Importation Organization of: USA B. Phytosanitary Authority of: ISRAEL C. Quantity: 17 KG. PPIS PLANT PROTECTION & INSPECTION SERVICE PROFESSIONAL ANIMAL INSPECTOR (SALMON)	
10. Treatment: -NOT APPLICABLE-		16. Place of issue: 8001 Eilat	
11. Additional information: -NOT APPLICABLE-		Date: Name of authorized official: Signature:	



U.S. Fish & Wildlife Service

Wildlife is any living or dead wild animal, its parts, and products made from it. Wildlife not only includes mammals, birds, reptiles, amphibians, and fish, but also invertebrates such as insects, crustaceans, arthropods, mollusks and coelenterates.



Certain shellfish and dead fish products that are to be eaten by humans or animals may be exempt if they do not require a permit under 50 CFR 17 (endangered and threatened species) or 50 CFR 23 (species listed under CITES – the Convention on International Trade in Endangered Species). Certain domesticated animals are exempt provided they did not originally come from the wild.

U.S. Food and Drug Administration (FDA)

- **Food**
- Dietary Supplements
- Drugs
- Vaccines, Blood, Tissue & Biotech
- Medical Devices
- Radiation Emitting Devices
- Cosmetics
- Veterinary Products
- Tobacco Products
- Living organisms



FDA at the border



- Nights, Holidays & Weekends
- Samples
- Hold vs. Use
- Notice of Action
- Redelivery

What do I need to start the import process?

Questions to be answered:

- Am I the producer or grower?
- What kind of product do I want to import?
- What is the FDA product code?
- Does my product require registration?
- Does my product have special documentary requirements?
- Is my product subject to any special review?
- Am I or is the manufacturer of my product under special review?



Minimum Steps to take in the import process?

- 1) Choose a qualified broker early on
- 2) Be prepared to discuss the “facts”
- 3) Broker will need a power of attorney
- 4) Importer will need an import bond
- 5) Importer will likely be vetted financially by broker before an account is set up
- 6) Importer, manufacturers, processors, packers must register with FDA
- 7) Goods to be imported should be classified prior to shipping
- 8) Product codes must be determined
- 9) Labeling should be verified as being acceptable



PREDICT

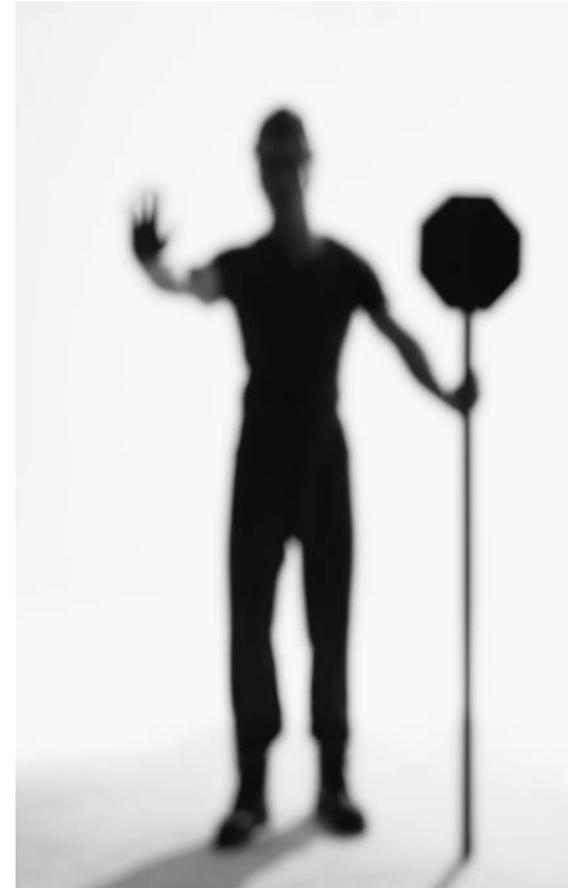


- Targeting software
- Smart programming
- Database mining
- Assigns risk



My product is being held up by FDA

- Talk to your broker NOT normally the “brokers fault”
- PREDICT scores
 - History of parties to transaction
 - Accurate data
 - Risky products
 - Type of process
 - Type of packaging
 - Inherent risk
 - Origin of product
- Natural Disasters
- Import Alerts
- Targeted Commodities



FDA Top 10 List



10 – State

9 – FCE/SID/Dims

8 – 510K

7 – Drug Codes

6 – Quantity

5 – Description

4 – MID/Registration #

3 – Type of Packaging

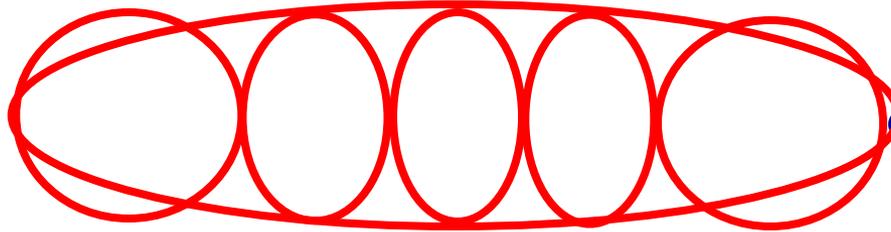
2 – Tariff Number

1 – Product Code

FDA Product Codes

03AGT12

White Bread/Plastic Bag



7 Characters

5 Distinct Elements

- Industry
- Class
- Subclass
- PIC (Process Indicator)
- Product



Food Safety Modernization Act of 2011



Major provisions

- Facility registration
- Hazard analysis
- Record keeping
- Foreign supplier verification
- Fees
- Certifications
- Inspections

What kind of Facility am I?



Standards for Produce Safety



Hazard Analysis and Risk-Based
Preventive Controls

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

Food Safety Modernization Act of 2011



Mandatory recall authority

- Voluntary procedures
- Order to cease distribution
- Informal hearing
- Recall order
- Failure to comply
- Recalled in error

Food Safety Modernization Act of 2011



Fees

- Re-inspection (facility)
- Re-inspection (port of entry)
- Recall

Don't be a Rock Star!

Engage your service provider early on.

Do your homework before you ship.

Provide clear and accurate documents.

Ensure all data needed to enter your goods is provided prior to arrival at the border.

Don't guess.

Choose your carrier wisely

Remember the importer of record is legally liable for any and all problems and errors

Is FDA available at the anticipated time of arrival at the border and at the port chosen?

Penalties and liquidated damages may be very high



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