U.S. Food and Drug Administration
Office of International Programs

Food Imports: Law & Process

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PRESENTATION OVERVIEW

I. General Overview of FDA Import Law
II. Prior Notice
III. Admissibility
IV. FSMA

Products Regulated by FDA

FDA has jurisdiction over:

- Human foods (exceptions: most meat and poultry)
- Animal feeds
- Cosmetics
- Drugs (both human and animal)
- Biologics (including human cells and tissues)
- Medical devices
- Electronic products that emit radiation
- Tobacco

FDA Imports Law

Federal Food Drug & Cosmetic Act (section 801)

- Section 801(a): Allows for refusal of imported FDA- regulated products for appearing to be adulterated or misbranded based on evidence
- Section 801(m): Requires Prior Notice of entries of food & feed products
- Section 801(l): Requires facilities, including foreign facilities, that manufacture, pack or hold food for consumption in the U.S. to register with FDA.

FDA Law - continued

FDA has jurisdiction over the products it regulates…

- Section 801 gives no new jurisdiction
- Section 801 provides for how FDA regulates those products at the time of arrival or entry into the U.S.

Food & Feed Imports

First Assessment: Prior Notice

- Section 801(m) of the Food, Drug and Cosmetic Act
- Concerned with:
  - food defense
  - food vulnerability
  - supply chain susceptibility
  - risk of intentional or unintentional contamination

Second Assessment: Import Admissibility Standards

- Section 801(a) of the Food, Drug and Cosmetic Act
- Concerned with:
  - food standards / legal requirements
  - food safety
  - adulteration
  - misbranding

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Prior Notice

Prior Notice

Section 801(m) of the FFD&CA

" …an article of food that is being imported or offered for import into the United States…shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission…of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; any country to which the article has been refused entry; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States…"

Prior Notice, continued

Food and Feed Imports Requiring Prior Notice

- Food imported for use, storage, or distribution in the U.S.
- Food transshipped through the U.S. to another country
- Food imported for future export
- Food for use in a Foreign Trade Zone

"Food" is defined as articles of food or drink for humans or animals, dietary supplements, chewing gum, or food components.

"Food" does not include food contact substances or pesticides.

Prior Notice, continued

Time Requirements For submission of Prior Notice

Shipments arriving:

- By land via road - No Less than 2 hrs. before port of arrival
- By land via rail - No less than 4 hrs. before port of arrival
- By air - No less than 4 hrs. before port of arrival
- By water - No less than 8 hrs. before port of arrival
- By international mail - Before the food is sent

Prior Notice, continued

PN Data Elements Required
(Not all inclusive)

Manufacturer (or Grower) -Name w/Food Facility Registration (FFR) # or *Name w/site specific address & "Reason" why FFR # not provided	Anticipated Arrival Info
Shipper	Anticipated Shipment Info
U.S. Consignee	Importer
Country of Origin	PN Transmitter & Submitter, if different
Product Identification	Entry Identifier

Prior Notice, continued

When can an article of food be refused for Prior Notice?

- When an article arrives with No or Untimely Prior Notice
- When the manufacturer is not registered with FDA
- If, upon review of the prior notice data, FDA determines that submitted information is false or inaccurate.
- If, upon review of the entry documentation or physical inspection, the FDA is advised by CBP or FDA Field Staff that prior notice is inaccurate or missing.

Once Prior Notice is satisfied, the entry proceeds to 801(a), admissibility review.

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Admissibility

Admissibility

Section 801(a) of the FFD&CA

"If it ***appears**** from the examination of such samples ***or otherwise**** that…

(1) such article has been manufactured, processed, or packed under insanitary conditions… or
(2) such article is forbidden or restricted in sale in the country in which it was produced … or
(3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)

then such article shall be refused admission…"

*Emphasis added.

Admissibility, continued

"**appears**" – provides FDA's standard of proof

- We can refuse entry to goods that:
  - Appear to be adulterated or misbranded
  - Appear to be unapproved new drugs
  - Appear to have been manufactured not in accordance with GMPs

Admissibility, continued

"**or otherwise**" – allows FDA to make admissibility decisions using:

Historical data
Examinations (vs. sample collections)
Information from other sources
Other evidence

Admissibility, continued

"…***shall*** be refused admission…" – directs FDA's action

- The intent of the law is to *deny importation* of violative articles
- Articles are expected and required to be in compliance *at the time of entry.*

Admissibility, continued

FDA will decide whether to:

- Release the goods
- Detain the goods without exam
  - Based on submission of required information
  - Based on import alerts
- Obtain more information:
  - Through Documents
  - Through Examination and/or Sample Collection

FDA can detain based upon “appearance” of a violation

- Importer has the right to give evidence to refute this appearance.
  - This is known as the “Detention and Hearing Process”
- Based on the evidence, the detention will either stand (refusal) or be overturned (release)
- Importer can also petition to recondition the goods to bring them into compliance
  - Relabeling a misbranded product
  - Cleansing an adulterated product
  - Making a product not FDA regulated
  - Reconditioning must be approved by FDA

Admissibility - Notices

FDA Detention Notice to importer and consignee

- Indicates our belief the articles are subject to refusal
- Reason(s) why
- Right to provide testimony (evidence)
- Timeframe for response
- Contact name/number

FDA provides Notice to importer and consignee, indicating intent to examine/sample

- Required by statute
- Importer/consignee to make articles available to FDA

Admissibility, refused product

If a product can not be brought into compliance, the product will be refused entry

- Refused product must be either destroyed or exported
  - Courts: importer's decision
- A redelivery notice is issued by CBP upon refusal
- Liquidated Damages (3x declared value) if products are not exported or destroyed
- FDA does have authority to seize product if certain criteria have been met

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The Food Safety Modernization Act (FSMA) and IMPORTS

Why is the law needed?

Globalization

- 15 percent of U.S. food supply is imported

Food supply more high-tech and complex

- More foods in the marketplace
- New hazards in foods not previously seen

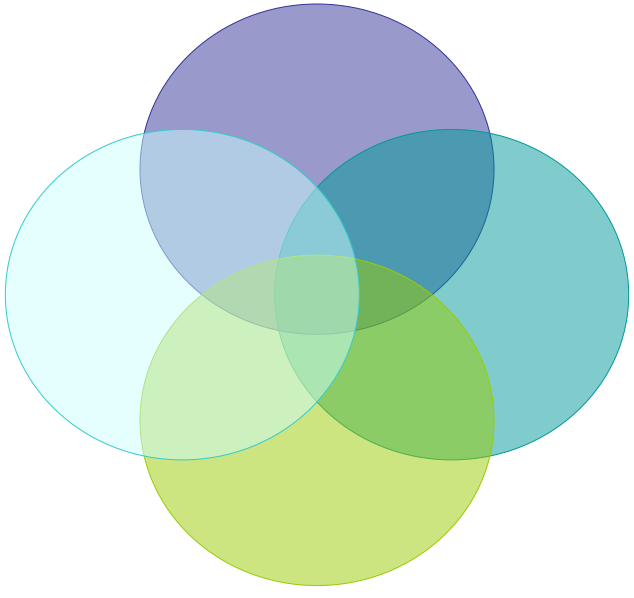
Shifting demographics

- Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

Main Themes of the Legislation

Prevention

Enhanced Partnerships



Inspections, Compliance, and Response

Import Safety

Import Safety: Most Groundbreaking Shift

- Current reliance on port-of-entry inspection cannot handle increase in imported food
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- Requires food from abroad to be as safe as domestic

FSMA – Where are we now?

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Thank you!

For more information:
http://www.fda.gov/ForIndustry/ImportProgram/default.htm