Bioterrorism and Food Defense: Imported Foods

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Agenda

- Why are we concerned about food defense?
- Import volume
- Prior Notice regulation
- Food Facility Registration
- Protein Surveillance Assignment
- Summary
Why Are We Concerned about Food Defense?

- No specific targeting information indicating attack on food supply is imminent
- Intelligence indicates that terrorists have discussed components of food sector
- Manuals for intentional contamination of food are widely available
- Concern exists for exploitation of soft targets, such as the food supply
Why Are We Concerned about Food Defense?

- Use of biological or chemical weapons against food supply could cause mass casualties
- Even an ineffective attack could cause significant economic and psychological damage
- Severity of attack dependant upon the agent and attack scenario used and the efficiency and effectiveness of detection and response
Import Volume History vs. Import FTE History
What types of goods are imported?

- Foods: 59%
- Devices and Rad Health: 28%
- Animal Drugs and Feed: 2%
- Biologics: <1%
- Human Drugs: 2%
- Cosmetics: 9%
The Bioterrorism Act

- **Title I** -- National Preparedness for Bioterrorism and Other Public Health Emergencies

- **Title II** -- Enhancing Controls on Dangerous Biological Agents and Toxins

- **Title III** -- Protecting Safety and Security of Food and Drug Supply

- **Title IV** -- Drinking Water Security and Safety
Prior Notice Regulation
Prior Notice Regulations

Under the authority of the Bioterrorism Act, signed by President Bush in June 2002, FDA is responsible for carrying out certain provisions of the Bioterrorism Act, particularly

**Title III**
Protecting Safety and Security of Food and Drug Supply

- Food Facility Registration (Sec 305)
- Prior Notice of Imports (Sec 307)
- Administrative Detention
- Maintenance of Records
Prior Notice of Imports

- Effective December 12, 2003
- This regulation requires the FDA to receive prior notice of all imported food shipments before entering the U.S.
Food Defense vs. Admissibility

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
  - significant public health risk

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
  - significant public health risk
Why PN is Required?

- Review and evaluate information before food arrives in the US
- Better deploy resources to conduct examinations
- Help intercept contaminated products
- Determine security and integrity of product
Sec. 307: Prior Notice of Imported Food

● Per the BTA, prior notice must include the identity of:
  – the article
  – manufacturer and shipper
  – grower (if known)
  – originating country
  – country from which it was shipped
  – anticipated port of arrival
  – additional enforcement efficient elements

● Elements dependent upon Mode of Transportation and Entry Type

● Time Requirements of Prior Notice
  – 2 Hours: Land (Truck, Car, Person)
  – 4 Hours: Air and Rail
  – 8 Hours: Sea
Risk Assessment

- PNC assessments utilize historical and intelligence databases from FDA, NTC, and OGAs to assess high risk shipments where food safety may be compromised.
- High Risk Food criteria researched and established with FDA Center for Food Safety & Applied Nutrition using ORM and CARVER-Shock techniques.
- Screening and targeting criteria is set in FDA’s OASIS system.
- Unique FDA risk-based rules weighted in CBP’s Automated Targeting System.
PNC Targeting in OASIS

● Screening criteria can be set for specific or broad ranges of products, country of origin, firms, individuals, PN bills, ports, carriers, and other shipping elements.

● Criteria can be changed/modified within moments to address threats as they develop or in response to information received from various INTEL sources.
BTA Holds and Other Actions

Regular Collaborations between PNC, FDA and OGAs stationed at the NTC and elsewhere:

BTA Exams – Over 9405 CBP Officers Commissioned for BTA Exams and Samples

BTA Holds - Made in conjunction with CBP at NTC and at the Local Ports

BTA Refusals - Made in conjunction with CBP at the Local Ports. (Over 460 lines in FY2006)
Prior Notice Refusals

When Can an Item Be Refused???

- When an item arrives with No or Untimely Prior Notice
- When the manufacturer is not registered with FDA
- If, upon review of the prior notice data, the PNC determines that submitted information is false or inaccurate.
- If, upon review of the entry documentation or physical inspection, the PNC is advised by CBP or FDA Field Staff that prior notice is inaccurate or missing.
- 460 refusals conducted in conjunction with CBP in FY2006
## PNs by Mode of Transportation

<table>
<thead>
<tr>
<th>Entry</th>
<th>Approx. %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sea</td>
<td>38.1</td>
</tr>
<tr>
<td>Truck</td>
<td>21.9</td>
</tr>
<tr>
<td>Air</td>
<td>21.4</td>
</tr>
<tr>
<td>Mail</td>
<td>14.9</td>
</tr>
<tr>
<td>Car</td>
<td>2.1</td>
</tr>
<tr>
<td>Rail</td>
<td>0.9</td>
</tr>
<tr>
<td>Other</td>
<td>0.7</td>
</tr>
</tbody>
</table>
Food Facility Registration Regulation
Registered Food Facilities

● As of November 20, 2006:
  ─ Domestic (U.S.) registrations: 153,254
  ─ Foreign registrations: 273,594
  ─ Total: 426,848

● For registration by country, see:
  http://www.cfsan.fda.gov/~furls/ffregsum.html
<table>
<thead>
<tr>
<th>FOREIGN COUNTRIES WITH ≥ 3,000 REGISTERED FACILITIES</th>
<th>NO. REGISTERED FOREIGN FACILITIES (171,837 TOTAL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAPAN</td>
<td>19,685</td>
</tr>
<tr>
<td>CHINA</td>
<td>15,141</td>
</tr>
<tr>
<td>CANADA</td>
<td>12,453</td>
</tr>
<tr>
<td>FRANCE</td>
<td>12,168</td>
</tr>
<tr>
<td>MEXICO</td>
<td>12,066</td>
</tr>
<tr>
<td>ITALY</td>
<td>10,970</td>
</tr>
<tr>
<td>VIETNAM</td>
<td>4,669</td>
</tr>
<tr>
<td>SPAIN</td>
<td>4,515</td>
</tr>
<tr>
<td>KOREA, REPUBLIC OF</td>
<td>4,224</td>
</tr>
<tr>
<td>INDIA</td>
<td>3,875</td>
</tr>
<tr>
<td>ECUADOR</td>
<td>3,770</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>3,476</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>3,472</td>
</tr>
<tr>
<td>GERMANY</td>
<td>3,283</td>
</tr>
<tr>
<td>CHILE</td>
<td>3,251</td>
</tr>
<tr>
<td>TOTAL (15 countries)</td>
<td>117,018 (68% of all foreign)</td>
</tr>
</tbody>
</table>

Data as of September 14, 2006
FDA Pilot Test of Emergency Contact System
(www.cfsan.fda.gov/~furls/ffregacc.html)

- Notified facilities by e-mail, fax, or phone using primary mode of transmission

<table>
<thead>
<tr>
<th>FACILITY</th>
<th>DOMESTIC</th>
<th>FOREIGN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of test facilities</td>
<td>400</td>
<td>400</td>
</tr>
<tr>
<td>Emergency contact information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone only</td>
<td>75 (18.7%)</td>
<td>46 (11.5%)</td>
</tr>
<tr>
<td>E-mail and phone</td>
<td>325 (81.3%)</td>
<td>345 (86.2%)</td>
</tr>
<tr>
<td>Fax and phone</td>
<td>0</td>
<td>9 (2.3%)</td>
</tr>
</tbody>
</table>
Domestic Test Facility Results

- FDA could only contact 361 of the 400 (90.3%) facilities; received response from 289 (72.2%) ECs
  - 244 persons verified is the EC (61.0% of test facilities)
  - 41 persons stated that they were **not** the EC (10.2%)
  - 4 persons did not speak English; could not verify status (1.0%)
  - 72 of the 400 test facilities (18.0%) failed to respond

- 39 of 400 test facilities (9.8%), telephone number provided in the Food Facilities Registration Database inaccurate
Foreign Test Facility Results

- FDA could only contact 351 of the 400 (87.8%) facilities; received response from 235 (58.8%) ECs
  - 192 persons verified is the EC/US Agent (48.0%)
  - 43 persons stated that they were not the EC/US Agent (9.2%)
  - 37 persons did not speak English; could not verify status (9.2%)
  - 79 of the 400 test facilities (19.7%) failed to respond
- 48 of 400 test facilities (12.0%), telephone number provided in the Food Facilities Registration Database inaccurate and 1 out of business (0.3%)
### Accuracy of Identity of Test Facilities’ Mode of Transmission & Identity of Emergency Contact/U.S. Agent

<table>
<thead>
<tr>
<th></th>
<th>Inaccurate primary e-mail, fax, or phone number</th>
<th>Accurate primary e-mail address, fax number, or phone number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inaccurate EC/US Agent</td>
<td>Accurate EC/US Agent</td>
</tr>
<tr>
<td>Domestic Test Facilities</td>
<td>18.5%</td>
<td>57.8%</td>
</tr>
<tr>
<td></td>
<td>Inaccurate EC/US Agent</td>
<td>Inaccurate EC/US Agent</td>
</tr>
<tr>
<td>Domestic Test Facilities</td>
<td>6.0%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Foreign Test Facilities</td>
<td>16.5%</td>
<td>43.5%</td>
</tr>
<tr>
<td></td>
<td>Inaccurate EC/US Agent</td>
<td>Accuracy of EC/US Agent Unknown</td>
</tr>
<tr>
<td>Foreign Test Facilities</td>
<td>10.3%</td>
<td>29.7%</td>
</tr>
</tbody>
</table>
## Estimated Accuracy of All Registered Facilities’ Primary Mode of Transmission

<table>
<thead>
<tr>
<th>All Registered Domestic Facilities</th>
<th>All Registered Foreign Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accurate</strong>&lt;br&gt;primary e-mail address, fax number, or phone number</td>
<td><strong>Accurate</strong>&lt;br&gt;primary e-mail address, fax number, or phone number</td>
</tr>
<tr>
<td><strong>Inaccurate</strong>&lt;br&gt;primary e-mail address, fax number, or phone number</td>
<td><strong>Inaccurate</strong>&lt;br&gt;primary e-mail address, fax number, or phone number</td>
</tr>
<tr>
<td>75.4 – 85.3%</td>
<td>78.5 – 88.5%</td>
</tr>
<tr>
<td>14.7 – 24.6%</td>
<td>11.5 – 21.5%</td>
</tr>
</tbody>
</table>
**Estimated Accuracy of the Emergency Contact System for All Registered Facilities**

<table>
<thead>
<tr>
<th></th>
<th>Accurate Primary Mode of Transmission and EC/US Agent</th>
<th>Inaccurate Primary Mode of Transmission or Inaccurate EC/US Agent</th>
<th>Accuracy of Primary Mode of Transmission and/or EC/US Agent Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Registered Domestic Facilities</td>
<td>52.0 – 61.9%</td>
<td>20.6 – 30.5%</td>
<td>12.6 – 22.4%</td>
</tr>
<tr>
<td>All Registered Foreign Facilities</td>
<td>38.5 – 48.5%</td>
<td>21.8 - 31.8%</td>
<td>24.7 – 34.7%</td>
</tr>
</tbody>
</table>
Recommended Follow-up Actions for FDA

- Notify test facilities with inaccurate data
- Enhance coding of database to do review checks (e.g., area code matches zip code)
- Prepare a “How to Guide” for industry that addresses common errors
- Post results on website
- Conduct 2\textsuperscript{nd} test in FY07 to see if accuracy has improved
Recommended Follow-up Actions for Facilities

It is **YOUR responsibility** to maintain accuracy

- Review ALL data in existing registrations
- You **must** (per the final rule):
  - Update any mandatory data that have changed
    - E.g., have you added new product lines to your production?
  - Cancel existing registrations if facility is out of business or has been sold
- You **should**:
  - Update any voluntary data that have changed
  - Cancel duplicate registrations for same facility
Protein Surveillance Assignment (PSA)-Background

- March/April 2007, FDA began investigating pet deaths in the U.S. associated with the consumption of pet food contaminated with melamine.
- Shipments of both wheat gluten and rice protein (and corn gluten in South Africa) imported from China have been implicated.
- FDA is taking this proactive measure to help ensure the safety of the U.S. food and feed supply.
PSA-Overview

- The assignment focus will be on:
  1) imported protein extracts and finished products (added later) in domestic status, and
  2) PNC directed assignments for ingredients/products of interest in import status (with the exception of vegetable protein concentrates, which are covered under Import Alert 99-29).

- May 1-June 30, 2007
PSA-Overarching Goals

- Examine, through inspection and sample analysis, ingredients and finished products imported from China (or transshipped from China) for the presence of melamine and other contaminants,
- Launch an educational campaign to make the food and feed industry more aware of the issues in light of the recent pet food recalls involving wheat gluten, rice protein concentrate and corn gluten; and
- Deter intentional contamination of food and feed through heightened and targeted preventive activities at various food and feed manufacturers who use a variety of protein ingredients to produce their products.
Domestic Inspections

- Coordination Team Directed
- Target food and feed ingredients and finished products of interest in Domestic status
- Inspections include:
  - Reconciliation inspection
  - Record review and collection (1 forward/1 back)
  - Sample Collection
  - ALERT and Assignment information offered
PSA Import Inspections

- PNC directed
- Target food and feed ingredients and finished products of interest not covered by the Import Alert
- Shipments held in “Import” status
- Inspections include:
  - Reconciliation inspection
  - Sample Collection
  - ALERT and Assignment information offered
Import Alert 99-29

- Issued 4/27/07
- "DETENTION WITHOUT PHYSICAL EXAMINATION OF ALL VEGETABLE PROTEIN PRODUCTS FROM CHINA FOR ANIMAL OR HUMAN FOOD USE DUE TO THE PRESENCE OF MELAMINE AND/OR MELAMINE ANALOGS"
- PRODUCTS: Wheat Gluten, Rice Gluten, Rice Protein, Rice Protein Concentrate, Corn Gluten, Corn Meal, Corn By-Products, Soy Protein, Soy Gluten, Proteins (includes amino acids and protein hydrosylates), Mung Bean Protein
PSA Status

- Over 120 inspections completed
- Over 160 samples processed
- Products have included wheat, rice, corn, soy ingredients, baby formula, gelatin, whey, meal replacement drinks, fish food, etc.
Hot Off the Press!!!
CARVER + Shock Tool

- FDA released the software version of the CARVER + Shock Vulnerability Assessment Tool on 6/15/2007
- [http://www.cfsan.fda.gov/~dms/vltcarv.html](http://www.cfsan.fda.gov/~dms/vltcarv.html)
- FREE!!!
Summary

- Volume of food imports continues to increase
- Re-examining FDA’s overall food protection strategy
- Working closely with foreign governments and industry
Questions?
Thank you very much!!

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