



U.S. Department of Health and Human Services

**Food and Drug Administration**

# **Overview of FDA's Proposed Regulations Implementing the Bioterrorism Act**

**Michael E. Kashtock, Ph.D.**

**Division of Plant Product Safety**

**Office of Plant and Dairy Foods and Beverages**

**Center for Food Safety and Applied Nutrition**

# Purpose of Presentation

- Provide an overview of proposed regulations implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“the Bioterrorism Act”) (PL 107-188):
  - **Section 303: Administrative Detention**
  - **Section 305: Registration of Food Facilities**
  - **Section 306: Establishment and Maintenance of Records**
  - **Section 307: Prior Notice of Imported Food Shipments**
- Provide an overview of FDA’s food security guidelines

# Proposed Registration Requirements

68 FR 5378 (Feb. 3, 2003)

*Statutory Deadline: December 12, 2003*  
*(Self-executing if FDA misses deadline)*

# Who Must Register?

- **Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food (subject to FDA's jurisdiction) for human or animal consumption in the U.S.**
- **Domestic facilities would be required to register whether or not food from the facility enters interstate commerce**

# What Facilities Does The Proposed Rule Exempt?

- Non-profit facilities
- Retailers
- Farms
- Restaurants
- Fishing vessels, except those that engage in processing as defined in FDA's seafood HACCP regulations (21 CFR 123.3(k))
- Facilities subject to the *exclusive* jurisdiction of the U.S. Department of Agriculture

# **Additional Exemption for Some Foreign Facilities**

- **Foreign facilities** that manufacture/process, pack or hold food also exempt IF . . .
  - . . . a subsequent foreign facility further manufactures/processes (including packaging) the food outside the U.S.

# **Proposal: What Information Is Required?**

- **Name, full address, phone number, fax number, and e-mail address of the facility**
- **Same information for the parent company, if the facility is a subsidiary**
- **All trade names the facility uses**

# **What Information Is Required?**

## **(cont.)**

- **Emergency contact person's information**
- **Food product categories (21 CFR 170.3)**
- **A statement that the information submitted is true and accurate and person is authorized to register the facility**
- **The name and contact information of the person submitting the registration**
- **Name of foreign facility's U.S. agent and the agent's contact information**

# Optional Information\*

(\* Mandatory registration fields still required)

- Preferred mailing address
- Type of activity (e.g., manufacturer/processor)
- Additional food product categories
  - E.g., dietary supplements, infant formula, animal feed
- Type of storage
- “Most/all” food product category (instead of mandatory food product categories)
- Approximate dates of operation, if seasonal

# Proposed Rule: How to Register

- **FDA strongly encourages electronic registration**
- **Paper registrations accepted if Internet access not reasonably available**

# What if Changes Occur?

- **Registration is one-time, not annual**
- **No registration fee**
- **But updates required within 30 days of change of any information previously submitted to FDA (mandatory or optional fields)**

# **What If A Facility Is Not Registered?**

- **Failure to register is a prohibited act**
- **Imported food from an unregistered foreign facility shall be held at the port of entry until facility is registered, unless FDA directs its removal to a secure facility**
- **Owner, purchaser, importer, or consignee must arrange for storage of the article of food in an FDA- designated secure facility**

**Proposed Requirements for  
Prior Notice Regulation  
68 FR 5428 (Feb. 3, 2003)**

*Statutory Deadline: December 12, 2003*

*Self-executing if FDA misses deadline\**

(\*Notice required of not less than 8 hours or more than 5 days until final regulations in effect)

# Proposal - Who is Authorized to Provide Prior Notice?

- The **purchaser or importer** of an article of food (or their agent) who resides or maintains a place of business in the U.S.
- The **arriving carrier or in-bond carrier**, if the article of food is imported for in-bond movement through the U.S. for export
  - E.g., Transportation for Exportation or Immediate Export entries

# **What Food is Not Subject to Proposed Prior Notice Requirements?**

- **Food in individual's personal baggage for personal consumption (themselves, family, friends)**
- **Meat, poultry and egg products that at the time of importation are subject to USDA's *exclusive* jurisdiction**

# Proposal: When Is My Prior Notice Due?

- **By noon of the calendar day before** the article of food arrives at the port of entry
  - *Time is based on time zone at port of entry*
- Notice *cannot* be given more than 5 days before arrival
- **Up to 2 hours before arrival:**
  - Amendments to provide more specifics about product identity
  - Updates to anticipated arrival information

# **How do I Submit Prior Notice, Amendments & Updates?**

- **Must be submitted electronically through FDA's Prior Notice System (Internet-based)**
  - **Will receive automatic confirmation of receipt with date and time**
  - **Available 24 hours/day, 7 days/week**

# **Proposal: What Information is Required in a Prior Notice?**

- **Submitter , firm/individual**
- **Entry type, consumption/export, Customs code**
- **Location if food is being held due to failure to submit prior notice (or adequate prior notice)**
- **Entry number and line number**
- **Identity of the article of food**
  - **FDA product code – 7 digits**
  - **Common/usual/market name/trade/brand name**
  - **Quantity**
  - **Identifiers, if applicable (e.g., lot/code number)**

# **What Information is Required in a Prior Notice? (cont.)**

- **Manufacturer and shipper\***
- **All importer(s), owner(s), consignees\***
  - \* **Must include registration number of facility associated with the food if applicable**
- **Grower, if known**
- **Originating country**
- **Country from which the article was shipped**

# **What Information is Required in a Prior Notice? (cont.)**

- **Anticipated arrival information**
  - Port of entry, date, time
- **Customs port of entry**
- **Carrier**
- **Submission type**
  - Initial, amendment of product identity, update to anticipated arrival, cancellation

# **Sec. 307: Prior Notice of Imported Food Shipments**

- **Prohibited act to fail to provide notice**
- **If no notice/adequate notice not provided, article refused admission**
- **Article held at the port of entry or in secure storage until proper notice is provided**
  - **Transportation and storage costs borne by the owner, purchaser, importer or consignee**

# **Proposed Recordkeeping Requirements**

**68 FR 25187 (May 9, 2003)**

***Statutory Deadline: December 12, 2003***

# Who Would Be Required To Establish And Maintain Records?

- **Domestic *persons*** that manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in the U. S.
  - *Persons* includes individuals, partnerships, corporations, cooperatives, associations, and government entities.
- **Foreign *facilities*** that manufacture, process, pack or hold food intended for human or animal consumption in the U.S., unless excluded

# Whom Does The Proposed Rule Exclude?

- Farms
- Restaurants
- Fishing vessels not engaged in processing\*
- Firms regulated *exclusively* by the U.S. Department of Agriculture (USDA)
- Pet food entities\* that are exempt from the BSE rule (21 CFR 589.2000)

\*These entities are *not* excluded from the records access provisions

# Whom Does The Proposed Rule Exclude? (cont)

- Foreign facilities, *if* food undergoes further manufacturing/processing (including packaging) by another facility outside the US, *unless* the activities of the subsequent facility are limited to a **de minimis** activity
  - If so, the facility that conducts the **de minimis** activity also must establish and maintain records
- Retail facilities (partial)
- Roadside stands selling *unprocessed* food from its farm or a neighboring farm
  - *No* exclusion from the records access provisions

# **Records Non-transporters Have To Establish And Maintain to Identify the Immediate Previous Source (IPS)**

**Non-transporters have to establish and maintain records to identify the non-transporter and transporter IPS of all food you *receive* that include:**

- **Firm name, including responsible individual and contact information (domestic or foreign)**
- **Description of type of food received, including brand name and specific variety**

# **Records Non-transporters Have To Establish And Maintain to Identify the IPS (cont)**

- **Date food was received**
- **Lot number or other identifier, if available**
- **Quantity and how the food is packaged (e.g., 25 lb cartons)**
- **Name, responsible individual, and contact information of the transporters who brought the food *to you***

# Non-transporters' Records Regarding the Immediate Previous Source

- Records must include all information *reasonably available* to you to identify the **specific source** of each ingredient that was used to make every lot of finished product
  - What is reasonably available may vary from case to case

# **Records Non-transporters Have To Establish And Maintain to Identify the Immediate Subsequent Recipient (ISR)**

**Essentially the same as the records non-transporters have to establish and maintain to identify the immediate previous source.**

# **Records Transporters Have To Establish And Maintain to Identify the IPS and ISR**

**Essentially the same as the records non-transporters have to establish;**

**However, transportation firms using multiple modes of transportation need to identify each and every mode of transportation and responsible individual(s) throughout transport.**

# Frequently asked questions

- **Do other recordkeeping requirements in statutes and regulations still apply?**
- **When do I have to create the records?**
- **Can I use existing records?**
- **In what format must I establish and maintain records?**
- **How long must the records be retained?**
- **What are the record availability requirements?**
- **What records are excluded?**
- **When would compliance with the recordkeeping rule be required?**

**Proposed Administrative  
Detention Requirements  
68 FR 25241 (May 9, 2003)**

*Statutory Deadline: None*

*FDA Publication Goal: December 12, 2003*

# **What are the criteria for detaining food?**

**An officer or qualified employee of FDA may order detention of food if credible evidence or information that the food presents a threat of serious adverse health consequence or death to humans or animals (SAHCODHA)**

- Applies to both domestic and imported foods**

# **Administrative Detention**

- **Detention must be approved at district director level or higher, as designated by the Secretary**
- **Detention period  $\leq 20$  days, unless Secretary needs more time ( $\leq 30$  days total) to pursue seizure or injunction**
- **FDA can direct the movement of the food to a secure facility, as appropriate**
- **Prohibited act to transfer an article in violation of a detention order or remove/alter any required mark or label**

# Proposed Expedited Procedures for Detained Perishable Foods

- If FDA initiates a seizure action against a detained perishable food, FDA will:
  - send the **seizure recommendation** to the U.S. Department of Justice (DOJ)  **$\leq 4$  calendar days after detention order issued**, unless extenuating circumstances\* exist
    - \*Includes, but not limited to instances when the results of confirmatory testing or other evidential development requires  **$> 4$  working days to complete**

# **When does a detention order terminate?**

- **FDA authorized representative will issue a detention termination notice if FDA terminates a detention order or the detention period expires**
- **Detention order deemed terminated if FDA fails to issue a detention termination order or detention period expires**

# Appeals

- **Any person who would be a claimant for the food, if seized under section 304(a) of the Act, can appeal a detention order**
- **Request of an appeal with or without an informal hearing must be addressed to the FDA District Director in whose district the food is located**
- **FDA Regional Food and Drug directors or officials senior to them preside at hearings, who may require hearing to be completed within 1 day**
- **Presiding officer will issue final agency decision**

# **Administrative Detention**

## **Right to Appeal**

- **BT Act requires Secretary, after an opportunity for informal hearing, to decide appeals in 5 days**
  - **Appeal decision is subject to judicial review**
  - **process terminates if Secretary files for seizure or injunction**
  - **detention order terminates if Secretary does not comply with appeal requirements**

# Next Steps

- These are *proposed* rules
  - No duty to comply now
  - Comments Period for all proposed rules are now closed.
  - FDA plans to publish the final rules for registration and prior notice by **Oct. 12, 2003** and have the registration system operational and to “test” the prior notice system at this time.
  - FDA plans to publish final rules for record keeping and administrative detention by **December 12, 2003**.

# **How Do I Get a Copy of the Proposed Rule(s)?**

**<http://www.fda.gov/oc/bioterrorism/bioact.html>**

- **Or write to:**

**Dockets Management Branch (HFA-305)**

**Food and Drug Administration**

**5630 Fishers Lane, Room 1061**

**Rockville, MD USA 20852**

## **For Further Information . . .**

- **For current information on FDA's efforts under the Bioterrorism Act :**

**<http://www.fda.gov/oc/bioterrorism/bioact.html>**

# **Guidance on Food Security Preventive Measures**

- **Guidance represents the agency's current thinking on appropriate measures that can be taken to minimize the risk of food being subjected to tampering or criminal or terrorist actions.**
- **It does not create or confer any rights for or on any persons and does not operate to bind FDA or the public.**

# **Guidance on Food Security Preventive Measures**

- **Published final guidance on 3/21/03**
  - **Food producers, processors, and transporters**
  - **Importers and filers**
- **Published draft guidance on 3/21/03**
  - **Retail food stores and food service establishments**
  - **Cosmetic processors and transporters**

# Guidance

- **Aid to operators of food producers, processors, and transporters**
- **Minimize the RISK that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions**
- **Requires the commitment of management and employees to be successful**

# Guidance

- **Areas Covered**

- **Management**

- **Human elements – staff, visitors**

- **Facility – physical security, lab safety**

- **Operations**

- **Incoming material, storage, water and utilities**

- **Finished products, mail/mail packages**

- **Access to computer systems**

# Food Security Preventive Measures Guidance

- **Emergency Point of Contact**
  - **FDA 24 Hr Contact (301) 443-1240**
  - **FDA's Website ([www.fda.gov](http://www.fda.gov))**
    - **Local FDA District Office**
    - **Manuals and publications**