Food and Drug Administration

Overview of Registration and Prior Notice Proposed Regulations Implementing the Bioterrorism Act

Howard E. Lewis
Director, Nashville Branch
New Orleans District

Background: FDA's Regulatory Development Timeline cont'd

- By Oct. 12, 2003: FDA plans to issue final rules and have Information Technology systems operational at this time (rules would be effective Dec. 12, 2003)

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 required to register whether or not food from the facility enters interstate commerce

Who Must Register
contd

- Foreign facilities may choose to designate their U.S. agent as their agent-in-charge for purposes of registration

- U.S. agent must reside or maintain a place of business in the United States

  - Proposed requirements consistent with FDA's drug, biologics, and device registration regulations found in 21 CFR parts 207, 607, and 807, respectively

What Food is Subject to FDA's Jurisdiction?

- Definition in sec. 201(f) of the Federal Food, Drug, and Cosmetic Act applies:

  - i.e., "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

- Examples of FDA-regulated food:
  - Food and food additives for man or animals
  - Dietary supplements and dietary ingredients
  - Infant formula

Examples of FDA-Regulated Food contd

- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned foods
- Live food animals
- Bakery goods, snack food, and candy

Proposed Definitions Contd

- Facility – an establishment or structure(s) under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for human or animal consumption in the U.S.

Proposed Definitions Contd

- Facility

  - A “facility” may be one food processing plant with multiple buildings in one location

  - A building that has multiple companies at the same address would be considered 2 or more facilities

Proposed Definitions Contd

- Manufacturing/processing

  -Making a food from one or more ingredients

  -Synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients

- E.g., cutting, peeling, trimming, washing, waxing, bottling, labeling, or packaging

Proposed Definitions Contd

- Packing – placing, putting, or repacking food into different containers without making any change to the form of the food
- Holding – storage of food

  - e.g. warehouses, cold storage facilities, storage silos, grain elevators, liquid storage tanks

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. Dept. of Agriculture

What Facilities Does FDA Not Regulate?

- Facilities that are subject to the exclusive jurisdiction of the U.S. Dept. of Agriculture (USDA)
- NOTE: USDA regulates meat products, poultry products, and egg products

Proposed Definitions contd

- Non-profit facility

  -A charitable entity that prepares, serves, or otherwise provides food to the public
  - E.g. food banks, soup kitchens, and nonprofit food delivery services
  - Must be exempt from paying income tax under the U.S. Internal Revenue Code

Proposed Definitions contd

- Retail facility:

  - A facility that sells food products directly to consumers *only*; and

  - A facility that manufacturers/processes food in that facility for direct sale to consumers from that same facility

Proposed Definitions contd

- Restaurant – a facility that prepares and sells food directly to consumers for immediate consumption
  - e.g., cafeterias; and hospital, nursing home, or day care kitchens; and by analogy, pet shelters, kennels and veterinary facilities that provide food directly to animals
  - Facilities that provide food to interstate conveyances (e.g., trains, planes) are **not** restaurants

Proposed Definitions contd

- Farm: a facility in one general physical location devoted to the growing of crops for food and/or the raising of animals for food (including seafood)

  - e.g., apple, orchards, dairy farms, feedlots, and aquaculture facilities

Proposed Farm Definition contd

Farm includes a facility that …

- Packs or holds food if all food is grown or raised on that farm or consumed on that farm; and
- Manufactures/processes food, if all of the food used in such activities is consumed on that farm or another farm under the same ownership

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.

Foreign Facilities— Register or Exempt?

- Register:
  -Manufacturing/processing a finished food product
  -Packing or holding a food product or food ingredient

- Exempt:
  -Manufacturing/processing a food ingredient that is subsequently further manufactured/processed outside the U.S.

“Mixed-Type” Facilities

- Some facilities may be “mixed-type” i.e. some activities exempt; others subject to proposed registration registration requirements
- E.g., grocery warehouse that sells food directly to both consumers and retailers

  -Facility would have to register because sales to retailers are not exempt

“Mixed-Type” Facilities contd

- Some farms also may be mixed type facilities, e.g., farm has a juice processing facility on-site and/or a roadside stand that sells food grown on farm directly to consumers
- Traditional farming activity, such as growing oranges: Exempt as farm

"Mixed-Type" Farm contd

- Manufacturing/processing (e.g., oranges into juice):

  -If juice is distributed into commerce (e.g., sold to a distributor or retailer): Register juice processing facility

  -If juice is sold directly to consumers at farm's roadside stand: Exempt as retailer

Proposal: What information is required

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

What Information is required: contd

- Emergency contact person's information (name, title, office and home phones, cell phone if available, and e-mail address, if available)
- Food product categories (21 CFR 170.3)
  - FDA will issue guidance soon containing Secretary's determination that food product categories are necessary for registration

What Information is Required: contd

- 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 statement
- 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

Optional Information*

(*Mandatory registration fields still required) contd

- Type of storage
- Approximate dates of operation, if seasonal

Proposed Rule: How to Register

FDA strongly encourages electronic registration

- Will be available 24/7 worldwide
- Will not allow registration to be submitted until all mandatory fields completed
- Will provide automatic receipt of registration and facility's registration number
- Internet access publicly available (e.g., libraries, copy centers)
- Reminder: U.S. agent can register foreign facility if authorized by facility

Proposed Rule: How to Register contd

- Paper registrations accepted if internet access not reasonably available

  - Much slower process (weeks to months)

  - Need to ensure form is legible and complete, else delays will occur

  - FDA will enter the information on the form and assign each facility a registration number in the order the forms are received

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

What if A Facility is Not Registered? contd

- 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 at least by noon the day before nor more than 5 days until final regulations in effect)

Sec. 307: Prior Notice of Imported Food Shipments

- Per the Act, the 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

Sec. 307: Prior Notice of Imported Food Shipments contd

- All statutory information, except grower, currently provided to Customs at time of entry

FDA's Prior Notice: Proposed Definitions

- Country of shipment – the country in which the food was loaded onto the conveyance that brings it to the U.S.
- Port of Entry – water, air, or land port at which the article of food is imported or offered for import into the U.S. (i.e., the port where food first arrives in the U.S.)
  - NOTE: May be different than port where food is entered for U.S. Customs' purposes

FDA's Prior Notice: Proposed Definitions contd

- Originating Country – the country from which the article of food originates:

  - Fresh produce or fresh aquacultured fish/seafood – country in which it is grown and harvested

FDA's Prior Notice: Proposed Definitions contd

- Wild-caught fish or seafood harvested in U.S. waters or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel – the U.S.
- All other food – country in which the article of food is manufactured/processed

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 Subject to the Proposed Requirements:

- The definition in Sec. 201(f) of the Federal Food, Drug, and Cosmetic Act applies

  - See previous examples given on slides 6 and 7

- Proposed definition the same as for Registration

What Food is Not Subject to Proposed Prior Notice Requirements:

- Food in individual's personal baggage for personal consumption (self, 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

Proposal: When is My Prior Notice Due? contd

- 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

How do I Submit Prior Notice, Amendments & Updates? contd

- If FDA's system is down, can submit notice in person, e-mail or by fax to FDA district office with responsibility for the geographical area in which the port of entry is located

- Addresses/fax numbers of district offices will be published at time of final rule

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)

Proposal: What Information is Required in a Prior Notice? contd

- Entry number and line numbers

- 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 or code number)

Proposal: What Information is Required in a Prior Notice? contd

- 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

Proposal: What Information is Required in a Prior Notice? contd

- Anticipated arrival information
  - Port of entry
  - Date
  - Time
- Customs port of entry
- Carrier (including Standard Abbreviation Carrier Code)

What if the Information Changes After I submit a Prior Notice?

- Amendments – relates to *Identity* of the product

  - To allow submitter to provide specifics that did not exist by deadline for initial submission

  - May be amended once if information did not exist at time of initial submission

What if the Information Changes After I submit a Prior Notice? contd

- Amendments – relates to *identity* of the product

  - Initial prior notice submission must indicate will amend

  - Cannot amend the *nature* of the food (e.g., can't change fish to shrimp)

- Due $\geq$ 2 hours before arrival at port of entry

What if the Information Changes After I submit a Prior Notice? contd

- Updates – required if anticipated arrival is:
  - 1 hour or more *earlier* than submitted; or
  - 3 hours or more *later* than originally submitted
- Due ≥ 2 hours before arrival at port of entry
- All other changes – cancel initial prior notice and submit a new prior notice

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

Regulatory Development Timeline

- FDA is developing 2 additional rules:

- Section 306: Establishment and Maintenance of Records

- Section 303: Administrative Detention

Proposed Regulation Requirements for Establishment & Maintenance of Records

- Final regulations to publish by Dec. 12, 2003

Who Must Establish and Maintain Records

- Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in U.S.
- Foreign facilities that manufacture, process, pack, or hold food intended for human or animal consumption in U.S.

What Records Must be Established and Maintained

1. Records necessary to identify the immediate non-transporter previous sources, whether foreign or domestic, of all food received, including:
   - Name of Firm
   - Responsible Individual
   - Address
   - Telephone Number
   - Fax Number

What Records Must be Established and Maintained contd

- e-mail address, if available
- Type of Food, including Brand Name and Specific Variety, e.g. Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce
- Date Received
- Lot Number or other Identifier, if available
- Quantity and Type of Packaging, e.g. 12 oz. bottles

What Records Must be Established and Maintained contd

- Name, Address, Telephone Number, Fax Number and e-mail address, if available, of Transporter who brought it

- Records must include information that is reasonably available to identify specific source of each ingredients used to make every lot of finished product

What Records Must be Established and Maintained contd

2. Records necessary to identify the immediate non-transporter subsequent recipients of all foods released, including

- Name of Firm
- Responsible Individual
- Address
- Telephone Number
- Fax Number and e-mail address, if available

What Records Must be Established and Maintained contd

- Type of Food, including brand name and specific variety
- Date released
- Lot Number or other identifier if available
- Quantity and Type of Packaging
- Name, Address, Telephone Number, and if available, Fax Number and e-mail address of Transporter who transported the food from you

What Records Must be Established and Maintained contd

- For Transporters, records for each food transported would have to include:

1. Name of Firm and Responsible Individual who had the food before you, their address, telephone number, and if available, fax number and e-mail address, and date you received it
2. Name of Firm and Responsible Individual who had the food immediately after you, their address, telephone number, and if available, fax number and e-mail address, and date you delivered it

What Records Must be Established and Maintained contd

3. Type of Food, including brand name and specific variety, lot number or other identifier if available, quantity, and type of packaging
4. Identification of each and every mode of transportation used, e.g. company truck, private carrier, rail, air, etc., and individual responsible from when food was first received until it was delivered