Overview of Bioterrorism Act
Establishment and Maintenance of Records Final

Regulatory Development of Rule

- Proposed rule published May 9, 2003 (68 FR 25188)
- 212 timely submissions received during comment period raising 220 major issues
- Final rule published Dec. 9, 2004 (69 FR 71561);
  http://www.fda.gov/oc/bioterrorism/bioact.html

Significant Changes Between NPRM and Final Rule

1 - Foreign facilities
   - All foreign entities excluded, except foreign persons who transport food in the U.S.

2 - Food contact substances, other than the finished container that contacts the food
   - excluded from recordkeeping requirements only / subject to record access provisions for existing records

3 - Recording lot or code number/other identifier if the information exists
   - deleted for all covered entities, except persons who manufacture, process, or pack food
Significant Changes Between NPRM and Final Rule (cont.)

4 - Record retention requirements (1 and 2 years)
- changed to 6, 12, and 24 months based on criteria similar to NIST definitions for perishable, semi-perishable and shelf stable foods

5 – Transporter requirements
- added option to use existing bill of lading requirements for road, water, rail and air transporters to comply with this rule
- added option to enter into agreement with non-transporter to keep records on transporter’s behalf

Significant Changes Between NPRM and Final Rule (cont.)

6 - Record availability requirements (4 hours/8 hours of request)
- revised to “as soon as possible, not to exceed 24 hours from the time of receipt of the official request”

7 - Compliance dates (6, 12, 18 months for large, small, and very small businesses, respectively)
- revised to 12, 18, and 24 months, respectively

8 - Exclusion for Pet Food not subject to BSE rule
- deleted exclusion

Significant Changes Between NPRM and Final Rule (cont.)

9 – Requirement to record “responsible individual”
- deleted requirement

10 - Definition of recipe
- revised; list of ingredients only is not a recipe
Significant Changes Between NPRM and Final Rule (cont.)

11 – Exclusion for retail facilities located in same general physical location as farm
   • replaced with exclusion for all retail food establishments with 10 or fewer FTE employees

12 – New exclusions added
   • Nonprofit food establishments
   • Packaging

Final Rule: Overview of Some Significant Definitions

• Farm: a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting.
  – e.g., apple orchards, dairy farms, feedlots, and aquaculture facilities

Definitions (cont.)

Farm includes a facility that . . .

• Packs or holds food, if all food is grown, raised, or consumed on that farm or another farm under the same ownership; 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
Definitions (cont.)

Food: 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
- Pet food
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
Examples of FDA-Regulated Food (cont.)
- 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

What Foods Does FDA Not Regulate?
- Foods to the extent they are under the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the:
  - Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or
  - Egg Products Inspection Act (21 U.S.C. 1031 et seq.)

Definitions (cont.)
- 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, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging
Definitions (cont.)

- **Nonprofit food establishment**: a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States
  - Includes central food banks, soup kitchens, nonprofit food delivery services
- Establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code

Definitions (cont.)

- **Packaging**: the outer packaging of food that bears the label and does not contact the food.
- Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act

Definitions (cont.)

- **Recipe**: means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product
- Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe
Definitions (cont.)

- **Restaurant**: a facility that prepares and sells food *directly to consumers for immediate consumption*
  - e.g., cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, nursing home kitchens, pet shelters, kennels and veterinary facilities

- Facilities that provide food to interstate conveyances (e.g., trains, planes) are *not* restaurants

Definitions (cont.)

- **Transporter**: person who has possession, custody, or control of an article of food in the U.S. for the *sole purpose* of transporting the food, whether by road, rail, water, or air.

  Includes a foreign person that transports food in the U.S., regardless of whether that foreign person has possession, custody or control of that food for the sole purpose of transporting that food.

Definitions (cont.)

- **Non-transporter**: a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation
Who is subject to this subpart?

- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import (“M→I”) food in the United States, whether or not it enters interstate commerce
- Foreign persons who transport food in the United States
- “Person” includes individual, partnership, corporation, and association

Who is excluded from all of the regulations in this subpart?

- Farms
- Foreign persons, except for foreign persons who transport food in the United States
- Restaurants

Who is excluded from all of the regulations in this subpart? (cont.)

- Restaurant/Retail facility if sales of food it prepares and sells to consumers for immediate consumption are > 90% of its total food sales
- Persons performing covered activities with food regulated exclusively by the USDA
Who is excluded from all of the regulations in this subpart? (cont.)

- Persons who M→I food for personal consumption

- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food
  - e.g., hotel concierge; reception desk in apartment building

Who is subject only to the record access and prohibited act provisions?

- Fishing vessels not engaged in processing

- Retail food establishments that employ 10 or fewer full-time equivalent employees (FTE’s)
  - FTE’s determined per individual establishment, not entire business for purposes of exclusion
  - NOTE: FTE calculation for exclusion is different than FTE calculation for applicable compliance dates

Who is subject to only the record access and prohibited act provisions?

- Nonprofit food establishments

- Persons who M→I food contact substances, other than the finished container that directly contacts the food
Who is subject to only the record access and prohibited act provisions?

- Persons who M→I food are subject to the record access requirements for existing records with respect to its packaging (the outer packaging of food that bears the label and does not contact the food)
  - All other persons who M→I packaging are excluded from all requirements of this subpart

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>ACTIVITY</th>
<th>COVERAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaging (outer packaging of food that bears the label and does not contact the food; does not include food contact substances)</td>
<td>Manufacture, process, pack, transport, distribute, receive, hold, or import</td>
<td>Excluded from all provisions, unless engaged in covered activity with respect to food (then subject to record access)</td>
</tr>
<tr>
<td>Food contact substances (other than the finished container that directly contacts food)</td>
<td>Manufacture, process, pack, transport, distribute, receive, hold, or import</td>
<td>Excluded from all provisions, except record access</td>
</tr>
<tr>
<td>Finished container that contacts food</td>
<td>Place food directly in contact with its finished container</td>
<td>No exclusions</td>
</tr>
<tr>
<td>Finished container that contacts food</td>
<td>All other activities with respect to finished container</td>
<td>Excluded from all provisions, except record access</td>
</tr>
</tbody>
</table>

Partial Exclusions

- Persons who distribute food directly to consumer -- excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients as to those transactions
  - Note: Consumers does not include businesses
Partial Exclusions

- Persons who operate retail food establishments that distribute food to persons who are not consumers –
  - e.g., existing business account

- Must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available

Establishment and Maintenance of Records by Non-Transporters

Non-transporters (e.g., manufacturers) must establish and maintain records that identify both the transporter and non-transporter IPS and ISR (indicated with solid red arrows above)

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 and contact information of the non-transporter IPS (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
- For persons who manufacture, process, or pack food, the lot or code number or other identifier (to the extent the information exists)
- Quantity and how the food is packaged (e.g., 25 lb cartons)
- Firm name and contact information of the transporter IPS who brought the food to you

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

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

- Firm name and contact information of the non-transporter ISR (domestic or foreign)
- Description of type of food released, including brand name and specific variety

**What Information Must Non-Transporters Keep in Records to Identify the ISR (cont)?**

- Date food was released
- For persons who manufacture, process, or pack food, lot or code number or other identifier (to the extent this information exists)
What Information Must Non-Transporters Keep in Records to Identify the ISR (cont)?

- Quantity and how the food is packaged (e.g., 25 lb cartons)
- Firm name and contact information of the transporter ISR who transported the food from you

Non-Transporters’ Records Regarding the ISR

- 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

Example 1: Common Storage Silo for An Ingredient (e.g., Flour)

Information reasonably available is the identity of all potential sources of the flour for each finished product.
Example 2: Dedicated Storage Silos for Each Ingredient Source

Source A

Source B

Source C

Manufacturing Plant

Cookies

Information reasonably available is the identity of the specific source of the flour for each finished product.

Requirements for Transporters to Establish and Maintain Records

Transporters have 5 options for meeting requirements in the regulation:

(1) Establish and maintain the following records themselves:
   • Names of the transporter’s IPS and transporter’s ISR (see diagram)
   • Origin and destination points

Option (1) requirement cont.:
   • Date shipment received and released
   • Number of packages
   • Description of freight
   • Route of movement during the time food transported (see diagram)
   • Transfer point(s) through which shipment moved
Various Transportation Companies

Trucks and planes are owned by different companies. The rule requires each company to keep records only of transactions to which it is a party (i.e., from whom it received the food and to whom it released the food).

Company A  Company B  Company C
Manufacturer  Retail Store

One Transportation Company with Multiple Modes of Transportation

All trucks and planes are owned by Company A (Purple Transportation Co.). The rule requires the company to keep records of when the food was put on each vehicle and who was responsible for the food during each leg of the trip.

Manufacturer  Retail Store

Requirements for Transporters to Establish and Maintain Records (cont.)

Establish and maintain records currently required by any one of the following:
(2) Department of Transportation’s Federal Motor Carrier Safety Administration of roadway interstate transporters (bills of lading)
(3) Department of Transportation’s Surface Transportation Board of rail and water interstate transporters (bills of lading)
Requirements for Transporters to Establish and Maintain Records (cont.)

(4) Warsaw Convention of international air transporters (air waybills)

(5) Entering into an agreement with the nontransporter IPS or ISR located in the United States to establish, maintain, or establish and maintain the required information.

Agreements Between Non-Transporters and Transporters Must Contain:

- Effective date
- Printed names and signatures of authorized officials
- Description of the records to be established and/or maintained

Requirements for Agreements (cont.)

- If the agreement includes maintenance of records:
  - Provision for the records to be maintained in compliance with the records maintenance provision
  - Records to be available to FDA as required by the record availability provision
Requirements for Agreements (cont.)

- Acknowledgement that the non-transporter assumes legal responsibility for establishing and/or maintaining the records

- Provision that if the agreement is terminated in writing by either party, responsibility for compliance reverts to the transporter as of the date of termination

Record Retention Periods

<table>
<thead>
<tr>
<th>Food having significant risk of spoilage, loss of value, or loss of palatability within . . .</th>
<th>Non-transporter Records</th>
<th>Transporter Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 days</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>&gt; 60 days but within 6 months</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>2 years</td>
<td>1 year</td>
</tr>
<tr>
<td>All animal feed, including pet food</td>
<td>1 year</td>
<td>1 year</td>
</tr>
</tbody>
</table>

What are the record retention requirements?

General:

- Required records must be created when food is received and released, except to the extent that the information is contained in existing records

- Records must be retained at the establishment where the covered activities occurred (onsite) or at a reasonably accessible location

- The maintenance of electronic records is acceptable
Consequences: New Prohibited Acts

It is a prohibited act to:
• Fail to establish or maintain records
• Refuse access to or verification or copying of any such required record
• Fail to make records available to FDA as required by section 414 or 704(a) of the act and this regulation

Consequences: New Prohibited Acts (cont.)

• Fail to establish, maintain, or establish and maintain records, or refuse to permit access to or verification or copying of any such required record, if you are a nontransporter IPS or ISR who enters into an agreement to do so on a transporter’s behalf

What are the compliance dates?

• Large Businesses (≥ 500 full time equivalent employees (FTE’s)): 12 months after the date of publication
• Small Businesses (11-499 FTE’s): 18 months after the date of publication
• Very Small Businesses (< 10 FTE’s): 24 months after the date of publication
Calculating FTE’s for compliance date purposes:

- The size of the business is determined using the **total number of FTE’s in the entire business**, not each individual location or establishment
  - A full-time employee counts as one FTE
  - Two part-time employees, each working half time, count as one FTE

- *This is different than calculation of FTE’s for retail exclusion*

Do other recordkeeping requirements in statutes and regulations still apply?

- **Yes** - covered persons must still comply with all other statutes and regulations related to the establishment and maintenance of records for foods
  - E.g., recordkeeping requirements for infant formula, juice, seafood, low acid canned food, animal feed, bottled water, color additives

Can Existing Records Satisfy the Requirements of this Subpart?

- **Yes** – to the extent they contain information required by this subpart

- Covered persons are responsible for supplementing existing records, if necessary, to ensure all required information is established and maintained

- Information required by this rule does *not* have to be kept in one set of records
What are the record availability requirements?

- When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA). . .

- . . . Any records and other information accessible to FDA under section 414 or 704(a) of the act must be made readily available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from the time of receipt of the official request.

What records are excluded from BT Act records access?

- Recipes for food (as defined in the rule)
- Financial data
- Pricing data
- Personnel data
- Research data
- Sales data (other than shipment data regarding sales)

Economic Impact of Final Rule

- Approximately 707,672 total facilities covered
  - 597,172 domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S.
  - 110,500 foreign facilities that transport food in the U.S.
Economic Impact of Final Rule

- Estimated per facility recordkeeping costs:
  - Learning costs: $120.00
  - Records redesign: $411.00
  - Additional records maintenance: $219.00

FDA Draft Records Access Guidance: FDA Procedures

- Specifies FDA’s draft procedures for accessing records when inspector believes the SAHCODHA threshold is met:
  - Notify FDA’s Emergency Operations Center (EOC)
  - EOC notifies the appropriate Center and the Office of Enforcement (OE) in the Office of Regulatory Affairs (either verbally or in writing)

FDA Draft Records Access Guidance Procedures (cont)

- The appropriate Center, with the concurrence of OE, determines that SAHCODHA threshold is met
  - OE concurs with any requests for access to records, and works with the appropriate Center to determine:
    - the scope of the request; and
    - the requested records are necessary to assess whether a food is adulterated and presents a SAHCODHA threat
FDA Draft Records Access Guidance

Procedures (cont)

– The Center consults with the Office of the General Counsel (OGC) on the determination of whether there is a reasonable belief an article of food is adulterated.

– OE consults with OGC on the scope of the records request

– Once all necessary determinations are made, OE conveys the information to the Director of the district in which the food is located, and, if necessary, coordinates with the District in which the records are maintained

FDA Draft Records Access Guidance:  How Will FDA Make a Request?

• An investigator or other FDA personnel upon presentation of credentials will submit a written notice, FDA 482 – Notice of Inspection, to the owner, operator, or agent in charge, and inform that person of the records requested and FDA’s legal authority to obtain these records.

  – Note: FDA may request additional records related to the implicated food article at a later time under the same authority.
FDA Draft Records Access Guidance:

- Information obtained under the records access provisions may include, but is not limited to, a company’s non-public confidential commercial or trade secret information.

Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and Freedom of Information Act, (5 U.S.C. 552) and the agency’s information disclosure regulations at 21 CFR Parts 20 and 21 govern the agency’s disclosure of information to the public.

FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information.

For Further Information . . .

- For current information on FDA’s efforts under the Bioterrorism Act or to sign up on our listserv: [http://www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html)
Outreach Materials and Tutorials Are Available On FDA’s Website

Coming Soon . . .

Questions?