The FDA's New Bioterrorism Regulations on Food, Beverage and Related Sectors

What They Mean for Your Country's Exports to the United States

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Registration of Foreign Food Facilities Under § 305 of FDA's Proposed Rule

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Who must register?

- All U.S. and foreign facilities engaged in the manufacturing, processing, packing or holding of food for consumption in the United States

How is "Food" Defined?

- Food and Drug Act defines as: 1) articles used for food or drink for man or animals; 2) chewing gum; 3) components of such articles
- Examples in Proposed Rule: Fruits, vegetables, fish, dairy products, eggshells, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy and canned goods

What is the deadline for registration?

- December 12, 2003

What happens if I don't register?

- "Prohibited Act" under Food and Drug Act for which individuals can be prosecuted under civil or criminal law
- Food will be held at port of entry in U.S. or at a secure facility, if FDA so orders
- Costs of detention to be borne by purchaser, owner, importer or consignee
- Secure facility: bonded warehouse, container freight station, centralized examination station

Who is responsible for registering a foreign facility?

- Owner, operator or agent in charge, if U.S. agent has been designated
- Definition of U.S. agent: A person residing or maintaining a place of business in the U.S.
- NOT a mailbox, answering service or other place where U.S. agent is not PHYSICALLY present

What must I register?

- Contact details for facility
- Name and address of parent company (if applicable)
- Emergency contact information for facility
- All trade names used by facility
- Food product categories which facility will import
- Contact details for U.S. agent (if U.S. agent has been designated)
- Statement certifying information submitted is true and accurate and person authorized to submit registration

How can I register?

- Electronically - using a website to be provided in and be operational by the time FDA's final rule is issued (October 12, 2003?)
- Potential Problem?
  - What if Final Rule delayed?
  - What if website not operational?
- Recommendation:
  - Register ANYWAY!!!

What will happen if I register?

- Registration number assigned to facility by FDA
- (Number not publicly available under Freedom of Information Act)
- Must be provided to FDA as part of Prior Notice each time a food is imported into the U.S.

Are there any exemptions for foreign facilities?

- If food from a foreign facility undergoes further manufacturing/processing by another facility located outside the U.S.
- NOTE: Exemption not applicable if further manufacturing/processing consists of adding labeling or any other activity of a de minimis nature.
- NOTE ALSO: Last foreign facility that manufacturers/processes a food must register even through food held at another non-U.S. site before shipment to U.S.

Are there any exemptions for foreign facilities? (continued)

- Fishing vessels (but not fish processing operations)
- Facilities regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, Poultry Products Inspection Act or Egg Products Inspection Act

Can anything be done to change FDA's Proposed Rule?

- Written comments (deadline April 4, 2003)
- Electronic address: www.fda.gov/dockets/ecomments
- Docket No. 02N-0276

FDA Proposed Rule for Prior Notice of Imported Food Under Section 307 of the Bioterrorism Act

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Who must submit a prior notice of imported food shipments?

- A purchaser or importer (or their qualified agent) who resides or maintains a place of business in the US
- The carrier (or in-bond carrier) of a transshipment

What food is covered?

- All food and beverages for:
  - Consumption
  - Storage
  - Immediate Export
  - Import for Export
  - Transshipment

What food is exempt?

- Food carried by individuals in their baggage for personal consumption
- Food subject to exclusive USDA jurisdiction
  - Meat
  - Poultry
  - Eggs

What information must be provided in the prior notice?

- For each food from the same manufacturer/growers
  - Identification of submitter
  - U.S. Customs entry type code, and U.S. Customs system (ACS) entry number, or other U.S. Customs ID number
  - If product is under "Hold"
    - Location
    - Date of arrival
    - Contact person at location

What information must be provided in the prior notice? (continued)

- Product identification
  - FDA product code
    (see www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm)
  - Common or usual name or market name
  - Trade or brand name (if different from common or market name)

What information must be provided in the prior notice? (continued)

- Quantity
- Lot or code numbers, or other identifier (if applicable)
- Manufacturer identification
- Growers (if known)
- Originating country

What information must be provided in the prior notice? (continued)

- Shipper
- Country from which food was shipped
- Anticipated arrival information
  - Port of entry
  - Date of arrival
  - Time of arrival

What information must be provided in the prior notice? (continued)

- Port where U.S. Customs entry will be made
- Anticipated date of U.S. Customs entry
- Identification of importer, owner and consignee
- Identification of carrier

How is the notice submitted?

- Electronically on FDA's web-based prior notice system

Will there be an FDA acknowledgement of receipt?

- Yes

When must prior notice be submitted?

- By noon, the day before the food arrives at the border crossing and not earlier than 5 days before arrival at a U.S. port

May the prior notice be amended or updated?

- Yes, up to 2 hours before arrival
- Amendment
  - One amendment per notice permitted
  - Only the product identity or quantity may be amended, and only if it did not exist by the deadline for submission

May the prior notice be amended or updated? (Continued)

- Update
  - Anticipated arrival information (port, date, time) must be updated if change is more than 3 hours later or 1 hour earlier than originally anticipated

Harmonization with U.S. Customs Service

- U.S. Customs is in the process of modifying its automated commercial system (ACS) to accommodate the additional FDA requirements of prior notice, but it is not expected to be completed until 2005
- The new U.S. Custom's system will be called Automated Commercial Environment (ACE)

What if there is no submission or an inadequate notice?

- The shipment will be refused entry
- The food must be held at the port of entry or in a secure facility
- The food may not be delivered to the importer, owner or consignee
- The purchaser, owner, importer or consignee is responsible for transportation and storage expenses

What if there is no submission or an inadequate notice? (continued)

- Importation to the U.S. without proper prior notice is a prohibited act

Effective Date for Implementation

- December 12, 2003

What if the rule is not final and effective by then?

- Default Procedure
  - Time frames for submission of prior notice would be at least 8 hours before, but not more than 5 days before the time of importation

Transportation Issues

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Differences from Customs Rules - Advance Notice Requirements

- **Port of Entry** - Water, air or land port at which the article of food is imported or offered for import into the United States - in other words, the port at which the food import first arrives in the United States (This in many cases will be different than the Customs port of entry for trade purposes)

- **Carrier** - Means transporter. Under Customs rules, advance notice can be for container

Differences from Customs Rules - Advance Notice Requirements

- **Country of Origin** -Country where product shipped to the U.S. is grown or produced
- Examples:
  - Fresh produce - country where article grown and harvested
  - Processed or canned food - country where article processed or canned

Differences from Customs Rules - Advance Notice Requirements (continued)

- Examples:
  - Fresh fish
    - If caught in waters of U.S., or by a U.S. flag ship, or processed on U.S. flag ship, country of origin is U.S.
    - If not, country of origin is flag of ship (but what if caught by ship of one flag and processed by ship of another flag?)

Who must provide notice?

- The purchaser or importer of an article of food (or their agent) who resides or maintains place of business in the U.S. - Carrier under Coast Guard and Customs requirements
- But must be carrier or in-bond carrier if the article of food is imported for in-bond movement through the U.S. for export (Transportation for Export or Immediate Export customs entries)

Registration Requirements

- Definition of “Facility” - Means any establishment, structure or structures 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 consumption in the United States.

Registration Requirements (continued)

- Transportation-related issues:
  - Fish-processing vessels can be facilities
  - Warehouses and foreign-trade zones can be considered facilities
  - Not clear if containers are facilities - not specifically exempted (e.g. what if processed food stored for days?)

Failure to Provide Notice or to Register - Consequences

- Violations subject to civil and criminal penalties
- Article is refused admission - held at entry port or secure location until proper notice made (costs borne by purchaser, importer, consignee or owner)
- If food with non-food items, articles of food must be dealt with before non-food items proceed
- Debarment - all shipments refused entry

Issues for Carriers and Brokers

- Notice of arrival information required under other regulations not sufficient (e.g. Coast Guard 96 hour notice, Customs 24 hour advance manifest)
- Liability - standard bills of lading not necessarily sufficient; consider assessment of liability between parties in drafting shipping contracts
- Notice may affect carrier and broker ability to completely fill containers - LTL shipments

Issues for Carriers and Brokers (continued)

- Trucks, rail carriers, especially from Mexico or Canada - waits at border re: advance notice
- Air carriers - problems re: refusal of entry because frequently do not know what carrying until “wheels up”
- Which carrier is responsible for giving notice for Transportation for Export and Immediate Export shipments

The Practical Consequences for Exports to the United States

CUSTOMS AND TRADE ISSUES

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FDA's Proposed Regulations Include More Than Simply Registration and Prior Notice

- **15 Sections** - The Act includes additional provisions that will affect importers of food and beverage products
  - **Sec. 302** - Protection against adulteration of food
  - **Sec. 303** - Administrative detention
  - **Sec. 304** - Debarment for repeated violations
  - **Sec. 305** - Registration of Food Facilities
  - **Sec. 306** - Maintenance and Inspection of records
  - **Sec. 307** - Prior Notice of Import Shipments
  - **Sec. 308** - Authority to Mark "Refused Admission"

Additional Provisions within the Proposed Regulations

- **Sec. 309** - Prohibition against port shopping
- **Sec. 310** - Notices to States
- **Sec. 311** - Debarment for repeated violations
- **Sec. 312** - Grants to States for Inspections
- **Sec. 313** - Surveillance of Zoonotic diseases
- **Sec. 314** - Authority for Other Officials to Inspect
- **Sec. 315** - Rule of Construction

Section 302 - Protection Against Adulteration of Food

- "**High Priority**" given to increasing the number of inspections, specifically targeted to imported food
- **Potential Difficulties**: Slower trade movement, potential national treatment inequities
- **Linkages** with other regulatory agencies e.g., Customs, ATF, and differing data requirements
- **Potential Difficulties**: Lack of system integration, multiple filing requirements

Section 303 - Administrative Detention
A Company's Goods are Detained - Now what?

- Detention if credible evidence of a threat of serious adverse health consequences or death to humans or animals
  - **How Long?** "Reasonable Period" (up to 20 days, unless greater period necessary to bring action, then not to exceed 30 days)
  - **Remove to Secure Facility -** Can't remove to importer's possession or be construed as delivery, even under bond
  - **Holds at Ports of Entry** - up to 24 hours to permit inspection
  - **Potential Difficulties**: Slower trade movement, potential national treatment inequities

Section 304 - Debarment for Repeat Violations

What does it mean to be debarred?

- Permissive or Mandatory Debarment possible
  - **Permissive -** Convicted of a felony relating to imports into US or has engaged in a pattern of importing or offering for import adulterated food
  - **Assisting Debarred Person Prohibited -** Can't assist a debarred person or import under their direction.
  - **Holds at Ports of Entry or Secure Facility** - Removal not allowed except delivery to person not debarred; provided food complies with Act
  - **Potential Difficulties**: Expense of proving that imported food qualifies on importer, you may not know a trading partner is debarred.

Section 306 - Maintenance and Inspection of Records -- What is required?

- **Inspection of all records and information** - shall extend to those that manufacture, process, pack, transport, distribute, hold or import food (excluding farms and restaurants)
- **Where** - "At any location" This would include foreign locations
- **How Long?** - For not longer than 2 years
- **Potential Difficulties** - Extraterritorial Inspections, record retention periods differ from Customs requirements

Section 308 - Authority to Mark Goods "Refused Admission" -- What can you do with such goods?

- **Marking of "United States: Refused Entry"** - If not required to be exported or destroyed, must be so marked at owner's expense, until brought into compliance
- **Misbranded Foods** - If it fails to bear the label and presents a threat to health with notice to owner or consignee
- **Potential Difficulties** - Potential delays to prove compliance and charges of liquidated damages on importer's bond

Section 309 - Prohibition Against Port Shopping -- Is a company limited to one port?

- **No Port Shopping after Refused Entry** - If food has previously been refused admission, an importer may not attempt reentry at another port unless they affirmatively establish, at owner's expense, that article complies
- **Potential Difficulties** - Suspicions may be raised if multiple ports are routinely used, even if for legitimate purposes, thus subjecting the importer to increased scrutiny

Sections 310, 311, 312, 313, 314 - Notices and Grants to States and Other Federal Officials - What does this mean?

- **Notices to States** - Of Imported Foods that present a threat authorizes the state to take appropriate action
- **Grants to States for Inspections and Surveillance** - To assist in examinations, inspections and investigations regarding potential adulterated imported food
- **Authority Granted to Other Federal Officials** - Multiagency involvement is authorized (e.g., ATF, Customs)
- **Potential Difficulties** - Multiple levels of inspections and investigations by state, as well as federal, officials

What is the Practical Effect for Importers?

- **Numerous Submissions of Data** - FDA expects 20,000 submissions of Prior Import Notices
- **No Integration of Systems** - Currently, the FDA data system is not integrated with Customs AES system.
- **No Coordination of Requested Data** - Multiple filing requirements may result
- **Potential Concerns** - Customs' new ACE system under development, but deployment after implementation of new regulations. Insufficient consideration of manual submissions

The Company's Imports are Detained - Now what Does a Company Do?

- **Practical Difficulty** - For perishable goods, e.g., fresh produce, fish and shellfish, the detention periods may be commercially prohibitive
- **Increased Documentation Requirements** - Provide more opportunity for potential error
- **Added Costs for Obtaining release** - At owner's expense
- **Complexity of Multiple Agency Involvement** - Customs has possession, FDA requires compliance, potential penalties from both agencies

What Other Practical Business Implications?

- **Increased Inspections** - FDA is planning to add 650 additional inspectors for regulatory enforcement, in addition to authorizing other federal and state officials
- **Increased Examinations, Investigations** - Companies and food products may be subjected to inspections in the U.S., at the ports of entry, while in possession of their carrier, and in non-U.S. facilities
- **Longer Lead Times Required** - To meet notice requirements, increased inspections, provide compliant data, and clearance of goods, JIT delivery will be unlikely

Potential for Severe Consequences

- Potential civil and criminal penalties
- Potential for liquidated damages under bonds
- Articles refused entry and storage charges incurred by owner or importer which may dilute profit margins and harm customer relations
- Potential Debarment from the “privilege” of importing

What Implications from a Broader Trade Perspective?

- No integration with existing U.S. preferential trade programs (e.g., NAFTA, CBERA, AGOA)
- Potential inequities under Most Favored Nation or National Treatment of existing trade agreements
- Participation in existing and developing U.S. trade programs (e.g., C-TPAT) will not excuse an importer from new regulations
- Other countries may impose similar, different, or even conflicting requirements
- Therefore, be proactive during the comment period

Managing Trade Implications

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The action "is part of our continuing effort to foster the development and availability of countermeasures to terrorist attacks," said Tommy G. Thompson, secretary of the Department of Health and Human Services. "We must and will do more to prepare and protect Americans against the threat of **bioterrorism.**"

Medical Letter on the CDC & FDA via NewsRx.com, March 2, 2003

Bioterrorism – a New Food Safety Trade Issue

In its many forms, food safety has become a major trade barrier. Differences in how food is raised or grown and prepared lead to trade disputes:

- Growth hormones in beef
- Salmonella, E Coli and other microbial contaminants
- Non-therapeutic antibiotic use
- Genetically modified crops.
- ***Bioterrorism – new***

The bioterrorism legislation and FDA rules formally introduce a new food safety concern – bioterrorism – the physical safety of food.

How intently will the U.S. use these new authorities?

New inspecting authorities:

- FDA's Center for Food Safety and Applied Nutrition, particularly Emergency Coordination and Response, has ***added 650 inspectors at the borders and port entries***, according to FDA Food Safety Director, Robert Brackett. (Congress Daily AM, February 25, 2003)

How intently will the U.S. use these new authorities? (continued)

New testing authorities:

- At the USDA Agricultural Outlook Forum last week, in answering my question, John Guzewich, Director Emergency Coordination and Response, FDA, stated that FDA is ***developing tests and methodologies to be able to test food at the borders***.

Which imports will be targeted for detention?

According to Mr. Guzewich, ***FDA is conducting risk analyses to identify risks***. This could mean that many countries and food groups could be labeled as high risk for adulteration. Some examples of targets could be:

- lesser developed countries that lack security infrastructure;
- countries that ship a lot of non-packaged or unprocessed foods, such as fruits and vegetables;
- countries close to other countries that are harboring terrorists; and
- countries containing terrorist groups.

Which imports will be targeted for detention? (continued)

Unfortunately, according to both Director Brackett and Mr. Guzewich, ***these analyses are classified, so they cannot advise industries on vulnerabilities***, but FDA hopes to release some of the information in the future.

Will other countries create similar regulations?

- Many countries may have the same concerns about bioterrorism
- Countries may want similar rules to establish a retaliation tool if U.S. applies rules "unfairly" to protect domestic producers.

Net Result:

- Countries labeled by the U.S. as "high risk" may end up on other countries' "high risk" lists, threatening market shares of "high risk" countries worldwide.

What can countries and their exporters do at this juncture?

Start Preparing for the Long-Term By:

Pursuing close and long-term relations with FDA, USDA, and other key agencies. Why?

- Government agencies are more apt to share sensitive information.
- Maintaining a relationship will help enormously if imports are ever detained.

Hiring outside counsel to create and maintain the collaboration and communication.

Participate in the public comment period

- Notify your industries and transportation authorities of these rules.
- Meet with Executive Branch officials, including FDA, USDA, and USTR officials.
- Meet with key congressional leaders.
- Submit written comments.

What can countries do to avert detention?

- **Comply with the regulations.** Seek counsel to make sure that your industries are ready and able to comply with the regulations.
- **Conduct risk analyses.** Your government or industries may want to conduct risk analyses, based on international methodologies, to identify vulnerabilities.
- **Seek technical assistance from FDA.** During the risk analyses processes, your country or industry may want technical advice from the U.S. government, such as FDA, which may reveal important information.
- **Organize into coalition(s) of countries.** Strength in numbers may influence the outcome of the final regulations and their implementation.

Long-term strategy for bioterrorism food safety issues

Existing trade frameworks that base standards on science, risk analysis, and include dispute resolution processes could be helpful.

However, it will take time for these processes to effectively include and deal with bioterrorism.

Existing Food Safety Frameworks:

- Joint FAO/WHO Codex Alimentarius Commission (CAC) was established in 1962 to protect the health of the consumer and ensure fair trade practices. CAC includes provisions for food hygiene, food additives, pesticide residues, contaminants, labeling and methods for analysis and sampling.

- Two committees exist that use risk analyses: Joint FAO/WHO Expert Committee on Food Additives and Contaminants and Expert committee on Microbiological Risk Assessment

- The World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade establish principles of transparency, equivalency, science-based standards, national sovereignty, and international harmonization for measures that protect animal, plant, and human health.

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