



Keeping America's Food Supply Safe – The Transporters' Role

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FDA Rules and Guidances



- BT Act Establishment and Maintenance of Records Final Rule – 21 CFR Part 1, Subpart J (*See Appendix for overview*)
- Guidance Documents for Transporters
 - Decontamination of Transport Vehicles
 - Preventive Measures Guidance Documents for Food, Bulk Milk, and/or Cosmetic Transporters



– **A.L.E.R.T.**



CFSAN

Food Defense Continuum

Food Defense is a term used to describe activities associated with protecting the nation's food supply from intentional contamination. The Food and Drug Administration has adopted 3 broad strategies that encompass its food defense activities:

Prevention > Response > Recovery





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Food Defense Continuum

Prevention

- Increase awareness among federal, state, local and tribal governments and the private sector to better understand where the greatest vulnerabilities lie; and
- Develop effective protection strategies to shield the food supply from intentional contamination



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Food Defense Continuum

Response

- Develop the capacity for a rapid coordinated response to a foodborne terrorist attack





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Food Defense Continuum

Recovery

- Develop the capacity for a rapid coordinated recovery from a foodborne terrorist attack



A photograph of two workers, a man and a woman, wearing hard hats and work clothes. The man is wearing a yellow hard hat and a light blue shirt, and the woman is wearing a blue hard hat and a dark blue shirt. They are standing outdoors, looking at a clipboard held by the man. The woman is holding a mobile phone. The background shows a white wall and some greenery.

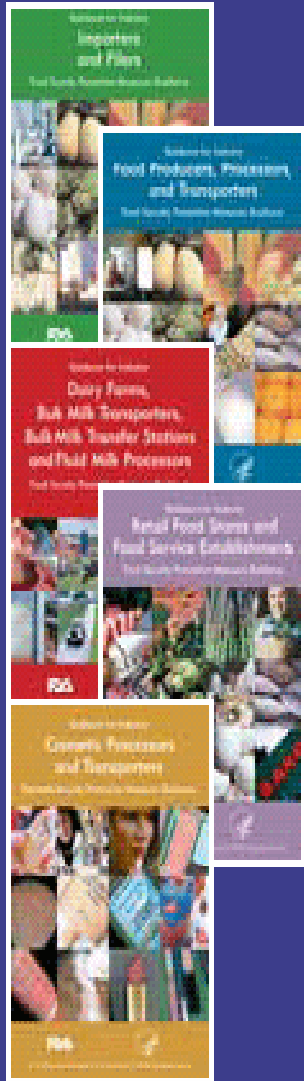
CFSAN

Integrating Food Safety and Food Defense

- Efforts to integrate food safety and food defense led to a need for the development of tools to assist regulatory stakeholders, such as federal, state and local inspectors, with the task of raising food defense awareness in industry.



Integrating Food Safety and Food Defense



- This effort began with the development of FDA Guidance documents written for specific segments of the food industry.
- After the issuance of the guidance documents in 2003, it became clear that a shorter message would be useful to spark thought and discussion around food defense issues.



A.L.E.R.T.



How do I ALERT transporters and operators of food establishments to make them more aware of Food Defense issues?




ALERT

In today's world it is important to be **ALERT** to protect your business.

- A** How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?
- L** How do you **LOOK** after the security of the products and ingredients in your facility?
- E** What do you know about your **EMPLOYEES** and People coming in and out of your facility?
- R** Could you provide **REPORTS** about the security of your products while under your control?
- T** What do you do and whom do you notify if you have a **THREAT** or issue at your facility, including suspicious behavior?

Can you answer these questions?

This message brought to you by the
U.S. Food and Drug Administration
U.S. Centers for Disease Control and Prevention
U.S. Department of Agriculture



For help in answering these questions,
check www.cfsan.fda.gov/alert

An **ALERT** for owners and
operators of food establishments
about the security of your facilities ...

See www.cfsan.fda.gov/alert for more information



CFSAN

FDA's ALERT Initiative

- Intended to raise awareness of food defense
- Applies to all aspects of the farm-to-table continuum
- Identifies 5 key food defense points:
 - **A**ssure
 - **L**ook
 - **E**mployees
 - **R**eport
 - **T**hreat





How do you *Assure* that the supplies and ingredients you use are from safe and secure sources?

- Know your suppliers
- Encourage your suppliers to practice food defense measures
- Request locked and/or sealed vehicles, containers, or railcars
- Supervise off-loading of incoming materials





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How do you *Look* after the security of the products and ingredients in your facility?

- Implement a system for handling products
- Track materials
- Store product labels in a secure location and destroy outdated or discarded product labels
- Limit access and inspect facilities
- Keep track of finished products
- Encourage your warehousing operations to practice food defense measures.



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What do you know about your *Employees* and people coming in and out of your facility?

- Conduct background checks on staff
- Know who belongs in your facility
- Establish an identification system for employees
- Limit access by staff
- Prevent customer's access to critical areas of your facility





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Could you provide *Reports* about the security of your products while under your control?

- Periodically evaluate the effectiveness of your security management system
- Perform random food defense inspections
- Establish and maintain records
- Evaluate lessons learned





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What do you do and who do you notify if you have a ***Threat*** or issue at your facility, including suspicious behavior?

- Hold any product that you believe may have been affected
- After reporting to local law enforcement officials:
 - For FDA regulated products contact the Food and Drug Administration
 - For slaughterers or processors contact USDA/Food Safety and Inspection Service.



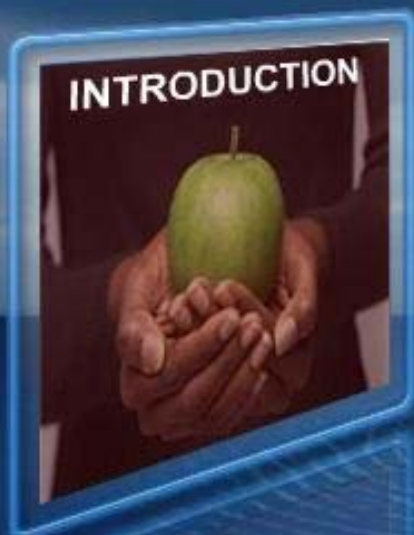
WEB-BASED TRAINING
NOW AVAILABLE AT
WWW.CFSAN.FDA.GOV/ALERT

MENU

INTRODUCTION

ALERT

WHAT'S NEXT?



NEXT ►



CONCLUSION

- The nation's awareness of terrorism has been heightened and there is an increased focus on protecting the nation's food supply.
- It is everyone's responsibility to recognize food defense as an important issue and to get involved.
- Being aware of the threats, identifying the vulnerabilities and taking action to mitigate the risks are activities where federal, state, local and private industry stakeholders must continue to work.



CONCLUSION

- FDA, along with its stakeholder partners, will continue to share the ALERT message and build complimentary pieces to help raise food defense awareness.
- We are encouraging all federal, state, local and private industry partners to consider ways that they can incorporate activities so that together, we ensure seamless integration of food defense across the food supply chain and enhance preparedness in the future.





U.S. Food and Drug Administration



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Food Defense and Terrorism



Overview

A.L.E.R.T.

Highlights

- ▶ Summaries of Competitive Food Defense Research Reports, 2005 - June 2006
- ▶ Food Defense Awareness Webcast - March 29, 2006
- ▶ Food Defense Acronyms, Abbreviations and Definitions - March 28, 2006

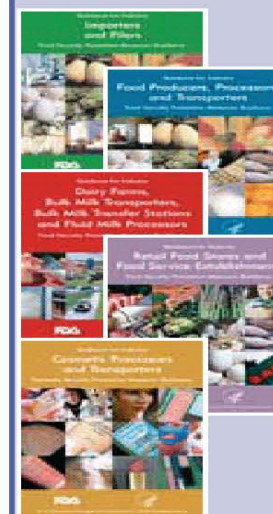
Upcoming Events

- Nothing Currently Scheduled

FDA works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply.

- **Food Defense Programs**
Food Emergency Response Network, Strategic Partnership Program - Agroterrorism
- **Training Materials and Announcements**
Training resources, upcoming courses, course registration
- **FDA Actions on Bioterrorism Legislation (Food Supply)**
(Bioterrorism Act of 2002)
 - [Administrative Detention](#)
 - [Registration of Food Facilities](#)
 - [Establishment and Maintenance of Records](#)
 - [Prior Notice of Imported Food Shipments](#)
- **Food and Cosmetic Security Preventive Measures Guidance**
- **Consumer Information**
FDA's counterterrorism role, Prior Notice policy (food gifts), food tampering, FAQs
- **Additional Information**
Information from FDA and Other Government Agencies

Food and Cosmetic Security Preventive Measures Guidance





Working to Keep Food and Cosmetics Safe and Promote Good Nutrition

**For more information on ALERT, please visit
www.cfsan.fda.gov/alert**



Appendix: Brief Overview of 21 CFR Part 1, Subpart J

For more information on Bioterrorism Act regulations:
www.fda.gov – Click on “Bioterrorism Act”

Bioterrorism Act Establishment and Maintenance of Records Final Rule

- *69 Federal Register (FR) 71561, Dec. 9 2004*
- 70 FR 8726, Feb. 23, 2005 (correction notice)
- Questions and Answers Guidance Document:
<http://www.cfsan.fda.gov/~dms/recguid4.html>
- **Records Access Guidance Document:**
<http://www.cfsan.fda.gov/~dms/secgui13.html>



Recordkeeping Rule: Two Sets of Requirements

- **(1) Requirement to Establish and Maintain Records – applies to entities specified in rule only**
- **(2) Records Access and Prohibited Act Provisions – applies to records a person may retain as a matter of business practice and to records required by (1)**
 - **NOTE: Persons may be subject to both; exempt from both; or exempt from (1), but subject to (2)**



Who Is Required To Establish And Maintain Records?

- **Domestic *persons*** that manufacture, process, pack, transport, distribute, receive, hold or import (M→I) food in the U.S.
- **Foreign *persons*** that transport food in the U.S.
 - ***Persons* includes individuals, partnerships, corporations, cooperatives, associations, and government entities.**



What Food Is Subject to Final Rule?

- Generally food under FDA's jurisdiction, with some exclusions
- 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.”





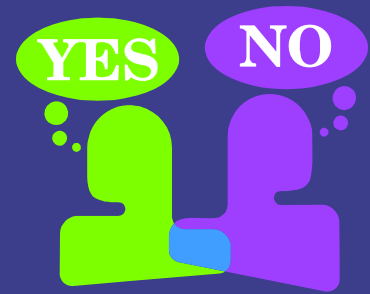
Definitions



- **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.
- **Non-transporter:** a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation



Transporters and Brokers: Who is Subject?



- **Brokerage division of shipping company**
 - Does not take custody of food; negotiates freight rates; assign contracts to independent carriers
- **Independent carrier in above example**
- **Brokers who only facilitate distribution, sale of transport of food by processing information or paperwork**
 - E.g. Customs brokers



Requirements for Transporters to Establish and Maintain Records – 5 Options

- (1) Establish and maintain records themselves, which includes information specified in the rule, including names of the transporter's IPS and transporter's ISR
- 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)



Requirements for Transporters to Establish and Maintain Records

- (3) Department of Transportation's Surface Transportation Board of rail and water interstate transporters (bills of lading)
- (4) Warsaw Convention of international air transporters (air waybills)
- (5) Entering into an agreement with the non-transporter IPS or ISR located in the United States to establish, maintain, or establish and maintain the required information

