

**U.S. Food and Drug Administration
Satellite Broadcast
“Product Security and Integrity Guidance: Roles and Responsibilities”
March 13, 2003, 1:00 – 3:00 p.m. ET**

Broadcast summary notes provided by
Michigan Department of Agriculture's
Food Safety Planning and Response Unit

Disclaimer: These notes do not represent MDA or FDA official opinions and are provided solely in the interest of sharing information with those who missed the broadcast. Everyone is encouraged to view the videotape for themselves. It may be possible to make arrangements for loaning out the MDA copy if anyone is interested, otherwise, a .pdf version of the PowerPoint slide presentation may be provided upon request.

FDA Regulator Role

The FDA's basic views on its role in food security are outlined in the document entitled "FIELD INSTRUCTIONS for "Food Producers, Processors, Transporters and Retailers: Food Security Preventive Measures Guidance". "Importers and Filers: Food Security Preventive Measures Guidance" (Text found in Attachment A)

Goals and issues to remember:

- o Informed, ongoing dialog between regulators and industry – expected to evolve over time
- o Don't record food security information on inspectional forms
- o Regulators should be informed of guidance but are not expected to be food security experts
- o Industry is responsible for implementing security measures outlined in any guidance documents

Food security is viewed as a guidance/information sharing issue – not a regulatory issue

- ?? FDA recognizes the overlap food security and food safety – GMPs and regulations
- ?? FDA plans to use its inspectional presence to sensitize industry of need to pay attention to physical security of their establishment
- ?? Partner with industry to facilitate information exchange and share ideas for potential improvements
- ?? Guidance is an array of steps – industry should chose which are appropriate on a voluntary basis
- ?? No food security audits are being conducted.
- ?? No extensive interviews of operators should be done to assess adherence. No notes of findings in inspection documents unless they reflect violations of food safety standards (HACCP Rules, GMPs, Food Code requirements)

Example: Juice HACCP and Seafood

- Manufacturers are required to maintain control of hazardous chemicals, contaminants
 - ?? Absence of controls would leave the facility vulnerable to person with ill intent
- ?? If written up for deviations from food safety regulations, the write up should not highlight food security vulnerabilities
- ?? If staff make personal notes, they should only write memory jog statements – cryptic notes can't identify vulnerability. Example: "back dock"
- ?? FDA expertise is investigation and inspections – staff can refer back to security guidance documents but don't want take on role of security consultants
- ?? The FDA, through Office of Criminal Investigations, has virtually daily contact with FBI, CIA
- ?? All information gets fed into vulnerability assessments and agency assignments
- ?? Some food industries are more reliant on others to ensure the security of foods – those that don't have actual physical control of products.
 - Importers
 - Those reliant on multiple ingredients
- ?? All facilities are still responsible for ensuring the safety of foods. Must work to develop business practices and relationships to ensure safety of foods. Leverage contracts and understandings to build accountability up and down the food supply chain.
- ?? Firms need to demonstrate "due diligence" when it comes to food safety.

Examination of product for food security (when there is reason to suspect a food has been tampered with)

- ?? Quantity – what was ordered/expected?
- ?? Identity “ “ “ “
- ?? Take same precautions as appropriate for food safety
- ?? Look for evidence of tampering on exterior packaging
 - Lot
 - Cases
 - Products
- ?? Note unusual sights, odors (chlorine, bitter almond, petroleum), packaging (as appropriate without compromising personal safety)
 - Unprofessional labeling
 - Inconsistencies in coding or labeling
- ?? These evaluations frequently not done at border ports – but at food facilities
- ?? If FDA finds something that raises suspicions – staff are required to document (take photos and contact supervisor), make copies of shipping documents
 - Contact FDA Office of Emergency Operations at 301-443-1240 – 24 hr

- FDA consumer complaint coordinators handle emergencies & non non-emergency complaints – a listing of contact numbers is found on the web at:
www.fda.gov/opacom/backgrounders/complain.html
- ?? Facilities should contact government officials if they identify potential terrorist or sabotage activity
 - Local law enforcement
 - Public health authorities

Changes in Threat Alert levels

- ?? FDA-provided guidance should be viewed as a baseline business security infrastructure– precautions that should be done regardless of alert level
- ?? Additional precautions may be appropriate dependent on circumstances
- ?? Information may be classified and unable to share with investigator or firm to avoid compromising sources.
- ?? Federal agencies may request targeted evaluations of specific products or facilities based on intelligence.
- ?? Stay alert – additional guidance will be provided as needed

Involving Food Facility Staff in Security Assessments

- ?? Employees are the eyes and ears in the day-to-day operations
- ?? To make that work need to equip them properly
- ?? Help them to be alert to potential vulnerabilities
 - Example: The doors propped open in the warehouse
- ?? Can't give them all tools – ex. Don't share full vulnerability assessment that highlight all weaknesses.
- ?? Importance of sharing positive messages rather than dwell on negatives
 - What we need to do to ensure safety – ex. Light it, lock it, limit access

Supervising food workers to ensure food security

- ?? Review whole range of employees to ensure appropriate level of oversight.
- ?? Means different things in different types of facilities
 - Production facility – direct line supervision is common
 - Convenience store – unannounced stop ins may be warranted
- ?? Think through vulnerabilities and what risks the firm is willing/unwilling to take
 - Ask questions i.e.: Is this needed? Does it have to be this way?

Disgruntled Employees

- ?? Background screening of new hires can be expensive, time consuming, may face legal hurdles
- ?? Evaluate whole range of employees but there is especially value in assessing those working in key areas of vulnerability
 - Those with access to higher risk areas
 - Those who work relatively unsupervised

Retail Security Options

- ?? Decrease access to food handling areas and other non public areas
- ?? Increase security in self service or bulk dispenser – particular attention is needed here
- ?? Some high security settings may need to be curtailed or particularly scrutinized during high threat time periods
- ?? Operational Risk Management (ORM) is like HACCP in some ways. Look at both probability and severity of risk
 - Then integrate both factors into a single decision on risk
 - Helps determine where it is most important to put in place preventative measures
 - Once preventative measures have been picked – looks at cost benefit analysis for measures – different than HACCP
- ?? Example of differing levels of control: lock on door vs. 24-hour security.
- ?? Determining which is appropriate depends on level of risk the firm is trying to protect against

One state's perspective: Paul Tierney, Massachusetts Department of Health

- ?? Need to be clear on distinguishing regulatory roles from voluntary information sharing partnership procedures
- ?? MA is focusing on conducting a food vulnerability assessment (farm, wholesale, retail), enhancing trace-back capability, and developing a Health Alert Network (with CDC funding)
- ?? Its inspectors are leaving self-assessment checklists with the facility
- ?? *MA has recent legislation stating that vulnerability assessment information is outside the public domain, therefore not subject to FOIA*
- ?? The New England states are taking a regional approach to Food Security
 - Some focusing on developing educational tools, others on conducting assessments
 - Ultimately would like to look at the “macro level” – evaluation of the entire supply chain

Food industry perspective: Jenny Scott, National Food Processors Association

- ?? Food Security Alliance was formed after 9/11
- ?? Share information – trends, tools, procedures – development of communication lines - disseminate to associations, which share with members
- ?? Industry associations are developing crisis management procedures for emergency management and several risk assessment tools
 - TEAM documents-“Threat Exposure Assessment and Management” process, based on ORM, targeted at food industry
 - Self assessment checklists
 - Food Security Manual for Processors, Distributors and Retailers, Tammy Morgan at 202-639-5934 or Tmorgan@nfpa-food.org

- ?? Associations have focused on protection personnel, property, proprietary information, and food products
- ?? Industry sectors are providing guidance that specifically addresses unique needs (ex. railroad transport)
- ?? Associations are developing workshops for training and education
- ?? Information Sharing and Analysis Center (ISAC)
 - Industry driven for industry leaders
 - Existing one is for food processors and retailers
 - Another one is being formed for a broader farm to table perspective
 - Participants can feed data from around nation into one center to look for trends and early detection. Not governmental so not subject to FOIA.
 - Used to share information on unusual situations and potential threats with experts who can analyze and determine if they are credible
 - ?? Pass information on to people who need to have the information and act on it
 - Linked with National Infrastructure Protection Center now housed with Dept Homeland Security and coordinated with FBI
 - Building strong relationships with law enforcement and regulatory agencies
- ?? Industry's view is that the government's role is to help develop and disseminate information
 - Particularly the smaller plants who don't have as wide access to information
 - Do research to develop test methods for suspected agents
 - Identify potential agents

Attachment A

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FIELD INSTRUCTIONS for "Food Producers, Processors, Transporters and Retailers: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance"

The above named guidance documents are designed primarily as aids for operators of food establishments (i.e. firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients or that prepare or distribute food at retail) and food importers, warehouses, and filers. This guidance is voluntary and is not tied to existing regulations. They identify preventive measures that these kinds of establishments can take to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. The documents set out goals in this regard and provide example strategies for achieving those goals.

You should not perform a comprehensive food security audit of the establishment, nor should you conduct an extensive interview in an attempt to determine the level of adoption of preventive measures listed in the guidance. The goal is to facilitate an exchange of information on the subject of food security. Management of the establishment should be encouraged to voluntarily implement those preventive measures that are appropriate for their operations. Not all of the guidance contained in this document is appropriate or practical for every food establishment, food importer, warehouse, or filer.

The guidance documents are also intended to be used by food regulatory officials during regular inspections/audits of food establishments, food importers, warehouses, and evaluation of filers. Based on the conditions observed during the normal course of the inspection/audit, the appropriate material in the guidance documents should be discussed with management of the establishment and a copy of the guidance should be provided during the close-out meeting. Additionally, any opportunities for improvement or enhancement of the establishment's preventive measures that were identified during the inspection/audit should be discussed with management, but should not be listed as violations (e.g. on FDA's form FDA-483 Inspectional Observations) unless they likewise constitute deviations from Current Good Manufacturing Practice.

The fact that the discussion took place and that a copy of the guidance document was provided should be recorded in the inspection report (e.g. FDA's Establishment Inspection Report [EIR]) or evaluation report, but the details of the inspectional findings in this regard should not be recorded. For example, under a section heading titled, "Food Security," the regulator should only state, " A copy of the Food Security Guidance Document was provided to and food security issues were discussed with (name of food establishment official)." Additionally, you should strive to minimize the quantity and detail

of notes taken relative to the establishment's food security program, taking only those needed to serve as a "memory jog" during the discussion with management.

If management of the establishment has suggestions for improvement of the referenced guidance he/she should be encouraged to provide comments to the Agency (see Federal Register Notice of Availability dated January 9, 2002).

[Food Security Guidance, Federal Register Notice of Availability](#) January 9, 2002

[Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance](#) January 9, 2002

[Importers and Filers: Food Security Preventive Measures Guidance](#) January 9, 2002

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