

AAI REGULATORY COMPLIANCE UPDATE

JULY 1, 2005



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Leopold Center Opens Grant Process

The Leopold Center's 2005 "Request for Pre-proposals (RFP) is available NOW at www.leopold.iastate.edu/research/rfp/2005.htm. Download the RFP from the web site or for a hard copy call 515-964-3711. Please submit pre-proposals in ecology, marketing and food systems or policy either electronically or as hard copy by 5 p.m., Monday, August 1, 2005.

Grain Security Plan

The FDA Bioterrorism rules are completely separate and different from the U.S. Department of Agriculture (USDA) requirement of a grain elevator that contracts to store grain for the U.S. government to have a written Grain Security Plan. AAI will provide a fact sheet on this issue in the next regulatory monitor.

Grain/Feed Bioterrorism Rules

Less than 4 years ago, security wasn't much of an issue in the grain industry. There was storage, cleanliness, grade and market concerns but never a concern that our nation's feed supply might be threatened. Times have changed. We must think ahead about how to handle these threats.

The Food and Drug Administration (FDA) Bioterrorism Preparedness Law requires **all grain elevators and feed mills that store grain for any human or animal consumption** to:

- a. Register their facility with FDA, if you have not done it yet, go to this website: <http://www.cfsan.fda.gov/~furl/ovffreg.html> - there is no fee to register
- b. Give the FDA prior notice of any shipment of grain into the U.S.
- c. Food products that might pose a threat of serious adverse health consequences or death may be detained
- d. Keep specific records to identify the immediate previous source of food (feed) received and the immediate subsequent recipient of where food (feed) is shipped

The record keeping or tracking of grain/feed in and out of an elevator is the most recent requirement. It was recently discussed at the Grain Elevator and Processing Society (GEAPS) in Ames. The discussion surrounded why and how to track movement of grain/feed within your facility. The following Fact Sheet details the requirements and deadlines.

The FDA will be the only agency authorized to request to see these records of tracking grain/feed within your facility. If FDA requests copies of your records, the request will be in writing and you will have 24-hours to respond.

The Bioterrorism Act makes failure to comply a prohibited act. Non-compliance can result in civil action in Federal court. FDA also can seek criminal actions in federal court to prosecute persons who fail to establish and maintain records, as required by the final rule. We will continue to pass along information we learn on how to accomplish this tracking of grain in, throughout, and out of your facility.

FDA Bioterrorism Record Keeping Fact Sheet

The latest portion of the FDA Bioterrorism Regulation requires keeping track of the immediate previous source (farmer) and subsequent recipients of food (buyer). This means you must track all movement of grain and feed from the time it comes into your facility, all bin-to-bin movement, and where it goes when loaded out of your facility.

WHO?

All Agribusinesses that manufacture, process, pack, transport, distribute, receive, hold or import food; and *place food directly in contact* with its finished container must create and maintain records for up to 2 years. Food includes a wide-range of foods and beverages, but for the agribusiness it includes:

- Raw agricultural commodities for use as food or components of food
- Animal feeds and pet foods
- Fruits and vegetables
- Dairy products and shell eggs
- Beverages (including alcoholic beverages and bottled water)

Who is exempt from the requirement:

- * Farmers
- * Restaurants
- * Foreign companies

Continued Fact Sheet

WHAT?

What must be included in the records?

Identify the immediate previous *sources* of all foods received (farmer or seller), including:

- * Name of the farmer or seller and all contact information
- * Description of type of food, including brand name and specific variety
- * Date received
- * Quantity and type of packaging (bag, bulk);
- * Identify the transporter of received food, including the name and contact information
- * *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*

Identify the immediate subsequent *recipients* of all foods released, including:

- * Name of the buyer and all contact information
- * Description of type of food, including brand name and specific variety
- * Date released
- * Quantity and type of packaging
- * Identify the immediate transporter of outgoing food, including the name and contact information.
- * *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*

The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. What is “reasonable available” will vary from case to case.

WHERE?

These records must be kept on file at the place of business.

HOW?

How does FDA request to see records?

An investigator or other FDA representative 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. You will have 24-hours to reply. FDA may request additional records related to the incident at a later time under the same authority.

WHEN?

- * Larger businesses covered by this rule must comply by December 9, 2005
- * Small businesses: 11 - 499 full-time equivalent employees must comply by June 9, 2006
- * Very small businesses: 10 or fewer full-time equivalent employees have to comply by December 9, 2006.

The term, *full-time equivalent employees* means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

WHY?

Traceability

- Tracing food to its origin is a growing world trend.
- Traceability serves several functions related to product quality, safety, security and authenticity.
- FDA bioterrorism rules will cause increasingly precise product tracking.
- Bulk grains will not be exempt; the best system will become the standard.
- Begin basic actions and documentation now.
- Look for operational efficiencies at the same time.

Tracking

- Initial bin assignment for every scale ticket
- Time-date stamp if possible
- Transfer records: amount, date/time, where to
- Regular measurements to verify records
- Connect physical records to quality records

The records that must be kept by these regulations are those that are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals.

WHAT IF I DON'T?

The Bioterrorism Act makes failure to comply a prohibited act. Non-compliance can result in civil action in Federal court. FDA also can seek criminal actions in federal court to prosecute persons who fail to establish and maintain records, as required by the final rule.