



**IOWA GRAIN QUALITY INITIATIVE  
AGRIBUSINESS ASSOCIATION OF IOWA**

**U. S. Food and Drug Administration  
Raw Agricultural Commodities, Animal Feed**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the Bioterrorism Act) was signed into law in June 2002. It gives the FDA the responsibility for protecting the nation's food supply and tracing incidents of adulteration of food by bio-terrorism or natural causes to their source.

Agribusinesses in Iowa and the Nations ( elevators and feed mills ) which receive, hold and distribute raw agricultural commodities, or receive, manufacture, hold and distribute animal feed and pet feed for consumption by human or animals are affected by this Act. There are two Sections of the Act which elevators and feed mills must take action on to comply with the law. Section 305 requires registration and Section 306 requires record maintenance.

**Section 305 – Registration**

- Registration of facilities went into effect on December 12, 2003.
- Registrations requirements apply to facilities that manufacture, process, pack, or hold food for human or animal consumption.
- Food includes raw agricultural commodities for use as food or components of food, and animal feed and pet feed.
- All agribusiness companies with one or multiple locations which meet one of the criteria listed must register that location.
- Registration is best done on line at <http://www.access.fda.gov/>

**Section 306 – Record Maintenance**

- Record maintenance applies to all registered facilities
- Record maintenance compliance began for businesses with 500 full-time employees or more on December 9, 2005.
- Record maintenance compliance will begin for businesses with 11 to 499 full-time employees on June 9, 2006, and 10 or fewer full-time employees on December 11, 2006.
- Records must be established and maintained by a person ( including individuals, partnerships, corporations, and associations ) which manufacture, process, pack, transport, distribute, receive, hold or import food, and persons who place food directly in contact with its finished container.

**Section 306 – Record Maintenance – Excluded from these regulations**

- Farms.
- Persons who do one of these activities for personal consumption.



### Section 306 – Record Maintenance – Non-transporters of food

- Non-transporters are persons (defined earlier) who own food or who hold, manufacture, process, pack, import, receive, or distribute food for the purpose other than transportation.
- Non-transporters must identify, establish and maintain records on two sources of food movement through their businesses. Those sources are the immediate previous source and the subsequent recipient of all food received and released.
- Records to establish – Immediate non-transporter previous sources of all food received. Sources are; farm, transportation company, dog food manufacturer
  - Name of firm, contact person, address, telephone number, fax number and e-mail address
  - Type of food – brand name – variety; soybean – low-linolenic; dog food – brand-x dog food.
  - Date received
  - Quantity and type of packaging – soybean – 3400 lbs.; dog food – 50 lb. bags
  - Food received from persons who manufacturer, process, or pack must include the lot or code number or other identifier.
  - Records to establish – the food received is based on one step back – who transported the food to your business and who produced the raw agricultural commodity or who supplied the ingredient or meal for the animal feed or who manufactured the dog food.
- Records to establish – Immediate non-transporter subsequent recipients of food released. Recipients are: who was the grain shipped to and who received the animal feed.
  - Name of firm, contact person, address, telephone number, fax number and e-mail address
  - Type of food – brand name – variety
  - Date received
  - Quantity and type of packaging
  - Food released from persons who manufacturer, process, or pack must include the lot or code number or other identifier.
  - Finished product records must identify the specific source of each ingredient that was used to make each lot of the food.
  - Records to establish – the food released is based on one step forward – who transported the food from the business and who received the raw agricultural commodity or who received the animal feed or who received the dog food.

### Section 306 – Record Maintenance – Transporters of food

- Records to establish – Transporter of food
  - A transporter is a person who has possession, custody or control of food
  - Name of transporters previous source and subsequent recipient source.
  - Origin and destination points
  - Date shipment received and date released



- Number of packages
- Description of freight
- Route of movement during the time the food was transported
- Transfer points through which the shipment moved

#### Section 306 – Record Maintenance – Records retention

- Type of food – raw agricultural commodities
  - Non-transporter – 2 years – from date received
  - Non-transporter – 2 years – from date released
  - Transporter – 1 year from date received and 1 year from date released
- Type of food – animal food, including pet food
  - Non-transporter – 1 year – from date received
  - Non-transporter – 1 year – from date released
  - Transporter – 1 year from date received and 1 year from date released

#### Section 306 – Record Maintenance – Records availability

- When FDA has a reasonable belief that an article of food is adulterated and present a threat of serious adverse health consequences or death to humans or animals.
- An inspection request after meeting reasonable belief is as soon as possible – but not to exceed 24 hours from official request.
- If required records are not established and maintained.
  - Failure to establish and maintain the required records or failure to make them available to FDA is a prohibited act
  - The Federal government can bring a civil action or criminal action in Federal court.

#### Section 303 – Detention

- Authorize FDA to order the detention of food if an officer or qualified FDA employee finds, during an inspection, examination or investigation, credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals

#### Acknowledgements

- U.S. Food and Drug Administration
  - <http://www.fda.gov/oc/bioterrorism/bioact.html>
- Iowa State University – Extension
  - Iowa Grain Quality Initiative – [www.iowagrains.org](http://www.iowagrains.org)
- Iowa State University of Science and Technology – Copyright © 2006 – all rights reserved

#### Questions and contact

- Howard E Shepherd – Iowa State University – Extension – Iowa Grain Quality Initiative – 515-294-3137 – [howard@iastate.edu](mailto:howard@iastate.edu)
- Training Module on FDA Record Maintenance at Iowa Grain Quality Initiative Web site on raw agricultural commodities and animal and pet feed.

