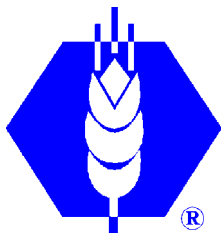


# **FDA's Bioterrorism Recordkeeping Regulations**

**...A Compliance Guide  
for Grain Elevators,  
Feed Manufacturers, Feed Dealers,  
Integrators, Grain Processors  
and Transporters...**



**National Grain and Feed Association**





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# NOTES



# Foreword

This document, developed by the National Grain and Feed Association (NGFA), provides guidance to assist the grain, feed and processing industry in complying with the U.S. Food and Drug Administration's (FDA) requirements to establish and maintain records under the Bioterrorism Act of 2002.

This document is organized in the following manner:


- A **Preface** section provides a brief overview of the four sets of bioterrorism-related regulations issued by FDA, recordkeeping being the final and most recent set.
- **Section 1** of this document contains an overview of the FDA bioterrorism recordkeeping regulations, as well as important definitions, the sectors of industry that are covered, sectors that are exempt from recordkeeping, and effective dates for the recordkeeping requirement.

A snapshot of the requirements that apply are previewed on pages 1-3 in the "In-A-Nutshell – Executive Summary of Recordkeeping Requirements." Readers are cautioned, though, that the executive summary is only a brief introductory overview and should not be relied upon to cover the myriad requirements and nuances that are part of this regulation.

- **Section 2** of this document reviews the specific information required to be kept under the FDA bioterrorism recordkeeping regulations. Accompanying the discussion of each issue are pertinent questions-and-answers that have been published by FDA in guidance documents accompanying the final regulations. See the **Contents** section for specific page references to the different topics.
- **Section 3** contains citations referencing important documents that can be accessed on the FDA bioterrorism recordkeeping regulations via the NGFA's website.

The topics discussed and guidance provided in this document are **not intended to be formal recommendations or advice**. Nor is this document intended to be a comprehensive compilation of all of the FDA bioterrorism recordkeeping requirements that apply to all sectors of the agricultural and food industry, which span producers to the food and beverage industries. Rather, this document is intended to provide information on those aspects of the FDA bioterrorism recordkeeping regulations that apply directly to companies encompassed within the NGFA's membership – namely, grain elevators, commercial feed mills, feed dealers, retail feed stores, feed ingredient manufacturers, grain processors, livestock and poultry integrators, and transporters.





This guidance document will be updated periodically as new information becomes available. The NGFA will notify members through its *NGFA Newsletter* and *NGFA E-Alert* publications concerning future updates, and will post future versions on the **NGFA-GEAPS Joint Facility Security Website** that can be accessed through the NGFA website homepage at [www.ngfa.org](http://www.ngfa.org). Readers also are reminded that this joint NGFA-GEAPS website is a valuable resource for keeping up-to-date on a wide range of developments concerning facility security and agroterrorism-prevention. Please visit the site frequently for updates.

We hope you find the information presented in this guidance document useful in complying with the FDA bioterrorism recordkeeping regulations. The NGFA encourages member companies to contact the Association with any additional questions on how these regulations may apply to specific business operations. NGFA members may send inquiries via email to [rgordon@ngfa.org](mailto:rgordon@ngfa.org), or call the NGFA at 202-289-0873.

We appreciate your membership in the NGFA!

# Preface

The U.S. Food and Drug Administration (FDA) on Dec. 9, 2004 issued final regulations implementing the section of the Bioterrorism Act of 2002 that requires most persons handling, storing, manufacturing, processing, packing, distributing or transporting agricultural commodities, feed, feed ingredients and food products to establish, maintain and provide access to records.

The recordkeeping provisions are contained in one of four broad sections of the Bioterrorism Act approved by Congress in June 2002 in the aftermath of the terrorist attacks of Sept. 11, 2001.


The other three sections of the Bioterrorism Act that pertain to grain, food, feed, feed ingredients and other agricultural commodities are as follows:

- **Facility Registration:** Domestic and foreign facilities (and their U.S. agents) that “manufacture, process, pack or hold (*i.e., store*) food for human or animal consumption in the United States were required to register with FDA under an interim final rule issued by the agency on Oct. 10, 2003. A final regulation was issued on Sept. 20, 2005. Among the types of facilities covered by the facility-registration requirement are grain elevators, feed mills, flour mills, corn and oilseed processors, pet food manufacturers, renderers and others. The facility registration requirement took effect on Dec. 12, 2003.

Information required to be submitted by facility registrants includes:

- the name, address and phone number for the facility, as well as the name and contact information for the parent company (*if applicable*);
- the name, address and phone number of the owner, operator or agent in charge of the facility, as well as an emergency contact number;
- all trade names used by the facility (*names under which the company does business, not the brand names of its products*);
- the applicable food (feed) product codes (*selected from an FDA-provided list*);
- statements certifying that the submitted information is correct and attesting that the person submitting it is authorized to do so; and
- the name of the U.S. agent or other designated person’s emergency contact phone number (*required for foreign facilities only*).





FDA's final regulations require that any of the required facility registration information be updated within 60 days of any changes.

- **Prior Notice of Imports:** Entities importing food, feed or feed ingredients into the United States are required to provide prior notice of such imports to FDA. The agency on Oct. 10, 2003 issued an interim final rule stipulating the requirements for prior notice, and those notification requirements took effect on Dec. 12, 2003.

Among the information required in prior notices are the identity of: 1) the type of food (feed) and the estimated quantity being imported; 2) the manufacturer of the product or, if known, the grower; 3) the shipper (*unless the product is being imported by mail*); 4) the country-of-production; 5) the identity of the importer, owners and ultimate consignee; 6) the carrier and mode of transportation; 7) the anticipated arrival information (such as the location, date and time); and 8) planned shipment information. Such notice is required to be made no more than five days before arrival, and by no less than two hours before arrival if by land by truck; four hours before arrival if by rail or air; and eight hours before arrival if by vessel.

- **Administrative Detention:** Under this provision of the Bioterrorism Act, FDA has the authority to impound food, feed or other agricultural products for up to 30 days if the agency has “credible evidence” that the shipment “presents a threat of serious adverse health consequences or death to humans or animals.” Activating a detention order requires approval by an FDA district director who has jurisdiction over the area where the shipment is located, or a senior FDA official. The detention period is designed to give FDA time to seek a court order preventing further movement of the suspect shipment. FDA issued final regulations on May 27, 2004 implementing the administrative-detention authority.

As a service to the industry, the NGFA is pleased to provide this guide for complying with the fourth major FDA bioterrorism regulation – the requirement to establish, maintain and provide access to records.



# Section 1

## Overview

### of FDA's Bioterrorism

### Recordkeeping Regulations

FDA's bioterrorism recordkeeping regulations require that those who "manufacture, process, pack, transport, distribute, receive, hold (*i.e., store*) or import food into the United States" establish and maintain records sufficient to identify the immediate previous source(s) and immediate subsequent recipient(s) of such food, as well as transporters used to haul such products.

Put simply, it is a one-step-back and one-step-forward product-tracing recordkeeping requirement.

Those covered by the regulations are required to maintain records containing information that is "reasonably available," including information that links inbound deliveries with outbound shipments.

#### In A Nutshell – Executive Summary

The following is a summary of the major elements of FDA's bioterrorism recordkeeping regulations that are discussed more comprehensively throughout the remainder of this guidance document:

FDA's bioterrorism recordkeeping regulations apply to:

- U.S. "persons" (which includes individuals, partnerships, corporations and associations) that store, manufacture, process, pack, transport, distribute, receive or import "food," regardless of whether such products enter interstate commerce. "Persons" subject to these regulations include those that operate facilities, such as grain elevators, feed mills, grain processors, feed ingredient manufacturers, retail feed stores and feed dealers, as well as transporters (truckers, railroads and barge lines).
- Foreign persons who transport food in the United States
- Those who place "food" directly in contact with the final finished container that will be received by consumers.

Under the regulations, "food" is broadly defined as it is in the federal Food, Drug and Cosmetic Act to mean "articles used for food or drink for man or





animals; chewing gum; and articles used for components of any such article.” So, it encompasses grain, processed agricultural commodities, feed and feed ingredients, among other products.

The regulations basically are divided into two broad tracks:

- **Non-transporters** (that is, facilities) are required to establish and maintain records containing information that is “reasonably available” to identify:
  - The “immediate previous source” (the seller) and “immediate subsequent recipient” (the buyer), including contact information. Nontransporters also are to keep records of information that is “reasonably available” to link inbound deliveries of agricultural commodities/ingredients to outbound shipments in which those products are contained or used.
  - The dates of inbound and outbound shipments.
  - The type and quantity of agricultural commodity received and shipped.
  - The identity of, and contact information for, the transporter from which the product was received and that was used to ship outbound product.
  - For manufacturers, processors and packers, the lot or code numbers (or other identifiers) of inbound and outbound products, but only to the extent such identifiers exist and to the extent that such information is “reasonably available.”
- **Transporters** (such as truckers, railroads and barge lines) that have possession, custody or control of an article of food for the sole purpose of transporting it (including foreign persons transporting food in the United States) are required to establish and maintain records containing information that is “reasonably available” to identify:
  - The “immediate previous source” (the shipper or other previous transporter) and “immediate subsequent recipient” (the destination or subsequent transporter), including contact information.
  - The dates the shipment was received and delivered.
  - A description of the type of shipment and the quantity of product hauled.
  - The origin and destination points, as well as route and any transfer points through which the shipment moved.

For both non-transporters and transporters, existing business records are sufficient for meeting the requirements of the bioterrorism recordkeeping regulations, *provided* such existing records contain the required information.

The effective date for the recordkeeping requirements depends upon the size of business involved. Large companies (those with 500 or more full-time equivalent employees) were required to begin establishing and maintaining records for covered activities occurring on or after Dec. 9, 2005. Companies with 11 to 499 full-time employees are to begin such recordkeeping on June 9, 2006. Small businesses – those with 10 or fewer full-time employees – are to begin such recordkeeping on Dec. 11, 2006.

FDA's regulations require that records involving receipt and shipment of raw grains and oilseeds be retained for two years from the date when the activity occurred (e.g., when the product was received/stored or shipped). For manufactured animal feed, including pet food and feed ingredients, records are required to be retained for one year from the date when the activity occurred. Feed manufacturers (including pet food and feed ingredient manufacturers) are required to maintain records for two years for raw grains and oilseeds used in the manufacturing of product. Transporters are required to maintain records for one year.

Before FDA can access records required under these regulations, the agency must have a “reasonable belief” that an article of food or feed is adulterated **and** presents a threat of serious adverse health consequences or death to humans or animals. FDA does **not** have the authority to inspect records required under the Bioterrorism Act unless this legal threshold is met. If the legal threshold is met, FDA is to submit a written notice (FDA Form 482c) to the owner, operator or agent in charge of the establishment. The affected establishment (e.g., facility or company) to which the notice is presented then is to provide access to the required records as soon as possible, not to exceed 24 hours thereafter.

Now, “the rest of the story . . .”

## Important Definitions

As a starting point for understanding FDA's bioterrorism recordkeeping regulations, it's important to get a handle on several key definitions used by the agency that are referenced throughout this document.

Here are several of the most important:

- **Farms:** A facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” includes: 1) facilities that pack or store food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership; and 2) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.





- **Food:** The regulations adopt the same expansive definition of “food” as used in Section 201(f) of the federal Food, Drug and Cosmetic Act: *“articles used for food or drink for man or other animals; chewing gum; and articles used for components of any such article.”* Examples of “food” include raw and processed grains, rice and oilseeds; animal feed and premixes; feed ingredients; pet food; live food-producing animals (such as cattle, swine and poultry); other raw and processed agricultural commodities; processed and semi-processed food products; bakery goods; snack foods; candy; canned foods; dietary supplements/ingredients; beverages (including alcoholic beverages and bottled water); infant formula; and other agricultural products. Thus, throughout this guidance document, the use of the term “food” has this all-encompassing meaning.
- **Manufacturing/Processing:** The process of making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. FDA provides the following examples of manufacturing/processing activities: rendering; milling; grinding; baking; labeling; packaging; freezing; cooling; bottling; distilling; cutting/peeling/trimming/washing/waxing, etc.; and extracting juice.
- **Non-Transporter:** A person who owns food or who stores, manufactures, processes, packs, imports, receives or distributes food for purposes other than transportation. This definition encompasses companies operating facilities such as: grain elevators, feed mills, feed ingredient manufacturing plants, pet food manufacturers, flour mills, dry- and wet-corn mills, oilseed processing plants, retail feed stores and others.
- **Non-Transporter Immediate Previous Source:** The supplier, seller and/or shipper from which the “food” product subject to recordkeeping is received. This refers to the establishment (e.g., farmer, feed ingredient supplier, grain elevator, feed mill, etc.) that last had possession of the “food” before it was transferred to another non-transporter (e.g., facility).
- **Non-Transporter Immediate Subsequent Recipient:** The buyer/receiver to whom the “food” product subject to recordkeeping is distributed. This refers to the establishment (e.g., grain elevator, feed mill, flour mill, bakery, etc.) that acquired the “food” from another non-transporter.
- **Packing:** Placing food in a container, other than the finished container that directly contacts the food and is received by the consumer. Examples include packaged feed sold to farms and other businesses.
- **Person:** Includes individuals, partnerships, corporations and associations that are subject to the recordkeeping requirements. These include entities that operate grain elevators, commercial feed mills, grain processing plants, retail feed stores and feed dealers, pet food manufacturing plants and transporters (truckers, railroads and barge lines).

- **Retail Food Establishment:** An establishment whose annual monetary value of sales of food/feed products directly to consumers (“consumers” do not include farms) exceeds the annual monetary value of sales of food/feed products to all other buyers (including businesses). The definition encompasses grocery stores, retail convenience stores, and retail farm supply and feed stores that sell bagged feed, pet food and feed ingredients over-the-counter directly to consumers and final purchasers for use in their own animals.
- **Transporter:** A person who has possession, custody or control of an article of food in the United States for the sole purpose of transporting the food.
- **Transporter Immediate Previous Source:** The person from whom a transporter received food. This immediate previous source can be either another transporter or a non-transporter (facility).
- **Transporter Immediate Subsequent Recipient:** The person to whom a transporter delivered food. This recipient can be either another transporter or a non-transporter (facility).

**Scope – Who’s Covered and Who’s Exempt**

Next, let’s look at the scope of the FDA bioterrorism recordkeeping regulation. Specifically, which entities are covered and which are exempt from one or more parts of the regulations?


### Who’s Covered

FDA’s bioterrorism recordkeeping regulations apply to “persons” who “manufacture, process, pack, transport, distribute, receive, hold (*i.e., store*) or import food into the United States,” regardless of whether the product enters interstate commerce. The regulations also apply to: 1) persons who place food directly in contact with its finished container, which includes processors that pack food into bags or containers sold to final consumers; and 2) foreign persons who transport food within the United States.

The law defines “persons” as encompassing individuals, partnerships, corporations and associations.

Importantly, the Bioterrorism Act defines “food” the same way that the Federal Food, Drug and Cosmetic Act does; that is, as “*articles used for food or drink for man or other animals; chewing gum; and articles used for components of any such article.*” Examples of “food” include raw and processed grains, rice and oilseeds; animal feed and premixes; feed ingredients; pet food; other raw and processed agricultural commodities; processed and semi-processed food products; and other agricultural products. Thus,





throughout this guidance document, the use of the term “food” has this all-encompassing meaning.

As a result, the bioterrorism recordkeeping requirements apply to persons operating:

- Grain elevators (including country, terminal and export facilities). FDA includes grain export elevators because, unlike the facility-registration requirement, the Bioterrorism Act does not limit the recordkeeping requirements to food consumed in the United States. FDA also states it believes coverage of export elevators is necessary “because foods intended for export could easily be diverted into domestic commerce.”
- Commercial feed mills, feed ingredient manufacturers and pet food manufacturers.
- Grain processors, including corn and flour milling operations, soybean processors and others.
- Retail feed stores and feed dealers (unless they meet the very limited exclusion requirement explained in the next section).
- Transporters, who are defined as those that have “possession, custody or control of an article of food (or feed) in the United States for the sole purpose of transporting the food by road, rail, water or air.” *[Emphasis added.]* Thus, railroads, truckers and barge lines that transport grains/oilseeds, feed and processed agricultural commodities are covered.

## Who’s Exempt

The Bioterrorism Act as passed by Congress specifically exempts the following entities entirely from the requirement to establish and maintain records under FDA’s bioterrorism recordkeeping regulations:

- **Farms.** FDA defines farms as “a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both.” The farm definition covers facilities that pack or store food, provided all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership, **including integrated livestock and poultry operations**. The farm exemption also includes facilities that manufacture and process food, again so long as the food that is being manufactured or processed is consumed on that farm or another farm under the same ownership.

So, what is the practical meaning of this farm exclusion?

According to FDA, the exemption for farms covers the activities of grain and oilseed producers who harvest and deliver raw commodities to a grain elevator, feed mill or processor. The preamble to the final rule expressly states that such harvesting and transportation activities are considered “incidental to traditional farming activities.” The exemption also applies to farms that mix, grind or manufacture feed on-farm, provided the feed is consumed by animals on that same farm or another farm under the same ownership.

The same treatment applies to livestock, dairy and poultry operations. For instance, FDA states that it “considers milking cows and collecting eggs from chickens to be ‘harvesting’ when applied to animals, because these activities are akin to harvesting crops.” Thus, beef cattle, dairy, broiler, layer and other animal production operations whose activities strictly are limited to raising and delivering meat, milk, eggs or fish to processors are exempt from the recordkeeping requirements.

In addition, the farm exemption is size neutral, and integrators under the final rule are considered to be farms “to the extent that these operations are devoted to raising animals for food, the growing of crops, or both, and otherwise engage in only those activities included in the farm definition.”

Farms also may be exempt from the recordkeeping rule when they process, grind and manufacture products from their own production, provided these further-processed products are used only for their own farming production. However, if these further-processed products (such as feed mixed/manufactured on-farm, hay/silage, hulls, etc.) are sold to another farm, feed store, business or customer that is not under the same ownership as the farm, then the farm’s processing, grinding or manufacturing facility no longer is exempt and is required to maintain records of those transactions.

This scenario is illustrated by the following question-and-answer from FDA’s guidance document accompanying the final rule:

#### ***Question-and-Answer on Farm Exemption***

***Q:*** “A farm grows, dries and chops alfalfa before releasing it to another person for use as animal feed. Is the farm still exempt from this regulation?”

***FDA:*** “No. Traditional farming activities, such as harvesting of grains, are covered under the farm exemption. However, this question implies that the drying and chopping are post-harvest activities, which would be considered manufacturing/processing and therefore are subject to this rule. Therefore, the facility drying and chopping alfalfa must establish and maintain records of the food’s receipt (immediate previous source) and release (immediate subsequent recipient)....”





Likewise, if the livestock, dairy, poultry or other animal production operation (e.g., integrator) is involved in the further processing or manufacturing of food-producing animals – or food products from such animals – those processing-related activities no longer are exempt from the recordkeeping requirement. This includes, for instance, livestock or poultry integrators that also operate a meat or poultry processing plant that further processes animals they produce for subsequent sale to consumers; in this case, the processing facility is required to establish and maintain records. The same applies to processing facilities that may be operated by dairy farms to pasteurize milk for subsequent sale. FDA says it still is evaluating its response to a question as to whether chicken layer operations are required to keep records if they pack eggs into cartons, since packaging is covered under the bioterrorism recordkeeping regulations.

One other note: Persons or facilities that manufacture, process, pack, transport, distribute, receive, hold (store) or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, Poultry Products Inspection Act or the Egg Products Inspection Act are excluded from all of the recordkeeping requirements with respect to that food while it is under the exclusive jurisdiction of USDA.

***Question-and-Answer on Recordkeeping for Raw Materials Received at Rendering Plants***

***Q:*** “Do the recordkeeping requirements apply to receiving of raw materials at rendering plants in cases where the raw materials are subject to USDA inspection? For instance, if raw cattle or chicken parts are received by a rendering plant for processing, at what point do records need to be maintained – when the inbound load is received or not until the raw animal material is further processed into meat-and-bone meal, poultry meal, feather meal, blood meal, etc.?”

***FDA:*** “The final rule exempts products that are under the exclusive jurisdiction of the U.S. Department of Agriculture (e.g., meat, poultry and egg products), but only so long as such products are under USDA’s exclusive jurisdiction. Since renderers also are regulated by FDA as an animal feed ingredient supplier, the animal byproduct described above would be subject to the recordkeeping requirements. The recordkeeping would apply to the inbound loads in the example of raw cattle or poultry material cited above, since the renderer and the rendering process is subject to FDA jurisdiction.”

In addition to farms (under the conditions described previously), each of the following also is entirely exempt from the requirement to establish and maintain records under this FDA regulation:



- **Brokers**, *provided* they do not directly own, manufacture, process, pack, transport, distribute, receive, hold or import food. Under these criteria, brokers (such as freight or customs brokers) are exempt **only** to the extent they act **solely** to facilitate distribution, sale or transportation of food **by processing information or paperwork associated with these functions**. For instance, FDA in its guidance document questions-and-answers accompanying the final regulation states that a person who enters into a contract to hold, manufacture, process, pack, import, receive, or **distribute** food is subject to the recordkeeping requirements, even if that person subcontracts the actual performance of the covered action to another entity. Further, FDA states that in cases in which the broker enters into a contract to distribute the food but, in addition, may own title to the food, the broker also is subject to the recordkeeping requirements.

### ***Question-and-Answer on Recordkeeping for Brokers***

**Q:** “A brokerage division of a shipping company handles nationwide shipping needs for several other shippers. The brokerage division does not physically take custody of the food, but negotiates the freight rates and assigns the contracts to independent carriers. Does the brokerage division have recordkeeping obligations under this regulation?”

**FDA:** “Yes. [The regulation] defines a transporter as a person who has possession, custody or control of an article of food in the United States for the sole purpose of transporting it. For the purpose of this regulation, a person, such as the shipping company above, who enters into a contract to transport an article of food and has control over the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity. In the above example, the freight broker and the independent carrier are transporters subject to the final rule. . . . This scenario differs from that (described in the final rule) that the recordkeeping requirements do not apply to brokers who act *only* to facilitate distribution, sale or transportation of food by processing information or paperwork associated with these functions, such as customs brokers who file entry information on food imported or offered for import with U.S. Customs and Border Protection. Brokers who do not *directly* manufacture, process, pack, transport, distribute, receive, hold (store) or import food are not subject to the requirements of this regulation.”  
[Emphasis in original.]

- **Foreign persons**, except those who transport food within the United States.
- **Restaurants**. The definition of restaurants includes pet shelters, kennels and other facilities that provide feed or pet food directly to animals. However, to be exempt, a “restaurant” that also includes a





retail facility that sells food products to consumers for later consumption must have 90 percent or more of its total food sales consist of food it prepares and sells directly to consumers for immediate consumption, with no further preparation (i.e., the restaurant portion of the operation).

- Persons performing food-related activities that are **under the exclusive jurisdiction of the U.S. Department of Agriculture**.
- Persons who manufacture, process, pack, transport, distribute, receive, hold (*i.e., store*), or import **outer food packaging** that does not come directly into contact with food or feed.
- Persons who manufacture, process, pack, transport, distribute, receive, hold (*i.e., store*) or import food for their **own personal consumption**.

FDA's bioterrorism recordkeeping rule also provides the following entities with **partial exemptions** from the requirement to establish and maintain records:

- Persons who distribute (sell) food **directly to end-consumers** are exempt from the requirement to establish and maintain records to identify the buyer/receiver of those products (i.e., the “immediate subsequent recipients”). Importantly, the term “consumers” does **not** include businesses, such as farms.
- Persons who operate retail food establishments (including feed stores and pet food retailers) that distribute food (feed) to persons who are **not** consumers must establish and maintain records to identify the immediate subsequent recipients (i.e., the buyer/receiver) **only to the extent the information is reasonably available**. In addition, retail food (feed) establishments that employ 10 or fewer full-time equivalent employees are exempt totally from the requirement to establish and maintain records, but not the record availability requirements for existing records. *[These exemptions are explained more fully on pages 21-25.]*

## Effective Dates for Recordkeeping Requirements

For establishments that are subject to the bioterrorism recordkeeping requirements, the effective date depends upon the number of full-time employees at a given business (*e.g., the entrepreneurship, partnership, corporation, association, etc.*), as illustrated in the following chart:

Business Size	Total Number of Full-Time Equivalent Employees	Compliance Date
Large	$\geq 500$	Dec. 9, 2005
Small	11 to 499	June 9, 2006
Very small	$\leq 10$	Dec. 11, 2006

The number of full-time employees is determined by dividing the business's total number of hours of labor for which salary or wages are paid directly to employees by the number of hours worked in a year (2,080 hours, based upon 40 hours per week for 52 weeks). When performing this calculation, the hours for **all** employees for the **entire business** (not just individual establishment locations) is to be used, regardless of whether those employees are engaged in activities related to food subject to this regulation.

Importantly, the recordkeeping requirements are **not** retroactive. They apply only to covered activities (such as grain receiving, feed/feed ingredient/pet food manufacturing, grain processing, etc.) that occur **on or after the effective dates**. For example, as reflected in the table above, records would **not** be required to be established for grain received in October 2006 during harvest by a country elevator with fewer than 10 employees; but if that grain were shipped on or after Dec. 11, 2006, that country elevator would be required to establish and maintain records of the outbound shipment. Likewise, a commercial feed mill with fewer than 10 employees would not be required to establish records for feed ingredients received in November 2006, but would be required to establish and maintain records for feed using those ingredients that is manufactured on or after Dec. 11, 2006.



# Section 2

## Recordkeeping Information Required by FDA

The kind of information required to be kept in records by those covered under the FDA regulations depends on whether the entity is a non-transporter (e.g., a facility or manufacturing plant) or a transporter.

### Recordkeeping for Non-Transporters (e.g., facilities)

For non-transporters covered by the FDA bioterrorism recordkeeping regulations — such as grain elevators, feed mills, grain processing plants and other facilities — FDA requires that records be established and maintained that contain “reasonably available” information identifying the following:

1. The immediate previous source (e.g., the supplier/seller) from which the covered product was received and the immediate subsequent recipient (e.g., the buyer/receiver) to which the product was shipped.
2. An adequate description of the type of food, feed or covered agricultural product received and/or shipped by the facility.
3. The date the product was received and/or shipped.
4. The quantity received and/or shipped, as well as the packaging (e.g., bag, bulk, etc.) used.
5. The lot or code number (or other identifier) of products received and/or shipped to the extent such information exists. Lot numbers do not need to be created for purposes of this regulation. Further, this particular recordkeeping requirement applies only to persons who manufacture, process or pack a food, feed or agricultural product, not to those whose sole activities are to store and/or ship (distribute) such products.
6. The transporter from which the inbound delivery was received and/or the outbound product was shipped.

Pages 12 through 21 provide additional information about each of these six recordkeeping information requirements for non-transporters, starting with the requirement to establish and maintain records of the immediate previous source and immediate subsequent recipient of covered agricultural products.

Nontransporters (e.g., facilities) are required to establish and maintain records of:

1. The “immediate previous source” (the supplier/seller or other source from which the establishment received the covered agricultural product)

and “immediate subsequent recipient” (the buyer/receiver to which the agricultural product was shipped/distributed). Information is to include the name, address and telephone numbers of the immediate previous source and immediate subsequent recipient, and, if available, their fax numbers and email addresses. FDA requires that this information be collected regardless of whether the immediate previous source or immediate subsequent recipient is a domestic or foreign firm. There is one extremely important exception: Non-transporters are **not** required to maintain records of the immediate subsequent recipient (the buyer/receiver) or the transporter used to haul the product if the shipment is directly to a final consumer. The definition of “consumer” does not include farms or other businesses.

***Questions-and-Answers on ‘Immediate Previous Source’  
and ‘Immediate Subsequent Recipient’***

***Q:*** “A non-transporter firm may receive a product from a vendor with multiple ship points. Currently, the firm’s systems cannot record the ship point. Is the firm required to record the actual ship point as the non-transporter immediate previous source, or just the contact information for the vendor?”

***FDA:*** “...[T]he non-transporter firm above must provide the specific address and other contact information of the legal person (the vendor) that released the food to them, but does not need to provide information regarding particular ship points of the vendor.” ***[NGFA Note: FDA further clarified to NGFA that the non-transporter receiver of agricultural products can establish and maintain records of either the physical holder (e.g., shipping point) or the corporate entity with which it entered into a contract to obtain the products. If the non-transporter has information on both the shipping point or corporate headquarters of the immediate previous source, FDA says it would prefer that records contain information on the location from which the product was shipped because it is more precise. But the agency said if the sales force at corporate headquarters enters into all transactions, and ships from a manufacturing facility at a different location, information on the corporate headquarters’ location may be all that the non-transporter immediate subsequent recipient has that’s “reasonably available.”]***

***Q:*** “A firm receives foreign products in an overseas container and processes them on behalf of the owner, the importer of record. Who is the immediate previous source? What if the importer of record considers the source of the product confidential commercial information?”

***FDA:*** “...In the above example, both the owner of the food and the firm receiving the food are non-transporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as





a matter of business practice, but legal responsibility remains with both parties. The non-transporter immediate previous source is the foreign non-transporter that released the food to the owner and receiving firm, whether or not this information is confidential. Again, as a matter of business practice, the receiving firm and/or owner may choose to arrange to have another establish and maintain records on their behalf at the location where the food is received or at a reasonably accessible location that contains the confidential information, but legal responsibility for providing the records, including information that the importer of record considers confidential . . . , remains with the owner and receiving firm.”

**Q:** “An animal feed manufacturer receives commingled product from three different facilities and produces an animal feed finished product. The product is sold directly to farmers as feed, and also to subsequent animal feed manufacturers who commingle it with other feed ingredients and make a final saleable product. What information must the records established and maintained by the original manufacturer contain?”

**FDA:** “[In this example,] the firm manufactures a product that is both a finished feed and a feed ingredient. . . . With respect to all other ingredients incorporated in the product, the manufacturer must establish and maintain records of receipt that include the information required (in the regulations), including the lot or code number or other identifier if it exists. [NGFA

**Note:** See subsequent discussion on lot numbers in #5, pages 16-18]. When the manufacturer releases the finished product, it must establish and maintain records of release to any person who is not an individual consumer, including farms. Although farms themselves are exempt from all requirements. . . . , records must be established and maintained by the non-transporter (including the original manufacturer) and transporter immediate previous source of food released to farms. [Emphasis added.]

2. An “adequate description” of the type of food/feed/agricultural product received or shipped. FDA states that this information is to be as specific as possible. For instance, a grain elevator would be expected to indicate in its records that a commodity being received is a certain kind or class of grain (such as U.S. No. 2 yellow corn). A feed manufacturer would be expected to include the product name or other descriptors commonly found on a label or feed tag.

#### ***Question-and-Answer on Agricultural Product Description***

**Q:** “How much detail is required in describing a food (e.g., different types of commodity grains, different varieties of a particular grain)?”

**FDA:** “Descriptions of commodity grains and produce must be as specific as possible (e.g., Roma tomatoes versus cherry tomatoes; sweet corn versus field corn). Per the rule preamble, this type of description

saves time and resources during a tracing investigation because it allows FDA to narrow its focus to the appropriate product during the investigation.”

3. The date the product was received and/or shipped.
4. The quantity received/shipped and the packaging used (e.g., bagged feed, etc.). Importantly, the regulation requires that those placing an agricultural product (e.g., food, feed, pet food, etc.) into direct contact with its finished container establish and maintain records on that container if that is the packaging that will be received by the final consumer. In its question-and-answer guidance document accompanying the final rule, FDA notes that “manufacturers placing products in contact with a finished container in which it will be received by an individual consumer (not a business) are required to establish and maintain records of the receipt of the finished container, and must identify the specific source of the finished container in the record of release of the finished food.” *[Emphasis added.]*


But the container/package recordkeeping requirement does not apply to outbound product being shipped to a business (which includes farms) that subsequently will use or repackage the product before sale to a final consumer. For example, under this provision, feed ingredient manufacturers whose products are delivered in bags to a feed mill or farm that subsequently uses those products in a commercial feed or feeds those products to animals would not be required to keep records of the identifiers of the bags, since the product is being sold to a business for subsequent use. But, of course, they would be required to keep records of other required information (e.g., the identity of the receiver, quantity, date, etc.) regarding the shipment.

So, the requirement to maintain records of packaging and containers in the grain, feed and processing industry applies primarily to feed and pet food manufacturers that manufacture and sell pet food or other products (e.g., ratite feed, bird seed, exotic animal feed, etc.) directly to final consumers (but not to farms) through feed stores, etc.

### ***Questions-and-Answers on Recordkeeping of Bags and Other Containers***

***Q:*** “The final regulation requires the person placing a food directly into contact with its finished container to establish and maintain records on the container that contacts the food. Since the definition of food includes food and feed ingredients, this requirement appears to apply equally to anyone placing any food ingredient into any container,





*as well as commercial packaging operations. This encompasses activities such as...placing grain into a grain silo, loading product into drums, loading a tank truck, or placing vegetables into a pickup truck, as well as more traditional food-packaging operations, such as filling a bottle of ketchup or canning tomatoes. Does 'finished container' apply to every container at every step in the supply chain?"*

**FDA:** "No. A finished container...is the packaging in which the finished food (or feed) will be received by an individual consumer (not by a business)."

5. For persons who manufacture, process or pack a food/feed/agricultural product, the lot or code number or "other identifier" (such as bar codes) of the product. Importantly, the lot number requirement applies only to the extent such a number exists. So, establishments are **not** required to create lot or code numbers for purposes of this regulation. But firms do need to maintain and track lot numbers in records to the extent they exist. Note, too, that establishments whose activities solely are limited to storing and shipping (distributing) agricultural commodities are not required to maintain lot or code numbers, even if they do exist; however, the requirement to establish and maintain records containing the lot/code number or other identifier does apply if these storage facilities also are engaged in manufacturing, processing or packing a food or feed.

In the preamble to its final regulation, FDA states that it learned through the comment period on the proposed rule that "tracking lot/code numbers or other identifiers throughout the manufacturing/processing and packing of food is not a problem, because it is currently being done or capable of being done. It is during the transporting, distribution and holding (storing) of food (e.g., from the warehouse distribution centers to the retail store or restaurant) that such tracking becomes a problem....The final rule does not require warehouse distribution facilities to track lot/code numbers or other identifiers."

In the grain, feed and processing industry, lot-number tracking will be most pertinent to feed manufacturers and grain processors (including flour mills, dry and wet corn mills, and soybean processors), since they are involved in manufacturing and processing operations and frequently establish and assign lot numbers to products. Such manufacturers and processors whose suppliers provide ingredients or additives that are designated with lot numbers would be expected to designate that lot number identity in company receiving records. Similarly, if the manufacturer or processor establishes a lot number for different production runs of finished product, those lot numbers are to be retained for purposes of FDA's recordkeeping regulations. As for



linking the lot numbers of specific ingredients to the finished product, FDA's recordkeeping regulations require that such records be established and maintained, but only to the extent such information is "reasonably available."

***Questions-and-Answers on Lot Numbers, Codes  
and Other Identifiers***

**Q:** *"A manufacturing firm may handle over a thousand different ingredients on the same day, and three or four lot codes of the same ingredient from the same supplier may be used on a particular day. Assuming the ingredients arrive at the manufacturing facility with lot codes, does the manufacturer have to track each lot code and link it to a finished product?"*

**FDA:** "Yes. The manufacturer is required...to establish and maintain records for each ingredient it receives, including the lot codes for each ingredient received if they exist. When the manufacturer releases a food, it must also establish and maintain records for that food. The records also must include both the lot code of the finished product if it exists, and the specific source of each ingredient used to make every lot of finished product, to the extent that information is reasonably available...."

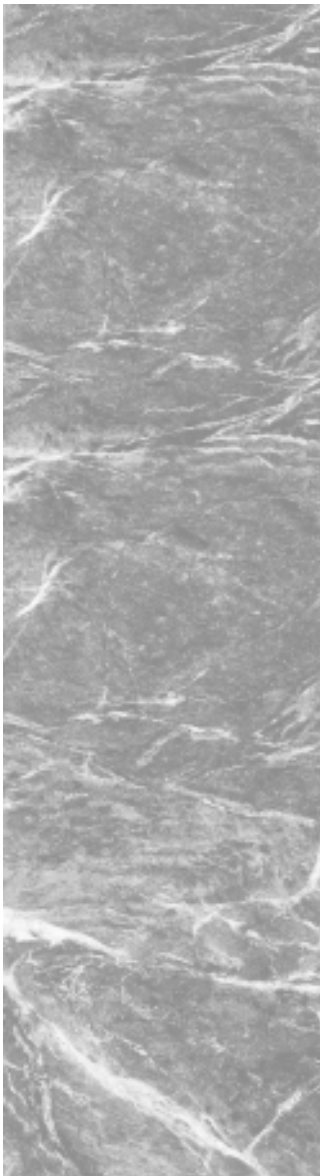
**Q:** *"If a manufacturer receives ingredients that have a lot number, but that lot number is not provided to the manufacturer by the ingredient supplier, is the manufacturer required to actively obtain the lot number of each ingredient?"*

**FDA:** "Yes. [The regulation] requires that persons who manufacture, process or pack food must establish and maintain records that include the lot or code number or other identifier for all food they receive, if that information exists. The manufacturer must obtain the lot numbers for each ingredient received from the ingredient supplier."

**Q:** *"Is a food processor required to physically examine each food product it receives in order to obtain the lot or code number information required..., or can the processor rely on the information provided by its immediate previous source? If the processor's immediate previous source fails to provide this information, must the processor obtain it by physical inspection of the food?"*

**FDA:** "Manufacturers, processors and packers are required to record lot or code numbers or other unique identifiers of the food they receive if this information exists.... These persons must ensure that they meet the requirement, regardless of whether the information is provided by their non-transporter immediate previous source. FDA does not intend to specify the manner in which these persons ensure that they have the required information, which may be obtained in various ways, including direct physical inspection and contractual obligations."





**Q:** “If a lot or code number or other identifier exists, but is not being used by a manufacturer, processor or packer as part of current business practice, is this business required to include that identifier in the records it establishes and maintains?”

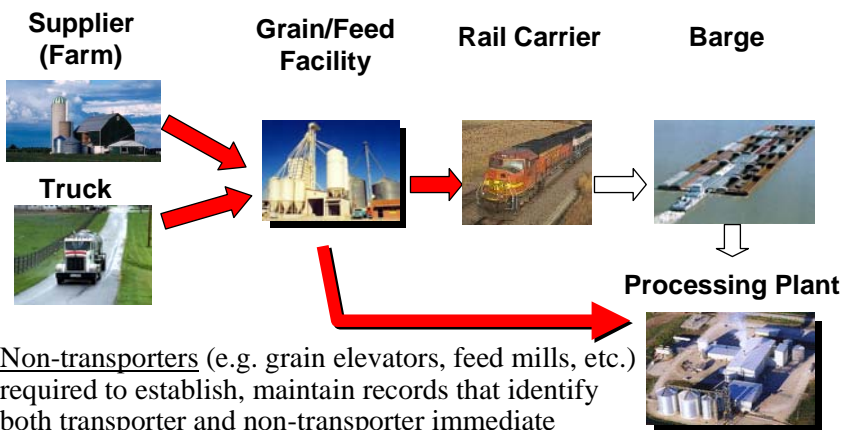
**FDA:** “Yes. [The regulation] requires the inclusion of a lot or code number or other identifier if it exists, regardless of its use in current business practice.” [Emphasis added.] [NGFA Note: For feed manufacturers, grain processors and others that may establish lot numbers for their finished products, this regulation requires that such lot numbers be included in the records established and maintained to identify the immediate subsequent recipient (e.g., buyer) of those finished products.]

**Q:** “Do feed manufacturers need to retain the supplier lot code number of the bags received from the bag supplier that are used to package animal feeds?”

**FDA:** “Yes. Persons who manufacture, process or pack food also must include lot or code numbers or other identifiers if the information is reasonably available. So, if the packaging has a lot number or other identifier, that information is required to be maintained in records.”

6. The transporter name, address and telephone number, and, if available, the fax number and email address. There is one important exception: Non-transporters are **not** required to maintain records of the transporter used to haul the product if the shipment is directly to a final consumer. The definition of “consumer” does not include farms or other businesses.

## Records Required for Non-Transporters (Facilities)



Non-transporters (e.g. grain elevators, feed mills, etc.) required to establish, maintain records that identify both transporter and non-transporter immediate previous source (supplier) and immediate subsequent transporter and recipient (buyer), as indicated with solid arrows.

The nearby diagram illustrates the non-transporter's obligation to establish and maintain records of the “immediate previous source” and “immediate subsequent recipient,” as well as the transporter used to haul the product:

In the situation depicted in the diagram, the records maintained by the non-transporter are required to contain information on the transporter and supplier from which it receives “food”

(e.g., grain, feed ingredients, etc.), as well as the immediate subsequent transporter it uses to haul the product and the immediate subsequent destination to which the product is shipped.

In the case of barge transportation, where agricultural commodities can be traded multiple times and the ultimate destination/purchaser is unknown to the originating shipper, the records maintained by the original shipper only are required to contain information on the entity to which it originally sold the commodity and the barge line used to haul the commodity. It then is the responsibility of each subsequent buyer and seller to maintain records of their respective transactions.

***Questions-and-Answers on Identifying Buyers  
in String Transactions***

**Q:** “A firm sells byproducts from its manufacturing process, but the rights to a certain quantity of byproduct may be resold several times. Is the immediate subsequent recipient the original buyer of the byproduct, or the entity that actually is the owner at the time the byproduct leaves the firm’s possession?”

**FDA:** “The manufacturing firm may identify either the original buyer or the actual recipient as the immediate subsequent recipient. . . . [B]oth the original buyer and the actual recipient are considered non-transporter immediate subsequent recipients, and both are responsible for complying with this regulation.”

Importantly, in its guidance document questions-and-answers accompanying the final regulations, FDA indicates repeatedly that it will allow non-transporters to identify the shipper, broker or other party as the transporter in cases where the non-transporter may not have access to “reasonably available” information about the identity of the transporter. Several specific examples follow. *[NGFA Note: In its responses, FDA’s use of the phrase “exercising enforcement discretion” is the agency’s terminology for stating that it will be flexible in applying this aspect of the final rule. In addition, FDA’s policy stance also applies to the responsibility of sellers to identify transporters in records in situations where they do not arrange for transportation of products they ship.]*

***Questions-and-Answers on Identifying Transporters in Records***

**Q:** “An animal feed manufacturer purchases a feed ingredient from a vendor. The vendor arranges transportation of the ingredient to the manufacturing facility. Does the feed manufacturer have to establish and maintain records that identify the actual transporter of the feed ingredient?”





**FDA:** “FDA intends to consider exercising enforcement discretion if the feed manufacturer identifies the vendor that made the contractual arrangement for the transport of the feed as the transporter immediate previous source.” *[Emphasis added.]*

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**Q:** *A public warehouse releases food to a non-transporter immediate subsequent recipient who makes its own arrangements for transporting the food from the warehouse to the recipient. The receiving firm sometimes does not provide details about the carrier who will transport the food from the warehouse. Is the warehouse now required to obtain information about the carrier?”*

**FDA:** “FDA intends to consider exercising enforcement discretion...if the warehouse identifies the receiving firm that made the contractual arrangement for transport of the food as the transporter immediate subsequent recipient.” *[Emphasis added.]*

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**Q:** *“A warehouse has information about the brokers who arrange deliveries and releases of food products, but not about the actual contract drivers and trucks that transport the products. Is this information required under this regulation?”*

**FDA:** “No...For the purpose of this regulation, FDA considers a transporter to include a person who enters into a contract to transport food, even if that action is subsequently subcontracted to another entity. In this case, the warehouse may identify as their transporter immediate previous source or immediate subsequent recipient either the freight broker or the contract driver...” *[Emphasis added.]*

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**Q:** *“A firm purchases a food ingredient from a broker who does not take actual possession of the food. Is the immediate previous source of the food the broker or the ingredient manufacturer (from whom the broker obtains the food)?”*

**FDA:** “The purchasing firm may identify either the broker or the ingredient manufacturer as its non-transporter immediate previous source...[A] non-transporter (is) a person who owns food or who holds (stores), manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. A person who enters into a contract to hold, manufacture, process, pack, import, receive, or distribute food is considered a non-transporter, even if that person subcontracts the actual performance of the covered action to another entity. In this example, the broker enters into a contract to distribute the food and in addition may own title to the food. For this reason, the broker is subject to the rule and an acceptable non-transporter immediate previous source for the purchasing firm.” *[Emphasis added.]*

FDA officials provided additional guidance to NGFA members concerning the transportation recordkeeping responsibilities of non-transporters (e.g., facilities) during the Association’s Country Elevator/ Feed Industry Conference in December 2005. Concerning deliveries of raw agricultural commodities from farms, FDA stated that grain-handling facilities should track and record the inbound transporter information if such information was “reasonably available.” But in cases where the producer is arranging his or her own transportation, FDA acknowledged that such information may not be “reasonably available.” In these situations, FDA said, it would suffice for the grain receiver to maintain records designating the producer as both the immediate previous source and the transporter of the product. FDA suggested that this be done by either indicating “same” or repeating the producer’s contact information in the recordkeeping field for the transporter, rather than leaving that information field blank.

The gist of FDA’s guidance concerning the obligation of non-transporters to keep records of transporters can be boiled down to this: If the non-transporter is arranging for the transportation, it is likely that FDA will determine that information on the transporter is “reasonably available,” and thus expect it to be found in the non-transporter’s records. However, if another entity – be it a farmer, broker, buyer or some entity other than the shipper/receiver – is contracting and/or arranging for the transportation, and such information is not “reasonably available,” the non-transporter may indicate in its records the identity of that other entity as the transporter instead of identifying the transporter itself.

## **Recordkeeping Requirements Applicable to Retail Food, Feed Stores**


Next let’s turn to the recordkeeping requirements that apply to retail food and feed stores.

FDA’s recordkeeping rule defines “retail food establishments” as those whose annual monetary value of sales of food/feed products directly to consumers (“consumers” do not include farms) exceeds the annual monetary value of sales of food/feed products to all other buyers (including businesses). This definition encompasses grocery stores, convenience stores, and retail farm supply and feed stores that sell bagged feed, pet food and feed ingredients over-the-counter to consumers and final purchasers for use in their own animals.

Here’s how FDA’s bioterrorism recordkeeping requirements apply to retail food/feed establishments that meet this definition:

1. All retail stores (except stores with 10 or fewer employees – see pages 22-23) are required to establish and maintain records of inbound purchases/deliveries of agricultural products received from their





“immediate previous source” (e.g., *suppliers*). This is the “one-step back” recordkeeping requirement.

2. Retail stores, just like all others subject to this regulation, are not required to establish and maintain records identifying the “immediate subsequent recipients” (e.g., *buyers/receivers*) or the transporters used to ship sales of food, feed, pet food products, etc., made directly to final consumers (again, “consumers” do not include farms; feeding operations involved in raising livestock, dairy cattle, poultry or other food-producing animals for subsequent sale; or other businesses).
3. Retail stores are required to establish and maintain records identifying sales/deliveries to businesses and other non-consumer “immediate subsequent recipients” (including farms and feeding operations) and the transporters used for such shipments to the extent such information is “reasonably available.”

The logic FDA used for deciding not to include farms, feeding operations and businesses within the definition of the term “consumers” is as follows: Businesses are involved in reselling the product to final consumers, and hence agricultural inputs such as feed and feed ingredients received by businesses remain in distribution. Meanwhile, farms or feeding establishments feed the product to animals that subsequently produce food or are processed and sold as food to final consumers.

Thus, retail food/feed establishments still are required to establish and maintain records of sales to farms, feeding operations, businesses and other entities that do not meet the definition of “consumers,” to the extent such information is “reasonably available.” In this regard, FDA states that retail food/feed establishments do not have to go to extraordinary lengths to determine if the sale is to a consumer or a business; the recordkeeping obligation applies “only to the extent the information is reasonably available, (such as) when the purchaser has an existing commercial account” with the retail store, FDA states.

4. Retail stores that employ 10 or fewer full-time employees are exempt from all of the recordkeeping rule requirements, except the requirement to provide FDA with access to existing records they otherwise already may keep as part of their normal business operations. Again, importantly, to qualify for this exemption, the store must meet the eligibility criteria in the definition for “retail food establishment” – namely, the majority of annual dollar value of product sales directly to “consumers” must exceed the annual monetary value of such sales to all other buyers (including farms, feeding operations and other businesses).

This “10-or-fewer employee exemption” applies to the individual retail food/feed store, and not the entire corporate ownership. So, for example, three retail feed stores that employ 10 or fewer employees qualify for the exemption **even if** they operate under a corporate entity that operates dozens of such stores with hundreds of employees altogether. Further, as explained later in this guidance document, FDA under the Bioterrorism Act must meet a high legal standard before it can gain access to normal business records that retail facilities may maintain; specifically, the agency must have a “reasonable belief” that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

This exemption for small retail food/feed stores is illustrated by the following question-and-answer from FDA’s guidance document accompanying the final rule:


***Question-and-Answer on Retail Store Exemption***

***Q:*** “*Is a retail food establishment (retail animal feed) that employs 10 or fewer full-time equivalent employees still exempt from the requirement to establish and maintain records (but not the record-access requirements for existing records) if they sell feed to a business or the feed sold is to be used in animals that will subsequently be sold as food?*”

***FDA:*** “This establishment is exempt if it meets the definition of a retail establishment... [the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food to all other buyers]. ...[F]ood distributed directly to consumers include sales of bagged feed, pet food and feed ingredients/additives over-the-counter directly to consumers and final purchasers for their own animals, unless the feed is to be used in animals that will be sold as food or used to produce food for sale. If this establishment with 10 or fewer full-time equivalent employees qualifies according to the criteria discussed above, it is exempt....” [*Emphasis added.*]

In addition, retail stores are **not** required to establish or maintain records of lot numbers of finished products (such as feed) **unless** the retailer also is involved in manufacturing, processing or repackaging those products, **and** such a lot or code number or other identifier exists. FDA’s final rule specifically states that only persons who **manufacture, process** or **pack** food are required to keep records of lot numbers, and only to the extent this information exists. Retail stores are **not** required to establish or maintain records of lot numbers of finished products where their **sole function** is to receive and distribute such products. Thus, the treatment for retail stores is identical to that accorded to other manufacturers (See discussion on lot numbers on pages 16-18).





So, to recap, what is the practical impact of the retail exemption for retail farm supply stores, feed dealers, and feed/pet food stores that aren't involved in the manufacture of product?

1. First, as is the case for **all persons** subject to the recordkeeping regulations, FDA states that retail store **sales** of bagged feed, pet food, feed ingredients/additives or other covered agricultural products over-the-counter **directly to final consumers** are exempt from the requirement to identify that **consumer recipient or the transporter** used to ship the product to that recipient. Importantly, even though **sales** may be exempt from recordkeeping, retail stores **still are required to establish and maintain records of incoming food/feed/feed ingredient/additive products that they purchase and receive from suppliers, unless they are eligible for the 10-or-fewer employee exemption** discussed previously.

As noted previously, FDA defines a retail store as an establishment that sells the **majority** of its annual dollar value of products **directly to consumers**; again, “consumers” do not include farms, feeding operations and other businesses.

2. In addition, FDA specifically states that retail stores must establish and maintain records for sales of feed and/or ingredients/additives to be fed to food-producing animals, since these sales are to a business (*e.g., a farm or feeding operation*), but only to the extent information about the buyer/receiver (“immediate subsequent recipient”) is available. As noted previously, FDA states that retail stores do not need to go to “extraordinary lengths” to determine if a sale is to a consumer or a business.
3. Finally, if the individual retail store employs **10 or fewer employees**, that specific store is exempt from the recordkeeping rule requirement to establish and maintain records of inbound products it receives. But such stores are required to provide FDA with access to existing records that they otherwise keep as part of normal business operations. This “10-or-fewer employee exemption” applies to each individual retail food/feed store, even if the individual store is part of a corporation that employs more than 10 persons.

**So, the bottom line:** Since the dollar value of sales by most **feed dealers** is to farms and feeding operations – instead of direct to final consumers – most feed dealers likely will **not qualify as a retail establishment**. In cases where the feed store’s annual monetary value of sales to farms, feeding operations and other businesses **exceeds** the value of product sales to consumers, the number of full-time persons employed by the feed dealer doesn’t matter, since the feed dealer does not meet the definition of “retail establishment” to begin with.

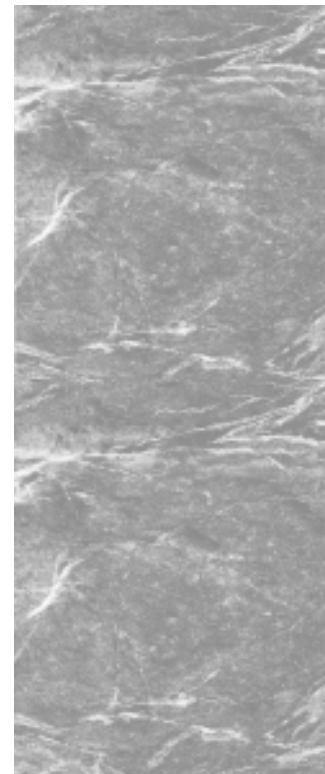


In such cases, feed dealers and feed stores are required to establish and maintain records for:

1. Inbound purchases of feed, pet food, feed ingredients, feed additives and other covered agricultural commodities that they purchase and receive from suppliers – their “immediate previous sources”; **and**
2. Sales and deliveries of feed, premixes, feed ingredients, feed additives and other covered agricultural commodities shipped to farms, feeding operations, businesses and other “non-consumer” buyers/receivers – their “immediate subsequent recipients.”

Farm supply stores – such as “farm-and-garden” retail stores – that sell covered agricultural products directly to consumers are more likely to qualify as a retail food establishment and for the “10-or-fewer-employee exemption.”

The following chart depicts the recordkeeping requirements that apply to retail food and feed stores under the various scenarios outlined in this section.

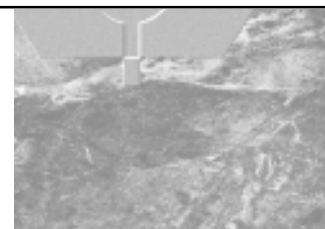


<b>Bioterrorism Recordkeeping Requirements for Retail Food/Feed Stores<sup>1</sup></b>		
<b>Type of Sale / Size of Store</b>	<b>Type of Records Required</b>	
	<b>Records of Suppliers/Transporters for <u>Inbound</u> Shipments (Immediate Previous Sources)</b>	<b>Records of Receivers/Transporters for <u>Outbound</u> Shipments (Immediate Subsequent Recipients)</b>
Direct Sales to Final Consumers	Yes, to extent such information “reasonably available”	No <sup>2</sup>
Sales to Non-Consumers (Farms and Other Businesses)	Yes, to extent such information “reasonably available”	Yes, to extent such information “reasonably available”
10 or Fewer Full-Time Equivalent Employees	No <sup>3</sup>	No <sup>3</sup>
More than 10 Full-Time Equivalent Employees	Yes, to extent such information “reasonably available”	Yes, to extent such information “reasonably available,” unless direct sale is to final consumer

<sup>1</sup> To qualify under definition of retail store, annual monetary value of sales of food/feed products directly to final consumers must be greater than annual monetary value of sales to all other customers (including farms and other businesses)

<sup>2</sup> Applies to **ALL** entities subject to bioterrorism recordkeeping regulations, including retail stores

<sup>3</sup> Required to provide FDA with access to existing business records kept as part of normal business operations



## Recordkeeping Requirements Applicable to Intra-Company Transfers

Records are not required for transfers of agricultural commodities, feed and food between facilities operating under the same legal entity – including vertically integrated companies – *provided* the product does not leave the “continuous control” of facilities and transportation conveyances operating under the same corporate ownership. But legally distinct entities – including subsidiaries of a parent company – are required to maintain records when commodities, feed and food are transferred between them.

In addition, FDA has clarified that vertically integrated companies subject to the recordkeeping regulations are required to maintain records of shipments hauled by independent transporters (*i.e., a transporter not owned by the same corporate entity*), even if the movement involves a transfer between two facilities owned by the same company. FDA’s rationale is that in these instances, the shipment is outside the control of the integrated firm during the time that it is in the possession of the independent transporter.

Although not required, vertically integrated companies as a practical matter may wish to keep records of intra-company transfers of commodities, feed, etc., between facilities operating under the same legal entity, since FDA under the regulation requires that records contain information that is “reasonably available” to link inbound ingredients and commodities with outbound shipments.

FDA’s guidance document accompanying the final regulation includes the following scenarios concerning recordkeeping obligations regarding intra-company transfers and vertically integrated companies:

### *Questions-and-Answers on Intra-Company Transfers*

**Q:** “What are the manufacturer’s and transporter’s recordkeeping obligations for a food product that is transported intra-company by a contract transporter? For example, a manufacturing firm may contract with a transporter to move food product, intra-company, from its manufacturing facility to its distribution center.”

**FDA:** “[The regulation] requires that persons who manufacture, process, pack, distribute, receive, hold or import food establish and maintain records whenever they release food to another person. . . . [I]ntra-company transfer of food is not subject to additional recordkeeping requirements, provided the food is not released to another person. In this example, the manufacturing firm temporarily releases the food to another entity (person), the contract transporter. The manufacturing firm would be required to establish and maintain records of the transfer of food (including lot numbers if they exist) from the facility to the transporter and non-transporter (the distribution center) immediate subsequent recipients.” [Emphasis added.]

**Q:** “If company Z owns facilities 1, 2 and 3, must it also own the trucks that transfer product from facility 1 to facility 2 and from facility 2 to facility 3 to be considered vertically integrated?”

**FDA:** “Yes. A vertically integrated company . . . is defined by continuous possession of an article of food. . . . [A] company is no longer integrated if the food passes out of its control and is released to another person before returning to the company’s possession. For example, if an independent transporter takes possession of the food . . . to transport it between two facilities owned by the same company, the company must establish and maintain records identifying the transporter and non-transporter immediate previous sources and immediate subsequent recipients. . . .” [Emphasis added.]

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**Q:** “Are two corporate entities part of the same vertically integrated company if they have the same controlling parent?”

**FDA:** “No. . . . If the two corporate entities are legally distinct persons, they are not considered part of the same vertically integrated company, and records of transfers of food between them must be established and maintained.” [Emphasis added.]

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**Q:** “If a non-transporter has a transporter subsidiary and uses that subsidiary to transport food to others, is the transfer from the non-transporter to the transporter subsidiary considered an internal transfer?”

**FDA:** “No. . . . [A] person must establish and maintain records whenever it releases food to another person. . . . A subsidiary is a distinct legal person and records of the transfer of possession from the non-transporter to the transporter subsidiary must be established and maintained.”

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**Q:** “If subsidiaries are legally distinct, but are managed operationally as a single entity, are they a single entity for purposes of this regulation?”

**FDA:** “No. . . . The exemption for vertically integrated companies only applies to distinct legal persons.”

---

**Q:** “If a vertically integrated manufacturer, packager and distributor contracts with a second firm for dedicated use of the second firm’s warehouse, would this qualify as being vertically integrated?”

**FDA:** “Yes. A vertically integrated company . . . is defined by continuous possession of an article of food. In the example above, because the integrator has ‘dedicated use’ of the second firm’s warehouse, it has retained continuous and sole possession of the food within its ‘person.’” [Emphasis added.]



## Recordkeeping for Transporters

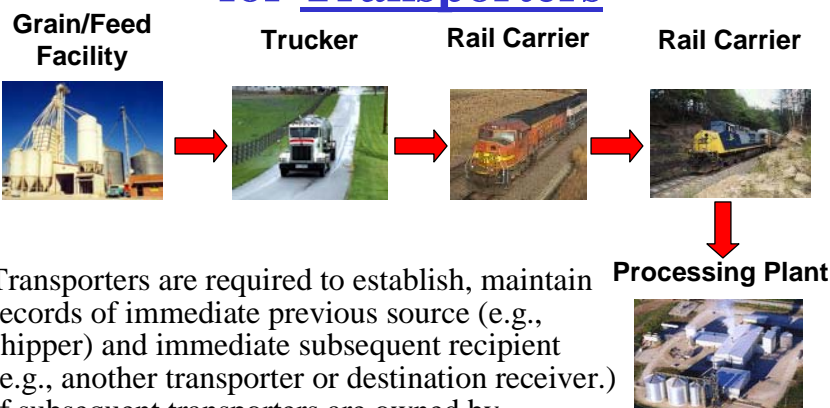
Transporters, such as railroads, truckers and barge lines, also are required to establish and maintain records that contain “reasonably available” information identifying:

- The “immediate previous source” (i.e., the shipper) from which the product was received and the “immediate subsequent recipient” (i.e., receiver) to which the product is being delivered.
- The origin and destination points of the shipment.
- The date the shipment was received and delivered.
- The quantity of product hauled (*e.g., tare weight, tonnage, number of bags, etc.*).
- A description of the freight hauled.
- The route of movement of the shipment.
- Any transfer or interchange points through which the shipment moved.

A couple of issues related to transporters:

- First, much, if not all, of the aforementioned recordkeeping information required by FDA will be contained on the bill of lading that accompanies the shipment. While it is the responsibility of truckers, railroads and barge lines to issue such bills of lading, in reality, many small trucking firms do not. In these situations, while not required by FDA, shippers may wish to consider issuing the bill of lading and have the truck driver sign it as a way of generating the record for the transportation movement.

### Records Required for Transporters



Transporters are required to establish, maintain records of immediate previous source (e.g., shipper) and immediate subsequent recipient (e.g., another transporter or destination receiver.) If subsequent transporters are owned by different companies, each transporter is required to keep records only of those transactions to which it is a party, as indicated by solid arrows.

- Second, in cases where the shipment is handled by transporters owned by different legal entities – for instance, an interchange of the shipment between the Burlington Northern Santa Fe and Canadian National Railways – each transporter is required to keep records indicating their respective role in transporting the shipment. The nearby diagram illustrates how this requirement applies to transporters.

Importantly, transporters have four other alternatives available for meeting the

recordkeeping requirements. They can establish and maintain the required records by utilizing the following options:

- roadway interstate transporters, by the U.S. Transportation Department’s Federal Motor Carrier Safety Administration;
- rail and water interstate transporters, by the U.S. Transportation Department’s Surface Transportation Board; or
- international air carriers, under the Warsaw Convention.

The final option for transporters to comply with the recordkeeping requirement is to enter into a binding legal agreement with the non-transporter immediate previous source (i.e., the shipper) or immediate subsequent recipient (i.e., the receiver) in which those parties agree to establish or maintain the required records on behalf of the transporter. FDA requires that such a legal agreement contain the following information:

- the effective date;
- the printed names and signatures of the authorized company officials entering into the agreement;
- a description of the records to be established or maintained;
- a provision stipulating that the records will be retained for the duration required by FDA (see pages 40-41);
- a provision acknowledging that the records will be made available to FDA if the legal threshold for access is met;
- an acknowledgement that the non-transporter assumes the legal responsibility to establish and maintain the required records; and
- a provision that if either party terminates the agreement in writing, the responsibility for establishing and maintaining records reverts to the transporter.

***Questions-and-Answers on Recordkeeping Requirements for Transporters***

***Q:*** “An independent transporter makes multiple deliveries of food from a single distribution center to multiple retail stores owned by a single company. Does the transporter have to establish and maintain records for each separate delivery along its route...?”

***FDA:*** “Yes. [The regulation]” provides multiple ways in which a transporter of food may establish and maintain records to comply with this regulation. However..., all include the requirement that the transporter identify the food’s destination. Each physical location that receives food is considered a destination....”





**Q:** “[*The regulation*] states that transporters must establish and maintain records that include the route of movement of an article of food in their possession. How detailed should this record of the route be?”

**FDA:** “Transporters...should record every transfer of the food between different vehicles owned by the firm while the food remains in that firm’s possession, including the location of each transfer. If no internal transfer of the food occurs, the origin and destination points at which the transporter received and released the food are sufficient to characterize the route of movement.”

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**Q:** “A firm’s freight brokerage division negotiates freight rates and assigns shipping to independent carriers. Is the brokerage division held liable if an independent carrier under contract is not in compliance with the regulation?”

**FDA:** “No. Both the freight brokerage and the independent carrier are transporters subject to this regulation. Both are responsible for complying with this rule, which either may do for the other as a matter of business practice. But legal responsibility for establishment and maintenance of records and for meeting the records-access timeframes... remains with both parties. For the purpose of this regulation, a person, such as the freight brokerage above, who enters into a contract to transport an article of food and has control over the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity. If the brokerage is relying on the independent carrier under contract or business practice to satisfy the brokerage’s duty to comply with this regulation, and the carrier fails to keep the requisite records, the brokerage is liable for the brokerage’s failure to comply.” [*Emphasis in original.*]

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**Q:** “There are ship owners that simply haul freight where the transporter is the owner of the container. The vessel owner is not considered the transporter; the owner of the container has the bill of lading and other information about the container’s contents and destination. Does the owner of the vessel now need to establish and maintain records?”

**FDA:** “A transporter is defined as a person who has possession, custody or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water or air. This definition also includes a foreign person (who) transports food in the United States, regardless of whether the foreign person has possession, custody or control of the food for the sole purpose of transporting the food. In the situation described above, the vessel owner has physical possession of the food container for the sole purpose of transporting the food and is considered the transporter...The vessel owner is therefore required to establish and maintain records... , so long as that vessel is transporting the food in the United States.”

## Use of Existing Business Records to Meet FDA's Recordkeeping Requirements

Can establishments use existing business records to comply with FDA's recordkeeping requirements?

The short answer is "yes," so long as existing business records capture the information required under FDA's bioterrorism recordkeeping regulations.

In its final rule, FDA "confirms that it is not necessary to develop a single record that contains all of the (required) information." The agency said its "intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations."


Thus, FDA does not require that non-transporters or transporters establish a duplicate or separate recordkeeping system to comply with the regulations, so long as existing records contain the required information. Instead, FDA's regulations stipulate the kind of information that must be maintained. The agency notes that the required information can be compiled from different records that the establishment already may be keeping. Thus, to the extent that establishments have existing business records that contain the required information, such records will suffice for FDA's purposes under the Bioterrorism Act.

FDA states that records may be kept in any format (including paper and electronic formats). FDA also does not stipulate that all of the required information be kept in one set of records or in one place. Instead, the agency stipulates that the required information be retained at the (on-site) establishment where the activities covered in the records occur, or at a reasonably accessible location.

But there is one important consideration that companies need to evaluate when deciding whether to rely on existing business records to meet the requirements under this FDA regulation, as well as the location where those records are maintained. As noted later in this guidance document (see page 43), the regulations require that covered establishments provide FDA with access to required information "as soon as possible" and in no case later than 24 hours after the agency submits a written request.

That's illustrated by the following question-and-answer exchange contained in FDA's November 2005 guidance document:





### ***Question-and-Answer on Accessing Bioterrorism Records***

**Q:** “A non-transporter establishes and maintains records at a site where covered activities are performed. The site is operated seasonally in a remote location and the non-transporter’s representatives may not be able to reach the site within 24 hours of FDA’s request for records access. Alternatively, the non-transporter’s representative may be able to reach the site within 24 hours to present the records, but FDA’s representatives are unable to reach the site in that time. Is the non-transporter failing to comply with the record-availability requirements...?”

**FDA:** “Yes. [The regulation] requires that in the appropriate circumstances, any applicable records must be made readily available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from the time of receipt of the request. A seasonally operated remote location that may not be reachable within 24 hours by either the non-transporter or FDA is not a readily available repository for records. Under these circumstances, the non-transporter should consider maintaining the records on-site or at a reasonably available off-site location...to avoid noncompliance with this regulation.”

### **What Constitutes ‘Reasonably Available’ Information?**

For the grain, feed and processing industry, which handles commodities and ingredients on a commingled basis, one of the most vexing aspects of FDA’s recordkeeping regulation is what constitutes “reasonably available” information that must be maintained in records.

### **Linking Inbound Deliveries with Outbound Shipments**

FDA states that records are to contain information that is “reasonably available” to link incoming deliveries of commodities and ingredients with outbound shipments. Because of the broad scope of the recordkeeping regulations across a vast array of industries – from raw commodities to finished food products, and everything in between – FDA intentionally is vague in defining what it means by “reasonably available.”

FDA in the preamble to its final rule states repeatedly that it intends to exercise flexibility in determining whether information is “reasonably available.” Here are several examples of such FDA statements:

- “What is ‘reasonably available’ is going to depend on the particular circumstances.”



- “[I]n many instances, it will be impossible to identify the specific source of a material that is held in bulk and that multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form.”
- “FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA’s intent to mandate reengineering of long-standing existing processes. For this reason, the final rule requires the identification of the specific source of each ingredient that was used to make every lot of finished product only when the food is released and only if this information is reasonably available.”

In its final rule, FDA cites the same hypothetical example it did in its proposed rule to illustrate what it would consider to be information that is “reasonably available” in a commingled-product situation. The case FDA uses involves a cookie manufacturer that sources flour from five different mills and stores the flour in a common silo before it is used in the manufacture of cookies. “In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were sources of the flour,” FDA states. “Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. The information reasonably available to the manufacturer would be the identity of all of the potential sources of the flour for each finished lot of cookies.”

But FDA also states in its question-and-answer guidance document accompanying the final regulations that it “is not sufficient to simply produce all records from a given time period or facility in response to a more specific request for information.”

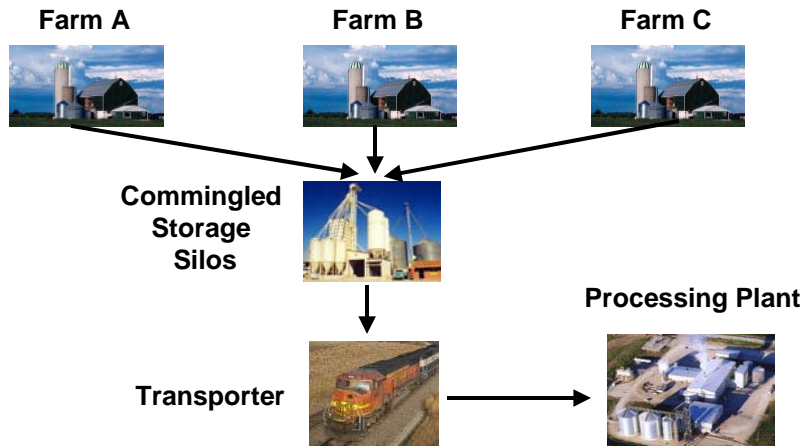
FDA notes that if the cookie manufacturer referenced in the hypothetical example instead had dedicated silos for each supplier of flour, the manufacturer would be expected to be able to provide records of the specific bin source of the flour used for each lot of finished product (e.g., cookies).

The differing situations of what is considered to be information that is “reasonably available” for purposes of the FDA recordkeeping regulation are depicted in the diagrams on page 34:



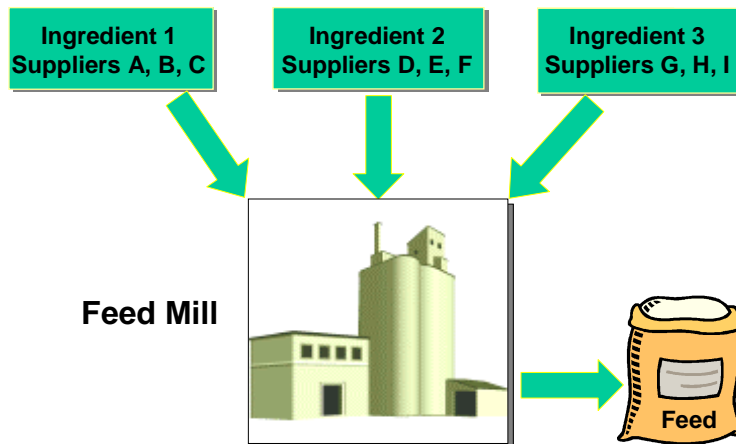


## What's "Reasonably Available" ...Commingled Storage ...



Information reasonably available is the identity of all potential sources of the grain shipped to processor

## What Is "Reasonably Available?" ...Identity Preserved/Dedicated Storage...



Information reasonably available is the identity of the specific sources of each ingredient for each finished feed

**Questions-and-Answers on ‘Reasonably Available’ Information  
for Records**

**Q:** “A bulk grain elevator receives many small lots from individual farmers, commingles them, and blends them to whatever specifications are required. What records and degree of lot specificity are required for the grain elevator?”

**FDA:** “For example, the facility may place 30 lots from farmers into a single storage bin, place another 30 lots into a second bin, and draw from both bins to create a blended product that is transferred to an immediate subsequent recipient. The record created for the outgoing blended product should indicate all immediate previous sources for the component grain; in this example, there may be as many as 60.”


**Q:** “What are the recordkeeping requirements: 1) if a firm receives its ingredients directly from farms and commingles them in storage bins on-site; 2) if the firm receives ingredients that already have been commingled by a distributor?”

**FDA:** “The source (e.g., identity of the supplier) of each shipment that enters a particular storage bin must be recorded. . . . In both cases, incoming sources of ingredients must be linked to finished products leaving the site to the extent that the information is reasonably available. . . . For example, if a lot of a product incorporated an ingredient from a particular bin and that bin was filled with a commodity derived from five immediate previous sources, then those five sources would be the reasonably available information for that ingredient. If the bin was refilled before being emptied and now may contain ingredients from up to 10 immediate previous sources, then this is the information that is reasonably available. If the firm receives ingredients that already have been commingled by a distributor, the firm only has to record the lot numbers of the food, as received, to the extent that information exists, and link incoming sources of ingredients to finished products leaving the site to the extent that the information is reasonably available. . . .”

**Q:** A feed mill receives ingredients and commingles individual shipments into bins which are never completely empty. Over the course of a year, a hundred or more lots could theoretically be part of any food drawn from a bin. Would the feed mill have to provide all these lot numbers for food it releases?

**FDA:** Yes. . . . When a food is released by a manufacturer, the firm must establish and maintain records that include information reasonably available to identify the specific source of each ingredient used to make every lot of finished product. . . . FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with specificity to the outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product.





Because the shipments of incoming material are commingled in the storage bin, the record created for every lot of food released by the manufacturer that incorporates material from the bin would include all possible sources of the material placed in the bin.” *[Emphasis added.]*

Let’s look at a theoretical example of how this “reasonably-available” interpretation might play out in practice.

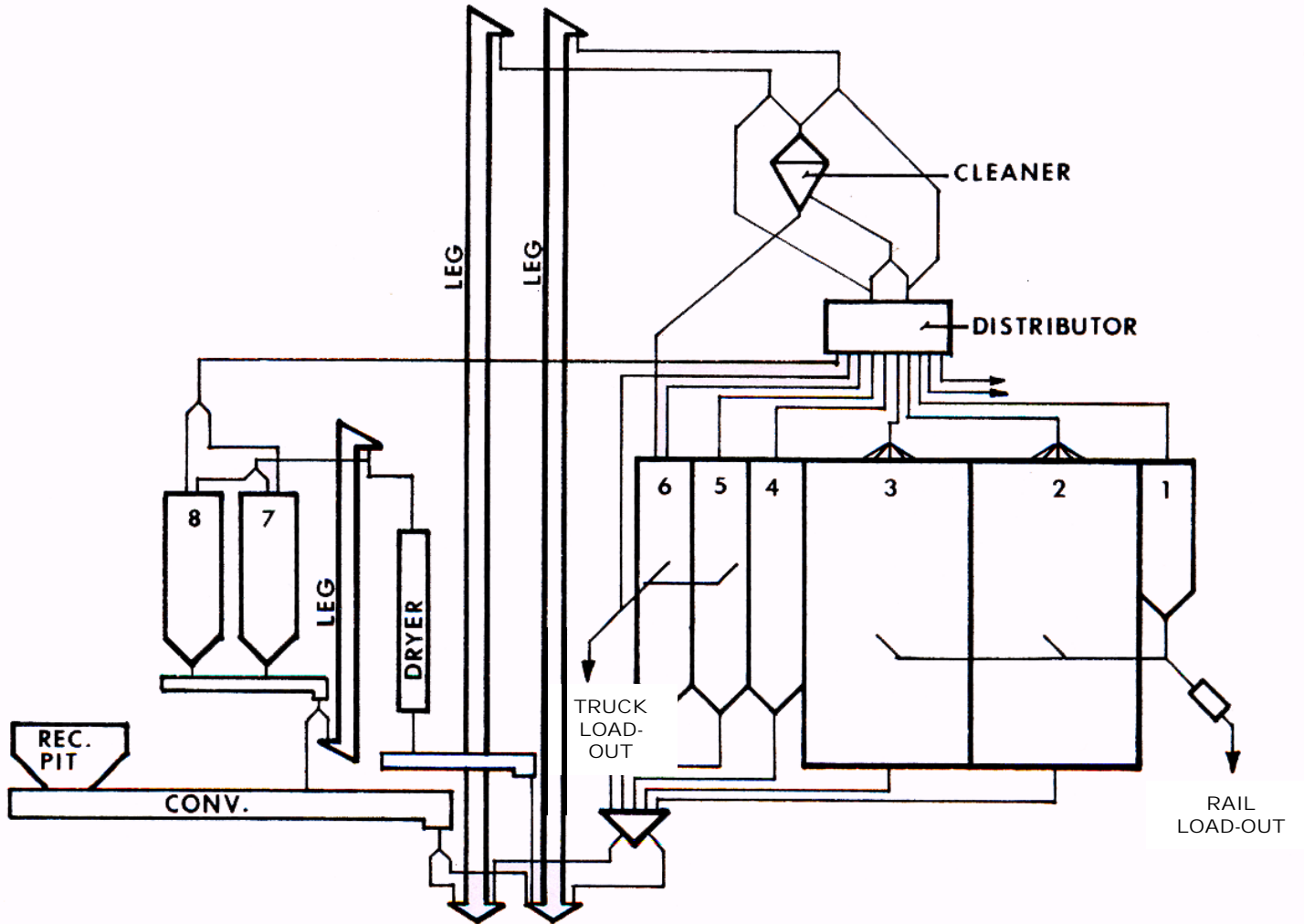
Theoretically, assume FDA becomes aware of an adulteration incident involving a batch of cookies that meets the legal threshold for the agency to access records (see pages 41-42). FDA would submit a records-access request to the bakery concerning the production history and sources of flour and other ingredients that conceivably could have been used in the adulterated batch of cookies. A separate records-access request might also be submitted to the transporter from which the bakery received the suspect ingredients.

The agency then would conduct a traceback investigation until it determined the source of the contamination. If, hypothetically, the investigation were to go as far back as the grain elevator that shipped wheat to the mill that produced the flour for the cookies, FDA most likely would ask the elevator for records of its outbound wheat shipments over a specific period of time to the flour mill, as well as for records of inbound grain deliveries from farmers or other commercial firms that conceivably could have comprised the outbound shipments. For instance, one conceivable way in which the grain elevator could comply with this requirement would be by maintaining records of the specific grain bins from which the commingled outbound product was drawn on specific dates, and record those bin numbers on outbound scale tickets or on other shipping records. The elevator also likely would be expected to provide records of producer deliveries into specific bins implicated in the incident.

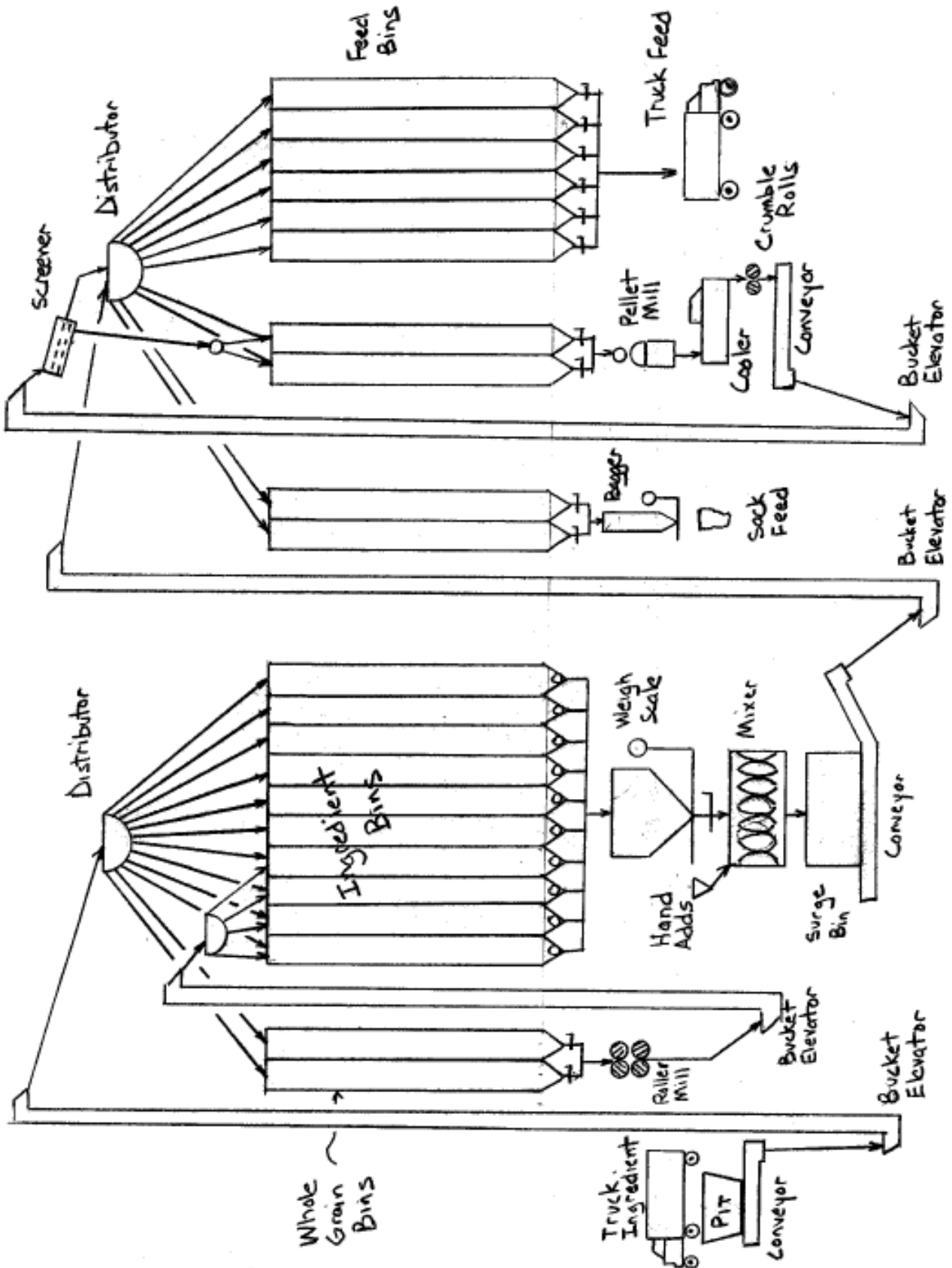
Thus, it may be useful for facility management to consider developing diagrams of their facilities that indicate the flow of commodities from bins to holding tanks to shipping bins to conveyances. This could be helpful in facilitating FDA’s investigation in the event such an adulteration incident occurs. Likewise, keeping records of when bins are emptied could be useful in limiting the scope of FDA’s records access and narrowing the volume of commodities that might otherwise be considered suspect if an adulteration incident occurs.

The sample schematic flow diagrams – of a country elevator, feed manufacturing operation and export grain elevator operation – presented on pages 37-39 may be useful as models for developing such flow diagrams:

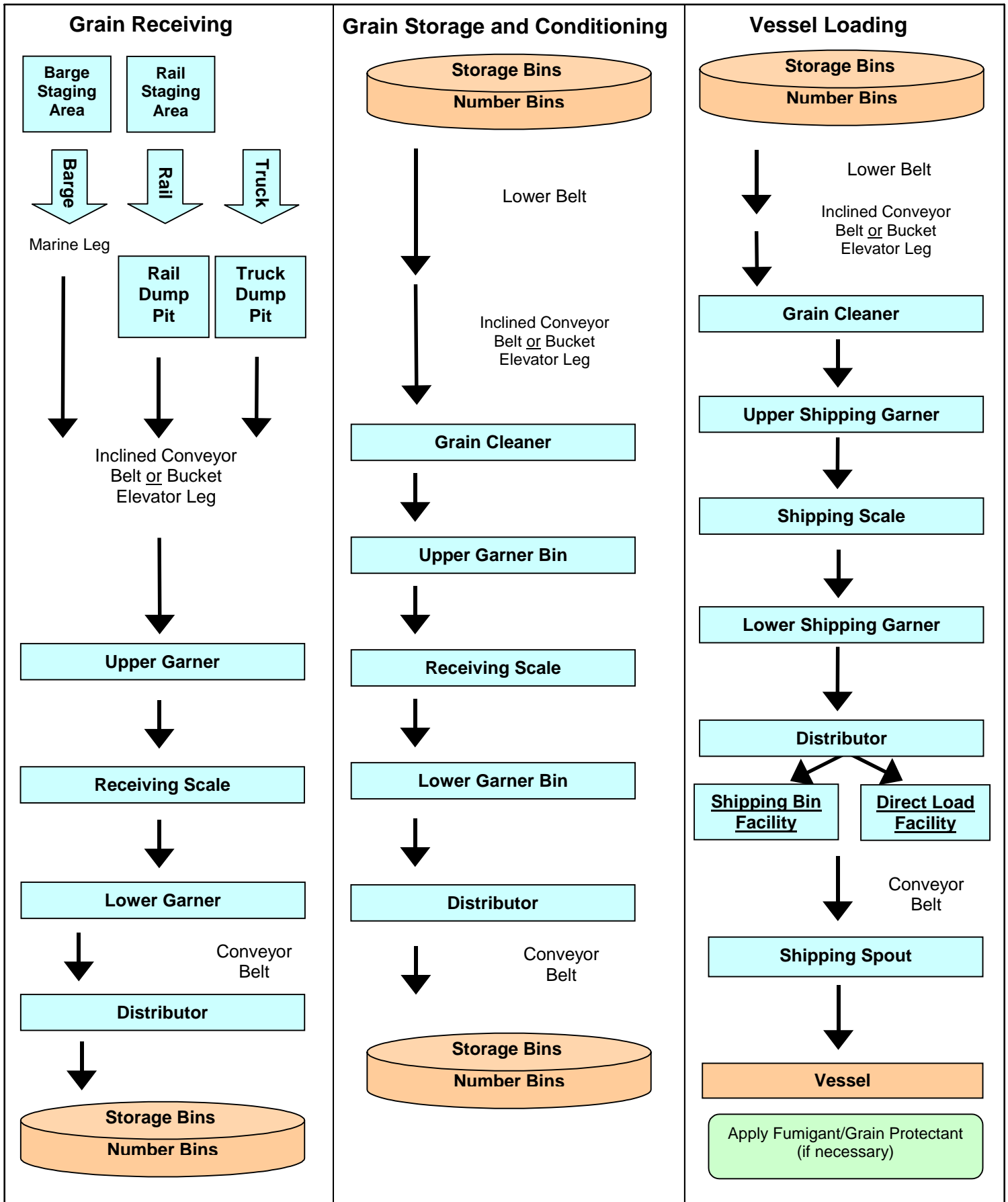
# Sample Country Elevator Flow Diagram



# Sample Feed Mill Flow Diagram



# Sample Grain Export Elevator Flow Diagram





## Deliveries from Farms

Another situation important to country elevators and feed mills involves information deemed to be “reasonably available” for deliveries of commodities from farms.

In this regard, FDA has told the NGFA that:

- Information that identifies the landowner, tenant or name/location of the farm – or a combination of this information – will be sufficient for meeting the “reasonably available” requirement. Thus, to the extent such information is captured on scale tickets, warehouse receipts or settlement sheets, those documents will suffice.
- Records that designate the producer as both the “immediate previous source” and the “transporter” will suffice in situations when information about the transporter delivering the commodity from farms to the facility is not “reasonably available.”
- If the producer does not have a specific street address, a rural route number, post office box number and/or telephone number will suffice.

## Records Retention and Access

This section contains information on how long firms are required to maintain records, as well as FDA’s authority to access such records.

### How Long Must Records Be Retained?

The length of the recordkeeping-retention requirement depends on how perishable the food is, as indicated in the following chart:

Food/Feed with Significant Risk of Spoilage, Loss of Value or Loss of Palatability within . . .	Non-Transporters ( <i>e.g., facilities</i> )	Transporters ( <i>e.g., railroads, trucks, barge lines</i> )
60 days	6 months	6 months
> 60 days but within 6 months	1 year	1 year
> 6 months (includes grains and oilseeds)	2 years	1 year
All Animal Feed (including pet food)	1 year	1 year



Thus, for raw grains and oilseeds, the record-retention period is two years from the date when the activity occurred (e.g., receiving/storage or shipment). For animal feed manufacturing, including pet food and feed ingredients, records related to the receipt of raw grains and oilseeds are to be maintained for two years from the date when the activity occurred, while records related to feed, pet food and feed ingredients are to be maintained for one year from the date of when the activity was performed (e.g., receiving of ingredients, manufacturing of feed or ingredient; shipment of feed, etc.).

### ***Question-and-Answer on Record-Retention Requirement***

**Q:** “A facility receives a product with a two-year record-retention requirement, holds it for three years, and then releases it. Is the facility required to retain the incoming records until or some time after the product is released, regardless of the holding period?”

**FDA:** “A facility is not required to maintain any record for longer than two years after its creation at the time of the transaction it describes, because Section 306 of the Bioterrorism Act explicitly limits the retention of records to two years or less. Records created when a food subject to the two-year record-retention requirement is received may be discarded after two years, even if the product remains in the facility. The facility still must establish and maintain records identifying the transporter and non-transporter immediate subsequent recipient when the food is released. . . ., even if the retention period for the record identifying the immediate previous source has expired. If a facility anticipates that it may hold food for longer than two years, it may wish to retain records of receipt for more than two years as a matter of business practice. Such records could be helpful to both the facility and FDA in the event of a traceback or trace-forward investigation.”

## **FDA Access to Records**

When can FDA demand access to records required to be kept under the Bioterrorism Act?

As noted previously, the Bioterrorism Act sets a relatively high legal threshold before FDA has authority to access records. Under the law, FDA has access to such records and other information **only when the agency has a reasonable belief that an article of food/feed is adulterated and presents a threat of serious adverse health consequences or death to humans or animals**. As an example, FDA has told the NGFA that the fall 2005 incident in which aflatoxin-contaminated dog food was linked to animal deaths would have been an instance in which the agency could have invoked its bioterrorism recordkeeping access authority if it chose to do so. Conversely, a detection of





high-pathogenic avian influenza (bird flu) in the United States likely would not meet the legal threshold to trigger a records access request from FDA under the Bioterrorism Act authority, since such a situation would involve an animal disease under the jurisdiction of USDA’s Animal and Plant Health Inspection Service rather than a feed- or food-adulteration incident. Importantly, however, it is reasonable to expect that FDA would act under other existing authority to encourage voluntary recalls of any feed that might be located on a farm where avian influenza has been diagnosed to prevent further spread of the disease.

Further, and very importantly, Congress did **not** provide FDA with “audit authority” to review such records as part of routine inspections the agency may conduct. So, FDA does **not** have authority to inspect records required under the Bioterrorism Act when conducting an inspection of a licensed medicated feed manufacturer unless the legal threshold for accessing such records is met. FDA currently is reviewing ways to ensure that industry sectors covered by the bioterrorism recordkeeping regulations are aware of the requirements to maintain such records. FDA officials have told the NGFA that one way this may be done is to ask if those covered are aware of the bioterrorism recordkeeping regulations and are prepared to respond to a request for access to such records within 24 hours if such a request is ever authorized. But FDA legally is prohibited from taking the next step to ask to see such records unless it meets the statutory threshold for accessing such records – namely, that the agency has credible evidence that an article of food/feed is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

**Kinds of Records FDA Can Access:** If FDA meets the legal threshold for accessing records, the type of records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding (storage) or importation of the suspect article of food/feed that are maintained by, or on behalf of, an entity subject to the recordkeeping regulation, and at any location such an entity operates. FDA states that if required, such records must be available for inspection and photocopying, or other means of reproduction.

Importantly, the law specifically prohibits FDA from having access to recipes (which encompass feed formulations); financial, pricing, personnel or research data; or sales data other than the shipment data regarding the sale of the suspect agricultural product.

**Procedures FDA Will Use to Access Records:** FDA says it will adhere to the following procedures if one of its inspectors believes a product meets the legal threshold:

1. First, the inspector is to notify FDA’s Emergency Operations Center.
2. Next, FDA’s Emergency Operations Center is to notify (either verbally or in writing) the appropriate FDA center (such as the Center for Food

Safety and Applied Nutrition in the case of food or grain products, or the Center for Veterinary Medicine in the case of feed, feed ingredients or pet food), as well as FDA's Office of Regulatory Affairs.

- 3.** FDA headquarters then will determine if the Bioterrorism Act legal threshold has been met; the scope of records access to be requested; and whether the requested records are necessary to assess whether a food is adulterated and presents a threat of serious adverse health consequences to humans or animals.
- 4.** Finally, FDA headquarters will obtain concurrence from FDA's Office of General Counsel before a request to access records is issued.

If each of the aforementioned procedural steps is met, an FDA investigator or other FDA personnel will submit a written notice – an *FDA Form 482c, "Notice of Inspection"* – to the owner, operator or agent in charge of the establishment (likely obtained from the facility registration also required under the Bioterrorism Act). Importantly, the notice will be directed to that specific establishment, and will be specific to records sought from that establishment. The FDA written notice will inform the establishment of type and scope of records to which FDA is requesting access, as well as the agency's legal authority for doing so. FDA notes that it has authority to request additional records related to the implicated article of food/feed at a later time.

**Deadline for Providing Access to Records:** As noted previously, if FDA meets the legal threshold for accessing records required under the Bioterrorism Act, access to such records must be provided as soon as possible, not to exceed 24 hours from the time the establishment receives an official request from the agency.

**Penalties for Failure to Comply:** The Bioterrorism Act makes failure to establish or maintain records a "prohibited act" under the Federal Food, Drug and Cosmetic Act. The federal government can bring civil or criminal action in federal court against violators.



# Miscellaneous Questions and Answers

The NGFA has received responses from FDA to the following additional miscellaneous questions:

## *Question-and-Answer on Recordkeeping for Processing Aids, Additives*

**Q:** “Are processing aids or incidental additives used in the production of food or feed, subject to recordkeeping under this regulation? For instance, do records need to be established and maintained for hydrogen used in refining oil or hexane used in soybean processing?”

**FDA:** “Yes. As explained in the preamble to the final rule (comment #96), the recordkeeping requirements in these regulations apply to all food unless specifically exempted. Processing aids may be food additives or a generally recognized as safe (GRAS) ingredient. In either case, they fall within the definition of food and are subject to these regulations. If the manufacturing process is such that a processing aid was used to make a specific lot of a finished food product, then the specific source of each processing aid should be identified in the records to the extent that information is reasonably available.”

## *Question-and-Answer on Recordkeeping for Water-Soluble Drugs*

**Q:** “Are water-soluble antibiotics subject to the recordkeeping requirements?”

**FDA:** “Yes. Since the definition of “food” means “articles used for food or drink for man or other animals; chewing gum; and articles used for components of such article,” water-soluble antibiotics administered through water or as an additive in feed are covered under the regulation.”  
[Emphasis added.]

# Section 3

## References

Carson, Louis. *“Bioterrorism Act Recordkeeping.”* Presented at the National Grain and Feed Association’s Country Elevator/Feed Industry Conference. December 6, 2005.

Food and Drug Administration. *“Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods; Notice of Public Meeting; Availability of Draft Guidance for Records Access Authority; Final Rules and Notice.”* December 9, 2004.

Food and Drug Administration. *“What You Need to Know About Establishment and Maintenance of Records.”* December 2004.

Food and Drug Administration. *“Protecting the Food Supply – Fact Sheet on FDA’s New Food Bioterrorism Regulation: Establishment and Maintenance of Records.”* December 2004; revised November 2005.

Food and Drug Administration. *“Guidance for Industry – Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2) – Final Guidance.”* November 10, 2005.

Many of these documents can be accessed from the joint NGFA/GEAPS Facility Security Website at [www.ngfa.org](http://www.ngfa.org).

