



Guidelines for Record-keeping and Product Tracking

Purpose and Overview:

Any safety program for food or feed requires a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken and information given to consumers or regulators, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems. It is necessary to ensure that a feed business can identify the sources from which the ingredients that are incorporated into a feed or feed ingredient have been supplied. The traceability of feed or feed ingredients intended to be incorporated into the food chain shall be established at all stages of production, processing and distribution.

General Standard:

All facilities that receive ingredients or products and recombine those ingredients to create a product with a new identity must have a system of ingredient lot tracking and product tracing. Ingredient lot tracking records the individual ingredient lots used in the manufacturing process and tracks each lot to its respective lots of finished products. Product tracing provides a complete list of all ingredient lots (where available) used in any lot of finished product.

Specific Requirements:

These requirements are identical to the FDA's Bioterrorism Act record-keeping rule requirements found in 21 CFR, Part 1.

Establishing a system where ingredients can be tracked through the process to all of their respective finished products and where all constituent ingredients in any final product can be determined requires a record-keeping system to be established and maintained to:

1. Identify and record each shipment of ingredient that is received for processing. Record at least the following information for each lot and for each transporter of the product.*
 - a. Vendor name
 - b. Vendor contact
 - c. Address
 - d. Telephone
 - e. Expiration date (if any and/or required by federal/state law)**
 - f. Exact product name and type of product received (e.g. wheat middlings, etc.)
 - g. Date received
 - h. Unique identification or lot number (if available)***
 - i. Quantity
 - j. Type of packaging (e.g. bulk, bag, can, etc.)

- k. Notes on condition of shipment and/or shipping container (if required by law)

*For the purposes of this section, bulk ingredients can utilize the same storage container, as long as the suppliers of the ingredients can be reasonably identified.

**Expiration date requirements are limited to certain medicated feed and firms' preservative requirements—not required by law and a few other instances.

***FDA's record-keeping rule does not require this information, but it must be a record maintained if it is available. Also, the medicated feed GMPs require, "A lot or control number, or date of manufacture or other suitable identification shall appear on the distribution record or the label issued with each shipment." (21 CFR § 225.110)

2. Establish a new identification for combined lots each time a uniquely identifiable lot is combined with another. Examples would include when ingredients are combined into a batch, or multiple batches of product, or when "premixed" batches of product already having a unique identification are combined into a single product. This would also include when multiple batches of product are combined into one pellet batch, or when multiple pellet batches are combined into a single finished product.
3. Provide a unique identification or lot number for each finished product or other suitable identification method. The number shall be shown on either the product label, invoice or shipping documents.
4. Provide a record of each shipment of finished product that identifies the destination of each product included in that shipment. The information recorded will include:
 - a. Customer name
 - b. Customer contact
 - c. Delivery address
 - d. Telephone
 - e. Expiration date (if any and/or required by federal/state law)*
 - f. Exact product name shipped
 - g. Date shipped
 - h. Unique identification or lot number
 - i. Quantity
 - j. Type of packaging
 - k. Information about the transporter including "a" through "d," "g," "i," and "j" above.

*Expiration date requirements are limited to certain medicated feed and firms' preservative requirements—not required by law and a few other instances.

5. Provide a record-keeping system that will allow supplier tracking such that a supplier of ingredients can be tracked forward through the process into all shipments of products containing that lot of ingredient. The record-keeping system will also support product tracing such that any supplier of a product can be traced back to each lot of ingredient that is contained within that product.

This record-keeping system can only work where lot numbers are supplied by one or more suppliers.

6. Create a record-keeping system that will produce supplier-tracking and product - tracing reports within a timely manner or as determined by a state or federal agency.

FDA's Bioterrorism Act rules require this information to be available within 24 hours of a request.

7. Assure that records are retained for a minimum of one year from the date of delivery of the product to the customer/dealer. Retained records must be maintained in an easily accessible format regardless of the system or data format.

This is the federal requirement for records retention.

8. Assure that if it is determined a product that is part of a batch or lot of feed fails to meet a feed safety requirement, that subsequent material shall be presumed to be so affected, unless further, detailed assessment provides evidence that the rest of the batch, or lot, does not fail to satisfy the feed safety requirements.

9. Assure that products entering the food chain, or are likely entering the food chain, shall be adequately labeled or identified to facilitate traceability. Products not destined to enter the food chain are exempt from this guideline.

These guidelines are consistent with FDA's record-keeping requirements (21 CFR Part 1, Subpart J)