

AFIA SAFE FEED/SAFE FOOD GUIDELINES AUDIT



Facility Company Name				
Date of Audit				
Facility Address				
Facility City/State/ZIP				
Person conducting audit				
Product Line				
A. Safe Feed/Safe Food Policy, Management, Control of Documents and Records, Communication and Review		Meets Requirements	Does not meet requirements	Requires Follow-up
1	A Food/Feed safety policy has been defined, reviewed and implemented by top management. Has the policy been communicated to each employee?			
2	Document control procedures are in place, and documents are accessible to appropriate personnel.			
3	The physical and chemical feed safety hazards in the <i>AFIA Hazard Guide</i> have been identified, reviewed and have control procedures, where applicable.			
4	Records retention procedures are defined and followed. Records must be maintained for one year from the date of manufacture of the finished product or the receipt of ingredients.			
5	The following records are maintained as appropriate to the product: <u>BSE feed rule</u> , medicated feed, formula/mixing instructions, production records, drug assays, and label files.			
6	Responsible personnel review the following: audit results, customer feedback, process performance and product conformity, status of preventative and corrective actions, follow-up action from previous management reviews, planned changes that could affect the food/feed system and recommendations for improvement.			
B. Human Resources /Training				
1	Personnel are competent for assigned tasks and received initial training and at least annual recertification.			
2	Job descriptions are maintained that include the responsibility and skills required by the employee to complete the job. The employee is evaluated to determine knowledge of the required skill.			
3	Personnel are properly trained in SOPs for restricted areas, and where appropriate, to avoid contamination or carry-over from internal or external sources.			
C. Facility Planning and Control				
1	A team has been formed to identify, evaluate, and control feed and food safety hazards.			
2	Checkpoints where hazards may enter the facility are identified and controlled.			
3	Verification, monitoring, inspection and test activities have been determined specific to the need of the product.			

D. Manufacturing and Processing		Meets Requirements	Does not meet requirements	Requires Follow-up
1	Records are maintained for each product which includes the supplier approval process, product specifications, formulation, label, and special manufacturing instructions.			
2	Procedures exist to monitor and measure the manufacturing processes.			
3	Procedures exist and are implemented to compare expected and theoretical results and to reconcile any differences. [see section J]			
E. Monitoring Devices				
1	Monitoring procedures have been established to evaluate incoming raw materials and finished products, where appropriate.			
2	Scheduled monitoring activities have been established and should include incoming raw material evaluation and finished product evaluation.			
3	Ingredient and finished product assays are performed on a scheduled basis, where appropriate.			
F. Infrastructure - Building, Equipment and Grounds				
1	Procedures exist for the review and evaluation by the feed safety team of feed and food safety hazards in the event of new or changed facilities or equipment.			
2	Buildings, equipment and grounds are adequately and routinely maintained.			
3	Scales and liquid metering devices are tested/calibrated upon installation and at least annually thereafter.			
4	Buildings are of suitable construction to minimize access by pests. A written pest-control program exists and a record of pest-control products used in the facility is maintained.			
5	Buildings provide adequate space and lighting.			
6	Equipment possesses the capability to produce a homogenous product that prevents, eliminates or reduces identified food/feed safety hazards. A procedure to test the mixer has been developed and includes corrective action to be taken when necessary. Mixers are tested/calibrated upon installation and annually thereafter.			
7	All equipment is of suitable size, design, construction, precision and accuracy for its intended use.			
8	All equipment is maintained to prevent lubricants and coolants introduction as unapproved additives to finished products. Where contact may be possible, food-grade products are used.			
9	All equipment is designed, constructed and maintained to facilitate inspection by the operator and the use of clean-out procedures when required.			
10	Work areas and equipment used for the manufacture and storage of ingredients and feed are kept separate from agrichemicals.			
11	Procedures exist and are implemented to ensure all equipment is routinely and properly cleaned to prevent contamination of feed and ingredients.			
12	Adequate procedures are established and used for all equipment in the production and distribution of ingredients and products to avoid contamination of feed and ingredients.			
13	Procedures are established to ensure a biosecure workplace and the firm is following the AFIA "Guide to Biosecurity Awareness" program.			

G. Ingredient Purchasing Process and Controls		Meets Requirements	Does not meet requirements	Requires Follow-up
1	Certification for compliance to 21 CFR 589.2000 is provided by suppliers where appropriate.			
2	Procedures are in place to monitor, qualify and disqualify suppliers on a scheduled basis and an approved supplier list exists.			
3	Procedures for conveyance of raw materials to plant are in place to ensure identification of food/feed safety hazards. Suppliers and transportation companies have agreed to clean-out procedure requirements for transportation vehicles. A truck receiving log is maintained, documenting clean-out and prior cargo in the truck.			
4	Suppliers are required to place a safety seal on incoming rail cars or trucks. A policy to handle broken bags has been developed and is being followed.			
H. Identification and Traceability				
1	Finished product is properly packaged and labeled for traceability (e.g. production codes), and other label regulatory requirements.			
2	Procedures for product traceability as required by the AFIA Safe Feed/Safe Food guidelines are documented and implemented, and the firm is complying with the FDA's Bioterrorism Act record-keeping rules.			
3	Bagged ingredients are stored in either original containers or containers with lot numbers for traceability and identification and controlled in mixing areas. Bulk ingredients are controlled in a similar manner, as appropriate.			
4	A sample retention program is defined and implemented. Retained samples are stored in an area away from production that minimizes the potential for contamination.			
5	Daily inventories of drugs are maintained.			
6	Procedures for proper storage to avoid contamination are established for both raw materials, ingredients and finished products.			
I. Customer-Related Processes				
1	Product specifications are defined within customer and regulatory requirements.			
2	Procedures for customers' feedback and complaints are in place.			
J. Control of Non-conforming Product				
1	Procedures to control non-conforming product have been established and implemented.			

* Items which do not meet the requirements need to be explained on a separate sheet

Signature of person conducting this audit _____ **Date** _____

Signature of management confirming this audit _____ **Date** _____

Explanation of the Guidelines Audit

A. Safe Feed/Safe Food Policy, Management, Control of Documents and Records Communication and Review:

- 1) A food/feed Safety policy has been defined, communicated, reviewed and implemented by top management. Has this policy been communicated to each employee?

Each facility should have an official written policy or corporate mission statement that declares its intention to provide safe food and feed. Such documentation confirms the resolve of the administration and top management to achieve compliance with FDA's Current Good Manufacturing Practices, AFIA's Safe Feed/Safe Food guidelines, and adherence to the company's Standard Operating Procedures and guidebook. AFIA has reviewed this statement in most cases during the application process unless the firm is HACCP or FCI- certified.

- 2) Document control procedures are in place, and documents are accessible to appropriate personnel.

Document control procedures should be based on 21 CFR 225.102 and 225.110 (Current Good Manufacturing Practices for medicated feed manufacturers). These records should be related to actual versus theoretical yield, mixing procedures/protocols, process control and standard operating procedures. Records should be easily identifiable in an organized filing system.

Each facility must be able to demonstrate that ingredients, food and feedstuff are traceable without difficulty one level backward and one level forward.

- 3) The physical and chemical feed safety hazards listed in the AFIA Safe/Feed Safe Food guidelines have been identified, reviewed and control procedures are in place, where applicable.

Generally, the hazards should be reviewed relative to products produced. For instance, mycotoxins are not a hazard in rendered products. Except for fish meal and fish oil, dioxins/PCBs are not a hazard reasonably likely to occur in feed. Pesticide/industrial contaminant residues are rare and where expected by the facility, a control process should be developed. For rendered animal/marine products, membership in the APPI program is adequate evidence that the facility has addressed pathogenic enteric microbial hazards. All other firms are unlikely to define this as a hazard, as scientific evidence is not there.

Heavy metals should be addressed in those mineral ingredients and co-products documented to have contained these. Levels for control of these may be found in the "2005 AAFCO Official Publication," which is based on the National Academy of Sciences/National Research Council's "Mineral Tolerances of Domestic Animals (1980)."

FCI RUPP certification or evidence of a program to comply with the FDA's BSE feed rule (21 CFR §589.2000) is required.

Licensed mills should be in compliance with the FDA's GMPs as of the date of the last inspection. This should be confirmed online by AFIA prior to the inspection. For non-licensed feed mills, the facility should be in compliance with the "relaxed" GMPs in 21 CFR, Part 225.

For other non-medicated feed additives, limitations, if any, by FDA should be followed and good practices should be adhered to. These would include an understanding of any ingredient interactions, limitations on ingredients, etc.

Other hazards may also be addressed by the firm, and agents should ask if there are more hazards the firm addressed.

- 4) Records retention procedures are defined and followed. Records must be maintained for one year from the date of manufacture of the finished product or the receipt of ingredients.

For most records in medicated feed plants and for Bioterrorism Act regulations, this is one year. Does the firm have one year's worth of records based on one year from the date of release of the product?

- 5) The following records are maintained as appropriate to the product: BSE feed rule, medicated feed, formula/mixing instructions, production records, drug assays, label files.

These should be as required by federal regulations, and as mentioned in #2 above.

- 6) Responsible personnel should review the following: audit results, customer feedback, process performance, product conformity, status of preventative and corrective actions, follow-up action from previous management reviews, planned changes that could affect the food/feed system and recommendations for improvement.

Find evidence that the responsible personnel regularly review these types of records or have a QA team perform such tasks.

B. Human Resources – Training:

- 1) Personnel are competent for assigned tasks and received initial training and at least annual certification.

Each facility should have proof that each employee has been trained in his or her particular task.

- 2) Job descriptions are maintained that include the responsibility and skills required by the employee to complete the job. The employee is evaluated to determine knowledge of the required skill.

Each facility should have written job descriptions for the various work tasks.

- 3) Personnel are properly trained in SOPs for restricted areas, and where appropriate, to avoid contamination or carry-over from internal or external sources.

A brief interview with randomly selected employees will validate if training was sufficient for the task or position at hand. In some cases, personnel may be required to wear protective gear or wash hands to prevent cross-contamination from batch to batch.

C. Facility Planning and Control:

- 1) A team has been formed to identify, evaluate and control feed and food safety hazards.

This may be the HACCP or QA team.

- 2) Checkpoints where hazards may enter the facility and are identified and controlled.

Each facility must demonstrate that critical control points have been identified and what controls are in place to prevent contamination, adulteration or unacceptable ingredients. The following check points may be areas for consideration.

1. *Toll-milled products—who inspects the toll miller?*
 2. *Shipping containers such as trucks, rail cars, tote bags, small packages and liquid ingredients. Are they cleaned out?*
 3. *Sub-standard macro-ingredients (toxins, salmonella, poor quality, etc.). What control is performed?*
 4. *Poorly designed or mislabeled process controls such as distribution or directional conveying systems. How do these affect finished products?*
 5. *Unguarded, unprotected ports of entrance to the plant such as a receiving pits, warehouse, liquid receiving ports, access to facility interiors.*
 6. *Unsecured property, buildings, etc.*
 7. *Poor boiler maintenance and steam tracer lines.*
 8. *Sub-standard purchasing contracts or purchase orders or lack of these items.*
- 3) Verification, monitoring, inspection and test activities have been determined specific to the need of the product.

Each facility must have control mechanisms in place for the hazards determined to be a risk. These mechanisms should be specific to the product produced. There need not be a chemical test for each hazard. These may include ingredient/raw material, as well as finished product surveillance.

D. Manufacturing and Processing:

- 1) Records are maintained for each product, which includes product specifications, formulation, labels and special manufacturing instructions.

Each facility must have written ingredient specification standards for all ingredients that are used in the facility. The facility must also have written food/feed specifications for all food/feed manufactured in the plant, which includes formulas, labels and any special manufacturing instructions such as flushing, sequencing, special handling of medicated feeds, pre-mixes, etc.

- 2) Procedures exist to monitor and measure the manufacturing processes.

The manufacturing facility must have sufficient documentation to support which bins or micro containers ingredients were drawn from, the batching time, distribution and the sequential order that a batch was processed and the method used to clean the system if flushing was required. There should be a method to account for the exact amount of ingredients (medications, pre-mix, macro ingredient, liquids, etc.) used and the accountability for over or under weighments.

Equipment measuring and processing devices should have calculation records that show when the equipment was tested and the calculation recorded and what adjustments were made to ensure accuracy. These processing devices would include:

- a. Liquid flow metering and timing devices (fat, molasses, binders, etc.)*
- b. Mixer testing results*
- c. Automatic dry matter feeders (salt, micro ingredient feeds, etc.)*
- d. Scale(s) maintenance and testing*
- e. Maintenance records and schedule checklists for various equipment and process controls*
- f. Computer-generated records are backed up and stored away from the facility*

Micro ingredients, medications, vitamins and minerals are routinely inventoried and conform to the facilities SOPs, testing and inventory policy.

Liquid ingredients, such as, fat, molasses and other liquid chemicals are routinely inventoried and conform to the facility's SOPs, testing and inventory policy.

Maintenance and calibration of equipment:

Equipment should be adequately inspected, cleaned and maintained. Equipment used for the generation, measurement or assessment of data should be adequately tested, calibrated and/or standardized.

The facility's SOPs should set forth in sufficient detail the methods, materials and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and should specify, when appropriate,

remedial action to be taken in the event of failure or malfunction of equipment. The written SOPs should designate the person responsible for the performance of each operation.

Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine or non-routine and followed the written SOPs. Procedures exist and are implemented to compare expected and theoretical results and to reconcile any differences.

Each facility must demonstrate a monitoring procedure that documents the differences between expected yields and actual yields and what procedure was used to reconcile or correct any differences. However, the emphasis for this review is the effect of these processes on feed safety. Remember, this is not a quality audit, but a feed safety audit.

- 3) Procedures exist and are implemented to compare expected and theoretical results and to reconcile any differences. [See section J]

There are actions that must be taken when thresholds are exceeded. The initial response when these thresholds are exceeded is to stop further production and investigate the reason for the difference. During the process of investigation there should be notes developed on each step of the investigation. These should include all equipment checked and the status of the equipment. All operators should be involved in the process of investigation. When issues are discovered during the investigation, all operators should be educated about the issues.

E. Monitoring Devices:

- 1) Monitoring procedures have been established to evaluate incoming raw materials and finished products, where appropriate.

Each facility must have a monitoring schedule or a certification schedule from vendors/suppliers for the potential hazards the facility has addressed from the AFIA SF/SF hazards list.

There is no set number of times a certain ingredient(s) or finished product(s) should be monitored except medicated feeds (see CGMPs). The schedule should be established by the facility, but should be done often enough to satisfy any concern for these potential hazards.

The best method used to assure hazard reduction is to require vendors and ingredient suppliers to furnish routine Certified Certificates of Analysis on various ingredients. This should be encouraged.

- 2) Scheduled monitoring activities have been established and should include raw material evaluation and finished product evaluation.

Determine what monitoring is completed to ensure feed safety. It should include some plan to address the AFIA SF/SF hazards in both incoming ingredients and finished products. What hazards are monitored in the finished products?

- 3) Ingredient and finished product assays are performed on a scheduled basis, where appropriate.

Each facility must demonstrate that it has a defined schedule as to when various ingredients or finished products should be assayed, where the facility has determined such is needed. The schedule should show the type of product to be assayed and what the expected result should be.

F. Infrastructure – Building, Equipment and Grounds:

- 1) Procedures exist for the review and evaluation of feed and food safety hazards in the event of new or changed facilities or equipment.

Each facility should evaluate newly installed equipment or remodeled feed processing or handling systems to ensure it does not create a hazard. A written hazard analysis should exist for each physical change involving equipment or processing flow in the plant.

- 2) Buildings, equipment and grounds are adequately and routinely maintained.

Each audited facility must demonstrate that each section of the plant is clean, orderly and practices routine house-keeping activity. The plant and its equipment should be free of any residue build-up. Bins, tanks and building roofs should be in sound condition and impervious to outside weather.

- 3) Scales and liquid metering devices are tested/calibrated upon installation and at least annually thereafter.

Each liquid meter should be tested and the results recorded. The meter should be checked on volume versus weight to determine the proper amount is being added. If the meter is determined to be out of compliance, review the corrective action taken to ensure the meter is working properly. After corrective action has been taken, review the follow-up tests to ensure actions taken meet the desired results and the meter is accurate.

- 4) Buildings are of suitable construction to minimize access by pests. A written pest-control program exists and a record of pest-control products used in the facility is maintained.

Buildings and foundations should be free of unrepaired cracks or structural flaws. An apron should extend around the perimeter of all structures and be free of any untrimmed weed growth or tall grass. Doors and windows should be in good repair and sealed tightly when closed. Opened doors and windows should be covered with screens.

- 5) Buildings provide adequate space and lighting.

Workers should be able to perform their routine duties without being hindered by inadequate space and lighting.

- 6) Equipment possesses the capability to produce a homogenous product that prevents, eliminates or reduces identified food/feed safety hazards. A procedure to test the mixer has been developed and includes corrective action to be taken when necessary. Mixers are tested/calibrated upon installation and annually thereafter.

Mixers should be relatively clean and mixer efficiency tests should be conducted periodically. Medicated feed assays performed by outside labs are acceptable also. Facility should be following the equipment manufacturers' recommendations on use, maintenance and upkeep.

- 7) All equipment is of suitable size, design, construction, precision and accuracy for its intended use.

Scale precision should be adequate for type of weighing. Size of mixers should be adequate for mixing loads. Scales should be tested for accuracy annually.

- 8) All equipment is maintained to prevent lubricants and coolants introduction as unapproved additives to finished products. Where contact may be possible, food-grade products should be used.

Ensure that bearings, seals, oil baths, gear boxes etc. have no visible leaks. Verify that lubricants used by maintenance personnel (especially pellet machine grease and oil) are classified as "feed or food grade." All boiler chemicals must be FDA- approved and maintained at the proper level.

- 9) All equipment designed, constructed and maintained to facilitate inspection by the operator and the use of clean-out procedures when required.

Check for a mixer access that enables an inspection and cleaning. Examine coolers, shakers and pellet machines to find out if their cleanliness and empty status can be physically verified. Check to see if elevator boots can be accessed and opened.

- 10) Work areas and equipment used for the manufacture and storage of ingredients and feed are kept separate from agrichemicals.

Ask to see supply of rodenticides, pesticides, chemicals, paints, lubricants, etc., and ensure that they are clearly identified and physically separated from any feed products. These do not have to be separated by a wall, but may be in a separate area.

- 11) Procedures exist and are implemented to ensure all equipment is properly cleaned to prevent unsafe contamination of feed and ingredients.

The official flushing and sequencing policies should be written and a review of them should be completed. These policies should apply to manufacturing feeds (especially for medicated products, urea, high salt and mineral products) and for ingredient receiving (especially urea, salt, calcium and phosphorus). Check batching records and the receiving logs for documentation that confirms flushing and sequencing policies are fulfilled.

- 12) Adequate procedures are established and used for all equipment in the production and distribution of ingredients and products to avoid contamination of feed and ingredients.

Review the routing and the final resting point (holding bin) for ingredients and finished feed products to ensure they are documented. Records should show the previous contents for any bulk feed or ingredient bin that is not dedicated to one single product. Ingredient receiving stream is equipped with magnets and screening devices and is checked regularly.

- 13) Procedures are established to ensure a biosecure workplace and the firm is following the AFIA “Guide to Biosecurity Awareness” program.

Is the facility aware of and utilizing AFIA’s “Guide to Biosecurity Awareness”? If not, leave a copy with the facility and determine if the facility is following similar guidelines.

G. Ingredient Purchasing Process and Controls:

- 1) Certification for compliance to CFR 589.2000 is provided by suppliers.

Check files for supplier’s agreements to comply with CFR 589.2000 (RUPP free status).

- 2) Procedures are in place to monitor, qualify and disqualify suppliers on a scheduled basis and approved supplier lists exist.

Examine approved suppliers list and compare it to daily entries on randomly selected Receiver’s Logs. Review the official written ingredient specifications which should address all incoming goods. All specifications should ban any form of adulterant or contaminant. Grains should contain a clause for “No unsafe level of mycotoxins” and minerals should contain a clause for “No unsafe level of pesticides or industrial contaminants” or similar statements.

- 3) Procedures for conveyance of raw materials to the plant are in place to ensure identification of food/feed safety hazards. Suppliers and transportation companies have agreed to clean-out procedure requirements for transportation vehicles. A truck receiving log is maintained, documenting clean-out and prior cargo in the truck.

Each facility should have addressed the possibility of conveyance contamination either by trucker certifications, required procedures for clean-out and/or inspection of containers prior to loading.

- 4) Suppliers are required to place a safety seal on incoming rail cars or trucks. A policy to handle broken bags has been developed and is being followed.

Incoming delivery trucks and cars should have seals on unloading and loading ports. Grain delivered direct from a local farm and hauled by the producer are exempt from this requirement provided the delivery truck does not stop between the farm and the facility. When bagged product is delivered by LTL or supplier- provided delivery trucks, special inspection procedures should be developed. The bags should be inspected for tears, signs that the bags have been wet, possible rodent damage to the bags and overall condition of the packages. Bags that are out of condition or show signs that the product could be contaminated should be rejected.

H. Identification and Traceability:

- 1) Finished product is properly packaged and labeled for traceability (e.g. production codes) and other label regulatory requirements.

Each facility should have a designated authority and a formal system for ensuring that the correct labels and bags are used in the packing process. Examine 5 or 6 warehoused feed products to confirm that they contain correct information (i.e. correct labels) and that their label fulfills the federal/state labeling requirements with respect to drug levels, warnings, adequate feeding directions for safe use, etc.

- 2) Procedures for product traceability as required by the AFIA feed safety guidelines are documented and implemented and the firm is complying with the FDA's Bioterrorism Act record-keeping rules.

Focus on whether there is adequate information sufficient to affect a recall or not.

- 3) Bagged ingredients are stored in either original containers or containers with lot numbers for traceability and identification (*required for drugs*) and controlled in mixing areas. Bulk ingredients are controlled in a similar manner, as appropriate.

Check the receiving log and the batching records to verify that lot numbers, if available, are recorded for bulk and bagged ingredients and then tracked from their receipt to being mixed into a finished feed.

- 4) Traceability procedures exist to facilitate product recalls.

A review of customer files to ensure that loading tickets contain the lot numbers for each feed product on the order is adequate. Ask if a mock recall has been used to determine

the viability of the tracking system. Review the mock recall and determine if all product produced was accounted for. If no mock recall had been performed, look for documentation to ensure all product could be recalled should the need arise. More information is detailed in the AFIA SF/SF “Guidelines for Recordkeeping and Product Tracking.”

- 5) A sample retention program is defined and implemented. Retained samples are stored in an area away from production that minimizes the potential for contamination.

A sample retention program should contain samples for every incoming product and every manufactured feed for a specified period of time. This time should be sufficient to assist in any potential recalls. Samples should be adequately stored and labeled.

- 6) Daily inventories of drugs are maintained.

Drug records should be reconciled on a daily basis and any significant discrepancies remedied. Drug records show drug name and potency, drug manufacturer, shipper, amount received, amount used and amount on hand for each day.

- 7) Procedures for proper storage to avoid contamination are established for both raw materials, ingredients and finished products.

Check the routing and the final resting point (holding bin) for ingredients and finished feed products for documentation. Records should show the previous contents for any bulk feed or ingredient bin that is not dedicated to one single product. All warehoused packaged goods are clearly labeled and handled to reduce the risk of feed safety issues.

I. Customer-Related Processes:

- 1) Product specifications are defined within customer and regulatory requirements.

Review custom feed products and medicated feed products to ensure they are complete. Compare feed labels to their respective formulas and look for whether illegal or off-label drug uses are being manufactured. All custom and medicated feeds conform to FDA regulations. Also, controlled ingredients are utilized appropriately (e.g. ethoxyquin, RUPP, selenium).

- 2) Procedures for customer’s feedback and complaints are in place.

Examine complaint file and customer feedback file if there is one. All complaints should be documented along with the results of any investigations.

J. Control of Non-conforming Products:

- 1) Procedures to control non-conforming products have been established and implemented.

A complete review of the system for handling non-conforming ingredients and products should be completed. The system should be written and non-conforming ingredients and products should be quarantined until an investigation proves that they fulfill quality standards. Ingredients that do not meet official specifications should be rejected and suppliers with repeated violations shall be dropped as approved suppliers. Non-conforming products should never reach the marketplace. All steps leading to the eventual rejection or approval of non-conforming ingredients and feed products should be documented and signed. However, these procedures should be reviewed in the context of feed safety and not quality issues.