



FSC36 SAFE FEED/SAFE FOOD GUIDANCE DOCUMENT

Guidance for Developing, Documenting, Implementing,
and Maintaining the Quality & Food Safety Program
(Version 7.0)



FSC36 Safe Feed/Safe Food (www.safefeedsafefood.org) is a facility certification program for the American Feed Industry Association (www.afia.org)



PREFACE

This document is intended to provide general guidance for facilities and auditors for FSC36 Safe Feed/Safe Food Certification Program. This guidance will assist facilities as they prepare for an audit.

The purpose of FSC36 Safe Feed/Safe Food implementation is not only to achieve certification, but to assure consistency across certified facilities and promote a culture of continuous improvement of a supplier's quality and food safety program. The guidance is not intended to cover every possible scenario that may be seen across the feed industry but provides a general guide of what could be acceptable to meet the requirements for a particular clause or area.

Effective implementation of FSC36 Safe Feed/Safe Food requires the commitment of the site management and the constant involvement and participation of site staff to maintain the quality and food safety program. The American Feed Industry Association (AFIA) is grateful to its Quality & Animal Food Safety Committee and numerous members that reviewed and contributed to this document.

This document has been revised and shall be referred to as FSC36 Safe Feed/Safe Food version 7.0.

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SECTION 1.0 Introduction

The purpose of the guidance document for FSC36 Safe Feed/Safe Food is to assist facilities (which are referred to as “suppliers” within this document) with designing, developing, implementing and maintaining a quality and food safety program that complies with the desired requirements as well as assist auditors with auditing suppliers seeking certification for FSC36 Safe Feed/Safe Food. This is not a definitive document and applicable in every situation. Suppliers, consultants and auditors are required to understand animal food safety (and quality, where applicable) risks in the feed industry in order to effectively control those risks.

The document includes the following:

- Registration and certification process
- Implementation process
- Introduction to this guidance document
- Guidance document for FSC36 Safe Feed/Safe Food
- Glossary
- Rules for using the Safe Feed/Safe Food seal or logo





Terms used in this document are defined in Appendix A: Glossary for FSC36 Safe Feed/Safe Food Guidance Document Version 7.0.

SECTION 2.0 Registration and Certification

2.1 AFIA Alignment with SQFI

AFIA aligned with Safe Quality Foods Institute (SQFI) to administer the Safe Feed/Safe Food certifications in October 2013. AFIA and SQFI signed a *Joint Program Implementation and Marketing Agreement* to bring AFIA certification programs into SQFI family of programs. SQFI is recognized by retailers and foodservice providers around the world who require a rigorous, credible animal food safety management system.

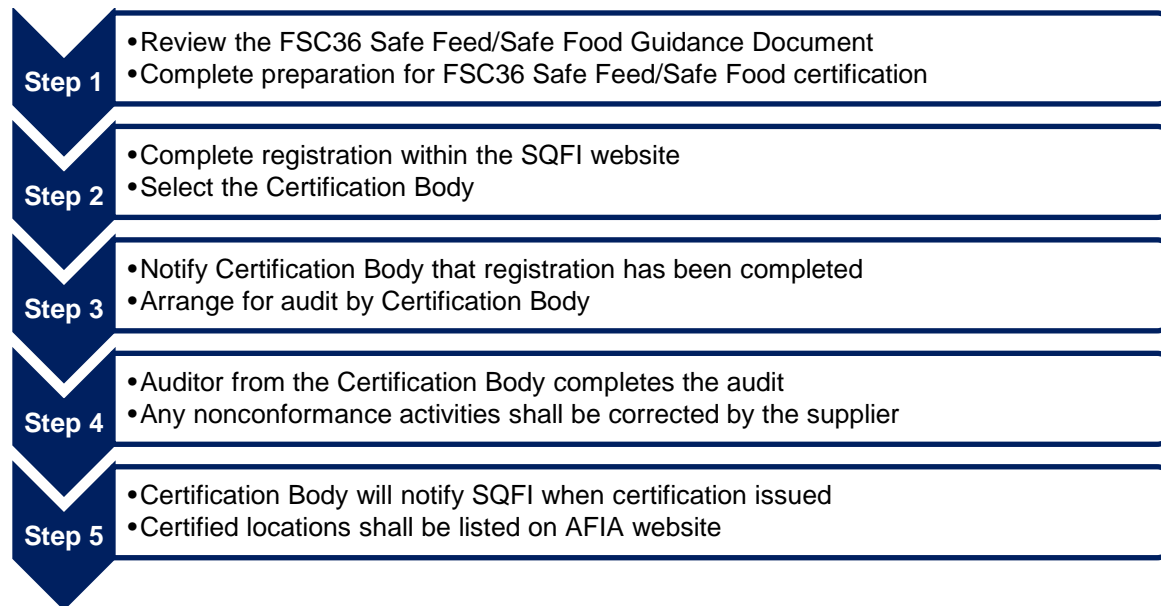
SQFI is recognized by the Global Food Safety Initiative (GFSI) and links primary production certifications to food manufacturing, distribution, and agent/broker management certifications. GFSI is an approved (benchmarked) choice of third-party food safety certification programs that are required by many in the retail food industry for their supplier’s participation. With the alignment with SQFI, AFIA recognizes two programs administered by SQFI as now benchmarked by GFSI for animal food.

<u>SQFI Code</u>	<u>Certification</u>		<u>GFSI Benchmarked</u>
FSC36	Safe Feed/Safe Food		
FSC34	Manufacturing of Animal Feeds		
FSC32	Manufacturing of Pet Food		

2.2 Registration and Certification Steps

The requirements for the certifications of FSC34 and FSC32 may be found within the SQF Code 7.2. The requirements for FSC36 Safe Feed/Safe Food certification are maintained by AFIA, which is the purpose of this guidance document.

FSC36 Safe Feed/Safe Food is a two-year certification. The supplier is required to register and ensure compliance with the requirements with the program each year. The steps to obtain FSC36 Safe Feed/Safe Food certification are outlined below.



Step 1 – The supplier should review the FSC36 Safe Feed/Safe Food guidance document and determine whether or not the location is ready for the certification. If not, the supplier should take steps to prepare for compliance based on the guidance document.

Step 2 – Registration within SQFI website.

- 1) A supplier must be registered within SQFI on the SQF website (www.sqfi.com) in order to seek FSC36 Safe Feed/Safe Food certification. For FSC36 Safe Feed/Safe Food certification, please see “FSC36 Safe Feed/Safe Food: SQF Reliance System User Guide – Registration to Certification.” This document may be found at www.safefeedsafefood.org. Also, a [Registration Users Guide](#) is provided on the SQF website.
- 2) Registration provides key contact and billing information for the certification. It is important that the correct key contact and email address are provided.
- 3) During registration, the certification body and the certification sought are selected. It is important for a supplier to know whether or not the certification body is approved to complete a FSC36 Safe Feed/Safe Food certification. If the supplier is uncertain about selecting a certification body, the supplier may designate as “unknown” within the selection field as the certification body may be changed at any time. However, before a certification body is able to complete the supplier’s audit or certification, the certification body *must* be correctly designated.
- 4) Re-registration is required annually. Once registered within the SQFI system, the database will notify the key contact for the supplier 90 days prior to registration renewal as a reminder. It is the responsibility of the supplier to ensure re-registration is completed. Thus, it is important the key

contact is correct within the SQF database for the supplier. Contact AFIA if you have any questions regarding the registration process.

- 5) Registration is independent of the certification process.

Step 3 – Certification body notification

- 1) Once registration or re-registration is complete, it is the supplier's responsibility to contact the selected certification body to begin the certification process.
- 2) After the certification body, has been notified that the supplier's registration is complete, the certification body initiates the audit process. The certification body selects the most appropriate qualified auditor for the supplier's certification audit.
- 3) The scope of the audit should be clearly defined before the audit. The entire site, including all premises, support buildings, silos, tanks, loading and unloading bays and external grounds must be included in the scope of certification. Where a supplier seeks to exempt parts of the site for any reason, the request for exemption must be submitted to the certification body in writing. However, all parts of the premises and process that are involved with the production, processing and storage of products, are included in the scope and cannot be exempted.
- 4) FSC36 Safe Feed/Safe Food is a two-year certification and an on-site audit is required to obtain certification. An on-site audit is required the first year while a surveillance audit (remote audit), may be completed the second year. An on-site audit may be completed the second year for the following reasons:
 - Preferred by the supplier
 - Supplier changes certifying bodies
 - Supplier scored less than 85% from the previous on-site audit.

The on-site audit covers all clauses within the FSC36 Safe Feed/Safe Food guidance document, excluding those identified as exempt by the supplier and the certification body prior to the audit. The surveillance audit covers all mandatory clauses.

- 5) Audits for the two-year certification are completed by the same certification body. Should a supplier choose to change certification bodies during a remote audit, a thorough assessment of the supplier by the certification body is required to ensure it complies the FSC36 Safe Feed/Safe Food requirements and there are not outstanding issues. An on-site audit is preferred for a supplier to change certification bodies, but not required if a remote audit is due. This is considered a transfer of certifications. If a supplier is due for on-site audit, an on-site audit must be completed to maintain certification.

Step 4 – Audits

- 1) The certification body works with the supplier to select a date for the on-site audit and a qualified auditor for the certification audit. The supplier and the certification body shall agree on the audit scope before the certification audit begins.
- 2) During the on-site audit, the auditor completes the audit checklist online within the SQF database. The checklist contains a list of the various clauses within the guidance document (see Section 5). The supplier is required to close nonconformance items or nonconformities before the certification can be issued. The certification body is responsible for issuing the certification.
- 3) For surveillance audit audits, the certification body collects sufficient information from the supplier to ensure compliance with the mandatory clauses is maintained. The certification body completes the

audit form for the supplier online within the SQF database. Any nonconformance items identified during the surveillance audit must be closed by the supplier within the timelines as outlined in Section 2.5. Failure to do so could result in a suspension of the supplier's certification. If the requirements of the surveillance audit are not met, the supplier shall be required to complete an on-site audit within 90 days. Guidance for a surveillance audit is found in Appendix C.

Step 5 – Certification notification

- 1) After all nonconformance items, if any, are closed, the certification body issues the FSC36 Safe Feed/Safe Food certification. The certification body notifies SQFI that the facility is certified. SQFI notifies AFIA and AFIA posts all FSC36 Safe Feed/Safe Food certified facilities on the safefeedsafefood.org website.

2.3 Audit Duration Guide

Once the certification body and Supplier have agreed on the scope of certification, the certification body shall provide the supplier with an estimate of the time it will take to complete the certification audit. The audit times will vary according to the size and complexity of the site operations. Factors that can impact on the audit duration include:

- The scope of the audit;
- The size of the site and the design of product;
- The number and complexity of product lines and the overall process;
- The level of risk associated with the finished products or ingredients;
- The complexity of the quality and food safety program design and documentation;
- The level of mechanization and labor intensiveness;
- The ease of communication with company personnel (consider different languages spoken); and
- The cooperation of the supplier's personnel.

An on-site audit for FSC36 Safe Feed/Safe Food certification is expected to take eight hours. However, more time may be needed based on the items shown above. Justification is required if the certification body deviates from this guide by greater than 30 percent.

A surveillance audit for FSC36 Safe Feed/Safe Food is expected to take four hours. The length of the audit is impacted by the items shown above as well as the supplier's score from the previous on-site audit. The purpose of the surveillance audit is to ensure the supplier's location is maintaining compliance with the certification.

In addition to audit time, the certification body shall provide the supplier with the time and expected costs for planning, travel, report writing and close out of nonconformance items.

2.4 System Clauses

All applicable clauses of FSC36 Safe Feed/Safe Food guidance document shall be checked as part of the certification audit. Where a clause is not applicable and appropriately justified, it shall be stated so by the auditor in the audit report.

Several clauses are noted as mandatory clauses and cannot be reported as “not applicable” or “exempt.” These clauses must be audited and compliance/noncompliance reported. The mandatory clauses are:

- SF/SF 1.1 Management Policy (M)
- SF/SF 1.2 Management Responsibility (M)
- SF/SF 1.3 Responsibility, Authority and Communication (M)
- SF/SF 2.2 Document Control (M)
- SF/SF 2.3 Records (M)
- SF/SF 4.1 Competency and Job Descriptions (M)
- SF/SF 4.2 Requirements for a Preventive Controls Qualified Individual (PCQI) (M)
- SF/SF 5.3.1 Pest Management (M)
- SF/SF 5.3.2 Pest Control Chemicals (M)
- SF/SF 5.4 Cleaning and Housekeeping (M)
- SF/SF 6.3.1 Process Control (M)
- SF/SF 6.3.3 Product Release (M)
- SF/SF 6.4.1 Finished Products Specifications (M)
- SF/SF 6.4.2 Product Formulation (M)
- SF/SF 6.6 Labeling (M)
- SF/SF 6.7 Nonconforming Products and Materials (M)
- SF/SF 6.8 Rework (M)
- SF/SF 6.11.1 Hazardous Chemical Storage Process (M)
- SF/SF 6.11.2 Hazardous Chemical Storage Area (M)
- SF/SF 7.1.1 Approved Vendors (M)
- SF/SF 7.2 Material and Packaging Specifications (M)
- SF/SF 8.7 Product Identification (M)
- SF/SF 8.8 Product Traceability (M)
- SF/SF 9.1 Components of a Food Safety Plan (M)
- SF/SF 9.3 Hazard Analysis (M)
- SF/SF 9.4 Preventive Controls (M)
- SF/SF 9.5 Corrective Actions (M)
- SF/SF 9.11 Regulatory Requirements (M)
- SF/SF 9.12 Recall Plan (M)

Mandatory clauses are designated with an “(M)” after the clause in FSC36 Safe Feed/Safe Food guidance document.

2.5 Nonconformities and Corrective Actions

Where the certification body auditor finds deviations from the requirements of FSC36 Safe Feed/Safe Food guidance document, the auditor shall advise the supplier of the number, description and extent of the nonconformities. Nonconformities against the FSC36 guidance document shall be graded as follows:

- Minor nonconformity is an omission or deficiency in the quality and food safety system that produces unsatisfactory conditions that if not addressed may lead to a risk to quality and food safety but not likely to cause a system breakdown.
- Major nonconformity is an omission or deficiency in the quality and food safety system producing unsatisfactory conditions that carry a quality or animal food safety risk and likely to result in a system breakdown.
- Critical nonconformity is a breakdown of control(s) at a critical control point, a prerequisite program, or other process step and judged likely to cause a significant public health risk and/or where product is contaminated.
- Critical nonconformity is also raised if the supplier fails to take effective corrective action within the time frame agreed with the certification body, or if the certification body deems that there is systemic falsification of records relating to animal food safety controls and the quality and food safety system.

All nonconformance items and their resolution shall be documented by the auditor. The following timelines shall be followed implementing corrective actions:

- Minor nonconformity – shall be corrected, verified and closed out by the certification body within 30 calendar days of the completion of the facility audit. Extensions may be granted by the certification body where there is no immediate threat to product quality and animal food safety, and alternative, temporary methods of control are initiated. The supplier shall be advised of the extended timeframe. Extended timeframes for close out of minor nonconformities shall not impede and delay certificate issuance.
- Major nonconformity – shall be corrected and appropriate corrective action verified and closed out in the SQF assessment database within 14 calendar days of the completion of the facility audit. In circumstances where the corrective action involves capital investment, structural change or cannot be corrected due to extenuating conditions, this period can be extended provided the corrective action time frame is acceptable to the certification body and temporary action is taken by the supplier to mitigate the risk to product quality and animal safety. However, in such cases, the nonconformity must still be closed out on the SQF assessment database and the auditor shall document all details of justification of the extension, how the risk is being controlled and the agreed completion date.
- Critical nonconformity – if the auditor from the certifying body considers that a critical nonconformity exists during a facility audit, the auditor shall immediately advise the supplier and notify the certification body. A critical nonconformity raised at a certification audit results in an automatic failure of the audit, and the supplier must reapply for certification.

2.6 Opportunities for Improvement

Opportunities for improvement are observations made by the auditor during a facility audit that identify issues that are not nonconformance items, but recognize that the practices conducted by the supplier are not industry best practices. They do not require a corrective action response by the supplier, but provide the supplier with an opportunity to improve their quality and food safety system.

2.7 The Audit Report

The auditor completes an electronic audit checklist when conducting audits. The audit checklist for FSC36 Safe Feed/Safe Food certifications is available on the AFIA website and is customized for the animal feed industry. The checklist is designed to ensure the uniform application of FSC36 Safe Feed/Safe Food audit requirements. It is used by auditors to record their findings and determine the extent to which supplier operations comply with stated requirements.

Nonconformance findings identified during the audit shall be accurately described in the audit report. The certification body shall make the audit report available to the supplier within 14 calendar days from the last day of the audit. The FSC36 Safe Feed/Safe Food audit report shall remain the property of the certification body's client (the supplier) and shall not be distributed to other parties without the permission of that client.

2.8 Responsibility for the Certification Decision

It is the responsibility of the certification body to ensure that audits undertaken by their auditors are thorough, that all requirements are fulfilled, and the audit reports are complete. The certification decision shall be taken by the certification body based on the evidence of compliance and nonconformity collected by the auditor during the audit. The certification body is responsible for deciding whether or not certification is justified and granted.

2.9 Audit Score and Rating

Based on the evidence collected by the auditor, each applicable aspect of the facility audit is scored when the audit report is uploaded to the SQF assessment database. The calculation uses the following factors:

- 0 = criteria meets requirements
- 1 = minor nonconformity; does not meet the criteria
- 10 = major nonconformity; does not meet the criteria
- 50 = critical nonconformity; does not meet the criteria

A single rating is calculated for the facility audit as $(100 - N)$ where N is the sum of the individual rating criteria allocated. The rating provides an indication of the overall condition of the supplier's site against the FSC36 Safe Feed/Safe Food guidance document, and also provides a guideline on the required level of surveillance by the certification body. The audit frequency at each rating level is indicated as follows:

Score Rating Certification Audit Frequency

- 96 – 100 = Excellent rating for 24 months
- 86 – 95 = Good rating for 24 months
- 70 – 85 = Compliance rating for 12 months
- 00 – 69 = Fails to comply; no certificate issued

A new rating score is provided after an on-site audit. If a facility desires a new rating score, an on-site audit may be scheduled rather than a surveillance audit during the second year of the certification. An on-site audit is required during the second year for facilities scoring 85 or less (compliance rating). Thus, facilities that

score above 85 receive a 2-year certification while facilities that score 85-70 receive a 1-year certification. Scores are confidential and are shared with the supplier only.

Certification also requires that all major nonconformities are closed out within fourteen 14 calendar days and minor nonconformities within 30 calendar days.

Surveillance audits are not scored. During the year when a surveillance audit is required (second year for suppliers with an Excellent or Good rating), the supplier's location maintains the score rating obtained during the last on-site audit. If the supplier desires a new score rating, an on-site audit must be completed. If the supplier is not able to provide sufficient information to demonstrate compliance with the requirements during the surveillance audit, an on-site audit shall be required within 90 days of completing the surveillance audit.

2.10 Suspending Certification

The certification body shall suspend the SQF certificate if the supplier:

- Fails to permit the re-certification or surveillance audit;
- Receives score rating less than 70;
- Fails to take corrective action;
- Fails to take corrective action within the timeframe specified; or
- Where based on objective evidence of the certification body, fails to maintain the requirements of FSC36 Safe Feed/Safe Food.
- Fails to inform the certification body of regulatory nonconformance findings (e.g., recalls) by federal, state or local agencies and provide adequate information that nonconformance findings have been properly addressed or corrected.

Where the supplier's certificate is suspended, or a supplier decides to discontinue FSC36 Safe Feed/Safe Food certification, the supplier's location status shall be updated on the AFIA website. If the supplier maintains a licensing agreement for use of the Safe Feed/Safe Food seal or logo, the supplier must discontinue use of the logo immediately and provide proof of actions taken. Guidance for use of the FSC36 Safe Feed/Safe Food seal (logo) is found in Appendix B.

When a supplier's location is suspended, the certification body shall inform the supplier of the reasons for the action taken and the date of effect. The certification body shall update the supplier's status within the SQFI database and inform AFIA on the notice of suspension sent to the supplier.

A suspended Supplier's location may return to certification after corrective actions have been implemented and the completion of an on-site audit by an AFIA approved certification body.

2.11 Complaints, Appeals and Disputes

When a supplier has cause to register a complaint about a certification body, or appeals or disputes a decision made by a certification body, including the activities and decisions of its auditors, the certification body shall investigate and resolve these matters without delay and keep a record of all complaints, appeals and disputes and their resolution. Records for complaints should be maintained for at least one year.

When a certification body receives a complaint about a supplier from other parties, the certification body is required to investigate and resolve the matter without delay and keep a record of all complaints, appeals and disputes and their resolution.

Appeals regarding decisions on the suspension and/or withdrawal of the Safe Feed/Safe Food certification by a certification body shall not delay the decision to suspend or withdraw the certification.

Where a complaint is registered about the conduct or behavior of an auditor or certification body personnel, the certification body shall investigate and resolve the complaint without delay and keep a record of all complaints and their resolution.

Where a complaint, appeal or dispute cannot be satisfactorily resolved between the supplier and the certification body, the matter shall be referred to AFIA for a resolution.

2.12 Situations where Safe Feed/Safe Food Certification is Not Applicable

FSC36 Safe Feed/Safe Food certification is applicable to many types of manufacturing or processing facilities. However, it is important to remember that the program is designed to certify the “process” and not “products”. Thus, the following are examples when FSC36 Safe Feed/Safe Food is not applicable:

- If a supplier repackages product only, the manufacturing processes for the packaged product must be certified in order for the packaged product to be recognized as Safe Feed/Safe Food certified and display the Safe Feed/Safe Food seal.
- If a product is toll-manufactured, the manufacturing processes for the toll-manufactured product must be certified in for this product packaging to use the Safe Feed/Safe Food seal.
- If a supplier receives a bulk ingredient or raw material only, and this material is shipped without further processing, the manufacturing processes for the bulk material must be certified in order for the supplier to be recognized as Safe Feed/Safe Food certified.

The above are only examples and the list is not exclusive. The certification body is responsible for ensuring the supplier meets the requirements for FSC36 Safe Feed/Safe Food, which should be covered in the scope of the audit.

2.13 FSC36 Safe Feed/Safe Food Certification Cost

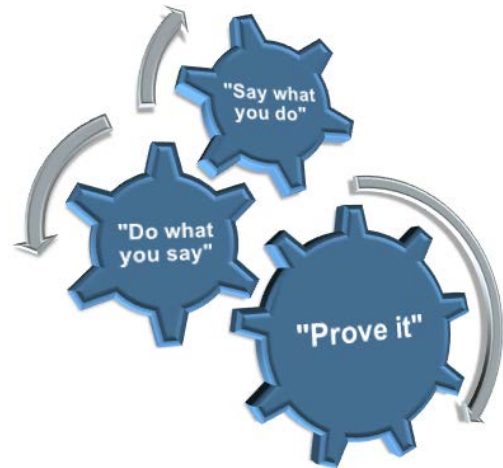
An on-site audit is expected to take 1 day and a fee of \$1200 is recommended by AFIA. However, a certifying body may determine more time is needed and a higher audit fee is required based on the time and work required for the particular facility (supplier) audit. A certifying body shall communicate on-site audit fees prior to scheduling the on-site audit and invoice the facility audited directly for the on-site audit fees plus reasonable travel expenses. The facility shall be solely responsible for payments of such fees and expenses to the certifying body.

A surveillance audit is expected to take 0.5 day and a fee of \$400 to \$600 is recommended by AFIA. However, a certifying body may determine more time is needed and a higher audit fee is required. As with an on-site audit, certifying body shall communicate surveillance audit fees prior to scheduling the surveillance audit. The certifying body shall invoice the facility audited directly for the surveillance audit fees plus reasonable travel expenses, if any. The facilities shall be solely responsible for payments of such fees and expenses to the certifying body.

SECTION 3.0 Implementation Process

To achieve FSC36 Safe Feed/Safe Food certification, the supplier must document and implement the relevant clauses described within the guidance document (see Section 5). It is also important to provide evidence of the supplier's quality and food safety system in the form of documents and records, which may be electronic (paper documents are not required). The implementation process is shown below.

- **Document** – Prepare policies, procedures, work instructions and specifications that address the relevant clauses of the FSC36 guidance document Version 7.0. In other words, “*Say what you do.*”
- **Implement** – Put into place the prepared policies, procedures, work instructions and specifications. In other words, “*Do what you say.*”
- **Provide Records** – Keep records to demonstrate compliance to the relevant clauses of the FSC36 guidance document. These records provide evidence of the function and control of the system. In other words, “*Prove it.*”



SECTION 4.0 Introduction to this Guide

4.1 Purpose and Scope of this Guide

The purpose of this document is to assist suppliers with designing, developing, documenting, implementing and maintaining compliance with the FSC36 Safe Feed/Safe Food requirements.

The relevant version number is identified in the document footer. Terms used in this document are defined in Appendix A: Glossary of the FSC36 Guidance Document Version 7.0.

This particular guide covers the requirements for FSC36 Safe Feed/Safe Food certification. It includes Current Good Manufacturing Practices (CGMPs) for animal food production as well as the requirements for an effective animal food safety program.

4.2 The Structure of the FSC36 Safe Feed/Safe Food Requirements

It is the intent of the FSC36 Safe Feed/Safe Food program to support the requirements outlined in the Food Safety Modernization Act (FSMA) as well as help drive continuous improvement of a supplier's quality and food safety program.

While the FSC36 certification does not require Hazard Analysis and Critical Control Points (HACCP) certification, the principles of HACCP are utilized to implement an effective food safety plan.

The requirements for FSC36 Safe Feed/Safe Food support a risk-based management system that is documented and implemented by a supplier of animal food or feed-related products to control food safety. The program includes:

- Commitment by site management to maintain a safe, quality animal food supply

- Hazard analysis and preventive controls that identify and control known or reasonably foreseeable hazards
- A food safety program that identifies known or reasonably foreseeable hazards and defines how such hazards are minimized, mitigated or controlled
- Product traceability and recall
- Control of contamination, particularly from high-risk materials, such as medications
- Staff training requirements

It is recognized that not all clauses of FSC36 Safe Feed/Safe Food are applicable to all feed or ingredient production facilities. Some clauses can be exempted if they are not relevant or mandatory. The supplier shall submit a written request to the certification body prior to the audit, to exclude that clause(s).

4.3 Format of Guidance Information

The requirements for compliance with FSC36 Safe Feed/Safe Food are described in section 5 of this document. There are 83 clauses that provide the requirements a supplier needs to develop, document or implement in order to receive certification. The auditor will use this same information to assess compliance of the supplier. An on-site audit checklist is available on the AFIA website for suppliers to assess its readiness.

In addition to providing the requirements for compliance, information is provided to help suppliers with implementation and help auditors with facility assessment for compliance.

Several clauses are noted as mandatory and cannot be reported as “not applicable” or “exempt.” These clauses must be audited and compliance status reported. Mandatory clauses are designated with an “(M)” after the clause name in section 5. A list of mandatory clauses is shown in section 2.4.

SECTION 5.0 Requirements for FSC36 Safe Feed/Safe Food

The requirements for FSC36 Safe Feed/Safe Food certification are described below.

The requirements for FSC36 Safe Feed/Safe Food support a risk-based management system that is documented and implemented by a supplier of animal food or feed-related products to control food safety.

Animal food and feed materials intended for consumption by animals should be produced, processed and handled in a safe manner. In order to accomplish this, feed processing premises are designed to facilitate proper processing, handling and storage of product. The guidance document for FSC36 Safe Feed/Safe Food provides an outline for the guidance on various aspects of manufacturing processes to assist in understanding various requirements. Many of the requirements for FSMA have been incorporated into the FSC36 Safe Feed/Safe Food guidance document. However, the supplier should review the FSMA requirements for animal food to ensure it complies with the regulation.

SF/SF 1 MANAGEMENT COMMITMENT AND RESPONSIBILITY

SF/SF 1.1 Management Policy (M)

- 1) Senior management shall prepare and implement a quality and food safety policy. The statement should consider the following items:
 - a) The organization’s commitment to provide quality and safe feed.

- b) The methods used to comply with its customer and regulatory requirements.
 - c) The organization's commitment to continuous improvement of its quality and food safety system.
 - d) The organization's commitment to establish and review animal food safety objectives.
- 2) The policy statement shall be signed by senior management and made available in a language understood by all staff. The policy statement should be displayed in a prominent position and effectively communicated to all staff.

Implementation Guidance

The purpose of the policy is to allow senior management to demonstrate its commitment to quality and food safety. This does not need to be a long, elaborate or complex document. The intent is to allow senior management to demonstrate its commitment to the quality and food safety processes.

An example policy is shown below:

"The ABC Feed Company is committed to providing safe, quality products to the industry that meet our customers' expectations as well as all regulatory requirements. We will accomplish this goal through:

- Excellent customer service
- A commitment to employee education and training
- Programs and processes that support regulatory compliance

For every employee, we say "Quality begins with me!"

The policy should be signed and dated by at least one senior management person. If possible, the policy should be posted for easy review by personnel.

Some companies may decide to develop more extensive quality and food safety policies. Senior management may elect to develop a quality and food safety policy that clearly demonstrates their commitment to the animal food safety system under the FSC36 Safe Feed/Safe Food program, and outline how the organization will achieve and maintain animal food safety. Within FSMA, management is responsible for the implementation of CGMPs.

In order to keep pace with changes in company policy, the quality and food safety policy must be reviewed at least annually by management. This review is normally done during a management review session.

The policy statement must be displayed in a location so all employees and visitors are aware of the supplier's policies. Multiple copies may be displayed, but they must be current and the same. Further, if your labor forces include employees who do not understand the native language of your country, you must post the policy statement in all additional languages which ensure that every employee may understand the quality and food safety policy.

SF/SF 1.2 Management Responsibility (M)

- 1) The supplier shall provide an organizational reporting structure, which includes personnel with responsibilities for quality and food safety.
- 2) Senior management shall ensure adequate resources are available to achieve the desired animal food safety objectives and support the development, implementation, maintenance and ongoing improvement of the quality and food safety system.

Implementation Guidance

An organizational reporting structure with key personnel listed is required. Positions with responsibility for quality and food safety shall be listed. This includes personnel, such as shift supervisors, that may be responsible for verification of records.

It is recommended that the organizational reporting structure be reviewed and approved by a member of senior management. The document should provide a snapshot of how key roles interact and share responsibility for quality and food safety.

The supplier should demonstrate that an environment exists in which employees are encouraged to report quality and food safety problems, if detected.

SF/SF 1.3 Responsibility, Authority and Communication (M)

- 1) Senior management shall designate a quality and food safety leader (Q&FS Leader) for manufacturing location or site implementing the requirements for FSC36 certification. The Q&FS Leader shall be a Preventive Controls Qualified Individual (PCQI).
- 2) The Q&FS Leader will be responsible for the development, implementation, review and maintenance of the quality and food safety system.
- 3) The Q&FS Leader shall be employed by the supplier as a company employee on a full-time basis and understand the FSC36 requirements relevant to the supplier's scope for FSC36 certification.
- 4) Personnel shall be informed of their responsibility for quality and food safety.
- 5) Personnel shall be informed of their responsibility to report animal food safety problems to personnel with authority to initiate action.

Implementation Guidance

Senior management, or management leader(s) at the supplier's location, is responsible for designating a person as the Q&FS Leader for the quality and food safety system for the site. The person should have authority to help drive the quality and food safety system throughout the location. This responsibility is often listed within the person's job description.

In addition, the Q&FS Leader should be a member of the animal food safety team.

The Q&FS Leader is required to be a PCQI. While this individual is not required to attend a FSCPA Preventive Controls for Animal Food course, it is highly recommended as this person will be highly involved with the food safety plan.

Senior management may use a consultant to support development of processes for compliance with FSC36 requirements. However, this person cannot be designated the Q&FS Leader for the site.

There should be documented instruction for staff to report quality and food safety problems to personnel with authority.

SF/SF 1.4 Management Review

SF/SF 1.4.1 Management Review Process

- 1) Senior management shall be responsible for reviewing the quality and food safety system.
- 2) Any changes to the food safety plan shall be reviewed during management review meetings.
- 3) The management shall establish processes for continuous improvement of the quality and food safety program.
- 4) A documented procedure shall be maintained that describes management review.

Implementation Guidance

Senior management should ensure that the entire quality and food safety program is reviewed annually. A written procedure should be maintained that outlines the process for management review including the frequency, information reviewed and responsibilities for actions to be taken.

The intent of the review is to provide direction for improvements to the program, including resources and changes. Reviews should include the quality and food safety policy, internal and external audit findings, corrective actions with their investigations and resolution, customer complaints with their resolution and investigation, as needed. Minutes of the meeting should be taken and kept as a record of the review. In addition, any follow up items should be maintained.

NOTE: The review of the entire quality and food safety program does not need to be completed at one meeting. The annual review may be divided into sections over defined periods, such as quarterly or monthly meetings.

SF/SF 1.4.2 Management Reviews Inputs and Outputs

- 1) Senior management review of inputs shall include information about the quality management system effectiveness. This may include (but not limited to) the following:
 - a) Customer complaints or customer satisfaction
 - b) Failures in the quality and food safety program
 - c) Nonconformities identified from audits (internal and external) completed since last meeting
 - d) Corrective actions taken for continuous improvement
 - e) Changes within processes or at the location that may impact product quality and food safety
 - f) Changes to the animal food safety program
 - g) Regulatory changes that may impact the quality and food safety program
 - h) Industry news or activities relevant to the quality and food safety program
- 2) Senior management is required to assess the effectiveness of the quality management system. This shall include (but not limited to) the following:
 - a) Recommendations to improve customer service or satisfaction
 - b) Continuous improvement to the quality and food safety system
 - c) Resources to implement an effective quality and food safety program and desired outcomes

- d) Review and modification to the quality policy as necessary

Implementation Guidance
<p>When completing a management review of the quality and food safety program, documents that should be considered include any document that might highlight deficiencies in the system, such as, customer complaint records, corrective action reports, internal and external audit reports and deviations from process control reports. Also, information that demonstrates the effectiveness or efficiencies of processes may be used during a management review.</p> <p>FSMA requires the PCQI to review preventive control implementation and effectiveness. This information should be shared during a management review, if preventive controls are maintained as described within FSMA.</p> <p>Major changes to a process, a process control or any change that could impact the ability of the system to deliver a safe quality food, may trigger a review of the food safety plan in addition to the annual review. These changes should be reviewed during the management review meetings.</p> <p>NOTE: The review of the entire program does not need to be completed at one meeting. The annual review may be divided into section over defined periods, such as quarterly or monthly meetings.</p>

SF/SF 1.4.3 Management Review Records

- 1) Records of management reviews shall be maintained.
- 2) Information shared during a management review shall be kept with the management review records.

Implementation Guidance
<p>Maintain records from management review. Records should be easily accessible and understandable. This should include a summary or minutes from the meeting with desired outputs or actions to be taken for continuous improvement.</p>

SF/SF 2 QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

SF/SF 2.1 General Requirements

- 1) The supplier shall establish, document, implement and maintain a quality and food safety system and continually improve its effectiveness.
- 2) The supplier shall establish and maintain a quality and food safety manual that includes:
 - a) The scope of the quality and food safety system, including exclusions from the FSC36 Safe Feed/Safe Food Certification Program.
 - b) Documented procedures that have been established for the quality and food safety system.
- 3) The supplier shall determine the processes needed for the quality and food safety system and their application throughout the organization.
- 4) Policies that impact the quality and food safety system shall be documented within the manual and maintained in either electronic and/or hard copy form.

- 5) The manual shall be readily available to personnel.

Implementation Guidance

The supplier's quality and food safety program includes the development of procedures and processes to ensure the desired level of quality and food safety is obtained. The documentation for the program should be organized and maintained within the quality and food safety manual.

Documentation within a quality and food safety manual may include a listing or description of company policies that provides direction to personnel and describes the commitment by top management and the company for quality and food safety. Quality and food safety policies may include descriptions of the following:

- a) Management commitment
- b) Management review
- c) Scope of the quality and food safety system and FSC36 certification
- d) Processes critical to ensuring the quality and food safety of products
- e) Animal food safety plan and processes to implement

The manual may include (but not limited to) the following:

- a) Quality and food safety policy statement
- b) Organization chart
- c) Quality and food safety policies implemented by the location
- d) A description of how the animal food safety plan will be achieved or maintained
- e) The scope of the certification and a list of the products covered
- f) Processes and procedures that ensure the implementation of the quality and food safety policies

SF/SF 2.2 Document Control (M)

- 1) The methods and responsibility for maintaining document control shall be maintained.
- 2) The supplier shall ensure personnel has access to current documents that impact their ability to complete their work.
- 3) Proper training for document control shall be completed to ensure records are accurate, indelible, and legible.

Implementation Guidance

To comply with this requirement, the supplier must establish a written procedure describing how personnel maintain, update and replace documents. The procedure must specify who is responsible for document control and assures documents are updated and securely stored.

Examples of documents that should be controlled are SOPs, work instructions, owner manuals for equipment, and raw material and finished product specifications. It is important the procedure include training requirements for personnel. Employees should have access to documents that impact their job responsibilities.

SF/SF 2.3 Records (M)

- 1) Records obtained by FDA in accordance with the record requirements for FSMA are subject to the disclosure requirements by FDA.
- 2) All records required by FSMA must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.
- 3) Records for FSMA compliance must:
 - a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
 - b) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;
 - c) Be accurate, indelible, and legible;
 - d) Be created concurrently with performance of the activity documented; and
 - e) Be as detailed as necessary to provide history of work performed.
- 4) All records must include:
 - a) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);
 - b) The date and, when appropriate, the time of the activity documented;
 - c) The signature or initials of the person performing the activity; and
 - d) Where appropriate, the identity of the product and the lot code, if any.
- 5) Records that are established or maintained to satisfy the requirements of FSMA may be maintained in an electronic format.
- 6) All records required by FSMA must be retained at the plant or facility for at least 2 years after the date they were prepared.
- 7) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (FSMA 507.31) or records that document validation of the written food safety plan (FSMA 507.45(b))).
- 8) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.
- 9) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.
- 10) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

- 11) The information required for FSMA do not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Implementation Guidance

FSMA maintains specific requirements for records (FSMA Subpart F). Most records for FSMA compliance are related to Subpart C Hazard Analysis and Risk-Based Preventive Controls.

Specific requirements for records for the food safety plan are discussed in clause 9.2 Records for the Food Safety Plan.

A written procedure for maintaining records is needed to help a personnel understand the requirements for records.

Records should be maintained as appropriate for products or materials manufactured or stored (warehouse). Products or materials with specific record requirements include bovine spongiform encephalopathy (BSE) feed rule, medicated feeds, formula/mixing instructions, production records, drug assays and label files.

Electronic records are acceptable. The supplier must have the means to manage electronic security of records, electronic signatures of monitors and reviewers, and the means for electronic review.

Records under two years are acceptable provided that the designated program has been implemented less than two years.

SF/SF 3 FSMA CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

The supplier shall ensure that it complies with CGMP requirements for FSMA animal food rule, which are described below. Other clauses within the guidance document may address similar requirements.

SF/SF 3.1 Personnel

- 1) The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food.
- 2) The methods for conforming to hygienic practices and maintaining cleanliness include:
 - a) Maintaining adequate personal cleanliness
 - b) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination
 - c) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers
 - d) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned
 - e) Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food packaging materials

Implementation Guidance

Senior management is responsible for ensuring personnel understand and are properly trained to manufacture safe animal food. This can be demonstrated through a properly organized quality and food safety system, which includes quality and food safety policy, documented procedures, personnel training, job descriptions, and management review as well as the other requirements outlined within the FSC36 Safe Feed/Safe Food guidance document.

SF/SF 3.2 Plant and Grounds

SF/SF 3.2.1 Facility Grounds

- 1) The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food.
- 2) Maintenance of grounds must include:
 - a) Properly storing equipment
 - b) Litter and waste removal
 - c) Cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests
 - d) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed
 - e) Adequately draining areas that may contribute to contamination of animal food
 - f) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed
- 3) Loading and unloading areas shall be maintained so as not to present a hazard to the animal food safety operation of the premises.
- 4) Perimeter of facility, when possible, should be fenced for biosecurity purposes. Access to the facility shall be controlled for animal food safety purposes.

Implementation Guidance

FSMA animal food rule provides specific requirements for maintaining grounds around a facility or site. Documented procedures help personnel understand the expectations of senior management. While records are not required by FMSA for CGMP implementation, records may be useful by site management to ensure practices are implemented.

SF/SF 3.2.2 Facility Structure

- 1) The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food packaging materials.
- 2) The facility must provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment.
- 3) The facility must be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination.
- 4) The facility must provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (e.g., steam) and fumes in areas where they may contaminate animal food and in a manner, that minimizes the potential for contaminating animal food.
- 5) The facility must provide adequate lighting in handwashing areas, toilet rooms, areas where animal food is received, manufactured, processed, packed, or held, and areas where equipment or utensils are cleaned.
- 6) The facility must provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.

Implementation Guidance

The purpose of CGMPs for facility structure is to ensure the safety of animal food or products that are manufactured by the facility. Written procedures would help personnel understand management's expectations for compliance with FSMA requirements.

SF/SF 3.2.3 Outside Storage

The facility must protect animal food stored outdoors in bulk from contamination by any effective means, including:

- 1) Using protective coverings where necessary and appropriate;
- 2) Controlling areas over and around the bulk animal food to eliminate harborage for pests;
- 3) Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.

Implementation Guidance

FSMA requirements for outside storage of ingredients are specific for suppliers that implement such practices (FSMA 507.17(c)). This clause will not apply to many suppliers seeking FSC36 certification.

SF/SF 3.3 Sanitation

- 1) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated.
- 2) Animal food-contact and noncontact surfaces of utensils (tools) and equipment must be cleaned and maintained and utensils (tools) and equipment stored as necessary to protect against the contamination

of animal food, animal food-contact surfaces, or animal food packaging materials. When necessary, equipment must be disassembled for thorough cleaning. In addition:

- a) When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and
 - b) In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.
- 3) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.
- 4) The following applies to toxic materials:
- a) Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:
 - (i) Those required to maintain clean and sanitary conditions;
 - (ii) Those necessary for use in laboratory testing procedures;
 - (iii) Those necessary for plant and equipment maintenance and operation; and
 - (iv) Those necessary for use in the plant's operations.
 - b) Toxic materials such as cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and
 - c) Other toxic materials (such as fertilizers and pesticides) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.
- 5) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food packaging materials.
- 6) Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests.

Implementation Guidance

FSMA animal food rule provides specific requirements for housekeeping and sanitation as CGMP requirements (FSMA 507.19 (c)). Many of these requirements are covered within 5.4 Cleaning and Housekeeping. However, the supplier should ensure these FSMA requirements are implemented if not listed within clause 5.4. Many of the requirements within clause 3.3 pertain specifically to facilities controlling microbiological hazards.

SF/SF 3.4 Water Supply and Plumbing

- 1) The following apply to the water supply (FSMA requirement):
 - a) Water must be adequate for the operations and must be derived from an adequate source;
 - b) Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils (tools), and animal food-packaging materials, or for employee hand-washing facilities;
 - c) Water that contacts animal food, animal food-contact surfaces, or animal food packaging materials must be safe for its intended use; and
 - d) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.
- 2) Plumbing must be designed, installed, and maintained to (FSMA requirement):
 - a) Carry adequate quantities of water to required locations throughout the plant;
 - b) Properly convey sewage and liquid disposable waste from the plant;
 - c) Avoid being a source of contamination to animal food, water supplies, equipment, or utensils (tools), or creating an unsanitary condition;
 - d) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
 - e) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.
- 3) Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.
- 4) A facility must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.
- 5) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food contact surfaces, or animal food-packaging materials.

Implementation Guidance

FSMA animal food rule provides specific requirements for water supply and plumbing as CGMP requirements (FSMA 507.20). Documented procedures help personnel understand the expectations of management. While records are not required by FMSA for CGMP implementation, records may be useful by management to ensure practices are implemented. Many of the requirements above may be documented within a preventive maintenance program.

SF/SF 3.5 Equipment and Utensils (Tools)

- 1) The following apply to plant equipment and utensils (tools) used in manufacturing, processing, packing, and holding animal food:
 - a) All plant equipment and utensils (tools), including equipment and utensils (tools) that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;
 - b) Equipment and utensils (tools) must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;
 - c) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;
 - d) Animal food-contact surfaces must be:
 - i. Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;
 - ii. Made of nontoxic materials; and
 - iii. Maintained to protect animal food from being contaminated.
- 2) Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food.
- 3) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device.
- 4) Instruments and controls used for measuring, regulating, or recording temperatures, pH, Aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.
- 5) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food.

Implementation Guidance

FSMA animal food rule provides specific requirements for ensuring equipment and utensils (tools) are cleanable, durable, and appropriate for the use intended (FSMA 507.22). The purpose is to ensure that equipment and utensils (tools) do not create food safety risks. Some of the requirements may not be applicable to a supplier due to the lack of freezers or compressed air.

SF/SF 3.6 Facility Operations

- 1) Management of the establishment must ensure that:
 - a) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements as described with FSMA animal food rule;

- b) Animal food, including raw materials, other ingredients, or rework is accurately identified;
 - c) Animal food-packaging materials are safe and suitable;
 - d) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;
 - e) Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;
 - f) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;
 - g) Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and
 - h) All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.
- 2) Raw materials and other ingredients:
- a) Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration.
 - b) In addition:
 - (i) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;
 - (ii) Raw materials must be cleaned as necessary to minimize contamination; and
 - (iii) Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;
 - c) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans;
 - d) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.
- 3) For the purposes of manufacturing, processing, packing, and holding operations, the following apply:
- a) Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;
 - b) Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (e.g., heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling A_w) must be adequate to prevent adulteration of animal food;

- c) Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;
- d) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;
- e) Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;
- f) Animal food that relies principally on the control of water activity (A_w) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe a_w level;
- g) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH;
- h) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in FSMA animal food rule.

Implementation Guidance

FSMA animal food rule provides CGMP requirements across a broad range of areas within plant operations (FSMA 507.22). Many of the requirements are covered in other clauses within the FSC36 guidance document, e.g., 5 Infrastructure, 6 Product Realization, 7 Purchasing Processes & Controls.

SF/SF 3.7 Holding and Distribution

- 1) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:
 - a) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and
 - b) Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.
- 2) The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the animal food product for the intended animal species.
- 3) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food.
- 4) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.
- 5) Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food.
- 6) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

- a) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
 - b) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
 - c) During holding, human food by-products for use as animal food must be accurately identified.
- 7) Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed.
 - 8) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Implementation Guidance

FSMA animal food rule provides CGMP requirements holding and distribution of animal food as well as human food (FSMA 507.27). The intent is to ensure animal food is properly identified, handled, and stored to prevent or protect against contamination. FSMA requirements for holding and distribution of human food for use or distribution for animal food (FSMA 507.28) are covered in item 6 above. Many of the requirements are covered in other clauses within the FSC36 guidance document, e.g., 5 Infrastructure, 6 Product Realization, and 7 Purchasing Processes & Controls.

SF/SF 4 PERSONNEL AND TRAINING

SF/SF 4.1 Competency, Training and Job Descriptions (M)

- 1) The supplier shall ensure that all individuals who manufacture, process, pack, or hold animal food are qualified individuals (QI) as defined within FSMA.
- 2) The supplier shall ensure that supervisory personnel have the appropriate education, training and experience to supervise the production of safe animal food.
- 3) The supplier shall ensure that personnel receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties. Records of such training are required.
- 4) The supplier shall describe competencies for personnel within job descriptions.
- 5) The supplier shall maintain a training program to ensure personnel are trained and competent. Records of training shall be maintained.
- 6) Where contractors are utilized, the supplier shall provide competency expectations to the approved vendor providing the services or work.
- 7) The supplier shall ensure that temporary workers are qualified individuals.
- 8) The supplier shall maintain adequate records of education, skills and experience of personnel.

Implementation Guidance

FSMA specifically requires that all individuals who manufacture, process, pack, or hold animal food be “qualified individuals” which means persons that have education, training, or experience (or combination thereof) necessary to complete their assigned duties (507.4(a)).

FSMA specifically requires training of all individuals who manufacture, process, pack, or hold animal food in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual’s assigned duties. This includes temporary workers. Records of such training shall be maintained for a minimum of two years (507.4(b and d)).

Thus, management should ensure that appropriate information and training is provided to personnel.

The supplier should establish a job description for each position and include the desired competencies for the responsibilities of the person. The supplier should maintain records of the training completed by personnel and competencies maintained.

Personnel need to understand their responsibility for ensuring the quality and safety of products produced. This may be accomplished through job descriptions. The management team needs to demonstrate its commitment to training personnel to ensure their competency to accomplish the desired expectations. This may include seminars, online training sessions, certifications or internal training programs.

FSMA requires the management of a facility to ensure that reasonable measures and precautions are taken to ensure that all personnel that work with animal food (or have contact with animal food components) conform to hygienic practices to protect against the contamination of animal food. Methods for conforming to hygienic practices and maintaining cleanliness include:

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;
- Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;
- Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and
- Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food packaging materials.

A supplier should maintain a written procedure or policy for personnel guidance in regards to hygienic practices.

Job descriptions should be maintained for each position within the facility. The job description should include key responsibilities for the position and requirements to ensure products are manufactured safely.

It is recommended that the supplier maintain a written procedure that describes the facility’s training program. An employee training program may include (but not limited to) the following:

- a) Training schedule for topics that impact the quality and food safety program.
- b) Key personnel responsible for managing the training schedule and process to ensure

training is completed timely, such as the human resources department.

- c) Training requirements for positions with responsibilities that impact the quality and food safety program.
- d) Training needs or competencies for positions impacting quality and food safety.
- e) Training on the principles of animal food hygiene and animal food safety relative to the facility and personnel.

The competency expectations of personnel completing work needs to be communicated to approved vendors providing the work or services (contractors) to ensure the vendor understands the supplier's requirements in regards to animal food safety.

SF/SF 4.2 Requirements for a Preventive Controls Qualified Individual (PCQI) (M)

- 1) One or more PCQI must do or oversee the following:
 - a) Preparation of the food safety plan (§ 507.31(b));
 - b) Validation of the preventive controls (§ 507.47(b)(1));
 - c) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;
 - d) Determination that validation is not required (§ 507.47(c)(4));
 - e) Review of records (§ 507.49(a)(4));
 - f) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7-working days;
 - g) Reanalysis of the food safety plan (§ 507.50(d)); and
 - h) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.
- 2) To be a PCQI, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.
- 3) A PCQI may be, but is not required to be, an employee of the facility.
- 4) The supplier shall maintain records of applicable training in the development and application of risk-based preventive controls, including the date of the training, the type of training, and the person(s) trained.

Implementation Guidance

The Q&FS Leader is required to be a PCQI; however, there may be more than one PCQI at a supplier. FSMA has specific requirements to be completed by personnel that are designated a PCQI (FSMA 507.53). The supplier should ensure that personnel that are PCQIs are trained and understand their responsibilities within this role. Training records are required. Although a person is not required to attend FSPCA Preventive Controls for Animal Food training, it is highly recommended.

SF/SF 4.3 Personnel Policies and Behavior

- 1) Personnel shall maintain proper hygiene relative to the employee's work area in order to ensure the safety of animal foods.
- 2) Personnel hygiene requirements shall be consistent with a biosecurity program to prevent the potential spread of disease or compromise the animal food safety plan.
The supplier shall maintain a policy for personnel behavior.
- 3) Fluids provided for consumption in the manufacturing or storage areas shall be controlled to prevent the potential for contamination.
- 4) Personnel shall be provided adequate facilities for cleaning to prevent the potential contamination of animal foods.
- 5) Clothing worn by staff engaged in handling animal food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products. Clothing shall be appropriate for the work area.
- 6) Personnel shall be trained on the required hygiene and personnel policies to ensure the biosecurity of the facility and safety of animal foods.

Implementation Guidance

Employees must be aware of risks to animal food products from the potential transmission of pathogens. Examples of potential pathogens are 1) Porcine Epidemic Diarrhea Virus (PEDV) and its spread to swine farms; or 2) salmonella into finished pet food. Personnel should understand the impact of personal hygiene of the food safety. This includes (but not limited to):

- Clothing and personal apparel.
- Shoes worn inside and outside of the facility.
- Dirt or filth that may be carried into the work area.

The supplier shall maintain a written procedure or policies for personnel behavior that includes (but not limited to):

- Permission for smoking, eating and chewing (e.g., gum, tobacco) in designated areas.
- Control measures to avoid hazards from jewelry.
- Permission of personal items (e.g., cell phones, smoking materials, medicines, etc.) in designated areas only.
- Maintenance of personal lockers so they are kept free of rubbish and soiled clothing.

The written procedure or policies should provide employees with guidance and requirements to prevent the spread of disease or potential physical contamination. Employees must be aware of the risks from physical contamination from jewelry or other items, such as cell phones, carried within a manufacturing facility.

SF/SF 4.4 Personnel Facilities

- 1) Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as needed.
- 2) Lunch room facilities shall be available for personnel that are kept clean and suitable to food consumption.
- 3) The supplier must provide employees with adequate, readily accessible toilet facilities.
- 4) The supplier must provide adequate handwashing facilities to prevent contamination of animal food.
- 5) First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.

Implementation Guidance

Designated areas for personnel to change clothing and prepare for entry in to and out of the facility are needed. A clean lunchroom area should be provided as well in order to maintain the safety of animal foods. The dining area should be kept clean and free from waste materials and pests, properly ventilated with adequate lighting and appropriate tables and seating.

The supplier should provide facilities and surroundings for employees to store personal items as well as shower or clean, as needed. The number of showers, toilets and basins should be based on the maximum number of staff likely to use the facilities at one time, as appropriate.

Sufficient restrooms/toilets are required within FSMA and should accommodate the number of staff. Toilets should be easy to clean and kept clean. Such facilities should be clean and maintained in good condition.

Lunchroom facilities should provide personnel with a clean dining area that prevents the risk of contamination of animal food. Designated lunchrooms must therefore be available for staff to take breaks and eat meals that are physically separated from animal food handling areas.

First aid facilities should be available and equipped with sufficient items to treat minor injuries.

SF/SF 4.5 Visitors

- 1) All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any animal food processing or handling area.
- 2) All visitors shall be required to follow the personnel behavior policies.
- 3) Visitors shall be aware of the biosecurity requirements to prevent the contamination of animal foods or feed ingredients, as directed by the facility.
- 4) Visitors shall enter and exit animal food handling areas through the proper staff entrance points and comply with all personnel hygiene requirements.

- 5) Visitors shall sign in and out of facilities for biosecurity and personnel safety reasons.
- 6) Visitors shall be made aware of any policies, practices or requirements, where applicable, that ensures the quality and food safety program, animal food safety plan and personnel safety requirements.

Implementation Guidance
<p>Visitors represent a potential risk to animal food safety and shall follow the same requirements when visiting the supplier as company personnel.</p> <p>Visitors should dress appropriately, including footwear, during a facility visit. Only invited guests should be allowed in to controlled areas. As an example, truck drivers should remain in restricted areas, unless otherwise approved.</p> <p>If needed, training of visitors should be completed and documented.</p> <p>Documentation of visitors should be maintained.</p>

SF/SF 5 INFRASTRUCTURE

SF/SF 5.1 Maintenance

- 1) The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and carried out in a manner that minimizes the risk of product, packaging or equipment contamination.
- 2) Maintenance staff and contractors shall observe the following practices when undertaking maintenance and repairs in any feed processing, handling or storage area:
 - a) Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded.
 - b) Failures of equipment shall be documented, reviewed and their repair incorporated into the maintenance control schedule, as needed.
 - c) Maintenance staff and contractors shall ensure materials or finished products are not contaminated during maintenance activities or pose a risk to animal food safety.
 - d) Ensure facility supervisors are notified when maintenance or repairs are to be undertaken in any feed handling area.
 - e) Inform the maintenance supervisor and the facility supervisor if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings and loose overhead fittings); when possible, maintenance is to be conducted outside processing times.
 - f) Remove all tools and debris from any maintenance activity area once it has been completed; inform the area supervisor and maintenance supervisor so appropriate cleaning and inspection can be completed prior to the commencement of facility operations.
- 3) The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.
- 4) Lubricants shall be fit for purpose, meet regulatory requirements and be food/feed grade where there is potential of direct contact with animal food.

- 5) Paint used in an animal food handling or contact zone shall be suitable for use and in good condition; paint shall not be used on any product contact surface.

Implementation Guidance

Maintenance procedures must be carefully planned, designed, documented and implemented to avoid contamination of product, materials or equipment and to ensure that maintenance staff, including contractors, have an understanding of the safety and quality implications of maintenance activities.

The procedures must describe the practices under which repairs are to be completed in any product handling or storage areas including the following of requirements that maintenance staff must observe:

- Maintenance of equipment or building structures must be completed in a manner that does not pose a risk to the product, materials (including packaging materials) or equipment
- The maintenance supervisors must ensure they are notified by all contractors engaged to complete work in any product handling areas
- They must ensure that all service contractors are aware of the supplier's personnel hygiene requirements and that they are provided with any necessary protective clothing or that protective clothing meets the same requirements as those of the supplier staff
- Maintenance staff and service contractors must ensure that they account for and remove all tools and debris from any maintenance activity once it has been completed in any product handling area and inform the area supervisor so appropriate sanitation can be completed
- Service contractors are to inform the maintenance supervisor if any required work poses a potential threat to product, packaging or equipment safety (i.e. pieces of electrical wire, damaged light fittings, loose fittings overhead, etc.)
- Maintenance should be conducted outside of the processing times. When maintenance is conducted during processing times, action needs to be taken to prevent contamination of the product.
- When necessary, maintenance must be conducted outside of processing times; service contractors shall notify the maintenance supervisor in the event of any breakage or damage that could expose products, packaging or equipment to contamination.
- Service contractors must notify the maintenance supervisor when work has been completed
- Plant supervisors and operators must ensure appropriate and effective clean-up measures are taken once all maintenance or service contractor activity is completed and prior to the commencement of plant operations.
- Review where food and non-food lubricants are being used and ensure that appropriate pre-requisite programs are in place to prevent cross-contamination.

SF/SF 5.2 Lighting and Work Areas

- 1) Lighting in manufacturing or handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.
- 2) Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or

fitted with protective covers as to minimize a risk for contamination.

- 3) A suitable area with sufficient lighting shall be provided for the inspection of the product if required.
- 4) Adequate ventilation shall be provided in enclosed manufacturing and animal food handling areas.
- 5) Work areas are suitable for personnel to complete required activities.

Implementation Guidance

Lighting shall provide minimum lux (foot candle) intensity to meet good manufacturing best practices appropriate to the commodity being processed.

Light fittings in feed processing and handling areas are required to be fitted with protective covers or have shatterproof lights installed. An acceptable practice is to recess the light into the ceiling, where possible or have it fitted flush to the ceiling. Where light fittings are not able to be recessed, they must be protected from accidental damage. In circumstances where light fittings are suspended from cables, the top of the fitting needs to be sloped at an angle that permits easy cleaning. Exposed light fittings should be included in a cleaning schedule.

Inspection areas shall be provided when inspection is required for the commodity being processed to preclude potential contamination of the processing line and other products. Lighting intensity should be adequate for product inspection areas. Equipment used at the inspection station shall not pose a threat to the product. The inspection area should provide adequate area for personnel to complete the required work and maintain a safe work area without the potential risk for contamination.

Positive air pressure should be maintained in high-risk processing areas, such as pet food manufacturing, to prevent airborne contaminants being drawn into the area. Ventilation in enclosed feed processing areas must meet applicable design and construction legislation and prevent condensation over feed and surfaces of feed contact equipment, where applicable. Vents and exhausts must be screened to prevent ingress of flying insects.

SF/SF 5.3 Pest Management and Control

SF/SF 5.3.1 Pest Management (M)

- 1) The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.
- 2) The pest and vermin management program shall:
 - a) Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program.
 - b) Identify the target pests for each pesticide application.
 - c) Outline the methods used to prevent and/or eliminate pest problems.
 - d) Outline the frequency with which pest status is to be checked.
 - e) Include on a site map the identification, location, number and type of bait stations set.
 - f) List the chemicals used.
 - g) Outline the requirements for staff awareness and training for the pest management program.

- h) Measure the effectiveness of the program to verify the elimination of applicable pests.
- 3) Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison shall not be used inside ingredient or animal food storage areas or processing areas.
- 4) Records of pest control applications shall be maintained.

Implementation Guidance
<p>The supplier should maintain a documented pest management program that identifies the known pests and integrates a number of preventative and control measures.</p> <p>The pest management program shall describe the development, implementation and maintenance of the pest management plan, including the target pests, prevention methods, frequency to check for pest status, a site map of locations and types of bait stations, list of chemicals and their safety data sheet, staff awareness and training of pest control measures, and what to do when they come in contact with a bait station. The program shall also measure the effectiveness of the program.</p> <p>The supplier shall maintain records of all pest control applications.</p>

SF/SF 5.3.2 Pest Control Chemicals (M)

- 1) Pesticides and other toxic chemicals shall be clearly labeled, stored, handled and applied by properly trained personnel.
- 2) They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of feed and feed contact surfaces.
- 3) The supplier shall ensure unused pest control chemicals and empty containers are disposed in compliance with regulatory requirements.

Implementation Guidance
<p>The pesticide and other toxic chemicals should be handled in accordance with the safety data sheets. Processes to ensure the safety of animal food should be followed in regards to handling these chemicals and chemical containers.</p> <p>Unused or empty pest control containers shall be disposed of in accordance with regulatory requirements, are not reused, are labeled and securely stored while awaiting collection or proper disposal.</p>

SF/SF 5.3.3 Pest Management Personnel

- 1) Pest control contractors shall be licensed and approved by the local relevant authority. If a pest control contractor is not used, company personnel shall be licensed and approved by local relevant authority.
- 2) Pest control contractors, or properly licensed personnel, shall:
 - a) Use only trained and qualified operators who comply with regulatory requirements
 - b) Use only approved chemicals

- c) Provide a pest control management plan which will include a site map indicating the location of bait stations and traps
- d) Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments
- e) Provide a written report of their findings and the inspections and treatments applied

Implementation Guidance
<p>Pest control contractors shall be trained, licensed and approved. A pest control management plan shall be provided including a site map indicating locations of the bait stations and traps. Contractors must check in with responsible person upon entering the premise and report back, with a written report, after completion of the inspection or treatments.</p>

SF/SF 5.4 Cleaning and Housekeeping (M)

- 1) The procedures and responsibility for the cleaning and housekeeping of animal food handling and processing equipment and environment, storage areas and staff amenities shall be documented and implemented.
- 2) A housekeeping program shall be outlined to ensure the facility, equipment and grounds are maintained appropriately to minimize the potential of contamination.
- 3) If warranted, a suitably equipped area shall be designated for cleaning tools or equipment. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product.
- 4) The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented.
- 5) If used, detergents and sanitizers shall be suitable for use in a feed manufacturing environment. The organization shall ensure an inventory of all commercial chemicals (detergents and sanitizers) purchased and used is maintained. If considered hazardous, training of staff on proper handling, use and disposal shall be maintained. Safety data sheets shall be maintained as needed.
- 6) A record of cleaning and sanitation activities and verification activities shall be maintained.

Implementation Guidance
<p>A written cleaning program shall be in place and fully implemented that includes provisions for effective cleaning of equipment, facilities, tools, amenities and external areas.</p> <p>The cleaning program shall identify the what, how, when and who for equipment and area of the facility being cleaned. Responsibilities shall be identified, including responsibility for the visual or test inspection and the verification of cleaning methods. Consideration shall be given to:</p> <ul style="list-style-type: none">a) What is to be cleaned;b) How it is to be cleaned;c) When it is to be cleaned;d) Who is responsible for the cleaning;

e) Methods used to confirm that it was cleaned properly

For small equipment items such as tools, knives, tubs, cutting boards, etc., a cleaning area should be provided, when necessary, with sufficient equipment and tools for the cleaning process, e.g., suitable racks for draining/drying equipment, utensils and protective clothing. These areas shall be identified and constructed so they do not present a hazard to other feed processing operations.

A written housekeeping program should be maintained to ensure personnel understand the expectations and requirements. A verification program for specific housekeeping requirements should be maintained for any equipment with contact surfaces for finished product or ingredients (such as mixers, surge bins, holding bins) may impact animal food safety.

Chemicals that may impact animal food safety must be approved for use by the appropriate authority. A file is maintained of safety data sheets for each chemical used. A description of the chemicals used, their dilution rate and method of application is documented. Chemical cleaners and sanitizers must be used and stored in an approved manner.

SF/SF 6 PRODUCT REALIZATION

SF/SF 6.1 Product Development

- 1) The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.
- 2) Where appropriate, product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by facility trials and product testing.
- 3) Records of all product design, process development and approvals shall be maintained.

Implementation Guidance

The supplier is required to describe the methods and who is responsible for the process by which new products are conceived and/or transformed into market applications. Product concepts may include products not previously produced by the company, a product presented to a new market or a totally new product or packaging. Methods should include specific procedures required for transition from pilot plants and test kitchens to in-plant implementation of production.

As the product is being prepared for transition from pilot or test phase to mass production, any new processes, equipment, additional handling, new packaging or storage conditions should be reviewed with identification of any possible animal food safety risks associated with new conditions. These risks must be assessed and adjustments made to the animal food safety plan prior to implementation. Any adjustments to animal food safety plan must be validated and verified by the Q&FS Leader prior to mass production of new product.

A written procedure for product development is needed. A key component is providing guidance for introducing a new product into production.

Safe handling information must be included on all packaging, as required by legislation (regulation) and/or customer use.

Records of all product design, process development and approvals shall be maintained.

SF/SF 6.2 Packaging and Materials Receiving Processes

SF/SF 6.2.1 Receiving Processes for Packaging Materials

- 1) The supplier shall verify that packaging meets the supplier's specifications upon receipt. All packaging materials shall comply with the relevant regulatory requirements.
- 2) The supplier shall verify that printed labeling on packaging complies with supplier's specifications upon receipt.
- 3) All packaging materials shall be provided by approved vendors.

Implementation Guidance

The supplier needs to show documented evidence that packaging materials have been inspected or that they come from an approved vendor. Packaging materials should comply with the supplier's specifications and regulatory requirements.

Verification of packaging materials may include certification that all packaging that comes into direct contact with animal food meets either regulatory acceptance or approval criteria. Documentation should either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis or letter of guarantee, tests and analyses shall be conducted and records maintained to confirm the absence of potential chemical migration from the packaging to the feed contents.

For packaging vendor verification, the facility must determine the need for a testing requirement of packaging based on the risk of the chemicals used and the origin of the packaging material. For packaging materials that are considered low risk, a letter of guarantee or certificate of conformance would also be acceptable.

SF/SF 6.2.2 Receiving Processes for Raw Materials and Ingredients

- 1) All raw materials and ingredients shall comply with the supplier's specifications and relevant regulatory requirements.
- 2) Processes for receiving raw materials and ingredients shall be clearly defined and documented.
- 3) Personnel responsible for receiving raw materials and ingredients shall be trained on the defined processes and procedures.
- 4) Records shall be maintained for incoming materials to ensure raw materials and ingredients are provided by approved vendors and comply with relevant regulatory requirements.
- 5) The supplier shall verify that labeling for raw materials and ingredients complies with supplier's specifications upon receipt.

Implementation Guidance

Verification of raw materials and ingredients comply with the supplier's specifications should be completed and documentation maintained. Documentation may be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, certificate of analysis or a certificate from the applicable regulatory agency. On-site testing may be completed as well, which may be an evaluation for physical, chemical or biological contamination.

SF/SF 6.2.3 Equipment at Receiving

- 1) Prior to receiving or unloading raw materials or ingredients, equipment delivering the materials (typically rail cars, trucks or tankers) shall be inspected for filth or other potential sources of contamination. Rejection criteria must be established.
- 2) Transportation vendors must comply with regulatory requirements as well as supplier delivery requirements.
- 3) Incoming rail cars and trucks should be sealed upon arrival when possible. A program to evaluate the safety of the incoming ingredients shall be in place seals are absent. This policy may be similar to the policy for bagged ingredients that have been opened or damaged during transport.

Implementation Guidance

Supplier should verify that the equipment delivering raw materials or ingredients (rail cars, trucks or tankers) are clean and do not pose a risk to contamination or the quality and food safety of the materials. Trucks should be inspected and rejected, if necessary, based on established rejection criteria. It is important that such criteria are communicated to the transportation vendor prior to delivery. Seals on rail cars and trucks are commonly used and should be requested for deliveries when possible. Transportation vendors should comply with regulatory requirements for incoming raw materials or ingredients, such as FSMA or BSE regulations.

SF/SF 6.3 Manufacturing Processes

SF/SF 6.3.1 Process Control (M)

- 1) Controls shall be implemented throughout the manufacturing process to ensure the quality and safety of the product.
- 2) The controls shall be consistent with CGMPs as authorized by the FDA within FSMA animal food rule.
- 3) Written procedures for the controls shall be maintained.
- 4) Records shall be available to verify the control has been completed and is effective.

Implementation Guidance

Process controls for manufacturing are considered the foundation for an animal food safety plan. These are often referred to as CGMPs or prerequisites. These processes should be clearly defined with written procedures and records of activities.

The FSMA requires the implementation of specific CGMPs. The supplier should develop written procedures to ensure these CGMPs are implemented.

SF/SF 6.3.2 Control of Raw Materials and Ingredients

- 1) Controls to minimize cross-contamination of raw materials and ingredients during processing shall be implemented to prevent an animal food safety risk.
- 2) Procedures shall be established and implemented to ensure regulatory requirements for handling raw materials and ingredients are followed.

Implementation Guidance

The supplier should develop processes to ensure cross-contamination of raw materials and ingredients are controlled. This includes receiving, shipping or manufacturing processes.

If the materials are subject to regulatory requirements, such as BSE, records should be maintained to confirm compliance.

SF/SF 6.3.3 Product Release (M)

- 1) The responsibility and methods for releasing products shall be documented and implemented.
- 2) The procedures shall ensure the product is released by authorized personnel, once all inspections and analyses are successfully completed and documented to verify regulatory requirements and other established quality and food safety controls have been met.
- 3) No product shall be released without proper approval.

Implementation Guidance

The intent of the clause is to ensure finished products are released and shipped only after it is assured that it is safe for animals. A written procedure is needed that describes the process and controls to ensure that products released and shipped are safe for animals. Records of all product release shall be maintained.

The facility is required to document a procedure outlining the responsibility and protocols for the release of products. This can be done by outlining in-line process measures that demonstrate that products are compliant with specified requirements.

The procedure should provide the details for releasing products from “quarantine” or “hold” status. The procedure must identify those staff positions with responsibility for releasing products and indicate the action they will take when results are outside specification, including reference to other procedures for holding, reworking or disposing of product.

The protocol must ensure that:

- All products released from “quarantine” or “hold” status, and their dispositions are recorded
- All staff is familiar with product release procedures and that personnel authorized to release

product are aware of their responsibilities

All products released from hold status must have records maintained. These records should provide the product name and identification, amount of product being held, reason for the hold, and the product disposition. Records should be reviewed routinely to ensure that holds are “closed out.” Any product that is still “on hold” must be physically or visually verifiable.

SF/SF 6.4 Finished Products

SF/SF 6.4.1 Finished Products Specifications (M)

- 1) Written finished product specifications shall be approved by the supplier to ensure customers' requirements are met.
- 2) Written finished product specifications shall be accessible to relevant staff or personnel.
- 3) A register of finished product specifications shall be maintained.

Implementation Guidance

A written finished product specification should be developed for each product (or group of similar products) covered under the certification. The specification must, as a minimum, comply with the appropriate animal food safety regulatory requirements (including labeling requirements) and must be updated, as needed. Copies of all finished product specifications and a master list of all the latest versions of these documents should be maintained.

Written finished product specifications may include microbiological and chemical limits, labeling and packaging requirements and rejection criteria. Other examples include physical (size/grade, color, net weight, etc.), chemical (salt, moisture, pH, percentage of fat, brix, viscosity, etc.) and the packaging specifications for the product.

The supplier is required to ensure that finished product specifications are kept up-to-date.

The supplier's customer may provide the finished product specifications and, if this is the case, it is advisable that both the supplier and their customer (e.g. a retailer) agree the specification is achievable and that they agree on the attributes (quality and safety) of a product to be supplied.

The specification must be made available to relevant processing staff in production, process control and quality and food safety personnel.

SF/SF 6.4.2 Product Formulation (M)

- 1) Product formulations shall be developed by authorized persons to ensure they meet the designated requirements. The formulations shall include all manufacturing instructions with regard to flushing, sequencing, special instructions and cleanout procedures.
- 2) Procedures shall be documented and implemented to ensure that approved product formulations are used to manufacture finished products. The supplier shall ensure that raw materials or ingredients prohibited from use in the manufacture of animal food are not introduced into the product.
- 3) All medications included in animal food must be added in accordance with label instructions and regulatory requirements. When medications are used within a facility, the following shall be followed:
 - a) Access to medications shall be restricted to trained and authorized personnel.

- b) A daily drug reconciliation inventory shall be maintained.
 - c) Animal medications shall be subject to proper rotation based on expiration date Expired medications shall not be used.
- 4) Records shall be maintained to ensure products are formulated accurately and adhere to product specifications.

Implementation Guidance
<p>Product formulation is a critical component on ensuring the safety of the animal food. Procedures and processes are needed to ensure its accuracy and compliance with desired results.</p> <p>The supplier shall establish defined processes to ensure the accuracy of product formulation. This includes the assurance the product meets the desired requirements, proper checks and verifications for accuracy.</p> <p>If feed-grade medications are used, the supplier must follow regulatory requirements as outlined within CFR 21 Part 225 for medicated feeds, if applicable.</p>

SF/SF 6.5 Customer Related Processes

SF/SF 6.5.1 Customer Requirements

- 1) The supplier shall review customer requirements related to the product are met.
- 2) The supplier shall determine:
 - a) Requirements specified by the customer.
 - b) Requirements not stated by the customer, but necessary for the specified or intended use (when known).
 - c) Regulatory requirements applicable to the product.
 - d) Any additional requirements considered necessary by the supplier to meet the needs or expectations of the customer.

Implementation Guidance
<p>The supplier should maintain processes to demonstrate it understands its customers' requirements. This includes product specifications, shipping requirements, billing requirements and other customer service related functions.</p> <p>The supplier should maintain processes to ensure that materials provided to customers comply with regulatory requirements, such as labeling or animal food safety requirements.</p> <p>The supplier should maintain processes to ensure it listens to customers' needs and expectations, including customer inquiries, requests and complaints.</p>

SF/SF 6.5.2 Customer Communication

- 1) The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities shall be documented and implemented.

- 2) The supplier shall determine and implement effective arrangements for communicating with customers. This includes (but not limited to):
 - a) Product information.
 - b) Enquiries, contracts or order handling.
 - c) Customer feedback, including customer complaints.
- 3) Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.
- 4) Records of customer complaints and their investigation shall be maintained.

Implementation Guidance

Customer complaints can be valuable information in regards to the quality and food safety of finished products. A defined process is required to ensure quality and food safety issues reported by customers are reviewed and corrected. Records of customer complaints and their investigation should be retained for a defined period.

The procedure should outline the responsibility for investigating customer complaints, initiating follow-up actions and communicating back to the customer how the complaint has been resolved. Procedure should include criteria for the determination of the validity of complaints.

If the facility's corporate function is responsible for managing the complaint management program, that program must still be reviewed by the auditor during the audit.

Customer complaint review should include a trend analysis for ongoing or persistent problems reported by customers.

Records of complaints should include corrective actions taken by the supplier. Corrective actions should be made when there is any observation within a facility that leads one to believe that quality and food safety is at risk. After the correction is made, the facility should investigate to determine the root cause of the issue. When the root cause of the problem is identified, corrective actions can be taken. This type of action helps to assure the continuous improvement of the system, resulting in fewer future problems since the root causes have been addressed.

All data should be evaluated to determine the cause of the incident and any corrective action that is needed to prevent the incident from occurring again. The investigation should have any follow up required and, if necessary, assign a responsible person to follow up. All investigations should determine the root cause of the incident.

Customer inquiries and requests should be handled in a timely manner. This is typically a responsibility of customer service and is described with job descriptions.

SF/SF 6.6 Labeling (M)

- 1) Finished products shall be labelled for identification. Each package shall be properly labeled.
- 2) If finished product is provided to the customer as bulk, a label shall be provided with shipment.
- 3) Labels shall comply with all federal, state and local regulatory requirements.
- 4) Labels shall be approved by appropriate personnel to ensure compliance with regulatory requirements.

Implementation Guidance

Proper labeling is a regulatory requirement for incoming raw materials and outgoing finished products or materials. The supplier should ensure raw materials, ingredients and finished products are labeled properly and comply with regulatory requirements.

Labels should be provided to customers for bulk materials.

SF/SF 6.7 Nonconforming Products and Materials (M)

- 1) The responsibility and methods outlining how nonconforming products and materials are handled shall be documented and implemented.
- 2) The supplier shall ensure:
 - a) Nonconforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product.
 - b) Relevant staff is trained on the organization's quarantine and release requirements applicable to product placed under quarantine status.
- 3) Quarantine records and records of the handling, corrective action or disposal of nonconforming product shall be maintained.

Implementation Guidance

The supplier is required to document the procedure that outlines how they label and identify products that do not conform to specifications. This also includes products that are rejected or quarantined pending the results of inspection. Nonconforming product includes raw materials or ingredients that may be rejected or quarantined because they do not meet the specifications. In circumstances where products, raw materials or packaging are condemned or rejected, you are required to detail how the condemned items are handled and disposed. The supplier is also required to describe how you will isolate nonconforming product in order to avoid its shipment.

The method for identifying nonconforming product must be communicated to relevant staff. This may be a system of tags, signs, designated storage locations, system holds or other methods that meet the intent of this section.

The supplier is required to keep all records of the disposition of nonconforming product including product that is reworked, repackaged, condemned and/or disposed.

Records outlining the corrective actions that include the date corrective actions were implemented, the person approving the corrective action and any follow-up required to ensure the nonconforming product does not pose an animal food safety hazard.

SF/SF 6.8 Rework (M)

- 1) The responsibility and methods outlining how product is reworked shall be documented and implemented.
- 2) The procedure shall ensure:
 - a) The process of reworking product is supervised by qualified personnel.

- b) Reworked product is clearly identified and traceable in compliance with regulatory requirements.
 - c) Each batch of reworked product is inspected or analyzed as required before release and distribution.
 - d) Inspections and analyses shall conform to the requirements outlined in Clause 7.5.
 - e) Release of reworked product shall conform to the requirements outlined for finished products.
- 3) Records of all reworking operations shall be maintained.

Implementation Guidance
<p>The objective of this clause is to ensure the products which are reworked, are of the same quality and standards as first run product.</p> <p>The supplier will need to provide documented evidence that the product has been reworked under qualified supervision. The product shall retain traceability and be clearly identified. Each lot is released only after inspection.</p> <p>An important clause of the rework procedure is the criteria for determination when product is to be reworked, how much can be reworked, under what conditions it may be reworked, and how is it to be identified and traced.</p> <p>Product, after being reworked, must be reviewed per company-designated quality and food safety checks to ensure that it meets all applicable specifications.</p> <p>Records of all reworking operations shall be maintained.</p>

SF/SF 6.9 Inventory Stock Rotation

- 1) A written procedure for ensuring effective stock rotation principles are applied shall implemented and maintained.
- 2) When applicable, the requirements by customers on stock rotation shall be implemented.
- 3) If “first in, first out” (FIFO) is not required for specific products, this shall be documented.

Implementation Guidance
<p>A stock rotation is more than the FIFO program. It is designed to manage product shelf life and codes based on customer specifications, conditions of the product, storage locations and inventory management.</p> <p>The criteria that determine when products are not to follow the FIFO process should be defined so that proper stock rotation can be achieved by the facility.</p> <p>The supplier must outline the persons and/or positions responsible for documenting and implementing the rotation program. The position responsible for implementing and maintaining the program must be clearly defined.</p> <p>The program must meet Supplier’s needs and their customers’ requirements.</p>

SF/SF 6.10 Storage of Materials and Finished Products

SF/SF 6.10.1 Storage of Raw Materials and Ingredients

- 1) Raw materials and ingredients shall be stored in such a manner to prevent cross contamination with other raw materials or ingredients
- 2) Raw materials and ingredients of a similar category or function should be stored in the same area, when possible, in order to minimize the severity of contamination, should it occur.
- 3) Raw materials and ingredients considered high risk shall be segregated or stored in a separate area to minimize contamination.
- 4) First In-First Out (FIFO) stock rotation shall be implemented and practiced, unless otherwise noted due to specific customer needs.
- 5) Lot numbers of raw materials and ingredients shall be easily identified for personnel to record for usage or shipment (traceability purposes).
- 6) Inventories for raw materials and ingredients within storage shall be easily obtained and maintained accurately.
- 7) Racking for storage shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room.
- 8) When racking is used, storage of raw materials and ingredients shall minimize the risks of contamination from one ingredient above another.
- 9) The storage of medications for use in feed manufacture shall be controlled and maintained in accordance with regulatory requirements or, in the absence of regulatory requirements, manufacturers' instructions.

Implementation Guidance

Raw materials and ingredients should be stored in designated storage area that protects the materials from contamination and deterioration. These materials shall be stored only in dry areas of the processing room when staged for use during processing or packing.

Written procedures describing storage practices and processes should be maintained.

Medication shall be stored in a restricted area to prevent unauthorized use. Only authorized and trained personnel shall be allowed to add or remove product from this area. Medications shall be stored in their original container or in an approved container and include the information of the drug with manufacturer information, lot number and expiration date. A FIFO inventory control process should be use.

As a best practice, original labels from the container should be maintained and stored on or in the container with the medication.

The racks provided for the storage shall be constructed of materials designed to be easy to clean.

SF/SF 6.10.2 Storage of Packaging

- 1) Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

- 2) Lot numbers for packaging shall be easily identified for tracking and traceability purposes.
- 3) Outdated or nonconforming packaging shall be identified as such. These materials shall be stored separately from other packaging to avoid improper use. Nonconforming packaging shall be discarded or disposition determined in a timely manner.

Implementation Guidance
Ensure that packaging storage areas are adequately protected from rodents and other pests. Packaging materials, which become feed contact surfaces, must be protected from dust and other contaminants while in storage. This can be accomplished by the use of plastic wrap or other means to protect the packaging material.

SF/SF 6.10.3 Storage of Finished Products

- 1) Finished products should be segregated or stored separately from raw materials and ingredients, where possible.
- 2) All finished products shall be identified with a lot code for tracking and traceability.
- 3) FIFO stock rotation shall be practiced with finished products, unless otherwise noted by customer.
- 4) Storage areas for finished products shall be designed to enable cleaning and housekeeping practices. Storage areas shall be maintained in a manner to prevent harborage of pests or vermin.
- 5) When racking is used, storage of finished products shall minimize the risks of contamination from one ingredient above another.

Implementation Guidance
Finished products should be stored in designated storage areas that protect the materials from contamination and deterioration. Written procedures describing storage practices and processes should be maintained.
FIFO stock rotation practices shall be implemented unless otherwise requested by customers or customer requirements.
It is recommended that finished products and ingredients be stored in separate areas to avoid the potential of cross-contamination; however, this is not required.

SF/SF 6.10.4 Storage of Nonconforming Materials

- 1) Raw materials, ingredients, packaging and finished products that are nonconforming shall be isolated in a designated storage area.
- 2) Nonconforming materials and finished products shall be labeled as nonconforming materials.
- 3) Nonconforming materials and finished products shall be discarded or disposition determined in a timely manner.
- 4) Storage area for nonconforming materials and finished products shall be designed to enable cleaning and housekeeping practices. Storage areas shall be maintained in a manner to prevent harborage of pests or vermin.

Implementation Guidance

Nonconforming raw materials, ingredients, packaging materials and finished products should be stored in a designated storage area that prevents the material from contaminating other materials. Written procedures describing storage practices and processes for nonconforming products should be maintained.

Ensure that storage area for nonconforming products is adequately protected from rodents and other pests. Area should be clean and free of debris. Nonconforming products should be reworked or discarded in a timely manner.

SF/SF 6.10.5 Bulk Storage of Ingredients and Finished Products

- 1) Bulk storage shall allow separation and segregation of materials to avoid cross-contamination.
- 2) Bulk storage bins or silos shall allow for cleaning and housekeeping practices. Bulk storage areas shall be maintained in a manner to prevent harborage of pests or vermin.
- 3) Bulk storage practices shall support regulatory requirements when applicable.
- 4) Records for bulk storage shall be maintained.

Implementation Guidance

Bulk ingredients and finished products must be stored in designated storage areas that protect the materials from contamination and deterioration. Written procedures describing bulk storage practices and processes should be maintained.

Bulk receiving and storage practices should comply with regulatory requirements for BSE, if applicable. Records should be maintained to ensure compliance.

Bulk bins and silos should be maintained in good working condition and housekeeping practiced to avoid contamination.

Bulk storage areas may involve floor storage. Supplier should maintain an environment that minimizes contamination as best as possible.

SF/SF 6.11 Storage of Hazardous Chemicals

SF/SF 6.11.1 Hazardous Chemical Storage Process (M)

- 1) Storage of hazardous chemicals and toxic substances shall not present a hazard to staff.
- 2) Storage of hazardous chemicals and toxic substances shall not present a hazard to manufacturing processes. This includes packaging, product handling equipment or areas in which the finished products or ingredients are handled, stored or transported.
- 3) Hazardous chemicals and toxic substances shall be clearly labeled.

Implementation Guidance

Chemicals may be transferred to a smaller, designated container (i.e. work or day tank) as long as the

container is controlled and used by authorized personnel and the container includes the original name of the chemical, manufacture instructions, warning and caution statements, and lot code.

Sanitizers and detergents should not be stored with pesticides or other toxic chemicals. Chemicals should be stored in original containers. All non-feed items shall be stored away from finished feed and ingredients to not present an animal food safety hazard.

SF/SF 6.11.2 Hazardous Chemical Storage Area (M)

- 1) Hazardous chemical and toxic substance storage areas shall be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals.
- 2) The storage area shall be adequately ventilated and provided with appropriate signage indicating the area is a hazardous storage area.
- 3) The storage area shall be maintained as a restricted access only. Personnel without formal training in the handling and use of hazardous chemicals and toxic substances shall not be allowed to work in this area.
- 4) Instructions on the safe handling of hazardous chemicals and toxic substances shall be readily accessible to staff.
- 5) The storage area shall be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility.
- 6) Suitable first-aid equipment and protective clothing shall be available in close proximity to the storage area.
- 7) In the event of a hazardous spill, the storage area shall be designed such that spillage and drainage from the area is contained.
- 8) The storage area shall be equipped with spillage kits and cleaning equipment.

Implementation Guidance

There may be one or more designated storage room(s) for the storing of chemicals. Chemical storage rooms should be correctly designed and constructed, and meet regulatory standards. Chemical storage rooms should be ventilated, secure and lockable.

SF/SF 6.12 Loading, Transport and Unloading Processes

- 1) The processes and practices applied during loading, transport and unloading of animal food or animal food ingredients shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Materials and finished products shall be loaded, transported and unloaded under conditions suitable to prevent cross-contamination.
- 2) Vehicles (trucks/vans/containers) used for transporting feed shall be inspected prior to loading or unloading to ensure they are clean, in good repair, suitable for the purpose and free from conditions that may impact negatively on the safety of finished products or materials.
- 3) Loading and unloading processes and practices shall be designed to minimize unnecessary exposure to conditions detrimental to the integrity of finished products, materials and packaging materials.

- 4) Procedures shall ensure incoming raw materials or ingredients comply with regulatory requirements and the supplier's specifications, where applicable.

Implementation Guidance
<p>Conditions for storage, loading and unloading will vary depending on the type and nature of the material. Documented procedures should cover each type (e.g., bulk, bagged, liquid, and packaging, etc.) of product delivered into or out of the site. Where contract services are used, the transport protocol should be referenced in the contract with the vendor.</p> <p>For all outbound trucks and trailers, a visual inspection must be conducted for cleanliness, pest infestation and structural conditions. The supplier should verify that all trucks/trailers are free of offensive odors. All inspection findings should be recorded and maintained.</p> <p>Loading and staging of product should not expose product to potential abuse or contamination.</p> <p>The supplier must verify all incoming shipments are from approved vendors, or are being shipped under prior arrangements made by site management. Visual inspection and documentation of all incoming shipments of raw materials or ingredients is required. The supplier must verify that all incoming carriers are in good repair, clean and free of offensive odors. All seal numbers shall be recorded on shipping documents before the seal is broken, if applicable. A plan of action should be in place that includes the disposition of the product if the seal is broken or does not match the bill of lading.</p>

SF/SF 7 PURCHASING PROCESSES AND CONTROLS

SF/SF 7.1 Vendors for Incoming Goods and Services

SF/SF 7.1.1 Approved Vendors (M)

- 1) Raw materials, ingredients, packaging materials and services that impact finished product safety shall be supplied by an approved vendor.
- 2) A written procedure defining the processes and procedures for vendor evaluation and approval shall be maintained. This shall include procedures for receiving raw materials, ingredients, packaging materials and services from unapproved vendors.
- 3) The responsibility for selecting, evaluating, approving and monitoring an approved vendor shall be documented and implemented.
- 4) A master list of approved vendors should be maintained, although this is not required. Records of inspections and audits of approved vendors should be maintained also. The supplier shall be required to demonstrate materials are received from approved vendors.
- 5) If an on-site audit is used to approve a vendor, the audit must be completed by a qualified auditor.
 - a) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.
 - b) All applicable training by a qualified auditor in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

Implementation Guidance

A “Vendor Approval Program” is considered a CGMP and is not related to the requirements for FSMA “Supply-Chain Program” discussed later in the guidance document. FMSA Supply-Chain Program is required when a preventive control is needed prior to receiving an ingredient for a hazard requiring a preventive control.

The greatest risks for many supplier locations come from outside of the location. The intent of this clause is to ensure that the measures to control the risks from vendors of raw materials, ingredients, packaging materials and services are controlled and documented.

The process for evaluating and approving vendors should be clearly defined. This may include (but not limited to):

- Vendor verification questionnaire prior to purchasing materials
- Analysis or testing results from the potential vendor of materials
- Routine sampling and testing program by the supplier and/or the vendor of materials
- On-site audit (second-party audit) of the vendor's manufacturing site
- Overview of the vendor's animal food safety plan
- Monitoring program by the vendor

The supplier should require approved vendors to verify they accept the specifications for materials provided. The supplier is required to demonstrate that methods of analyses conform to recognized industry standards. The responsibility for raw material inspections and vendor approval should be included in the job descriptions.

The supplier should maintain a list of approved vendors, including contract service providers (e.g. pest control, cleaning services, etc.).

SF/SF 7.1.2 Unapproved Vendors or Temporary Sourcing

- 1) The receipt of raw materials, ingredients and packaging materials received from unapproved vendors shall be acceptable in an emergency situation provided before use.
- 2) Procedures describing the inspection and approval of temporary sourcing of raw materials, ingredients and packaging materials shall be maintained.
- 3) The use of unapproved vendors or temporary sourcing of incoming goods or services shall be documented.
- 4) Records shall be maintained showing the use of unapproved vendors and controls implemented to ensure the quality and safety of incoming goods.

Implementation Guidance

The supplier should establish a procedure as to how materials are sourced in emergency situations from vendors that are not on the approved vendor list. Records of review of inspection and/or analyses should be documented and reviewed.

SF/SF 7.2 Material and Packaging Specifications (M)

- 1) Specifications for all materials and packaging, including (but not limited to) raw materials, ingredients, feed additives, hazardous chemicals and processing aids that impact finished product safety shall be documented and kept current.
- 2) The methods and responsibility for developing and approving detailed specifications shall be documented.
- 3) Process to provide specifications to vendors for review and approval shall be defined. A record of vendor acceptance or approval of the specifications shall be maintained and readily assessable by appropriate personnel.

Implementation Guidance
<p>Specifications for packaging are important to ensuring the safety of materials used. It provides direction and requirements to vendors that provide these materials to the supplier.</p> <p>The supplier is required to maintain specifications for raw materials and ingredients that impact finished product safety. Raw material and ingredient specifications could include information such items as color, grade, nutritional data, size, weight, type of packaging, etc.</p> <p>A master list of raw material specifications should be maintained. It is recommended that a version number and approval date be included on the master list so that the specifications are updated (maintained) as needed and that all relevant departments have the most updated information.</p>

SF/SF 7.3 Contract Service Providers

SF/SF 7.3.1 Specifications for Contract Service Providers

- 1) Specifications for contract services that have an impact on finished product safety shall be documented and approved.
- 2) Relevant training requirements of contract personnel shall be specified and documented.
- 3) Training records of contract personnel shall be maintained.

Implementation Guidance
<p>The objective of the contract service and contract manufacture clauses is to ensure that the measures to control the identified raw material hazards are adequate in order to ensure the safety of the finished product is not compromised. The contract service does not need to directly involve product safety, but could still indirectly affect the product or Supplier's location. The supplier should detail what types of training that contract service providers are required to provide. Training examples include training done by service provider, training completed by the supplier, or certifications.</p>

SF/SF 7.3.2 Contract Manufacturing

- 1) All finished products, "work in progress" materials and services provided by contract manufacturers shall meet the desired specifications by the supplier.
- 2) Specifications for desired activities to be completed by contract manufacturers shall be maintained.

- 3) Records demonstrating the compliance of contract manufacturers to the desired specifications from the supplier shall be maintained.
- 4) The supplier shall verify all customer requirements are being met, ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

Implementation Guidance

A contract manufacturer is a vendor who is outside the direct control of the certification program, but who is contracted to manufacture a product to fulfill or supplement a Supplier or a customer order. The products may be similar to those produced by Supplier or completely different. The outside manufacturing facilities must be able to follow company product safety and quality requirements and meet the supplier and customer specifications.

The supplier must define how they will ensure that product produced by the contact manufacturer meets their customer specifications. A verification schedule, with a sampling plan as needed, must be defined.

All contract manufacturers should be listed as approved vendors.

Records shall be maintained of all contract reviews and changes to contractual agreements and their approvals.

SF/SF 8 VALIDATION AND VERIFICATION

SF/SF 8.1 Responsibility, Frequency and Methods

- 1) The Q&FS Leader shall be a preventive controls qualified individual.
- 2) The Q&FS Leader shall ensure validation and verification activities are completed accurately.
- 3) The Q&FS Leader shall determine the frequency and methods used to validate and verify animal food safety fundamentals, critical limits and other animal food safety controls identified in the food safety plan.
- 4) Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:
 - a) Validation that the preventive control is appropriate for control of the hazard (see FSMA 507.47)
 - b) Verification that monitoring is being conducted (see FSMA 507.39 and 507.40)
 - c) Verification that appropriate decisions about corrective actions are being made (see FSMA 507.39 and 507.42)
 - d) Verification of implementation and effectiveness (see FSMA 507.49)
 - e) Reanalysis of the food safety plan as necessary (See FSMA 507.50)
 - f) Records of verification activities are maintained (see FSMA Subpart F)

Implementation Guidance

FSMA has specific requirements for validation and verification of preventive controls (see references to FSMA noted above). Within FSMA, validation and verification are required for process preventive controls. It is important to understand that validation and verification are different. Validation is proving that you are doing the right things. Verification is the proving that you are doing what you say you are

doing.

There are no definitive verification and validation methods and they will vary among companies or facilities.

Q&FS Leader shall be responsible for establishing a frequency schedule and methods for verifying and validating the various programs. A consultant may be utilized by the facility to aid in verification activities; however, the ultimate responsibility for verification and validation must belong to the Q&FS Leader.

Records should be maintained to ensure all monitoring tasks are completed at the defined frequency.

SF/SF 8.2 Validation

- 1) The supplier shall validate that the preventive controls are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.
- 2) Validation of the preventive controls:
 - a) Must be performed (or overseen) by a preventive controls qualified individual
 - b) Must be completed before implementation within the food safety plan
 - c) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards
- 3) The supplier does not need to validate (see FSMA 507.47(c)):
 - a) Sanitation controls
 - b) Recall plan
 - c) Supply-chain program
 - d) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.
- 4) After validation of the preventive control, the supplier shall demonstrate the control measures can be implemented as designed. Within 90 calendar days after production of the applicable animal food first begins. If this is not possible the PCQI shall provide justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.
- 5) Re-validation shall occur whenever processes or procedures change that are implemented for the purpose to minimize, mitigate or control animal food safety hazards.
- 6) Records of all validation activities shall be maintained.

Implementation Guidance

The Q&FS Leader is responsible for ensuring that CGMPs and animal food safety limits achieve their intended purpose. The facility must demonstrate how the validation methods ensure the level of control required for the targeted animal food safety hazard. The facility must also have documentation showing that the methods and control measures provide the level of control needed.

Validation methods must demonstrate that the correct control measures are implemented. Possible information to support validation include:

- Scientific literature;
- Peer-reviewed published research; and
- In-house or laboratory challenge studies.

If technology is being used in a manner that is different from what is described within literature or research, then the supplier must demonstrate how the revised manner of use conforms to the original claim of intervention.

Many have difficulties distinguishing the difference between validation and verification. A simple means to determine the differences is below:

- Verification - Are you following the prescribed procedures as they are written, or simply, are you doing what you say you are doing?
- Validation - Does the prescribed procedures work? Is the process or preventive controls effective? Does it accomplish the desired result?

The animal food safety plan must be reviewed annually.

SF/SF 8.3 Equipment Calibration

- 1) The methods and responsibility for the calibration and re-calibration of measuring, testing and inspecting equipment used for monitoring activities shall be documented and implemented.
- 2) Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.
- 3) Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the supplier shall provide evidence to support the calibration reference method applied.
- 4) Mixers shall be tested/calibrated for uniform mixing as follows:
 - a) Upon installation
 - b) On a regularly scheduled basis (minimum of once per year)
 - c) When batch results indicate the need
 - d) After major repairs
- 5) Calibration records shall be maintained.

Implementation Guidance

The facility should ensure the equipment, once calibrated, is protected so that measurements remain accurate and only operated by authorized personnel and using approved methods. Calibration methods and frequency meet national or international standards where appropriate. Records of calibration should be readily available and complete.

SF/SF 8.4 Verification of Implementation and Effectiveness

- 1) The supplier shall verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing hazards requiring a preventive control. To do so, the shall conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system:
 - a) Calibration of process monitoring and verification instruments (or checking them for accuracy);
 - b) Product testing for a pathogen (or appropriate indicator organism) or other hazard;
 - c) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and
 - d) Review of records within 7-working days after the records are created, by (or under the oversight of) a PCQI to ensure:
 - (i) That records are complete
 - (ii) The activities reflected in the records occurred in accordance with the food safety plan,
 - (iii) That the preventive controls are effective,
 - (iv) That appropriate decisions were made about corrective actions
 - e) If record review exceeds 7-working days after the records were created, the PCQI shall prepare (or oversees the preparation of) a written justification for the extended timeframe
 - f) Other activities appropriate for verification of implementation and effectiveness.
- 2) As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, the supplier shall establish and implement written procedures for the following activities:
 - a) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy)
 - b) Procedures for product testing, including:
 - (i) Testing method is scientifically valid
 - (ii) Identify the nutrient, microorganism or other analyte(s) to be measured/tested;
 - (iii) Specify the procedures for identifying samples, including their relationship to specific lots of product
 - (iv) Include the procedures for sampling, including the number of samples and the sampling frequency

- (v) Identify the test(s) conducted, including the analytical method(s) used
 - (vi) Identify the laboratory conducting the testing; and
 - (vii) Include the corrective action procedures (see FSMA 507.42(a)(1))
- c) Procedures for environmental monitoring (if implemented), including:
- (i) Testing method is scientifically valid
 - (ii) Identify the test microorganism(s)
 - (iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;
 - (iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
 - (v) Identify the test(s) conducted, including the analytical method(s) used;
 - (vi) Identify the laboratory conducting the testing; and
 - (vii) Include the corrective action procedures (see FSMA 507.42(a)(1))

Implementation Guidance
FSMA has specific requirements for verification of implementation and effectiveness of preventive controls (FSMA 507.49). These requirements are applicable for preventive controls only. If no hazards requiring a preventive control are identified within the food safety plan, the supplier is exempt from clause 8.4 Verification of Implementation and Effectiveness.

SF/SF 8.5 Product Sampling and Inspection

SF/SF 8.5.1 Processes for Product Sampling

- 1) Raw materials, ingredients, finished products and work in progress shall be sampled as described within a written procedure or process.
- 2) Sampling requirements of raw materials and ingredients shall be established and implemented to ensure the quality and food safety of finished products.
- 3) The supplier shall maintain sample retention times that comply with supplier and customer requirements.
- 4) Work in progress materials shall be sampled as needed to ensure the quality and food safety of finished products.
- 5) Samples shall be clearly labeled to identify the type of materials within the sample, lot code and date of sampling.

Implementation Guidance
Sampling is a routine component of receiving or manufacturing for raw materials, ingredients, finished products and often “work in progress” materials. The supplier should demonstrate that sampling of product for inspection or analysis is completed using recognized sampling methods. A sample

retention policy should be in place for both ingredients and finished feeds.

Retention times should be established and should adhere to the requirements as established by the supplier. Retention times may vary based on the type of material, material storage conditions, regulatory requirements or customer requirements.

Samples should be labeled properly for identification and traceability. Material or product names, lot codes, date of sampling and person collecting the sample are important items to include on the label.

The staff should be qualified, trained and competent to complete sampling.

SF/SF 8.5.2 Inspection and Analysis of Raw Materials and Ingredients

- 1) All raw materials and ingredients shall be inspected upon arrival to determine whether it is acceptable for use.
- 2) Testing or analysis of raw materials and ingredients shall be clearly defined.
- 3) Testing or analysis of raw materials and ingredients shall be completed at planned intervals to ensure the quality and safety of finished products.
- 4) Testing or analytical results for raw materials and ingredients shall be maintained. Results shall be reviewed at planned intervals to determine variations in raw materials.
- 5) Testing and analytical results shall be traceable by raw material and ingredient lot numbers.
- 6) Testing or analytical processes shall be validated. All analyses shall be conducted to nationally recognized methods or alternative methods, which are validated as equivalent to the nationally recognized methods. Where external laboratories are utilized to conduct input or product analysis, the laboratories should be accredited to ISO 17025 or an equivalent national standard.
- 7) Records of all inspections and analyses shall be maintained.

Implementation Guidance

Inspection processes for raw materials and ingredients should be clearly defined to the assist personnel with the desired outcome from the inspection. This may include a physical assessment for contamination, review or collection of documentation, or testing upon receipt (hold/release status).

If testing or analyses are conducted, the results must be finalized before the raw materials and ingredients are shipped to a customer or used within manufacturing.

The supplier should demonstrate that analyses are completed by a laboratory that is accredited to ISO 17025 or equivalent standard methods. These methods may be described in your specifications indicating that the laboratory is classified as an approved vendor.

Records should be maintained that allows traceability of testing or analytical results to the sample, including lot code of raw material or ingredient. Information from previous results should be used to evaluate vendors.

SF/SF 8.5.3 Inspection and Analysis of Finished Products

- 1) Finished products shall be inspected prior to release to determine whether it is acceptable for use. This may include confirmation of compliance with regulatory requirements or the supplier's specification, if applicable.
- 2) Production records shall be reviewed and approved to ensure the quality and food safety of the finished product.
- 3) Testing or analysis of finished products shall be clearly defined, if applicable.
- 4) Testing or analysis of finished products shall be completed at planned intervals to ensure the quality and safety of finished products.
- 5) Testing or analytical results for finished products shall be maintained. Results shall be reviewed at planned intervals to determine variations in raw materials or ingredients.
- 6) Testing and analytical results shall be traceable by finished product lot number and/or production date.
- 7) Testing or analytical processes shall be validated. All analyses shall be conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard.
- 8) Records of inspections and analyses shall be maintained.

Implementation Guidance

The facility is required to document a procedure outlining the methods needed to inspect finished product, as well as work in progress, to ensure it meets the process or finished product specification in relation to animal food safety. Inspections, test or analyses of finished product must be finalized before delivery to a customer. Finished product testing is to be defined by the supplier and its customers.

The facility should identify those with responsibility for sampling, inspecting and testing finished product and "work in progress," and identify the methods used to collect samples and complete these tests, inspections and analyses.

The types of testing that are conducted on finished product should be determined by the finish product specification. Examples are varied and can include physical (count, weight, size, texture), chemical (fat, salt, moisture, brix, pH) or microbiological (aerobic plate count, yeast and mold, coliforms) criteria or variables. It is not valid to simply retest a sample when results are obtained that are not desired by the facility.

If external laboratory analyses are used, the supplier must demonstrate that such analyses are completed by a laboratory that is accredited to ISO 17025 or equivalent standard methods. These methods may be described in your specifications indicating the laboratory is classified as an approved vendor.

The staff should be qualified, trained and competent to complete sampling inspection and analyses and you will keep records of all inspections, tests and analyses made.

The supplier should identify those with responsibility for sampling, inspecting and testing finished product and work in progress and identify the methods used to collect samples and complete these tests, inspection and analyses.

SF/SF 8.6 Internal Audits

SF/SF 8.6.1 Internal Audit Process

- 1) The supplier shall complete internal audits at planned intervals to determine whether the quality and food safety system:
 - a) Conforms to the requirements established by the supplier; and
 - b) Is effectively implemented and maintained.
- 2) The internal audit schedule shall take into consideration the status and importance of the processes and areas to be audited, as well as results from previous audits.
- 3) The audit criteria, scope, frequency and methods shall be defined.
- 4) A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
- 5) Records of the audits and their results shall be maintained.

Implementation Guidance

Internal audits are considered a key component for communication with management and critical to driving continuous improvement within the quality and food safety program.

The supplier is required to prepare an internal audit procedure describing how internal audits of the quality and food safety program will be conducted and identify who is responsible for scheduling and conducting internal audits.

The audit program must include:

- An audit schedule (when audits will be conducted);
- Audit criteria (the area and requirements assessed);
- Responsibility (who will conduct the audit); and
- Corrections and corrective actions (the response to the audit).

The entire quality and food safety program should be audited at least annually (twice per year is preferred). Some areas may be audited more frequently due to the potential risks within this area.

Internal audits are helpful with the verification of CGMPs and animal food safety limits.

The outcomes of all internal audits, including any corrective actions taken, must be recorded.

SF/SF 8.6.2 Internal Auditors

- 1) Internal auditors shall be objective and impartial during the audit process.
- 2) Auditors shall not audit their own work.
- 3) Staff conducting internal audits shall be trained in internal audit procedures.
- 4) Records of audit training shall be maintained.

Implementation Guidance

An internal auditor training program should be documented. The training should cover:

- Internal audit procedures including the planning and scheduling of internal audits
- Preparing internal audit reports
- Initiating and following up on audit findings

The supplier should use personnel who are separate from the area being audited to conduct internal audits, where possible, to ensure the objectiveness of the internal audit. The inclusion of the words "where possible" illustrates that, in the case of some very small Suppliers, this may not be possible.

SF/SF 8.6.3 Internal Audit Corrective Actions

- 1) Management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without due delay to eliminate detected nonconformities and their causes.
- 2) Management responsible for the area being audited shall verify the effectiveness of corrections or corrective actions.
- 3) Management responsible for the area being audited shall ensure verification activities are recorded.

Implementation Guidance

Management for the area being audited is responsible for ensuring corrections and corrective actions from internal audit findings. Records should be maintained to demonstrate the timely completion of corrections and corrective actions as well as the effectiveness of the actions taken.

SF/SF 8.7 Product Identification (M)

- 1) Raw materials, ingredients, "work-in-progress" material and finished products shall be properly identified.
- 2) The methods and responsibility for identifying raw materials, ingredients, "work-in-progress" material and finished products shall be documented and comply with regulatory requirements, if needed.
- 3) The product identification system shall be implemented to ensure raw materials, ingredients, "work-in-progress" material and finished products are clearly identified during all stages of receipt, production, storage and dispatch.
- 4) Product identification records shall be maintained.

Implementation Guidance

An effective identification system and process is important in regards to traceability, which is a regulatory requirement (Bioterrorism Act).

The supplier should be able to clearly identify raw materials, ingredients and "work-in-progress" materials throughout the process.

Product that is still in process may be identified in a variety of ways. The facility could use bin tags, pallet tags, colors, product tags, etc. The facility must be able to demonstrate to the auditor how the

product identification system works for “work-in-progress” materials and for finished products. The facility should expect that the auditor will select product at various stages during the process and ask for the origin of product, raw material vendor, etc., to test the identification system. This would include bin labeling, routing of ingredients and finished products.

The product label needs to contain information that accurately describes the product in accordance to customer specification and/or regulatory requirements.

The supplier should prepare a procedure outlining who is responsible for maintaining the product identification system and include in the procedure the methods used to identify product.

When shipping finished product, the facility must ensure the product is clearly identified and that all product identification details are accurately described on dispatch documents or otherwise included with a shipment once it leaves the business.

Product identification records shall be maintained by the supplier.

SF/SF 8.8 Product Traceability (M)

- 1) The responsibility and methods used to trace product shall be documented and implemented to ensure finished product is traceable to the customer (one level forward).
- 2) The methods shall provide traceability through the process to the supplier and date of receipt of materials, packaging and other inputs (one level backward).
- 3) Traceability is maintained where product is reworked. Any finished product containing rework shall be traceable to ensure that:
 - a) Customers receiving the product can be identified; and
 - b) Lot numbers for ingredients, including those within the rework, can be identified.
- 4) The effectiveness of the product trace system shall be tested at least annually.
- 5) Records of raw and packaging material receipt and use, and product dispatch and destination shall be maintained.

Implementation Guidance

The supplier should prepare a written procedure for traceability of raw materials, ingredients and finished products. The procedure should be evaluated or tested annually in order to ensure its effectiveness.

The supplier must have a system that enables you to trace product to your customer. The product traceability system must account for materials, packaging and processing aids used that may impact on quality and food safety.

Traceability is a "one level forward, one level backward" as noted within regulatory requirements. Procedures must include details of how all materials, packaging and processing aids are "linked" through to the finished product; and must outline how they will account for the reuse of reworked product. The product traceability procedure must outline how the supplier will trace product to a customer and who is responsible for implementing and maintaining the product traceability system.

SF/SF 8.9 Animal Food Defense and Biosecurity Plan

- 1) An animal food defense and biosecurity plan(s) shall be documented, implemented and maintained.
- 2) An animal food defense plan shall include:
 - a) Name of the management person responsible for animal food defense and biosecurity.
 - b) Methods implemented to ensure only authorized personnel have access to the facility grounds, production equipment and vehicles, and manufacturing and storage areas through designated access points.
 - c) Methods implemented to protect sensitive processing points from intentional adulteration.
 - d) Measures taken to ensure the security of storage for materials, packaging, equipment and hazardous chemicals.
 - e) Measures implemented to ensure materials (bulk or bagged) as well as finished product are held under secure storage and transportation conditions.
 - f) Methods implemented to record and control access to the premises by employees, contractors and visitors.
- 3) The animal food defense and biosecurity plan(s) shall include processes or procedures to prevent the spread of disease to animals. This includes contact during transport or delivery to animals susceptible to disease.
- 4) Records for the animal food defense and biosecurity plan(s) shall be maintained.

Implementation Guidance

The supplier must prepare, implement and maintain an animal food defense and biosecurity plan(s) that outlines the methods, responsibility and criteria for preventing animal food adulteration caused by deliberate acts of sabotage. The plan(s) should also include steps to prevent the spread of disease, such as porcine epidemic diarrhea virus (PEDV), through exposure to contamination. Steps to implement animal food defense and biosecurity may be implemented into one plan or two separate plans.

This plan must be reviewed, at minimum, on an annual basis. The supplier must designate a member of management who has responsibility for animal food defense. This responsible individual must assure that there are procedures in place for recording and controlling access to areas of the facility by employees, contractors and visitors.

The protocol must identify how the facility limits access to designated areas of the operation to only appropriately authorized employees. The supplier's location must implement steps to protect sensitive processing points from intentional contamination. The protocol should explain how the company ensures the secure storage and transportation of materials, packaging, equipment, hazardous chemicals and finished product.

The supplier is free to develop adequate measures to ensure control through a wide variety of solutions.

SF/SF 9 ANIMAL FOOD SAFETY PLAN

SF/SF 9.1 Components of a Food Safety Plan (M)

- 1) The supplier shall prepare, or have prepared, and implement a written food safety plan. One or more PCQI must prepare, or oversee the preparation of, the food safety plan.
- 2) The written food safety plan must include a written hazard analysis (see FSMA 507.33(a)(2)) and preventive controls for hazards requiring preventive controls (see FSMA 507.34(b)).
- 3) When hazards requiring preventive controls are identified, the supplier shall maintain the following:
 - a) A recall plan for products that are impacted by the hazard
 - b) Written procedures for monitoring the implementation of the preventive controls (see FSMA 507.40(a)(1))
 - c) Written corrective action procedures for the preventive control (see FSMA 507.42(a)(1))
 - d) Written verification procedures to ensure the effectiveness of the preventive control (see FSMA § 507.49(b))
- 4) When a preventive control is implemented by a supplier, the supplier shall maintain a written supply chain program as defined in FSMA Subpart E.
- 5) A reanalysis of the food safety plan as a whole shall be completed at least once every three years. In addition, a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:
 - a) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
 - b) Whenever you become aware of new information about potential hazards associated with the animal food;
 - c) Whenever appropriate after an unanticipated animal food safety problem in accordance (see FSMA 507.42(b))
 - d) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.
- 6) A process flow diagram shall be added to the food safety plan that demonstrates a general flow of manufacturing processes.
- 7) The food safety plan shall be maintained at the manufacturing location and signed by the person in charge of the facility.

Implementation Guidance

FSMA has specific requirements for a food safety plan (FSMA 507.31). The food safety plan is the primary record that demonstrates compliance with FSMA.

Item 6 above is the only item within Clause 9.1 Components of a Food Safety Plan that is not required within FSMA. However, it is required for FSC36 Safe Feed/Safe Food certification.

SF/SF 9.2 Records for the Food Safety Plan (M)

- 1) The supplier shall maintain the following records documenting implementation of the food safety plan:
 - a) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance (see FSMA 507.36(a)(b))
 - b) Records that document the monitoring of preventive controls, if any
 - c) Records that document corrective actions
 - d) Records that document verification for preventive controls, if any. This includes:
 - i. Validation for the preventive control
 - ii. Verification of monitoring
 - iii. Verification of corrective actions
 - iv. Calibration of process monitoring and verification of instruments
 - v. Product testing
 - vi. Environmental monitoring
 - vii. Review of records
 - viii. Reanalysis of the food safety plan
 - e) Records that document the supply chain program for preventive controls, as outlined in FSMA Subpart E
 - f) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.
- 2) Records for the food safety plan shall be maintained for at least 2 years.

Implementation Guidance

FSMA has specific requirements for food safety plan records (FSMA 507.55). The food safety plan is the primary record that demonstrates compliance with FSMA. Records for the food safety plan should comply with FSMA Subpart F also, which are included within clause 2.3 Records for more discussion on records.

SF/SF 9.3 Hazard Analysis (M)

- 1) The supplier shall conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.
- 2) The hazard analysis must be written.
- 3) The hazard identification must consider:
 - a) Known or reasonably foreseeable hazards that include:
 - (i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens

- (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep)
- (iii) Physical hazards (such as stones, glass, and metal fragments)
- b) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:
 - (i) The hazard occurs naturally;
 - (ii) The hazard may be unintentionally introduced; or
 - (iii) The hazard may be intentionally introduced for purposes of economic gain.
- 4) The hazard analysis must include an assessment of:
 - a) The severity of the illness or injury if the hazard were to occur and;
 - b) The probability that the hazard will occur in the absence of preventive controls.
- 5) The hazard evaluation must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
- 6) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:
 - a) The formulation of the animal food;
 - b) The condition, function, and design of the facility and equipment;
 - c) Raw materials and other ingredients;
 - d) Transportation practices;
 - e) Manufacturing/processing procedures;
 - f) Packaging activities and labeling activities;
 - g) Storage and distribution;
 - h) Intended or reasonably foreseeable use;
 - i) Sanitation, including employee hygiene; and
 - j) Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

Implementation Guidance

FSMA has specific requirements for completing a hazard analysis (FSMA 507.33). The analysis should include an assessment of biological, chemical and physical hazards. Hazards that occur naturally, hazards that may be unintentionally introduced or intentionally introduced must be assessed. Upon completion of an assessment of severity and probability for known or reasonably foreseeable hazards, hazards that require a preventive control should be identified and preventive controls determined.

Environmental pathogens must be included in the hazard assessment, as required by FSMA.

Records of the hazard analysis are required to demonstrate the process was completed correctly.

SF/SF 9.4 Preventive Controls (M)

- 1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated.
- 2) Preventive controls are required when:
 - (i) Control points are identified as a critical control points (CCPs)
 - (ii) Control points, although not CCPs, are also appropriate for animal food safety.
- 3) Preventive controls must be written.
- 4) Preventive controls include, as appropriate to the facility and animal food:
 - a) Process controls – this includes procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include (as appropriate to the facility and type of animal food manufactured):
 - (i) Parameters associated with the control of the hazard
 - (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.
 - b) Sanitation controls – this includes procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, include (as appropriate to the facility and type of animal food manufactured) procedures, practices, and processes for the:
 - (i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment
 - (ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product
 - c) Supply-chain controls – this includes the supply-chain program, which is required for preventive controls that are implemented for ingredients prior to receipt (see FSMA Subpart E)
 - d) Other controls – this includes any other procedures, practices, and processes necessary to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food. Examples of other controls include hygiene training and other current good manufacturing practices.
 - e) Recall plan – this includes procedures, practices, and processes to accomplish a recall of product(s) impacted by a preventive control
- 5) If a supplier uses refrigeration for storage of unexposed packaged animal food, it is required to maintain preventive controls to ensure temperature is maintained (see FSMA 507.51).

Implementation Guidance

FSMA has specific requirements for implementing preventive controls (FSMA 507.34). If a hazard with preventive controls is identified, the supplier must establish preventive controls to ensure the hazard is controlled. FSMA describes four types of preventive controls: process, sanitation, supply-chain, and other.

A food safety plan does not require preventive controls in order to be complete. If no hazard(s) requiring a preventive are identified, no preventive controls are required.

FSMA requires a recall plan when a hazard requiring a preventive control is identified (FMS 507.38) and is considered a part of preventive controls. FSC36 Safe Feed/Safe Food requires a recall plan as described in clause 9.11 Recall Plan.

SF/SF 9.5 Corrective Actions (M)

- 1) The supplier shall establish and implement written corrective action procedures as appropriate to the nature of the hazard and the preventive control that must be taken if preventive controls are not properly implemented.
- 2) For each preventive control, the corrective action procedures must describe the steps to be taken to ensure that:
 - a) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control
 - b) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur
 - c) All affected animal food is evaluated for safety
 - d) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated
- 3) A corrective action for a preventive control shall be implemented for the following reasons:
 - a) A preventive control is not properly implemented and a corrective action procedure has not been established
 - b) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective
 - c) A review of records finds that the records are not complete
 - d) Activities conducted did not occur in accordance with the food safety plan
 - e) Appropriate decisions were not made about corrective actions.
- 4) If action is taken in a timely manner to identify and correct a minor and isolated problem that does not directly impact product safety, a corrective action is not required.
- 5) Records shall be maintained for corrective actions related to preventive controls.
- 6) Records shall be maintained for corrective actions taken for nonconformance findings other than preventive controls.

Implementation Guidance

FSMA has specific requirements for corrective actions for preventive controls for hazards requiring a preventive control (FSMA 507.42). These are addressed within item 3 above.

A corrective action program is an effective method to drive continuous improvement. Information from CAPAs is useful for management review. The supplier should establish a written procedure to capture nonconformance items and identify actions necessary to correct, prevent or improve.

SF/SF 9.6 Supply-Chain Program for FSMA Subpart E Compliance

- 1) The supplier shall establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the supplier has identified a hazard requiring a supply-chain-applied control (see FSMA Subpart E for specific requirements). NOTE: a supplier is not required to implement a supply-chain-applied control.
- 2) A supplier does not need to maintain a supply-chain program when:
 - a) When there is not a hazard requiring a preventive control.
 - b) When the receiving facility controls the hazard.
 - c) When a customer or downstream entity provides written assurance that they control the hazard. (see FSMA 507.36)
 - d) When an importer is in compliance with the foreign supplier verification program for the raw material or other ingredient (see FSMA Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals).
 - e) When the food is supplied for research or evaluation use.
- 3) When product or material for research or evaluation use, the supplier shall:
 - a) Ensure that the product or material is not sold or distributed to the public
 - b) Label it with the statement “for research or evaluation use only”
 - c) Ensure that it is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose.
 - d) Ensure the product is used only for this purpose, and any unused quantity is properly disposed of
 - e) Product is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public.
- 4) The supply-chain program must be written.
- 5) When a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier, the supplier must:
 - a) Verify the supply-chain-applied control
 - b) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity’s applicable documentation, and document that review and assessment.

Implementation Guidance

FSMA has specific requirements for a supply-chain program as preventive controls (FSMA Subpart E). It is important to not confuse this requirement with a vendor approval program as they are different. FSMA supply-chain program is an option for a preventive control for a hazard requiring a preventive control. A vendor approval program is a CGMP to ensure the quality and safety of incoming ingredients and raw materials.

It is likely that supply-chain applied controls will not be applicable to most animal food manufacturers. However, if a hazard requiring a preventive control is identified, the supplier is required to develop a supply-chain program for preventive controls.

SF/SF 9.7 When Implementation of Preventive Controls Is Not Required

- 1) If the supplier is a manufacturer/processor, it is not required to implement a preventive control for a hazard (identified hazard) requiring a preventive control when:
 - a) The supplier determines and documents that the animal food could not be consumed without application of an appropriate control;
 - b) The supplier relies on its customer to ensure that the identified hazard will be significantly minimized or prevented (see FSMA 507.36(a)(1)(2)(3)(4)).
- 2) The supplier shall disclose in documents accompanying the animal food that the animal food is not processed to control identified hazard (see FSMA 507.36(a)(2)(3)).
- 3) The supplier shall obtain annually from its customer written assurance that it will follow procedures that significant minimize or prevent the identified hazard requirements (see FSMA 507.36(a)(2)(3) and 507.37).
- 4) The supplier shall obtain annually from its customer written assurance that it will sell the product to another entity that agrees, in writing, to follow procedures that significant minimize or prevent the identified hazard requirements or to obtain a similar written assurance from the entity's customer (see FSMA 507.36(a)(4) and 507.37).

Implementation Guidance

FSMA has specific requirements for when a supplier does not need to implement preventive controls (FSMA 507.36). If the customer accepts responsibility for controlling the hazard, documentation of such communication is required (FSMA 507.37). Records are needed to ensure the hazard in controlled.

SF/SF 9.8 Management Components of Preventive Controls

- 1) Preventive controls that are process controls require monitoring, validation (if applicable), corrective actions, and verification of implementation and effectiveness.
- 2) Preventive controls that are supply-chain applied controls require corrective actions and verification of implementation and effectiveness.
- 3) Preventive controls that are sanitation controls require monitoring, corrections or corrective actions, and verification of implementation and effectiveness.

Implementation Guidance

FSMA has specific requirements for implementing different types of preventive controls (FSMA 507.39). For each type of preventive control identified within FSMA, specific components and records are needed to ensure the hazard is controlled.

SF/SF 9.9 Monitoring of Preventive Controls

- 1) The supplier shall establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.
- 2) The supplier shall monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.
- 3) The supplier shall document the monitoring of preventive controls and review records to ensure effectiveness of the preventive control.
- 4) Refrigeration temperature during storage of animal food, if applicable, shall be recorded to demonstrate that the temperature is controlled, or exception records demonstrating loss of temperature control. Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

Implementation Guidance

FSMA has specific requirements for monitoring preventive controls (FSMA 507.40). A written procedure is required for monitoring preventive controls. This should include a review of records to ensure effectiveness. If refrigeration is used by the supplier, monitoring records are required.

SF/SF 9.10 Records for Preventive Controls

- 1) Records required for preventive controls and obtained by FDA are subject to the disclosure requirements (see FSMA 507.200).
- 2) The supplier shall make records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.
- 3) Records for the preventive controls must:
 - a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records) or electronic records.
 - b) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;
 - c) Be accurate, indelible, and legible;
 - d) Be created concurrently with performance of the activity documented
 - e) Be as detailed as necessary to provide history of work performed.
- 4) All records must include:

- a) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);
- b) The date and, when appropriate, the time of the activity documented;
- c) The signature or initials of the person performing the activity; and
- d) Where appropriate, the identity of the product and the lot code, if any.

Implementation Guidance
FSMA has specific requirements for records for preventive controls (FSMA 507.55). Records for preventive controls should demonstrate that the hazard is controlled. Copies of records provided to FDA are subject disclosure by FDA. The requirements for such records are consistent with clause 2.3 Records.

SF/SF 9.11 Regulatory Requirements (M)

- 1) The supplier shall ensure that facility or location complies with all federal, state and local regulatory requirements.
- 2) The supplier shall ensure at the time of delivery to its customer that the finished products, raw materials and ingredients comply with all regulatory requirements. This includes compliance with regulations applicable to maximum residue limits, animal food safety, packaging, product description, nutritional, additive labeling and to relevant established industry codes of practice.
- 3) The methods and responsibility for ensuring the organization is kept informed of changes to relevant regulations, scientific and technical developments and relevant industry codes of practice shall be documented and implemented.
- 4) The supplier shall maintain defined procedures for complying with regulatory requirements.
- 5) Processes shall be established to ensure the facility is aware of all regulatory requirements.
- 6) Personnel responsible for compliance with regulatory requirements shall be trained on relevant procedures.
- 7) Procedures shall define individuals responsible for communicating regulatory requirements to management and site personnel.
- 8) If the site is subject to FDA inspections or audits, a procedure for reacting to a visit by an FDA official for an inspection or audit shall be defined. Appropriate personnel shall be trained on these procedures.

Implementation Guidance
The supplier is required to comply with all regulatory requirements from federal, state and local authorities. Personnel responsible for ensuring the supplier or site is aware of regulatory requirements should be identified. The supplier should establish processes and procedures to ensure that products provided to customers meet regulatory requirements and these processes should be verifiable. If the site is subject to FDA inspections, a defined procedure should be written for personnel to follow. Training on the procedure should be completed and available, if requested.

SF/SF 9.12 Recall Plan (M)

- 1) The responsibility and methods used to withdrawal or recall product shall be documented and implemented.
- 2) The procedure shall:
 - a) Provide the scope of the recall
 - b) Identify those responsible for initiating, managing and investigating a product withdrawal or recall.
 - c) Describe the management procedures to be implemented including sources of legal and expert advice.
 - d) Outline a communication plan to inform customers, consumers, regulatory authorities and other essential bodies in a timely manner appropriate to the nature of the incident.
 - e) Identify the information or data for collection to ensure the effectiveness of the recall.
 - f) Provide processes to determine product disposition upon recovery.
- 3) Investigation shall be undertaken to determine the root cause of a withdrawal or recall. Details of the investigation and any actions taken shall be documented.
- 4) The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually (“mock” recall or traceability exercise).
- 5) Records of all product withdrawals and recalls shall be maintained.

Implementation Guidance

Clause 9.12 Recall Plan is independent of the recall requirements for FSMA. Within FSMA, a recall plan is required only if a hazard requiring a preventive control is identified. For clause 9.12, a recall plan is required in order to comply with FSC36 Safe Feed/Safe Food. The components for a recall plan required by FSMA are similar to the requirements for FSC36 Safe Feed/Safe Food. A recall plan is considered a good business practice.

The facility must prepare a withdrawal and recall procedure describing the methods, responsibilities and management procedures they will implement in the event of a product withdrawal or recall.

The supplier should identify a “Crisis Management Team” that includes key decision-makers or leaders at the supplier’s location. They are required to review and test the withdrawal and recall procedure at least annually and verify that the instructions continue to be relevant.

It is recommended that withdrawal and recall procedure be tested annually (“mock” recall). Records for the testing of the withdrawal must include all supporting documentation used to identify product included within the withdrawal.

A successful “mock” recall, or traceability exercise, should be completed within 24 hours. A goal should be 100 percent of product identified within four hours or regulatory requirement. Customer specifications for product traceability should be considered as well. Any nonconformance items identified during the exercise should be investigated by the supplier and corrective actions taken with verification for effectiveness.

Any withdrawal or recall shall be investigated to determine the root cause. The details of the investigation and any actions taken shall be documented. The supplier is required to maintain records of all withdrawals and recalls.

Note: If a product withdrawal or recall is implemented, the certification body and AFIA must be notified within 24 hours. This should be included within the written procedures.

SF/SF 9.13 Waste Disposal

- 1) The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.
- 2) The supplier shall ensure portable containers, vehicles waste disposal equipment, collection bins and storage areas are maintained in a serviceable condition and cleaned regularly so as not to attract pests and other vermin.
- 3) The supplier shall maintain adequate provisions for the disposal of all solid processing. Waste held on site prior to disposal shall be stored so as not to present a hazard.

Implementation Guidance

Waste removal must be handled properly to avoid any animal food safety risk.

A waste disposal plan should be prepared to ensure the potential for increased risk to animal food safety is avoided.

SF/SF 10 FSC36 SAFE FEED/SAFE FOOD SEAL REQUIREMENTS

SF/SF 10.1 Compliance with Safe Feed/Safe Food Seal Licensing Agreement

- 1) The supplier shall comply with the requirements for using the FSC36 Safe Feed/Safe Food seal (logo) as described within the LICENSING AGREEMENT FOR USE OF THE SAFE FEED/SAFE FOOD SEAL. See Appendix B for an overview of the agreement.
- 2) The supplier shall ensure the FSC36 Safe Feed/Safe Food seal (logo) complies with the size requirements for use on packaging.
- 3) The supplier shall ensure the FSC36 Safe Feed/Safe Food seal (logo) complies with the color requirements as defined within the agreement.
- 4) When the seal (logo) is used on packaging or labels, the supplier shall print the following (similar language) in reasonably close proximity to the FSC Safe Feed/Safe Food seal or logo: "This feed was produced in a facility certified in the American Feed Industry Association's Safe Feed/Safe Food Certification Program; for details go to: www.safefeedsafefood.org." Another optional statement to consider is: "Safe Feed/Safe Food is AFIA's facility certification program (www.safefeedsafefood.org)."

Implementation Guidance

AFIA provides a seal (logo) for use by Suppliers that obtain the FSC36 Safe Feed/Safe Food certification. Suppliers must sign the LICENSING AGREEMENT FOR USE OF THE SAFE FEED/SAFE FOOD SEAL before using the logo or seal for marketing purposes. Many Suppliers that sign the licensing agreement use the logo on packaging. It is important that the seal comply with the requirements as provided in the licensing agreement. A brief summary of these requirements is shown in Appendix B of this document.

A statement similar to that listed in item 4 above must be print with the seal (logo) when used on

packaging or labels. If the seal (logo) is used on marketing or promotional materials that is not attached to finished products, the statement is not required.

If a Supplier has not signed the licensing agreement and does not use the logo, it is exempt.

APPENDIX A

Glossary for FSC36 Safe Feed/Safe Food Guidance Document Version 7.0

Animal Food	Any single or multiple materials, whether processed, semi-processes or raw, which is intended to be fed directly to food producing animals, or companion animals. Also referred to as “feed.”
Animal Food Safety Plan	A written plan that describes the supplier's processes and practices to monitor product safety, identify deviations from control parameters and define corrections necessary to keep the process under control. As required by FSMA, this includes: hazard analysis, preventive controls, vendor verification program, recall plan, procedures for monitoring the implementation of preventive controls, corrective action plan and verification procedures.
Audit	A systematic and independent examination of a Supplier's quality and food safety program by an auditor to determine whether feed/food safety, hygiene and management activities are undertaken in accordance with that system documentation and comply with the requirements of the FSC36 Safe Feed/Safe Food guidance document, as appropriate, and to verify whether these arrangements are implemented effectively.
AFIA	American Feed Industry Association
Audit Checklist	The list of audit questions, customized for FSC36 Safe Feed/Safe Food and audit scope, downloaded for the auditor to use when conducting an FSC36 audit.
Auditor	A person that completes the audit for the supplier's quality and food safety program. An auditor must work for a licensed certification body that is approved to provide certifications for FSC36 Safe Feed/Safe Food. The auditor must be trained on FSC36 Safe Feed/Safe Food requirements.
Certification	Approval by a Certification body of a Supplier's quality and food safety program as complying with the FSC36 Safe Feed/Safe Food program, as appropriate, following a certification audit. Certify, certifies and certified shall have a corresponding meaning under the FSC36 Safe Feed/Safe Food program.
Certification Body	An entity that has entered into a license agreement with AFIA authorizing it to certify a Supplier's quality and food safety program in accordance with the ISO/IEC Guide 65:1996, the FSC36 Safe Feed/Safe Food guidance document, and general requirements.
Codex Alimentarius Commission	The internationally recognized entity whose purpose is to guide and promote the elaboration and establishment of definitions, standards and requirements for foods, and to assist in their harmonization and, in doing so, to facilitate international trade. The Commission Secretariat comprises staff from the Food and Agriculture Organization and the World Health Organization.
Correction	An action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and prevent affected animal food from entering commerce). Shall have the same meaning as “corrected.”

Corrective Action	<p>Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action shall include:</p> <ul style="list-style-type: none">a) Determine/document any immediate action required/taken:<ul style="list-style-type: none">• Determine the cause of the problem• Evaluate action needed on the identified cause• Determine if the problem exists elsewhere in the system and implement actions neededb) Document the results of the action taken: <p>Review/verify and document effectiveness of action taken with objective evidence</p>
Critical Nonconformity	<p>A breakdown of control(s) at a critical control point, a pre-requisite program or other process step and judged likely to cause a significant animal or public health risk and/or where product is contaminated. Critical nonconformity is also raised if the supplier fails to take effective corrective action within the timeframe agreed with the certification body, or if the certification body deems that there is systemic falsification of records relating to animal food safety controls and the quality and food safety system.</p>
Current Good Manufacturing Practices (CGMPs)	<p>The combination of management and manufacturing practices designed to ensure animal food products and materials are consistently produced to meet relevant legislative and customer specifications.</p>
Clause	<p>Refers to one of the multiple defined requirements within the FSC36 Safe Feed/Safe Food guidance document that audited by the certifying body for certification. Specific clauses (or clauses) are mandatory. Exemptions to clauses should be determined by the supplier and certifying body before an on-site audit is completed.</p>
Exemption	<p>A review process of clauses for FSC36 Safe Feed/Safe Food that should be completed by the supplier with the certifying body prior to the audit to determine which clauses, if any, do not apply to the audit for certification. Mandatory clauses cannot be exempt.</p>
Facility	<p>The supplier's premises. The production, manufacturing or storage area where product is produced, processed, packaged and/or stored, and includes the processes, equipment, environment, materials and personnel involved. This includes supporting areas such as maintenance, electrical or boiler rooms, also. The facility must be managed and supervised under the same operational management. The facility is the site audited during an on-site audit.</p>
Feed	<p>Any single or multiple materials, whether processed, semi-processes or raw, which is intended to be fed directly to food producing animals, or companion animals. Also, referred to as "animal food."</p>
Finished Product(s)	<p>Those products that are considered to have completed processing requirements by a Supplier and are ready for use by its customers.</p>
FSMA Animal Food Rule	<p>An abbreviation for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals of the Food Safety Modernization Act (FSMA).</p>

Food Sector Category (FSC)	A classification scheme established to assist in a uniform approach to management of the SQF program as defined by the SQFI. FSC36 is assigned to AFIA's Safe Feed/Safe Food program that is developed and maintained by AFIA.
HACCP	The Hazard Analysis Critical Control Point and refers to the following two universally accepted guidelines and definitions contained therein: a) HACCP guidelines developed and managed by the Food and Agriculture Organization's CODEX Alimentarius Commission. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application – Annex to CAC/RCP 1 – 1969, Rev. 4-2003), – “A system, which identifies, evaluates and controls hazards which are significant for food safety.” b) HACCP guidelines developed and managed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Hazard Analysis and Critical Control Point Principles and application Guidelines, Adopted August 14, 1997 – “A systematic approach to the identification, evaluation, and control of food safety hazards” together referred to as the HACCP Guidelines.
Hazard	Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals (taken from FSMA animal food rule).
Hazard Requiring a Preventive Control	A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system (taken from FSMA animal food rule).
Ingredient	A raw material that has been further processed and used within animal feed.
Known or Reasonably Foreseeable Hazard	A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food (taken from FSMA animal food rule).
Major Nonconformity	An omission or deficiency in the quality and food safety system producing unsatisfactory conditions that carry a quality or animal food safety risk and likely to result in a system breakdown.
Minor Nonconformity	An omission or deficiency in the quality and food safety system that produces unsatisfactory conditions that if not addressed may lead to a risk to quality and animal food safety but not likely to cause a system breakdown.
NACMCF	The National Advisory Committee on Microbiological Criteria for Foods of the United States of America.

Nonconformity (or Nonconformance)	Lack or deficiency in the quality and food safety system producing unsatisfactory conditions. See Minor, Major, or Critical Nonconformities for more details.
Opportunity for Improvement (OFP)	An observation made by the auditor during a site audit that identifies an issue that is not a nonconformity but recognizes that the practices conducted by the supplier are not industry best practice. It does not require a corrective action response by the supplier, but provides the supplier with an opportunity to improve their quality and food safety system.
Q&FS Leader	An individual, designated by a producer/supplier to develop, validate, verify, implement and maintain that producer's/supplier's quality and food safety program.
Premix	A blend of ingredients that may be used within an animal food. This typically includes vitamins, minerals, additives or medications.
Prerequisite Program	A procedural measure that when implemented reduces the likelihood of an animal food safety hazard or a food quality threat occurring, but one that may not be directly related to activities taking place during production. Current Good Manufacturing Practices (CGMPs) are often referred to as prerequisites.
Preventive Controls Qualified Individual	a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system (taken from FSMA animal food rule).
Qualified Auditor	A person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required. A qualified individual must have technical expertise obtained by a combination of training and/or experience appropriate to perform the auditing function.
Qualified Individual	A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment (taken from FSMA animal food rule).
Raw Material	A natural resource that is in an unprocessed or minimally processed state and may be used within animal food.
Receiving Facility	A facility that is subject to subparts C and E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier (taken from FSMA animal food rule).
Re-certification	A re-certification by a certification body of a Supplier's quality and food safety system as a result of a re-certification audit. FSC36 Safe Feed/Safe Food is a two-year certification.

Re-certification Audit	An audit of the supplier's SQF System within 30 calendar days of the anniversary of certification.
Registration	The process in which a Supplier completes an official listing of its facility on the SQFI website. Registration is required before the supplier can complete Certification. Re-registration is required annually.
Rework	Finished products, feeding materials (raw materials and ingredients), including work in progress, that is clean, unadulterated and that has left the normal product flow and requires action to be taken on it before it is acceptable for release and is suitable for reuse within the process.
Scope of Certification	The food sector categories (FSC) and those products to be covered by the certificate, which includes the mandatory clauses and those clauses not exempt.
Senior Management	Management of the supplier that is responsible for the direction and decisions for the facility or corporation.
Supplier	The establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/ processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a <i>de minimis</i> nature (taken from FSMA animal food rule).
Surveillance Audit	A review of the supplier's quality and food safety system documentation to ensure the system documentation substantially meets the requirements of FSC36 Safe Feed/Safe Food, as appropriate. A surveillance audit is performed by the same certifying body that completed the on-site audit for the supplier during the previous year. The surveillance audit is used to ensure the supplier maintains the requirements for FSC36 Safe Feed/Safe Food until the next on-site audit.
Validation	The process or procedure that ensures that the activity to control a hazard achieves the intended result and actually works. This is consistent as defined in the NACMCF Hazard Analysis and Critical Control Point Principles and Application Guidelines, Adopted August 14, 1997, as amended from time to time and the Food and Agriculture CODEX Alimentarius Commission Hazard Analysis and Critical Control Point (HACCP) – Guidelines for Implementation and Use, ALINORM 97/13A as amended from time to time.
Vendor	A provider of materials or services to a Supplier. For materials, this includes raw materials, ingredients, premixes, packaging or any item used to manufacture products. For services, this includes co-manufacturing or further processing of products, as well as support work completed by contractors. Vendor is not limited to the specific providers of materials and services.
Verification	The process or procedure that ensures that the activity or control measure was done according to its design. As defined in the NACMCF Hazard Analysis and Critical Control Point Principles and Application Guidelines, Adopted August 14, 1997 as amended from time to time and the Food and Agriculture CODEX Alimentarius Commission Hazard Analysis and Critical Control Point (HACCP) – Guidelines for Implementation and Use, ALINORM 97/13A as amended from time to time.

APPENDIX B

Guidance for FSC36 Safe Feed/Safe Food Seal or Logo



Upon receiving FSC36 Safe Feed/Safe Food certification, the facility may use the FSC36 Safe Feed/Safe Food Seal or logo ("Safe Feed/Safe Food seal"). Before using the seal (logo), the facility ("Licensee") must complete and sign the LICENSING AGREEMENT FOR THE USE OF THE SAFE FEED/SAFE FOOD SEAL (licensing agreement).

The intent of this guidance is to provide directions and an overview of the requirements for using the logo. Please refer to the licensing agreement for specific requirements.

- 1) Upon completing and signing the licensing agreement, the Safe Feed/Safe Food seal (logo) may be used in connection with feeds or materials (raw materials or ingredients) for food-producing animals or companion animals.
- 2) The Licensee may use the Safe Feed/Safe Food seal (logo) on all labels and labeling of feed products at the facility that holds a valid certification issued by certifying bodies. Using the "Use of the Safe Feed/Safe Food seal" on labels and labeling shall be in compliance with the following requirements:
 - a) The Safe Feed/Safe Food seal (logo), when used on feed packaging, shall be at least two linear inches, but not more than four linear inches in height and placed at least three linear inches from the edge of the package. When used on feed tags (labels that are attached to a feed package), the seal (logo) shall be at least one-half linear inch, but not more than one linear inch in height.
 - b) A statement along the lines of the following shall be printed in reasonably close proximity to the Safe Feed/Safe Food seal (logo): *"This feed was produced in a facility certified in the American Feed Industry Association's Safe Feed/Safe Food Certification Program; for details go to: www.safefeedsafefood.org."* Another optional statement to consider is: *"Safe Feed/Safe Food is AFIA's facility certification program (www.safefeedsafefood.org)."*
- 3) Licensee may, at its option, use the Safe Feed/Safe Food seal (logo) on all labels and labeling of food for human consumption derived from animals fed exclusively feeds produced in a facility certified by AFIA under the Safe Feed/Safe Food Certification Program. See the licensing agreement for details for using the seal (logo) for this purpose.
- 4) Licensee may, at its option, use the appropriate Safe Feed/Safe Food seal (logo) in advertising or promotional material. See the licensing agreement for more details and directions for using the logo for this purpose.
- 5) Where licensee operates more than one feed manufacturing establishment and not all such establishments hold valid certifications under the FSC36 Safe Feed/Safe Food Certification

Program, licensee may, at its option, use the appropriate Safe Feed/Safe Food seal (logo) on non-product-specific materials only in compliance with the following requirements:

- a) The appropriate Safe Feed/Safe Food seal may be used on signage only for those establishments that hold valid certifications under the FSC36 Safe Feed/Safe Food Certification Program, unless licensee complies with B below.
- b) The Safe Feed/Safe Food seal (logo) may be used on non-product-specific advertising or other promotional materials, letterheads and in similar ways, if a statement along the lines of the states which establishments have been certified. See the licensing agreement for more details and directions for using the seal (logo) for this purpose.
- 6) The Safe Feed/Safe Food seal (logo) may be printed in either black and white or with “PMS 286” or equivalent color and white. AFIA must approve any deviation in color before use in writing.
- 7) Licensee agrees not to state or suggest, directly or indirectly, in connection with any use of the Safe Feed/Safe Food seal (logo), that any particular lot of product has been inspected and certified for compliance with FDA, state or other requirements.
- 8) Except as provided in this license, the Safe Feed/Safe Food seal (logo) may only be used with the express written permission of AFIA.
- 9) This license shall continue in effect until terminated in accordance with the following provisions:
 - a) This license shall be deemed terminated with respect to any facility if the licensee chooses not to have that facility participate annually under the FSC36 Safe Feed/Safe Food Certification Program, or if that facility fails an inspection and the appeal procedure established by AFIA has been exhausted.
 - b) AFIA may terminate this license by written notice, effective upon receipt, for any material breach of this license by licensee. Material breach includes, but is not limited to, Licensee’s knowing use of the Safe Feed/Safe Food seal (logo) in violation of this license.
 - c) Either party may terminate this license with 30 days written notice to the other party.
- 10) Following termination of this license in its entirety, licensee shall immediately stop all use of the Safe Feed/Safe Food seal (logo). Following termination of this license with respect to a specific facility, the licensee shall immediately stop all use of the Safe Feed/Safe Food seal (logo) in connection with product produced at that facility. However, in either case, the Safe Feed/Safe Food seal (logo) may be used on labels and labeling of any product produced before the date of termination.
- 11) Should the licensee decide to not renew the FSC36 Safe Feed/Safe Food certification, the licensee shall stop all use of the Safe Feed/Safe Food seal (logo) on the day following the expiration date of FSC36 Safe Feed/Safe Food certification for the facility.
- 12) Licensee agrees that it will not modify or otherwise misuse the Safe Feed/Safe Food seal (logo) or bring the Safe Feed/Safe Food seal (logo) into disrepute. Licensee also agrees not to violate any federal or state trademark law concerning the use of the Safe Feed/Safe Food seal (logo).
- 13) Licensee acknowledges AFIA’s ownership of the Safe Feed/Safe Food seal (logo), and will not in any manner represent that licensee has any ownership therein, and will not knowingly in any way impair AFIA’s ownership interest.
- 14) Licensee acknowledges that use of the Safe Feed/Safe Food seal (logo) in violation of the terms of this license may cause AFIA irreparable harm, the amount of which may be difficult to ascertain and,

therefore, agrees that AFIA has the right to apply to a court of competent jurisdiction for an order restraining any further misuse, and for such other relief as may be appropriate.

- 15) See the licensing agreement for more details about the use of the Safe Feed/Safe Food seal.

See AFIA's LICENSING AGREEMENT FOR THE USE OF THE SAFE FEED/SAFE FOOD SEAL for more details about using the AFIA FSC36 Safe Feed/Safe Food logo.

APPENDIX C

FSC36 Safe Food/Safe Feed Surveillance Audit Guidance

FSC36 Safe Feed/Safe Food is a two-year certification and an on-site audit is required to obtain certification. An on-site audit is required the first year while a surveillance audit (remote audit) may be completed the second year. The surveillance audit covers all mandatory clauses as identified within the FSC36 Safe Feed/Safe Food guidance document (see Section 5). The supplier is required to close nonconformance items or nonconformities before the certification can be issued.

For surveillance audits, the objective of the certification body is to collect sufficient information from the supplier to ensure compliance with the mandatory clauses is maintained. The following is guidance for suppliers and certification bodies for completing surveillance audits for FSC36 Safe Feed/Safe Food.

- 1) The surveillance audit should be scheduled and completed +/- 30 days of the anniversary date of the last on-site audit. The certification body is responsible for scheduling the surveillance audit and designating the auditor. Suppliers that do not complete the surveillance audits in a timely manner are subject to removal from the Safe Feed/Safe Food certified facility listing on the website. Verification of completed surveillance audits will be completed by AFIA on a random basis.
- 2) The supplier should retrieve the [FSC36 Safe Feed/Safe Food Surveillance Audit checklist](#) from the Safe Feed/Safe Food website. Within the column for “Supporting Compliance Information”, the supplier should provide information to support the compliance with this clause. The supplier should save the file and send to the certification body.
- 3) The certification body shall receive the inputs within the FSC36 Safe Feed/Safe Food Surveillance Audit checklist from the supplier. The auditor shall determine additional information needed to confirm the supplier maintains compliance with the FSC36 Safe Feed/Safe Food guidance document. The information should be provided in a manner that is acceptable to both parties. As an example, electronic copies, US postal delivery, photographs, screenshots, or visual review (e.g., webcast or Skype) are acceptable. If preferred, the surveillance audit may be replaced by another on-site audit.
- 4) The auditor and supplier must reserve at least a 4-hour period and be available for a conference during this time. Capability for web-viewing of documents is recommended, but not required. The objective of the conference call is to review the surveillance audit checklist with entries/inputs from the supplier.
- 5) Certification body is responsible for completing the FSC36 Safe Feed/Safe Food Surveillance Checklist within the SQFI database. Based on the surveillance audit results, the status of the supplier as certified is maintained or an on-site audit is scheduled.
- 6) Any nonconformance items identified during the surveillance audit must be closed by the supplier within the timelines as outlined in Section 2.5. Failure to do so could result in a suspension of the supplier’s certification. If the requirements of the surveillance audit are not met, the supplier shall be required to complete an on-site audit within 90 days.
- 7) The surveillance audit is not scored.
- 8) The certification body shall provide a copy of the completed Surveillance Audit report to the supplier within 30 days of closure of any nonconformance items by the supplier.