# FSC36 SAFE FEED/SAFE FOOD: Guidance for Developing, Documenting, Implementing, Maintaining and Auditing the Program (Edition 6.0)

Version 6.0

# 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 implement the various clauses 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 and promote a culture of continual improvement of a Supplier's quality and feed safety program. The guidance is not intended to cover every possible scenario that may be seen across the feed industry. It is not definitive 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 feed safety program. The American Feed Industry Association (AFIA) is grateful to its Quality 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 6.0.

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# SECTION 1.0 Introduction

The purpose of the guidance document for FSC36 Safe Feed/Safe Food is to assist Suppliers with designing, developing, implementing and maintaining a quality and feed 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 6.0.

# 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.

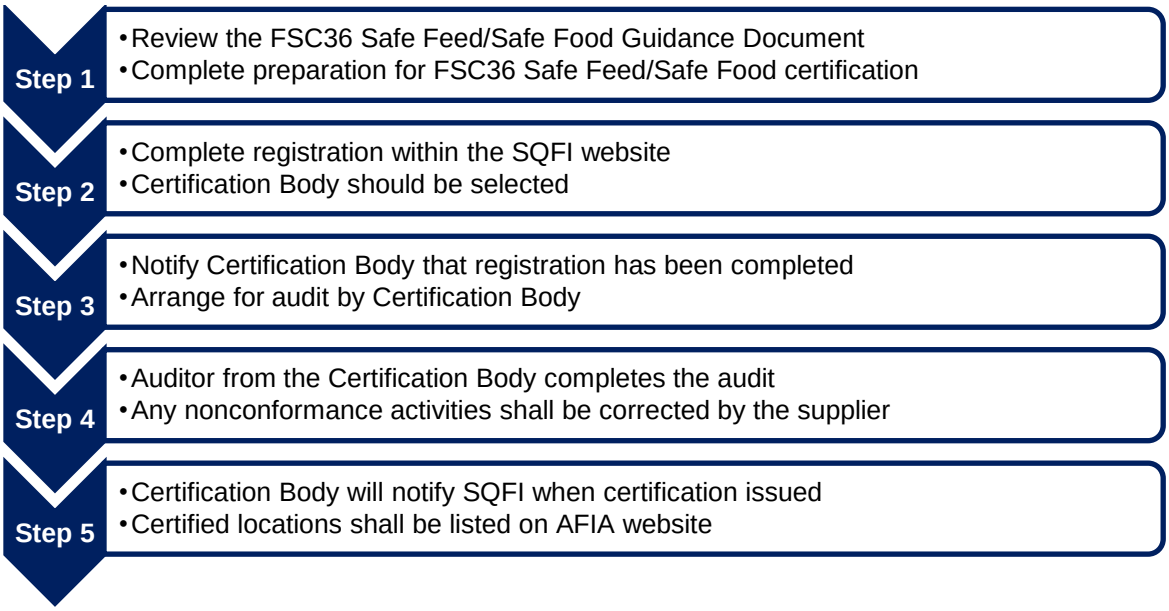
SQFI is recognized by the Global Food Safety Initiative (GFSI) and links primary production certifications to food manufacturing, distribution, and agent/broker management certifications. GFSI is an approved (benchmarked) choice of third-party food safety certification programs that are required by many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

| SQFI Code | Certification | GFSI Benchmarked |
|---|---|---|
| FSC36 | Safe Feed/Safe Food | |
| FSC34 | Animal Feed Manufacturing Facility<br>Animal Feed Ingredient Facility |   |
| FSC32 | Pet Food Manufacturing Facility Pet<br>Food Ingredient Facility |   |

## 2.2 Registration and Certification Steps

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

FSC36 Safe Feed/Safe Food is a two-year certification. However, 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.

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, which is a remote audit, may be completed the second year. An on-site audit may be completed the second year as well, if preferred by the Supplier, or determined necessary based on the previous on-site audit. The on-site audit covers all elements 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 remote audit covers all mandatory elements.
5) Audits for the two-year certification are completed by the same Certification Body. Should a Supplier choose to change certifying bodies, an on-site audit is needed.

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 elements 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 remote audits, the Certification Body collects sufficient information from the Supplier to ensure compliance with the mandatory elements is maintained. The Certification Body completes the audit form for the Supplier online within the SQF database. Any nonconformance items identified during the remote 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 remote audit are not met, the Supplier shall be required to complete an on-site audit within 90 days.

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 its website (www.afia.org).

### 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 feed 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 Elements

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

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

- 1.1 Management Policy (M)
- 1.2 Management Responsibility (M)
- 1.3 Responsibility, Authority and Communication (M)
- 2.2 Quality and Feed Safety Manual (M)
- 2.3 Document Control (M)
- 2.4 Records (M)
- 3.1 Competency and Job Descriptions (M)
- 3.2 Training and Awareness (M)
- 4.4.1 Pest Management (M)
- 4.4.2 Pest Control Chemicals (M)
- 4.5 Cleaning and Housekeeping (M)
- 5.3.1 Process Control (M)
- 5.3.3 Product Release (M)
- 5.4.1 Finished Products Specifications (M)
- 5.4.2 Product Formulation (M)
- 5.7 Nonconforming Products and Materials (M)
- 5.8 Rework (M)
- 5.11.1 Hazardous Chemical Storage Process (M)

- 5.11.2 Hazardous Chemical Storage Area (M)
- 6.1.1 Approved Vendors (M)
- 6.2 Raw and Packaging Materials Specifications (M)
- 7.7 Product Identification (M)
- 7.8 Product Traceability (M)
- 8.1 Animal Food Safety Fundamentals (M)
- 8.2 Animal Food Safety Plan (M)
- 8.2.1 Animal Food Safety Plan Responsibilities (M)
- 8.2.3 Hazard Analysis of Processes (M)
- 8.2.4 Hazard Analysis of Materials (M)
- 8.2.5 Preventive Controls (M)
- 8.3 Corrective and Preventive Actions (M)
- 8.4 Regulatory Requirements (M)
- 8.5 Recall Plan (M)

Mandatory elements are designated with an "(M)" after the element 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 feed safety system that produces unsatisfactory conditions that if not addressed may lead to a risk to quality and feed safety but not likely to cause a system element breakdown.
- Major nonconformity is an omission or deficiency in the quality and feed safety system producing unsatisfactory conditions that carry a quality or feed safety risk and likely to result in a system element 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 feed 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 feed 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 feed 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 nonconformances, 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 feed 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.

Deviations identified during the audit shall be accurately described in the audit report and corrective action requests raised which fully describe the element requirement and the reason for the nonconformity. 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). A surveillance audit may be completed the year following an on-site audit. 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), 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 in the opinion of the Certification Body, fails to maintain the requirements of FSC36 Safe Feed/Safe Food.

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 also notify SQFI and 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 the Certification Body.

### 2.11 Complaints, Appeals and Disputes

When a Supplier has cause to register a complaint about a Certification Body's activities, 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.

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 SQF certification by a Certification Body shall not delay the decision to suspend or withdraw the certification.

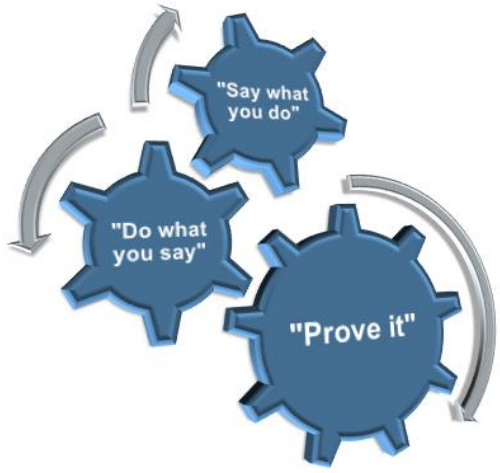
Where a complaint is registered about the conduct or behavior of an auditor or Certification Body personnel, the Certification Body shall investigate and resolve the complaint without delay and keep a record of all complaints and their resolution.

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.

# SECTION 3 Implementation Process

To achieve FSC36 Safe Feed/Safe Food certification, the Supplier must document and implement the relevant elements described within the guidance document (see Section 5). It is also important to provide evidence of the Supplier's quality and feed safety system in the form of documents and records. The implementation process is shown below.

- *Document* – Prepare policies, procedures, work instructions and specifications that address the relevant elements of the FSC36 guidance document Version 6.0. 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 elements of the FSC36 guidance document. These records provide evidence of the function and control of the system. In other words, *"Prove it."*




# SECTION 4 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 6.0.

This particular guide covers the requirements for FSC36 Safe Feed/Safe Food certification. It includes current Good Manufacturing Practices (CGMPs) for animal feed 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 feed 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 animal 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 feed or feed-related products to control animal food safety. The program includes:

- Commitment of the site management to maintain a safe, quality feed supply and the management processes that must be in place to do so;
- Hazard analysis and preventive controls that identify and control hazards;
- An animal food safety program that identifies quality threats and defines their control;
- Product traceability and recall;
- Control of contamination, particularly from high-risk materials, such as medications; and
- Staff training requirements.

It is recognized that not all elements of FSC36 Safe Feed/Safe Food are applicable to all feed or ingredient production facilities. Some elements 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 element(s).

### 4.3 Format of Guidance Information

The following section explains the elements and sub-elements of FSC36 Safe Feed/Safe Food and provides guidance on what a Supplier needs to do to develop, document and implement its requirements, and provides information on what the auditor may be looking for to confirm compliance.

The following format is used throughout:

**MAJOR ELEMENT AREA NUMBER AND NAME**

**Element Number and Name**

**Sub-element Number and Name**

This section will describe the requirements for FSC36 Safe Feed/Safe Food compliance.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br>This will include the interpretative comments of what the element or sub-element requires or definitions of the terms used. This will include suggestions of what is required to be done by the Supplier to document and implement this element or sub-element. The information provided is not considered exhaustive and may not apply in every situation. It is meant to provide guidance and interpretation. |

| Auditing Guidance |
| --- |
| This will include suggestions of what the auditor may seek as evidence of compliance for this sub-element ("Ensure that…"). The information provided is not exhaustive and may not apply in every situation. |

Several elements are noted as mandatory elements and cannot be reported as "not applicable" or "exempt." These elements must be audited and compliance status reported. Mandatory elements are designated with an "(M)" after the element in FSC36 Safe Feed/Safe Food guidance document.

# SECTION 5 Requirements for FSC36 Safe Feed/Safe Food Certification

The requirements for FSC36 Safe Feed/Safe Food certification are described below. It includes CGMPs for animal feed production as well as the requirements for an effective animal food safety program.

It is the intent of the FSC36 Safe Feed/Safe Food program to support the requirements as outlined in FSMA as well as help drive continuous improvement within a Supplier's location quality and feed safety program.

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

Feed and feed materials intended for consumption by animals must be produced, processed and handled in a safe and efficient manner. In order to accomplish this, feed processing premises shall be 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 each aspect of the manufacturing process to assist in understanding various requirements. It also details some of the fundamental practices that must be in place to protect the safety and quality of feed.

## 1 MANAGEMENT COMMITMENT AND RESPONSIBILITY

### 1.1 Management Policy (M)

1) Management shall prepare and implement a policy statement that outlines at a minimum:
   a) The organization's commitment to provide quality and safe feed
   b) The methods used to comply with its customer and regulatory requirements and continually improve its quality and feed safety system
   c) The organization's commitment to establish and review animal food safety objectives
2) The policy statement shall be signed by management, made available in a language understood by all staff, and displayed in a prominent position and effectively communicated to all staff.

| Implementation Guidance |
| --- |
| *What does it mean?*<br>At this level, the owner or most senior responsible person is required to document and sign a quality and feed safety policy that clearly demonstrates their understanding of their animal food safety responsibility under the FSC36 Safe Feed/Safe Food program, and outlines how the organization will |

achieve and maintain animal food safety. This includes a stated commitment to make the appropriate resources available to implement an animal food safety plan. The policy may be signed by an individual that represents senior management and who has decision-making authority in management. The intent is to demonstrate management's commitment to implement an effective quality and feed safety system. In order to keep pace with changes in company policy, the quality and feed 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 feed safety policy.

**Auditing Guidance**

Ensure that:

- A signed quality and feed safety policy is available.
- The policy is adequately communicated to personnel.
- Policy is posted in a prominent area for review by personnel.
- Policy is provided in additional languages, if needed.

## 1.2 Management Responsibility (M)

1) The organizational reporting structure describing those who have responsibility for quality and feed safety shall be defined and communicated within the organization.

2) The 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 feed safety system.

**Implementation Guidance**

*What does it mean?*

An organizational structure should be available with key personnel listed. Positions with responsibility for quality and feed safety should be listed. The structure should be reviewed and approved by personnel responsible for the Supplier's human resources or a member of senior management. The document should provide a snapshot of how positions interact and share responsibility for quality and feed safety.

The Supplier's location needs to demonstrate that an environment exists in which employees are encouraged to report quality and feed safety problems, if detected.

**Auditing Guidance**

Ensure that:

- An organizational reporting structure is available and approved, showing personnel with quality and feed safety responsibilities.

- Adequate resources are available to meet the defined quality and feed safety objectives.
- Management demonstrates a commitment to quality and feed safety based on actions or activities, such as management team meetings, training of personnel and available resources.

## 1.3 Responsibility, Authority and Communication (M)

1) The management leader or team shall designate a quality and feed safety practitioner (also known as the Practitioner) for each site. The Practitioner will be responsible for and have authority to oversee the development, implementation, review and maintenance of the quality and feed safety system, including: animal food safety fundamentals outlined in Element 8.1, and the animal food safety plan outlined in Element 8.2; to take appropriate action to ensure the integrity of the quality and feed safety program; and communicate to relevant personnel all information essential to ensure the effective implementation and maintenance.

2) The Practitioner shall be employed by the Supplier as a company employee on a full-time basis, hold a position of responsibility in relation to the management of the quality and feed safety system, and understand the FSC36 requirements relevant to the Supplier's scope of certification. Although HACCP certification by the Practitioner is not required, the Practitioner should have a grasp of the principles of HACCP and command the ability to identify hazards and develop preventive controls to reduce or prevent potential animal food safety risks.

3) All staff shall be informed of their responsibility to report animal food safety problems to personnel with authority to initiate action.

### Implementation Guidance

*What does it mean?*

The management team, or management leader of the location, is responsible for designating a person as the Practitioner for the quality and feed safety system. The person should have authority to drive the quality and feed safety system throughout the location. This responsibility is often assigned to the quality and feed safety leader for the location and is listed on the person's job description. In addition, the Practitioner should be the leader of the animal food safety team.

The Practitioner is the individual designated by management to develop, validate, verify and maintain the location's animal food safety plan. The Practitioner may engage the services of a consultant to support validation and verification of quality and feed safety system and FSC36 requirements.

Personnel need to understand their responsibility for ensuring the quality and safety of products produced. 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.

The responsibility for animal food safety should be conveyed to every employee. This may be accomplished through job descriptions at all levels. Job descriptions for key personnel need to include a provision to cover for their absence. You must also provide documented instruction to staff to report animal food safety and quality problems to personnel with authority to initiate action.

Management must also document how they will provide resources to achieve the quality and feed safety objectives. Management should demonstrate to employees their support of the development, implementation and maintenance as well as ongoing improvement of the quality and feed safety system.

**Auditing Guidance**

Ensure that:

- Practitioner for the location has been identified and is employed full time by the Supplier.
- Practitioner understands the principles of HACCP and is capable of managing the animal food safety system, which should be based on the information provided during the audit.
- A training program exists that ensures personnel understand their requirements for quality and feed safety.

## 1.4 Management Review

### 1.4.1 Management Review Process

1) Management shall be responsible for reviewing the quality and feed safety system and documenting the review procedure.

2) Any changes to the animal food safety plan shall be reviewed during management review meetings.

3) The management shall establish processes to improve the effectiveness of the quality and feed safety program to demonstrate continuous improvement.

4) A documented procedure shall be maintained that describes management review and its process. It shall include frequency, expected attendees, general overview of information to be reviewed and expected actions to be taken.

**Implementation Guidance**

*What does it mean?*

Management should ensure that the entire quality and feed safety program is reviewed annually. A written procedure should be maintained that outlines the process for the management review including the frequency, information reviewed and responsibilities for actions to be taken. The management review should be led by the president, general manager or leader of the facility or operation. The practitioner may assist with gathering information and participate in the management review. Actions taken by the management team should be assigned to management team members.

The intent of the review is to provide direction for improvements to the program, including resources and changes. Reviews should include the quality and feed safety policy, internal and external audit findings, corrective actions with their investigations and resolution, customer complaints with their resolution and investigation, as needed.

All reviews and major changes to the quality and feed safety program should be documented by the Practitioner. Documentation should include reasons for any changes.

NOTE: The review of the entire quality and feed 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.

**Auditing Guidance**

Ensure that:

- Written procedure for management review is maintained and controlled.
- The entire quality and feed safety program has been assessed by management.
- Management team determines actions needed based on the inputs discussed during the meeting.
- Any changes to the animal food safety plan have been validated by the Practitioner.

### 1.4.2 Management Reviews Inputs and Outputs

1) 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) Any failures in the quality and feed safety program
   c) Nonconformities identified from audits (internal and external) completed since last meeting
   d) Corrective and preventive actions taken for continuous improvement
   e) Changes within processes or at location that may impact product quality and feed safety
   f) Changes to the animal food safety program
   g) Regulatory changes that may impact the quality and feed safety program
   h) Industry news or activities relevant to the quality and feed safety program

2) The 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 feed safety system
   c) Sufficient resources to implement an effective quality and feed safety program and desired outcomes

**Implementation Guidance**

*What does it mean?*

When completing a management review of the quality and feed 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.

Major changes to a process, a process control or any change that could impact the ability of the system to deliver a safe quality feed, may trigger a review of the animal food safety plan in addition to the annual review. Any changes to the animal food safety plan shall be validated and verified by the Practitioner before implementation. These changes should be reviewed during the management review meetings.

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.

**Auditing Guidance**

Ensure that:

- Sufficient information is reviewed during management review to assess the effectiveness of the quality and feed safety system.
- Management provides an assessment of the information provided in regards to the effectiveness of the quality and feed safety system, determines whether changes in the system are needed and whether or not sufficient resources are provided to meet the desired goals for the quality and feed safety system.
- The animal food safety fundamentals and the animal food safety plan have been reviewed when (if) any changes have been implemented that may impact the Supplier's ability to deliver safe animal food.
- Any changes to the animal food safety plan have been validated by the Practitioner.

### 1.4.3 Records for Management Review

1) Records of management reviews shall be maintained. This shall include a running list of recommended actions and their current status.

2) Information shared during a management review shall be kept with the management review records.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Records of management reviews are maintained and complete.

## 2.0 QUALITY AND FEED SAFETY MANAGEMENT SYSTEM

### 2.1 General Requirements

1) The Supplier shall establish, document, implement and maintain a quality and feed safety system and continually improve its effectiveness.

2) A quality and feed safety manual shall be maintained.

3) The Supplier shall determine the processes needed for the quality and feed safety system and their application throughout the organization.

4) Quality and feed safety policies may be used to provide insight into the practices that drive the implementation and procedures for the quality and feed safety program. Quality and feed safety policies may include descriptions of the following:

   a) Management commitment.

   b) Management review.

   c) Scope of the quality and feed safety system and FSC36 certification.

   d) Processes critical to ensuring the quality and feed safety of products.

   e) Animal food safety plan and processes to implement.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br><br>The Supplier's quality and feed safety program includes the development of procedures and processes to ensure the desired level of quality and feed safety is obtained. The documentation for the program should be organized and maintained within the quality and feed safety manual.<br><br>Documentation within a quality and feed 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 feed safety. |
| **Auditing Guidance** |
| Ensure that:<br>• General requirements for the quality and feed safety system have been established and documented.<br>• Information within the quality and feed safety manual is accurate and current. |

## 2.2 Quality and Feed Safety Manual (M)

1) The Supplier shall establish and maintain a quality manual that includes:

   a) The scope of the quality and feed safety system, including exclusions from the FSC36 Safe Feed/Safe Food Certification Program.

   b) Documented procedures that have been established for the quality and feed safety system.

2) Polices that impact the quality and feed safety system shall be documented within the manual and maintained in either electronic and/or hard copy form.

3) The manual shall be readily available to personnel.

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

a) Quality and feed safety policy statement

b) Organization chart

c) Quality and feed 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 feed safety policies

| **Implementation Guidance** |
|---|
| *What does it mean?*<br><br>The Supplier is required to develop and maintain a quality and feed safety manual. The manual should include any policies that impact the quality and feed safety system. The scope of the quality and feed safety system should be included. If there are exclusions for the FSC36 Safe Feed/Safe Food certification, the justification should be provided in detail.<br><br>The manual should include all documents created specifically for the quality and feed safety system, such as standard operating procedures for the CGMPs. Procedures should be maintain in an understandable format for personnel to follow and implement. Documents should be controlled and easily obtainable by personnel, if needed. A controlled listing of procedures is needed. There is no prescribed format for documents or how the quality and feed safety manual should be organized in order to comply with the FSC36 Safe Feed/Safe Food requirements. It is important that the quality and feed safety manual meet the Supplier's requirements and allow effective communication within its network or system. |
| **Auditing Guidance** |
| Ensure that:<br>• A quality and feed safety manual is established and maintained.<br>• Information within the quality and feed safety manual is accurate and current. |

## 2.3 Document Control (M)

1) The methods and responsibility for maintaining document control shall be maintained.

2) The Supplier shall ensure staff has access to current documents.

3) Proper training for document control is needed to ensure records are as accurate as possible.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br><br>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. |

**Auditing Guidance**

Ensure that:

- A procedure for document control has been established and has been implemented.
- Training on document control is defined and records of training are maintained.

## 2.4 Records (M)

1) Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and retained for a minimum of two years or as otherwise required by customers or regulatory compliance.

2) The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.

3) All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

4) A list of records shall be maintained.

**Implementation Guidance**

*What does it mean?*

A written procedure for maintaining records is needed to comply with this requirement. 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 to monitor a quality and feed safety program. The Supplier must have the means to manage electronic security of records, electronic signatures of monitors and reviewers, and the means for electronic review which must be demonstrated to the auditor.

A list of records that are kept should be maintained with the retention times for these records provided. It is recommended that a minimum time be listed vs. a specific length of time. Records under two years are acceptable provided that the designated program has been implemented less than two years and the Supplier demonstrates adequate program implementation.

**Auditing Guidance**

Ensure that:

- A written procedure for records is maintained and implemented.
- Records are legible and properly stored.
- A list of records that are kept is maintained.

## 3 PERSONNEL AND TRAINING

### 3.1 Competence and Job Descriptions (M)

1) The Supplier shall determine the necessary competence for personnel performing work affecting the quality and feed safety of products or services.

2) Competencies shall be described within job descriptions. All personnel shall have a job description.

3) Where contractors are utilized, competency expectations shall be provided to the approved vendor providing the services or completed work.

4) The Supplier shall maintain adequate records of education, skills and experience of personnel.

**Implementation Guidance**

*What does it mean?*

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 competencies maintained or achieved by personnel.

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

**Auditing Guidance**

Ensure that:

- Job descriptions are available for personnel with competencies required for responsibilities of the position or duties assigned.

### 3.2 Training and Awareness (M)

1) Where applicable, the Supplier shall provide training or take actions to achieve the desired competence for personnel.

2) Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the quality and feed safety system as well as regulatory requirements.

3) An employee training program shall be documented and implemented. A training program may include (but not limited to) the following:

   a) Training schedule for topics that impact the quality and feed 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 feed safety program.

d) Tracking of employee training needs.

e) Training needs or competencies for positions impacting quality and feed safety.

4) Instructions, such as SOP's, work instructions and training manuals, shall be available to personnel to support training.

5) Training materials and the delivery of training shall be provided in language understood by staff.

6) The Supplier shall ensure that personnel are aware of the relevance and importance of their job activities and how they contribute to the achievement of the quality and feed safety objectives.

**Implementation Guidance**

*What does it mean?*

Training should be completed for each person in regards to the importance of quality and feed safety. The training should outline the actions required by the person to control or prevent potential hazards. A record of the training shall be kept.

While HACCP is not required, the principles of HACCP are needed to effectively complete hazardous analysis and preventive control training. It is recommended that HACCP training be completed by key personnel through specific HACCP training seminar, online training or video training.

Once the training requirements are identified, the Supplier should ensure that staff is trained to competently carry out their duties and responsibilities. Clear and concise instructions are needed to ensure employees understand the requirements and expectations. This may be accomplished through SOP's, work instructions, seminars, videos or on-the-job training. Photos and diagrams can be particularly useful to overcome language barriers or when a task involves a number of different steps.

The Supplier should provide training materials and proper training in the appropriate language if the primary language for personnel is different from the primary language of the Supplier's business.

There should be records maintained of all training and any follow up required for all personnel.

**Auditing Guidance**

Ensure that:

- A defined training program has been established and implemented.
- Personnel are trained for positions that directly impact the quality and feed safety of finished products as well as the animal food safety plan.
- Training is tracked to ensure personnel are trained appropriately as scheduled.
- Training program is effective.
- Key personnel understand the principles are HACCP and that these personnel are capable of completing a hazard analysis and implementing preventive controls as required for the animal food safety plan. This is demonstrated and provided by the Supplier.

## 3.3 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. This includes (but not limited to):
   a) Clothing and personal apparel.
   b) Shoes worn inside and outside of the facility.
   c) Dirt or filth that may be carried into the work area.

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.

3) The Supplier shall maintain a policy for personnel behavior that shall include (but not limited to):
   a) Permission for smoking, eating and chewing (e.g., gum, tobacco) in designated areas.
   b) Control measures to avoid hazards from jewelry.
   c) Permission of personal items (e.g., cell phones, smoking materials, medicines, etc.) in designated areas only.
   d) Maintenance of personal lockers so they are kept free of rubbish and soiled clothing.

4) Fluids provided for consumption in the manufacturing or storage areas shall be controlled to prevent the potential for contamination.

5) Personnel shall be provided adequate facilities for cleaning to prevent the potential contamination of animal foods.

6) Clothing worn by staff engaged in handling feed 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.

7) 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

*What does it mean?*

Employees must be aware of risks to the feed 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 pet food.

Also, employees must be aware of the risks from physical contamination from jewelry or other items, such as cell phones, carried within a manufacturing facility.

The Supplier shall maintain policies that provide employees with guidance and requirements to prevent the spread of disease or potential physical contamination.

**Auditing Guidance**

Ensure that:

- Personnel policies are established and maintained to ensure proper hygiene for the relative work areas are maintained.
- Personnel policies are established and implemented to ensure physical contamination from jewelry or other loose objects is prevented.
- A clothing policy is established and maintained to maintain animal food safety as well as personnel safety. Employees and visitors must wear clean clothing and footwear appropriate for the processing area.
- Smoking, eating, chewing and drinking are not permitted in production areas.
- Personnel should be trained with documentation of the understanding these requirements.

## 3.4 Personnel Facilities

1) Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as needed.

2) Changing rooms shall be available, clearly designated and maintained as necessary for animal food safety.

3) Lunch room facilities shall be available for personnel. The facilities shall be:
   a) Kept clean and free from waste materials and pests.
   b) Ventilated with adequate lighting.
   c) Appropriate tables and seating.

4) Restrooms shall be readily accessible without jeopardizing the animal food safety plan.

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**

*What does it mean?*

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

Sufficient restrooms/toilets are required to accommodate the number of staff. Toilets should be easy to clean and kept clean.

The personnel 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 feed handling areas.

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

**Auditing Guidance**

Ensure that:

- Changing room(s) for personnel are maintained in clean and good condition; appropriate equipment and items are provided for employees to store personal items and clean or wash as needed.
- First aid supplies are readily available, as needed.
- Restroom or toilet facilities are clean and maintained in good condition.

## 3.5 Visitors

1) All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any feed 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 feeds or feed ingredients.

4) Visitors shall enter and exit feed 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 feed safety program, animal food safety plan and personnel safety requirements.

**Implementation Guidance**

*What does it mean?*

Visitors represent a potential risk to animal food safety and shall follow the same requirements as personnel when visiting the facility.

Visitors should dress appropriately, including footwear, during a facility visit. Only invited quests should be allowed in to controlled areas. As an example, truck drivers should remain in restricted areas.

If needed, training of visitors should be completed and documented.

Documentation of visitors should be maintained.

**Auditing Guidance**

Ensure that:

- Visitor policies are established and implemented to ensure the integrity of the biosecurity program and the safety of animal foods.
- A record of visitors is maintained.

## 4 INFRASTRUCTURE

### 4.1 Facility Construction and Surfaces

1) Facilities and contact surfaces shall be constructed of materials that will not contribute to an animal food safety risk.

2) Floors shall be constructed of material that can be effectively cleaned, drained and is impervious to liquids.

3) In areas where water is used, floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Water shall not be allowed to pond or become stagnant.

4) Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be kept clean.

5) Wall to wall and wall to floor junctions shall be designed to be cleaned in order to prevent the accumulation of debris.

6) Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed so as to allow ease of cleaning.

7) Doors, hatches and windows and their frames shall be of a material and construction that meets the same functional requirements for internal walls and partitions.

8) Animal foods shall be processed and handled in areas that are fitted with a ceiling or other acceptable structures that is constructed and maintained to prevent the contamination of products.

9) Stairs, catwalks and platforms in feed processing and handling areas shall be designed and constructed so as not to present a product contamination risk and shall be kept clean.

10) The Supplier shall take precautions to prevent glass or plastic fragments from entering product or packaging.

**Implementation Guidance**

*What does it mean?*

The facility and contact surfaces at the site shall be constructed in a way that would be easily cleanable and prevent contamination to the finished product or the process.

Water should not be allowed to pool or build up within or around the facility.

Facilities must be designed and constructed in such a way as to minimize the risk to product safety and in some instances to offer protection to the product. The extent to which these elements are

relevant will depend on the type of processes housed and whether the product is enclosed or exposed.

Today's feed facilities are designed generally to exclude windows in feed processing areas. However, older plants may have glass windows. The Supplier must, as part of their foreign matter control program, identify any windows that could pose a hazard to unpackaged product and primary packaging if shattered. Windows away from the immediate processing areas are generally not recognized as posing a hazard to packaged feed. Windows close to processing areas and skylights that are located immediately above product processing or packaging areas can pose a hazard. The Supplier must take precautions to prevent glass or plastic fragments from entering product or packaging should such windows break. Window ledges should also be sloped downward for ease of cleaning and to prevent their use for unwanted storage of tools or other materials.

All stairs, catwalks and platforms that are positioned over any portion of the processing area where product is exposed, shall be constructed so as to not present a product contamination risk. Stairs, platforms and catwalks shall be kept clean and not used to store tools and equipment.

**Auditing Guidance**

Ensure that:

- The facility and contact surfaces at the site are constructed in a way that would be easily cleanable and do not pose a threat to contamination of finished products or the manufacturing process.
- Facility is cleaned sufficiently to avoid potential contamination risk.
- Constructions of the manufacturing area for finished product is designed and maintained to avoid potential contamination.
- Stairs, catwalks and platforms do not pose a risk for contamination.

## 4.2 Equipment and Maintenance

### 4.2.1 Equipment

1) Equipment and tools shall be designed, constructed, installed and operated so as to be fit for purpose, constructed to facilitate cleaning and maintenance, and not pose a contamination threat to animal food products.

2) Installation of new equipment shall be assessed for potential risks and animal food safety plan updated.

3) Changes to equipment shall be documented. Potential risks due to the changes shall be assessed and reported.

**Implementation Guidance**

*What does it mean?*

Feed processing equipment shall be designed, constructed and maintained in accordance with manufacturer and/or industry standards.

Whenever new equipment is installed or current equipment is modified, a risk assessment should be completed and the animal food safety plan updated, if necessary. Records should be maintained and stored.

**Auditing Guidance**

Ensure that:

- Equipment is appropriate for the purpose for which it is used.
- Equipment does not pose a risk for contamination to finished product, “work in progress” product, raw materials or ingredients.
- Records for installation of new equipment or changes to existing equipment that may impact quality and feed safety are maintained
- Animal food safety plan reflects installation of new equipment or changes to existing equipment, as needed.

### 4.2.2 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 feed.

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**

*What does it mean?*

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.)
- 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

Where machinery located over product lines or feed contact surfaces require lubrication, only food/feed grade lubricant is to be used. Even then, feed-grade lubricant is still a quality hazard and must be used sparingly to avoid contact with product.

**Auditing Guidance**

Ensure that:

- A preventive maintenance program is established and implemented.
- Records documenting an effective maintenance program are provided, including when equipment failure or nonconformities occur.
- Appropriate lubricants are used.

## 4.3 Lighting and Work Areas

1) Lighting in feed manufacturing and 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 feed handling areas.

5) Work areas are suitable for personnel to complete required activities.

### Implementation Guidance

*What does it mean?*

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 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.

### Auditing Guidance

Ensure that:

- Lighting is appropriate in work areas for personnel to complete required work.
- Lighting or light fixtures do not pose a risk for potential contamination.
- Inspection areas for materials, “product-in-process” materials or finished products are maintained in a work environment that allows personnel to complete required work in a safe manner without the

risk of contamination.

- Ventilation is sufficient to maintain a proper work environment as well as prevent or minimize the potential risk of contamination.

## 4.4 Pest Management and Control

### 4.4.1 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 feed storage areas or processing areas.

4) Records of all pest control applications shall be maintained.

**Implementation Guidance**

*What does it mean?*

There is a documented pest management program that identifies the known pests and integrates a number of preventative and control measures.

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.

The Supplier shall maintain records of all pest control applications.

**Auditing Guidance**

Ensure that:

- An effective pest management program has been established and implemented.
- Records are available to demonstrate the implementation of the pest management program and actions to correct pest problems, if relevant.

### 4.4.2 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 accordance with regulatory requirements.

**Implementation Guidance**

*What does it mean?*

The pesticide and other toxic chemicals should be handled in accordance with the safety data sheets. Processes to ensure the safety of animal feed should be followed in regards to handling these chemicals and chemical containers.

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.

**Auditing Guidance**

Ensure that:

- Safety data sheets for pesticides and hazardous chemicals are readily available.
- Empty containers are handled and disposed appropriately to avoid the potential of animal feed contamination.

### 4.4.3 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** |
|---|
| *What does it mean?*<br>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. |
| **Auditing Guidance** |
| Ensure that:<br>• Personnel that implement the pest management program are qualified and records are maintained. |

## 4.5 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** |
|---|
| *What does it mean?*<br>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. |

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:

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 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.

**Auditing Guidance**

Ensure that:

- A cleaning and housekeeping program outlining the methods, equipment and areas for cleaning shall be established and implemented.
- If designated area for cleaning exists, the area shall be maintained in such a manner as to not to interfere with manufacturing operations, equipment or product.
- Cleaning products shall be maintained in a manner to ensure personnel safety and product quality and safety.
- Cleaning and housekeeping verification is maintained, where warranted.

## 4.6 Exterior

1) The grounds and area surrounding the premises shall be maintained and kept free of waste or accumulated debris so as not to attract pests and vermin.

2) Loading and unloading areas shall be maintained so as not to present a hazard to the animal food safety operation of the premises.

3) 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**

*What does it mean?*

Proper maintenance and control of the exterior area of the facility is important to implementing an effective biosecurity plan.

The exterior grounds should be clean to ensure no harborage of pests for vermin. The grounds should be free of debris, waste or excess equipment or salvage from the within the facility.

Access to the facility should be controlled with entry areas controlled or locked. Signs should be posted noting that entry into the facility is not allowed by unauthorized personnel.

**Auditing Guidance**

Ensure that:

- Exterior grounds are clean and well maintained in order to prevent harborage of pests and vermin.
- No excess equipment or salvage material is stored on the grounds in an uncontrolled manner.
- Access to the facility is controlled with signage; if possible, perimeter of the facility is controlled.

## 5 PRODUCT REALIZATION

### 5.1 Product Development

1) The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

2) 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**

*What does it mean?*

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 Practitioner 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.

**Auditing Guidance**

Ensure that:

- New products are introduced effectively without increasing the potential for hazards to animal food safety. Even if the facility's corporate function is responsible for creating the product development program, that program must still be reviewed by the auditor during the audit to ensure the communication with the location.
- The auditor must look at how the facility was made aware of new or revised products or product formulations, how the facility implemented the new or revised products and how the facility verifies that the new or revised products are being followed within the facility.
- Finally, the auditor should verify how the facility is using the information that is provided by corporate to complete the transition from test project to actual mass production. Research and trial data by universities or recognized Suppliers may be used.

*NOTE: Auditor shall ensure proprietary information is not compromised and confidentiality is maintained. Auditor should focus on processes and not products.*

## 5.2 Packaging and Materials Receiving Processes

### 5.2.1 Receiving Processes for Packaging Materials

1) Packaging shall be verified that it meets the Supplier's specifications upon receipt. All packaging materials shall comply with the relevant regulatory requirements.

2) Packaging materials shall be verified to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of packaging materials may include certification that all packaging that comes into direct contact with feed 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.

3) Any printed labeling on packaging shall be verified that it complies with Supplier's specifications upon receipt.

4) All packaging materials shall be provided by approved vendors.

**Implementation Guidance**

*What does it mean?*

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.

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.

**Auditing Guidance**

Ensure that:

- Supplier is able to demonstrate that packaging is inspected and approved upon receipt.
- Packaging materials are provided by approved vendors.
- Packaging materials do not create a quality and feed safety risk.

### 5.2.2 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) Labeling for raw materials and ingredients that are received shall be verified that it complies with Supplier's specifications upon receipt.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Supplier is able to demonstrate that packaging is inspected and approved upon receipt.
- Packaging materials are provided by approved vendors.
- Packaging materials do not create a quality and feed safety risk.

### 5.2.3 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. In the absence of seals a program to evaluate the safety of the incoming ingredients shall be in place. This policy may be similar to the policy for bagged ingredients that have been opened or damaged during transport.

**Implementation Guidance**

*What does it mean?*

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 feed 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.

**Auditing Guidance**

Ensure that:

- Supplier inspects equipment (rail cars, trucks, tankers) prior to receiving or unloading raw materials or ingredients for potential risks of contamination
- Supplier maintains rejection criteria for equipment delivering raw materials or ingredients.
- Transportation vendors comply with regulatory requirements as well as Supplier's delivery requirements.

## 5.3 Manufacturing Processes

### 5.3.1 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 Federal Food, Drug and Cosmetic Act to complement the preventive controls required by FSMA.

3) Written procedures for the controls shall be maintained.

4) The control shall be validated to ensure the correct process has been implemented.

5) Records shall be available to verify the control has been completed and is effective.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br><br>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.<br><br>The FSMA requires the implementation of specific CGMPs. The Supplier should develop written procedures to ensure these CGMPs are implemented.<br><br>The validation and verification of CGMPs demonstrate the reason and justification for their implementation. A table listing CGMPs that provides the validation and verification process may be used to assist with training and establishing a planned monitoring program. |
| **Auditing Guidance** |
| Ensure that:<br>• Supplier has established written procedures for CGMPs.<br>• Supplier demonstrates that CGMPs have been verified and validated. |

### 5.3.2 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** |
|---|
| *What does it mean?*<br><br>The Supplier should develop processes to ensure cross-contamination of raw materials and ingredients are controlled. This includes receiving, shipping or manufacturing processes.<br>If the materials are subject to regulatory requirements, such as BSE, records should be maintained to confirm compliance. |
| **Auditing Guidance** |
| Ensure that:<br>• Supplier has established processes to ensure cross-contamination of ingredients is controlled.<br>• If applicable, the Supplier maintains records to ensure compliance with regulatory requirements. |

### 5.3.3 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 feed safety controls have been met.

3) No product shall be released without proper approval.

**Implementation Guidance**

*What does it mean?*

The intent of the element 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 under “quarantine” or “hold” status is released by authorized personnel only after the product has successfully passed inspection

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.

**Auditing Guidance**

Ensure that:

- A defined process for the release of products is established and implemented.
- Products that are released are safe for animals.
- Records are maintained for release of products.

## 5.4 Finished Products

### 5.4.1 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.

3) Written finished product specifications may include microbiological and chemical limits, labeling and packaging requirements.

4) A register of finished product specifications shall be maintained.

**Implementation Guidance**

*What does it mean?*

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.

A finished product specification may 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 feed safety personnel.

**Auditing Guidance**

Ensure that:

- Finished product specifications are established and maintained.
- A master list of finished product specifications is maintained.

### 5.4.2 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. Attention shall be paid to assuring raw materials or ingredients prohibited from use in the manufacture of animal feed are not introduced into the product.

3) All medications included in animal feed 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** |
|---|
| *What does it mean?*<br><br>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.<br><br>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.<br><br>If feed-grade medications are used, the Supplier must follow regulatory requirements as outlined within CFR 21 Part 225 for medicated feeds, if applicable. |
| **Auditing Guidance** |
| Ensure that:<br>• Formulation procedures and processes are established and implemented.<br>• Proper checks and verifications are established to ensure the accuracy of the product formulations.<br>• If medicated feeds are manufactured, regulatory requirements are followed, if applicable.<br>• Records are maintained to ensure the accuracy of formulations. |

## 5.5 Customer Related Processes

### 5.5.1 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**

*What does it mean?*

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.

The Supplier should maintain processes to ensure that materials provided to customers comply with regulatory requirements, such as labeling or animal food safety requirements.

The Supplier should maintain processes to ensure it listens to customers' needs and expectations, including customer inquiries, requests and complaints.

**Auditing Guidance**

Ensure that:

- Supplier maintains processes to service customers effectively
- Suppler maintains processes to ensure products comply with regulatory requirements
- Supplier maintains processes to listen to customers

### 5.5.2 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:
   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**

*What does it mean?*

Customer complaints can be valuable information in regards to the quality and feed safety of finished products. A defined process is required to ensure quality and feed 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 feed 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 preventive 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.

**Auditing Guidance**

Ensure that:

- Documented procedure is available for the review and reaction to customer complaints.
- The auditor shall look at how the Supplier was evaluates customer complaints.
- Records of customer complaints are maintained.
- Corrective actions are taken, when appropriate.
- If management by a corporate office, the auditor shall ensure an effective process has been developed and followed to review and react to customer complaints.

## 5.6 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Raw materials and finished products are labeled properly.

## 5.7 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 methods applied 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 aware of and 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- A defined process has been established and implemented to control nonconforming products, raw materials, ingredients and packaging.
- Training of key personnel has been completed and records maintained to ensure understanding of process to control nonconforming products, raw materials, ingredients and packaging.
- Records are available that demonstrate the effective control of nonconforming products, raw materials, ingredients and packaging.

## 5.8 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 Element 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**

*What does it mean?*

The objective of this element is to ensure the products which are reworked, are of the same quality and standards as first run product.

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.

An important element 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.

Product, after being reworked, must be reviewed per company-designated quality and feed safety checks to ensure that it meets all applicable specifications.

Records of all reworking operations shall be maintained.

**Auditing Guidance**

Ensure that:

- A define process for reworking products has been established and implemented.
- Records demonstrating control and traceability of products containing rework are available.

## 5.9 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**

*What does it mean?*

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.

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.

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.

The program must meet Supplier’s needs and their customers’ requirements.

**Auditing Guidance**

Ensure that:

- A defined inventory stock rotation process is established and implemented.

## 5.10 Storage of Materials and Finished Products

### 5.10.1 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 should be stored, when possible, in a separate area or segregated to a specific area to minimize contamination.

4) 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. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Storage practices for raw materials and ingredients materials are established and implemented.
- Storage facilities are clean and properly maintained.
- Medications and medicated feeds are stored appropriately to ensure the integrity of the materials and finished products.
- Lot numbers are identifiable and maintained with materials.
- Records are maintained, as needed, to ensure the storage practices are implemented.

### 5.10.2 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**

*What does it mean?*

Ensure that packaging storage areas are adequately protected from the elements, 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.

**Auditing Guidance**

Ensure that:

- Storage practices for packaging and packing materials are established and implemented.
- Storage facilities are clean and properly maintained.
- Lot numbers are identifiable and maintained with packaging materials.
- Records are maintained, as needed, to ensure the storage practices are implemented.

### 5.10.3 Storage of Finished Products

1) Finished products should be 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Storage practices for finished products are established and implemented.
- Storage facilities are clean and properly maintained.
- Lot numbers for medications are identifiable and maintained with materials.
- Records are maintained, as needed, to ensure the storage practices are implemented.

### 5.10.4 Storage of Nonconforming Materials

1) Raw materials, ingredients, packaging and finished products that are nonconforming shall be isolated in a dedicated 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**

*What does it mean?*

Nonconforming raw materials, ingredients, packaging materials and finished products must 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 the elements, rodents and other pests. Area should be clean and free of debris. Nonconforming products should be reworked or discarded in a timely manner.

**Auditing Guidance**

Ensure that:

- Storage practices for nonconforming materials and finished products are established and implemented.
- Storage area is clean and properly maintained.
- Area for nonconforming materials and finished product is a designated area for nonconforming materials or finished products.
- Nonconforming materials and finished products are reworked or discarded in a timely manner.
- Lot numbers are identifiable and maintained with materials.
- Records are maintained, as needed, to ensure the storage practices for nonconforming products or materials are implemented.

### 5.10.5 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, when possible.

3) Bulk storage practices that support regulatory requirements shall be implemented and maintained, when applicable.

4) Records for bulk storage shall be maintained.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Bulk storage practices, ingredients and finished products are established and implemented.
- Bulk storage area is clean and housekeeping is practiced.
- Records for bulk storage are maintained to ensure the storage practices are implemented, as needed.
- Compliance with regulatory requirements is maintained, if applicable.

## 5.11 Storage of Hazardous Chemicals

### 5.11.1 Hazardous Chemical Storage Process (M)

1) Hazardous chemicals and toxic substances shall be stored so as not to present a hazard to staff as well as the manufacturing of finished products. This includes packaging, product handling equipment or areas in which the finished products or ingredients are handled, stored or transported.

2) Processing tools and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

3) Daily supplies of chemical used for emergency cleaning of feed processing equipment or surfaces in feed contact area, may be stored within or in close proximity to a processing area provided access to the chemical storage facility is restricted to authorized personnel.

4) Pesticides, rodenticides, fumigants and insecticides shall be stored in such a controlled manner so as not to present a hazard to animal food.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Supplier maintains processes to control hazardous chemicals.
- Hazard chemicals do not pose a risk to the quality and feed safety of raw materials, ingredients or finished products.
- Instructions for safe handling of chemicals are readily available.

### 5.11.2 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- There is at least one designated storage area for storing chemicals.
- The storage area is controlled appropriately so as not to present a hazard to staff as well as the manufacturing, storing and transporting of finished products or ingredients.
- A detailed inventory of stored chemicals is maintained.
- No tools, equipment, raw materials or finished products are stored with hazardous chemicals.

## 5.12 Loading, Transport and Unloading Practices

1) The practices applied during loading, transport and unloading of animal feed or feed 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 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**

*What does it mean?*

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, 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.

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.

Loading and staging of product should not expose product to potential abuse or contamination.

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.

**Auditing Guidance**

Ensure that:

- Loading, transport and unloading procedures have been established and implemented.
- Records are available demonstrating the implementation of such procedures.
- Records shall demonstrate compliance by transportation vendors to regulatory requirements and the supplier's specifications.

## 6 PURCHASING PROCESSES AND CONTROLS

### 6.1 Vendors for Incoming Goods and Services

#### 6.1.1 Approved Vendors (M)

1) Raw materials, ingredients, packaging materials and services that impact on 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. Supplier shall be required to demonstrate materials are received from approved vendors.

**Implementation Guidance**

*What does it mean?*

The greatest risks for many Supplier locations come from outside of the location. The intent of this element 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.).

**Auditing Guidance**

Ensure that:

- A defined process for vendor evaluation and approval has been established and implemented.
- Records demonstrating the approval process for vendors are available.
- A master list of approved vendors is maintained and is current.
- All materials and services are provided by approved vendors.

### 6.1.2 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. Procedures describing the inspection and approval of temporary sourcing of raw materials, ingredients and packaging materials shall be maintained.

2) The use of unapproved vendors or temporary sourcing of incoming goods or services shall be

documented.

3) Records shall be maintained showing the use of unapproved vendors and controls implemented to ensure the quality and safety of incoming goods.

| Implementation Guidance |
|---|
| *What does it mean?*<br><br>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. |
| **Auditing Guidance** |
| Ensure that:<br><br>• Processes for receiving raw materials, ingredients, packaging materials and services from an unapproved vendor are established and implemented. |

## 6.2 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.

4) A master list of raw and packaging material specifications and labels shall be maintained and kept current.

| Implementation Guidance |
|---|
| *What does it mean?*<br><br>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.<br><br>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.<br><br>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. |

**Auditing Guidance**

Ensure that:

- A written procedure has been established and implemented to ensure the packaging and material specifications meet the desired requirements.
- Written specifications are available for all packaging and materials, including (but not limited to) ingredients, feed additives, hazardous chemicals and processing aids that impact finished product safety shall be documented and kept current.
- Records for specification approval are maintained.
- Records for specification acceptance by the vendors are maintained.

## 6.3 Contract Service Providers

### 6.3.1 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**

*What does it mean?*

The objective of the contract service and contract manufacture elements 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 require. Training examples could be training done by service provider, training completed by the Supplier, or certification as demonstration of training.

**Auditing Guidance**

Ensure that:

- Specifications for contract service providers are approved by the providing vendor.
- Training requirements for contract service providers are provided.
- Records for training are maintained and available.

### 6.3.2 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Agreements with contract manufacturers ensure products adhere to the requirements and product specifications.
- Records are maintained that demonstrate the compliance of products to requirements and specifications.
- Contract manufacturers are approved vendors.

## 7 VALIDATION AND VERIFICATION

### 7.1 Responsibility, Frequency and Methods

1) The practitioner is responsible for ensuring validation and verification activities are completed accurately.

2) The frequency and methods used to validate and verify animal food safety fundamentals, critical limits and other animal food safety controls identified in the animal food safety plan shall be documented and implemented to meet their intended purpose.

3) Records of all validation and verification activities shall be maintained.

**Implementation Guidance**

*What does it mean?*

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. Examples of verification and validation (but not limited to) are shown below:

| CGMP's | Verification | Validation |
|---|---|---|
| Foreign material control | Magnet checks/records; Screening checks/records | FDA choking limits; customer requirements; equipment owner's manual |
| Employee Handbook (Rules and Regulations) | Written tests; direct observation of work | Regulatory compliance; job description requirements |
| Rework | Records/documentation | Regulatory compliance (FD&C Act) |
| Ingredient specifications | Sample testing; certificate of analysis | Scientific data |

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

Practitioner 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 practitioner.

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

**Auditing Guidance**

Ensure that:

- Verification and validation of the various monitoring, inspection and analysis steps have been completed, and have been established and implemented.
- Records for the verification and validation processes are followed.

## 7.2 Validation Effectiveness

1) The methods shall be documented and implemented that describe the responsibility and criteria for validating the effectiveness of CGMPs and animal food safety limits.

2) The methods shall ensure that:

   a) CGMPs achieve the desired results.

   b) Animal food safety limits are selected to achieve the designated level of control of the identified animal food safety hazard(s).

   c) Animal food safety limits and control measures individually or in combination effectively provide the level of control required.

   d) Changes to processes or procedures are assessed to ensure controls are still effective.

e) Ensure that CGMPs and animal food safety limits are re-validated at least annually.

3) Records of all validation activities shall be maintained.

**Implementation Guidance**

*What does it mean?*

The practitioner 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, which includes validation of the animal food safety limits. Thus, validation of the animal food safety limits for CGMPs should be completed annually.

**Auditing Guidance**

Ensure that:

- Documented procedures for validating CGMP and animal food safety limits are established and implemented.
- Validation records demonstrate the correct processes are implemented for CGMPs and animal food safety limits.

## 7.3 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. This includes (but not limited to) CGMPs, quality and feed safety program, animal food safety plan and other process controls.

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 are tested/calibrated as follows:
   a) Upon installation
   b) On a regularly scheduled basis
   c) When batch results indicate the need
   d) After major repairs and annually thereafter

5) Calibration records shall be maintained.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br>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. |
| **Auditing Guidance** |
| Ensure that:<br>• Mixer calibration program is established and implemented.<br>• Calibration records for equipment are maintained and readily available. |

## 7.4 Verification Schedule and Monitoring Activities

1) A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.

2) The methods, responsibility and criteria for verifying the effectiveness of monitoring CGMPs and animal food safety limits shall be documented and implemented.

3) Procedures shall provide actions to be taken by personnel if or when nonconformities occur during the verification process.

4) Records of the verification of monitoring activities shall be maintained.

| **Implementation Guidance** |
|---|
| *What does it mean?*<br>The Supplier must document the methods, responsibilities and criteria that are employed for verifying the effectiveness of monitoring CGMPs and animal food safety limits. Monitoring activities may include monitoring of weight records, product testing records, mixing times and in-process quality checks. |

Electronic records can be used for monitoring activities. Suppliers must be able to demonstrate how records are reviewed for verification purposes. Each person that monitors information must have a unique electronic signature so it can be verified that records were recorded by the individual as assigned.

You must have a verification schedule that:

- Describes the quality and feed safety system's verification activities;
- Outlines the frequency of verification;
- Designates the person responsible for each verification activity; and
- Provides for a log of verification activity.

Records of the verification of monitoring activities shall be maintained.

**Auditing Guidance**

Ensure that:

- Methods for verification of preventive controls are established and implemented.
- Schedule for verification activities is maintained with relative information to document its accuracy and effectiveness.
- If nonconformities are observed, activities should demonstrate effective corrective actions and change management.
- Records are maintained for verification of CGMPs and animal food safety limits.

## 7.5 Product Sampling and Inspection

### 7.5.1 Processes for Product Sampling

1) The methods, responsibility and criteria for sampling raw materials, ingredients, finished product and work in progress shall be documented and implemented.

2) Sampling requirements of raw materials and ingredients shall be established and implemented to ensure the quality and feed 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 feed 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**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Documented procedures are established and implemented for sampling, inspection and analysis of raw materials, ingredients, finished products, and “work-in-progress” material, as needed.
- Records for sampling, inspection and analysis are maintained.

### 7.5.2 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. This may include confirmation of compliance with regulatory requirements or the Supplier’s specification, if applicable.

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 shall be accredited to ISO 17025 or an equivalent national standard.

7) Records of all inspections and analyses shall be maintained.

**Implementation Guidance**

*What does it mean?*

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 must 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.

**Auditing Guidance**

Ensure that:

- Documented procedures are established and implemented for sampling, inspection and analysis of raw materials, ingredients, finished products and “work-in-progress” material, as needed.
- Records for sampling, inspection and analysis are maintained.
- Accredited laboratories are used for testing.

### 7.5.3 Inspection and Analysis of Finished Products

1) All 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 feed 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 all inspections and analyses shall be maintained.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Documented procedures are established and implemented for sampling, inspection and analysis of finished products, and "work-in-progress" material, as needed.
- Records for sampling, inspection and analysis are maintained.
- Accredited laboratories are used for testing.

## 7.6 Internal Audits

### 7.6.1 Internal Audit Process

1) The Supplier shall complete internal audits at planned intervals to determine whether the quality and feed 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**

*What does it mean?*

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

The Supplier is required to prepare an internal audit procedure describing how internal audits of the quality and feed 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 feed 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.

**Auditing Guidance**

Ensure that:

- The audit schedule is adequate for the Supplier, based on the observations from the facility assessment of the facility.
- The entire quality and feed safety system is audited at least annually.
- Corrections or corrective actions are implemented for nonconformities identified during internal audits.

### 7.6.2 Internal Auditors

1) Internal auditors shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

2) Staff conducting internal audits shall be trained in internal audit procedures.

3) Records of audit training shall be maintained.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Internal auditors have been trained.
- When possible, auditors do not audit their own work.

### 7.6.3 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) Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

**Implementation Guidance**

*What does it mean?*

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.

**Auditing Guidance**

Ensure that:

- Corrective actions for nonconformities identified during internal audits have been implemented and completed in a timely manner.
- The management staff of an area being audited responded to nonconformities identified during an internal audit in a timely manner.

## 7.7 Product Identification (M)

1) The methods and responsibility for identifying raw materials, ingredients, “work-in-progress” material and finished products shall be documented and implemented.

2) 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. Finished product is labeled to the customer specification and/or regulatory requirements.

3) Product identification records shall be maintained.

### Implementation Guidance

*What does it mean?*

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.

### Auditing Guidance

Ensure that:

- An effective system to identify raw materials, ingredients, “work-in-progress” material and finished products has been established and implemented.
- Product identification records are maintained.

## 7.8 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**

*What does it mean?*

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 feed 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.

**Auditing Guidance**

Ensure that:

- The Supplier maintains an effective traceability procedure and process for materials, packaging and finished products (one level forward, one level backward).
- Records are maintained to support an effective traceability program. The auditor may test the facility traceability program during the audit simply by selecting a finished product or “work in progress” material and ask for information on source of raw materials or ingredients.
- Traceability method is evaluated or tested at least annually.

## 7.9 Animal Food Defense and Biosecurity Plan

1) An animal food defense and biosecurity plan(s), with responsibility and criteria for preventing feed adulteration caused by a deliberate act of sabotage or terrorist-like incident, shall be documented, implemented and maintained.

2) An animal food defense plan shall be prepared and include:

a) Name of the management person responsible for feed 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**

*What does it mean?*

The Supplier must prepare, implement and maintain an animal food defense and biosecurity plan(s) that outlines the methods, responsibility and criteria for preventing feed 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.

**Auditing Guidance**

Ensure that:

- An animal food defense and biosecurity plan(s) has been developed with controls in place to ensure the security of the facility.
- A management team member has been assigned authority for the animal food defense and biosecurity plan(s).
- Records are available for the animal food defense and biosecurity plan(s).

# 8 ANIMAL FOOD SAFETY PLAN

## 8.1 Animal Food Safety Fundamentals (M)

1) The property, buildings and equipment shall be located, constructed, designed and maintained to facilitate the production, manufacture, handling, storage and/or delivery of safe feed.

2) The Supplier shall ensure the relevant animal food safety fundamentals are applied or excluded according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that animal food safety is not compromised.

3) CGMPs applicable to the scope of certification that outline the means by which animal food safety is controlled and assured shall be documented and implemented.

**Implementation Guidance**

*What does it mean?*

Implementing animal food safety fundamentals ensures that feed intended for consumption by animals is produced, processed and handled in a safe and efficient manner. In order to accomplish this, feed processing premises shall be designed to facilitate proper processing, handling and storage of product. Fundamental practices must be in place to protect the safety and quality of feed.

The facility must prepare an animal food safety plan that makes provisions to ensure fundamental animal food safety practices are adopted and maintained. A site plan showing the location of the premises may be used to indicate that the premises are approved for the intended purpose.

CGMPs should comply with regulatory requirements, if applicable. CGMPs may include (but not limited to) personnel practices; training of personnel; calibration of equipment; pest management; premises and equipment maintenance; cleaning and sanitation (as needed); control of physical contaminants; vendor approval; transport and delivery; and waste management.

CGMPs shall be documented and implemented as applicable to the scope of the certification. Each CGMP must be validated and verified by the Practitioner with documentation.

**Auditing Guidance**

Ensure that:

- The property, buildings and equipment are suitable for manufacturing, storing and provide products safe for animals.
- CGMPs are established to ensure the safety of animal food.
- Exclusions of CGMPs have been justified.

## 8.2 Animal Food Safety Plan

### 8.2.1 Animal Food Safety Plan Responsibility (M)

1) An animal food safety plan shall be developed, effectively implemented and maintained. The plan shall outline the means by which the organization controls and assures animal food safety.

2) An animal food safety team shall be created to develop and support the implementation and maintenance of the animal food safety plan. The team shall include personnel from various areas within operations.

3) The Practitioner shall be responsible for ensuring the animal food safety plan is developed, implemented and maintained in accordance with the quality and feed safety system.

4) Management shall approve the animal food safety plan.

**Implementation Guidance**

*What does it mean?*

Every facility that provides feed, raw materials, ingredients or packaging for animals is required to prepare an animal food safety plan. A thorough analysis of the process to identify the potential risks for animal food safety is required. A hazard analysis of each process, material and packaging is needed in order to establish preventive controls for the risk. Documentation of this process is required.

While HACCP is not required, the principles for HACCP provide excellent guidance for developing an effective animal food safety plan. The components of the animal food safety plan include those required by the FSMA.

Tasks associated with the animal food safety plan should be documented. Staff should be trained on SOP's, work instructions and other appropriate materials to ensure the animal food safety plan is effective.

An Animal Food Safety Team should be formed to develop the animal food safety plan.

Records for the animal food safety plan are required, including the process flow, hazard identification, preventive controls, verification and validation activities, corrective actions taken when failures occurred, recall plan, minutes from meetings and a brief summary of the animal food safety plan.

Anytime there are changes to processes, such as new equipment, or the incorporation of a new type of an ingredient, the animal food safety plan should be reviewed. Also, any issues that impact the quality and feed safety program, the animal food safety plan should be reviewed.

**Auditing Guidance**

Ensure that:

- Animal food safety plan has been developed and includes the various elements as required by FSMA.
- Observed failures of the animal food safety plan by the auditor during the audit, product contamination issues that are not properly addressed by the Supplier, instances of corrective actions not being completed for failures of critical limits, or falsification of records associated with the animal food safety plan could be considered *critical nonconformities* of the audit.
- Animal food safety plan is appropriate for the scope of the certification.
- Proper records for the animal food safety plan are maintained.

### 8.2.2 Process Flow Diagram

1) A process flow diagram shall be a component of the animal food safety plan.

2) The process flow diagram shall outline the processes within the receiving, storing, manufacturing and shipping of raw materials, ingredients or finished products.

3) The process flow shall be approved by the animal food safety team.

4) The process flow shall be verified annually, or when changes to the animal food safety plan are implemented, whichever is shorter.

**Implementation Guidance**

*What does it mean?*

A process flow diagram should be developed by the Animal Food Safety Team. The team should verify the accuracy of the process flow diagram at least annually, or after an update to the animal food safety plan, whichever is shorter.

The purpose of developing a process flow diagram is to assist with identifying the potential hazards in a more organized and consistent manner.

**Auditing Guidance**

Ensure that:

- The Animal Food Safety Team has developed and verified a process flow diagram.
- The process flow diagram has been verified at least annually, or since the last update of the animal food safety plan (whichever is shorter).

  NOTE: FSMA does not require Suppliers maintain a process flow diagram. Thus, a Supplier may decide to not develop. Process flow diagrams are recommended but not required.

### 8.2.3 Hazard Analysis of Processes (M)

1) A hazard analysis shall be completed for each area or process within the process flow diagram.

2) The animal food safety team, or appropriate personnel, shall complete the hazard analysis for each area or process.

3) Records of the hazard analysis shall be maintained.

**Implementation Guidance**

*What does it mean?*

A hazard analysis of processes should be completed as a part of the animal food safety plan. The process flow diagram should be a tool to assist with this process.

The Animal Feed Safe Team should identify hazards and determine how to control them, if any. Records of the team completing this process should be maintained.

Critical control points, if any, should be properly identified as such.

**Auditing Guidance**

Ensure that:

- A hazard analysis of processes has been completed by the Animal Food Safety Team
- Records of the hazard analysis of processes are maintained

### 8.2.4 Hazard Analysis of Materials (M)

1) A hazard analysis shall be completed for incoming raw materials, ingredients and packaging materials.

2) The animal food safety team, or appropriate personnel, shall complete the hazard analysis for incoming raw materials or ingredients.

3) Records of the hazard analysis shall be maintained.

**Implementation Guidance**

*What does it mean?*

A hazard analysis for incoming raw materials or ingredients (and packaging materials) should be completed as a part of the animal food safety plan. As with processes, the Animal Feed Safe Team should identify hazards and determine how to control them, if any. Records of the team completing this process should be maintained.

**Auditing Guidance**

Ensure that:

- A hazard analysis for incoming raw materials, ingredients and packaging materials has been completed by the Animal Food Safety Team.
- Records of the hazard analysis for incoming raw materials or ingredients are maintained.

### 8.2.5 Preventive Controls (M)

1) Written procedures shall be established and implemented for controls of identified hazards where applicable.

2) The Supplier shall validate processes as appropriate for control of hazards.

3) The Supplier shall verify processes are accomplishing the desired preventive control.

4) Records from preventive controls shall be monitored on a planned basis to determine the need for continuous improvement within the process, if any.

5) Corrective actions shall be taken when a preventive control is not effective. The animal food safety plan shall be updated if warranted.

**Implementation Guidance**

*What does it mean?*

Based on the hazard analyses, the Animal Food Safety Team should determine appropriate preventive controls to control the hazards. Some of the hazards may be controlled through CGMPs or the vendor verification program. If not, additional preventive controls need to be established.

If critical control points are identified, proper controls shall be established and maintained.

The preventive controls should be validated to ensure they accomplished their intended purpose. In addition, verification processes should be developed to ensure the preventive control is working. Records should be maintained for each preventive control and reviewed for potential changes or improvements in the process (preventive actions).

If a preventive control fails, corrective action procedures should be followed. A root-cause analysis of the problem should be completed and corrective actions taken to ensure it does not reoccur, if possible. Records should be maintained for the corrective action.

If changes are made to preventive controls, the animal food safety plan should be reviewed.

**Auditing Guidance**

Ensure that:

- Preventive controls have been established for identified hazards.
- Records for preventive controls are reviewed on a planned basis.
- Corrective actions have been taken when a preventive control failed.
- The animal food safety plan was reviewed and updated, as needed, based on preventive control activities.

## 8.3 Corrective and Preventive Actions (M)

1) The Supplier shall maintain a written procedure that describes the Supplier's processes for corrections, corrective actions and preventive actions.

2) The responsibility and methods outlining how corrections, corrective actions and preventive actions are investigated, resolved, managed and controlled shall be documented and implemented.

3) Records of all investigation and resolution of corrections, corrective actions and preventive actions shall be maintained.

**Implementation Guidance**

*What does it mean?*

When significant problems or issues that involve quality and feed safety arise, the Supplier is required to take corrections, corrective action or preventive action in a timely manner.

- Corrections are considered a "short-term fix," or a quick action taken to remediate a specific problem and make adjustments to regain immediate control.
- Corrective actions are "long-term fixes" designed to identify the root cause of the problem, and to take actions that will prevent reoccurrence.
- Preventive actions are steps taken before a problem occurs due to the observations or identification of potential problems.

This process is designed to minimize the risk that the situation will occur again.

The Supplier must document a procedure that describes the responsibility for investigating and identifying the causes of problems, including a breakdown of preventive controls relating to the quality and feed safety system. Further, the facility must document how these problems are resolved, the methods the facility will use and what action is taken to prevent the recurrence of the problem.

Corrections should be made when there is any observation within a facility that leads one to believe that product animal 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.

If a potential problem is identified before it occurs, actions may be taken to prevent. This type of preventive action helps to assure the continuous improvement of the system, resulting in fewer future problems since the root causes have been addressed.

Essentially the facility should outline and demonstrate how you will manage corrective actions, identify who is responsible for managing it and describe what methods are used to resolve any safety or quality issues.

The Supplier is required to maintain records of corrections, corrective actions and preventive actions taken.

**Auditing Guidance**

Ensure that:

- A written procedure for corrections, corrective actions and preventive actions has been established and implemented.
- Responsibilities for corrective actions are clearly defined.
- Completed corrective and preventive actions were effective.
- Records for corrections, corrective actions and preventive actions are maintained.

## 8.4 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** |
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| *What does it mean?*<br><br>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.<br><br>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. This includes (but not limited to) FDA inspections for FSMA compliance, BSE compliance, medicated feeds or routine sampling requests. |
| **Auditing Guidance** |
| Ensure that:<br><br>• The Supplier understands the regulatory requirements that comply with its facility or location.<br>• Supplier has defined processes to ensure it complies with regulatory requirements.<br>• Personnel responsible for compliance with regulatory requirements are trained on defined processes and procedures. |

## 8.5 Recall Plan (M)

1) The responsibility and methods used to withdrawal or recall product shall be documented and implemented.

2) The procedure shall:

   a) Identify those responsible for initiating, managing and investigating a product withdrawal or recall.

b) Describe the management procedures to be implemented including sources of legal and expert advice.
c) Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident.

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).

5) Records of all product withdrawals and recalls shall be maintained.

**Implementation Guidance**

*What does it mean?*

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 goal for success of the "mock" recall should be 100 percent of product identified within 24 hours or per customer specification or regulatory requirement. 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.

**Auditing Guidance**

Ensure that:

- A recall procedure has been established and implemented.
- A "mock" recall is completed at least annually and records maintained.
- If a withdrawal or recall has been completed since the last audit, the processes were implemented correctly and corrective actions were completed.
- Records for withdrawals or recalls since the last audit are reviewed for completeness.

## 8.6 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

*What does it mean?*

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.

### Auditing Guidance

Ensure that:

- Waste disposal processes are established and implemented to avoid animal food safety risks.

## 8.7 Water and Air

1) If water is used as a potential ingredient or additive within a finished product, the Supplier shall ensure the safety of the water for animal food.

2) Records shall be maintained to ensure the water used as an ingredient or additive is safe for animal use.

3) Compressed air that comes into contact with animal feed shall be clean and present no risk to animal food safety.

### Implementation Guidance

*What does it mean?*

Water that may be used as an additive or finished product ingredient may be a risk for contamination. Likewise, compressed air that comes into contact with animal food may represent an animal food safety risk.

Water quality should be monitored to ensure the safety when added to animal food. This may include microbiological and chemical testing for monitoring of its safety.

The Supplier should take precautions to ensure compressed air, when exposed to animal foods, does not reduce the safety of animal foods.

**Auditing Guidance**

Ensure that:

- Water, when used as a potential ingredient or additive in animal food, does not pose an animal food safety risk.
- Records are maintained for water that may be used for animal food that documents its safety.
- Compressed air that has direct contact with animal food does not pose a food safety risk.

## 9 FSC36 SAFE FEED/SAFE FOOD SEAL REQUIREMENTS

### 9.1 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."*

**Implementation Guidance**

*What does it mean?*

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 from this element or clause.

| **Auditing Guidance** |
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| Ensure that:<br>• The Supplier uses the seal (logo) as outlined within the LICENSING AGREEMENT FOR USE OF THE SAFE FEED/SAFE FOOD SEAL.<br>• The Supplier adheres to the size requirements for the seal (logo) when used on packaging or marketing materials.<br>• The Suppliers adheres to the color requirements for the seal (logo) when used on packaging or marketing materials.<br>• When the seal (logo) is printed on packaging or labels, the Supplier prints the following statement (or a statement similar) reasonably close to the FSC36 Safe Feed/Safe Food seal or logo:<br>*"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."* |

# APPENDIX A
# Glossary for FSC36 Safe Feed/Safe Food Guidance Document Version 6.0

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| **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 feed 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 feed 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 feed 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 feed 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** | Action to eliminate a detected nonconformity. Shall have the same meaning as “corrected.” |

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| **Corrective Action** | Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action shall include:<br><br>a) Determine/document any immediate action required/taken:<br>• Determine the cause of the problem<br>• Evaluate action needed on the identified cause<br>• Determine if the problem exists elsewhere in the system and implement actions needed<br><br>b) Document the results of the action taken:<br>• Review/verify and document effectiveness of action taken with objective evidence |
| **Critical Nonconformity** | 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 feed safety system. |
| **Current Good Manufacturing Practices (CGMPs)** | The combination of management and manufacturing practices designed to ensure feed products and materials are consistently produced to meet relevant legislative and customer specifications. |
| **Element (or Clause)** | 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 elements (or clauses) are mandatory. Exemptions to elements should be determined by the Supplier and certifying body before an on-site audit is completed. |
| **Exemption** | A review process of elements for FSC36 Safe Feed/Safe Food that should be completed by the Supplier with the certifying body prior to the audit to determine which elements, if any, do not apply to the audit for certification. Mandatory elements cannot be exempt. |
| **Facility** | 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. |
| **Feed** | 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." |
| **Finished Product(s)** | Those products that are considered to have completed processing requirements by a Supplier and are ready for use by its customers. |

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| **FSMA Animal Food Rule** | 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). |
| **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:<br><br>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."<br><br>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. |
| **Ingredient** | A raw material that has been further processed and used within animal feed. |
| **Major Nonconformity** | An omission or deficiency in the quality and feed safety system producing unsatisfactory conditions that carry a quality or feed/food safety risk and likely to result in a system element breakdown. |
| **Minor Nonconformity** | An omission or deficiency in the quality and feed safety system that produces unsatisfactory conditions that if not addressed may lead to a risk to quality and feed/food safety but not likely to cause a system element 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 feed 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 feed safety system. |

**Practitioner**

An individual, designated by a producer/supplier to develop, validate, verify, implement and maintain that producer's/supplier's quality and feed safety program. The Practitioner details shall meet the following requirements:

- Be employed by the company as a permanent full time employee and hold a position of responsibility in regard to the management of the company's quality and feed safety program;
- Have completed a HACCP training course or be experienced and competent to implement and maintain HACCP-based food safety plans; and
- Have an understanding of the FSC36 Safe Feed/Safe Food guidance documents.

**Premix**

A blend of ingredients that may be used within an animal feed. This typically includes vitamins, minerals, additives or medications.

**Prerequisite Program**

A procedural measure that when implemented reduces the likelihood of a feed/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.

**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.

**Raw Material**

A natural resource that is in an unprocessed or minimally processed state and may be used within animal feed.

**Re-certification**

A re-certification by a certification body of a Supplier's quality and feed 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.

**Remote Audit**

Audit completed by the Certification Body without visiting the site of the Supplier. This is a form of a surveillance audit.

**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 feed sector categories (FSC) and those products to be covered by the certificate, which includes the mandatory elements and those elements not exempt. |
| **Supplier** | Any feed business involved in the production, manufacture, processing, transport, storage, distribution or sale of finished products, raw materials, feed ingredients, packaging materials or providing support services to the feed sector and run by a person, company, cooperative, partnership, joint venture, business or other organization who has, or agrees to have, a Certification Body carry out audits and certification of its quality and feed safety system. |
| **Surveillance Audit** | A review of the supplier's quality and feed 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."*

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.