SAFE FEED/SAFE FOOD UPDATE

New FSC36 Safe Feed/Safe Food Guidance Document (Part 2)

In the last SAFE FEED/SAFE FOOD UPDATE (Volume 3), the major changes to the FSC36 Safe Feed/Safe Food guidance document were reviewed. In this issue, we will discuss key changes in the format of the audit and audit process.

Assessment of nonconformities. Where the Certification Body auditor finds deviations from the requirements of FSC36 Safe Feed/Safe Food guidance document, the auditor shall advise the "Supplier" (the location seeking certification) 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.

- Opportunities for improvement are observations made by the auditor during a facility audit that identify issues that are not nonconformities, 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.

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

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 Safe Quality Food 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 shown in the table below.

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 (remote audit) during the second year of the certification. An on-site audit is required during the second year for facilities scoring 85 or less

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

(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._

Surveillance audits are not scored because it is an abbreviated audit. 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.

Achieving FSC36 Safe Feed/Safe Food Certification. 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."_

The structure of the FSC36 Safe Feed/Safe Food requirements. It is the intent of the FSC36 program to support the requirements outlined in the Food Safety Modernization Act 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 certification, the principles of HACCP are utilized to implement an effective animal food safety plan.

The requirements for FSC36 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 are applicable to all feed or ingredient production facilities. Some elements can be exempt 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).

Format of guidance information. For each element and sub-element, guidance information is provided for facilities to understand the expectations for meeting the requirements for certification. The guidance information explains the elements and sub-elements of FSC36 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? 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 a "(M)" after the element in the FSC36 Safe Feed/Safe Food guidance document.

The new FSC36 Safe Feed/Safe Food guidance document is designed to improve the certification process and help facilities drive continuous improvement. The new guidance document shall be implemented by March 1.

Food Safety Certification Programs
Which program is right for me?

Which certification is right for me? AFIA offers four certification options for quality and food safety programs. The right one for you depends upon your business and your target customers. A brief description of the certification options is provided in the chart below.

Safe Feed/Safe Food Certifications

International Safe Feed/Safe Food
- Internationally recognized program that aligns with FAMI-QS
- Designed for feed additives and premixes

FSC32 Manufacture of Pet Food
- GFSI recognized program that meet FSMA regulatory requirements
- Designed for pet food manufacturers or ingredient suppliers

FSC34 Manufacture of Animal Feeds
- GFSI recognized program that meet FSMA regulatory requirements
- Designed for feed manufacturers and ingredient suppliers

FSC36 Safe Feed/Safe Food
- Fundamentals for compliance with FSMA
- Designed for North American feed manufacturers

An update in the guidance document describing the requirements for FSC36 Safe Feed/Safe Food certification is now available on the Safe Feed/Safe Food website (learn more in future newsletters). The goal of the updates is to provide a certification that meets the regulatory requirements for FSMA as well as drive continuous improvement within the facility's quality and food safety program.

AFIA is dedicated to driving continuous improvement in the delivery of a safe and wholesome feed supply for the growth and care of animals. AFIA maintains its commitment to help its members and the

total feed industry to develop quality and food safety programs to meet and exceed the expectations of its customers.

Contact AFIA

For technical assistance, please contact Dr. Henry Turlington, AFIA director of quality and manufacturing regulatory affairs, at (703) 650-0146. For administrative assistance, please contact Shakera Daley, AFIA accounting and administrative coordinator, at (703) 558-3571.

Safe Feed/Safe Food Website

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