

Guidance for Rendering Plants Certifying in:

The Rendering Code of Practice and AFIA's FSC36 Safe Feed/Safe Food

This guidance, along with AFIA's FSC36 Safe Feed/Safe Food guidance will provide the information needed to certify plants and to comply with future FDA regulations.



National Renderers Association



PREFACE

This document is intended to provide guidance for rendering facilities and auditors seeking certification in the Rendering Code of Practice and/or the FSC36 Safe Feed/Safe Food Certification Program. This guidance, along with the guidance to FSC36 (version 6.0) from the American Feed Industry Association (AFIA) will assist facilities as they implement the various requirements as they prepare for an audit.

The purpose of the Rendering Code of Practice and 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 food safety program. The guidance is not intended to cover every possible scenario that may be seen across the rendering and feed industries. It is not definitive but provides a general guide of what could be acceptable to meet the requirements for a particular area. Many of these will be similar for rendering plants and feed plants, but this document will detail some important differences.

Effective implementation of the Rendering Code of Practice and/or FSC36 Safe Feed/Safe Food requires the commitment of the site management and the constant involvement and participation of site staff to maintain the quality and food safety program.

SECTION 1.0 Introduction

This guidance document for renderers and the FSC36 Safe Feed/Safe Food guidance for feed plants is intended to assist Suppliers with designing, developing, implementing and maintaining a quality and food safety program that complies with the desired requirements as well as assist auditors with auditing Suppliers seeking certification for the Rendering Code of Practice and/or FSC36 Safe Feed/Safe Food. This is not a definitive document and applicable in every situation. Suppliers, consultants, and auditors are required to understand feed safety (and quality, where applicable) risks in the rendering and feed industries in order to effectively control animal food risks. Many elements will be similar for rendering plants and feed plants, but this guidance will detail some important differences.

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0 for the following:

- Registration and certification process for Safe Feed/Safe Food
- Glossary
- Logo rules

Rendering plants certifying in FSC36 Safe Feed/Safe Food via the Safe Quality Foods Institute (SQFI) detailed in the FSC36 Safe Feed/Safe Food Guidance Document Version 6.0 will automatically be certified also in the Rendering Code of Practice. To receive AFIA SF/SF certification, plant managers need to go the SQFI website, register and request an audit, and pay a fee of \$250. AFIA has also developed a step-by-step guidance to navigate the SQFI website. Contact NRA for any of these guidance materials: dmeeker@nationalrenderers.com

Renderers desiring the Rendering Code of Practice certification only, and not FSC36 Safe Feed/Safe Food certification, could bypass SQFI and request an audit from Validus. However, the same FSC36 guidance and audit points will be used.

Contact information for Validus (formerly Facility Certification Institute (FCI)):

Phone: 866-320-7751

Website: <http://www.validuservices.com/on-site-audits/facility-certified-institute-audits/>

Auditing Guidance

The goal of these certification programs is not to ensure that every plant operates in the same fashion, but rather to ensure that they identify, analyze, and mitigate significant risks. Plants vary in their raw materials, layout, equipment, and processes so flexibility is needed when assessing the animal food safety program for effectiveness. There are different ways to accomplish animal food safety goals.

For example, the guidance calls for product labeling at several stages. While many feed products have a package with a panel of printed label information, work in progress during the manufacture of ingredients may be identified by a chalk mark on a bin, by a wired sensor linked to a control panel, or by an electronic chip tracking material and recording in a computer database. As long as hazards are avoided, any method is acceptable.

SECTION 2.0 Registration and Certification

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 1-7 for these items:

- 2.1 AFIA Alignment with SQFI
- 2.2 Registration and Certification Steps
- 2.3 Audit Duration Guide
- 2.4 System Elements
- 2.5 Nonconformities and Corrective Actions
- 2.6 Opportunities for Improvement
- 2.7 The Audit Report
- 2.8 Responsibility for the Certification Decision
- 2.9 Audit Score and Rating
- 2.10 Suspending Certification
- 2.11 Complaints, Appeals and Disputes

SECTION 3 Implementation Process

To achieve Rendering Code of Practice and/or FSC36 Safe Feed/Safe Food certification, the Supplier must document and implement the relevant elements described within these guidance documents (see Section 5). It is also important to provide evidence of the Supplier's quality and food safety system in the form of documents and records. 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

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 8-9 for these items:

- Purpose and Scope of this Guide
- The Structure of the FSC36 Safe Feed/Safe Food Requirements
- Format of Guidance Information

SECTION 5 Requirements for the Rendering Code of Practice

The requirements for the Rendering Code of Practice certification are in many cases the same as Safe Feed/Safe Food certification described in the FSC36 Guidance Document Version 6.0 which includes CGMPs for animal feed production as well as the requirements for an effective animal feed safety program. These programs also support the requirements as outlined in the Food Safety Modernization Act. This document will point out only differences in rendering that may be approached in ways varying from feed plants but still appropriate.

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.

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 10-14 for these items:

- 1 MANAGEMENT COMMITMENT AND RESPONSIBILITY
 - 1.1 Management Policy (M)
 - 1.2 Management Responsibility (M)
 - 1.3 Responsibility, Authority and Communication (M)
 - 1.4 Management Review
 - 1.4.1 Management Review Process
 - 1.4.2 Management Review Inputs and Outputs
 - 1.4.3 Records for Management Review

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 15-24 for the following items, but in some cases these items may apply differently in rendering plants as described:

- 2 QUALITY AND FEED SAFETY MANAGEMENT SYSTEM
 - 2.1 General Requirements
 - 2.2 Quality and Feed Safety Manual (M)
 - 2.3 Document Control (M)
 - 2.4 Records (M)
- 3 PERSONNEL AND TRAINING
 - 3.1 Competence and Job Descriptions (M)
 - 3.2 Training and Awareness (M)
 - 3.3 Personnel Policies and Behavior

Finished product areas of a rendering plant compare reasonably to feed mills, but the raw material side of a rendering plant does not. Hygiene requirements before the cooking operation may be less stringent if adequate separation is maintained from the cooked side.
 - 3.4 Personnel Facilities
 - 3.5 Visitors

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 24-32 for the following items, but in some cases these items may apply differently in rendering plants as described:

4 INFRASTRUCTURE

4.1 Facility Construction and Surfaces

The areas of a rendering plant in which finished product is stored may be expected to meet construction and surface requirements similar to feed mills. However, the areas of the plant in which raw materials are handled need not meet these requirements. Cleaning requirements before the cooking operation may be less stringent if adequate separation is maintained from the cooked side.

4.2 Equipment and Maintenance

Lubricants need not be food/feed grade if direct contact with animal feed is prevented by design or other measures.

4.2.1 Equipment

4.2.2 Maintenance

4.3 Lighting and Work Areas

Rendering plants do not usually maintain a positive air pressure within processing areas because it's necessary to utilize negative air pressure and controlled ventilation to the outside in order to prevent odors from escaping. Screening of vents and exhausts to prevent ingress of flying insects would not be appropriate nor effective in many areas of rendering operations.

4.4 Pest Management and Control

4.4.1 Pest Management (M)

4.4.2 Pest Control Chemicals (M)

4.4.3 Pest Management Personnel

4.5 Cleaning and Housekeeping (M)

4.6 Exterior

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 33-52 for the following items, but in some cases these items may apply differently in rendering plants as described:

5 PRODUCT REALIZATION

5.1 Product Development

Product development is not likely to occur in most rendering plants, and thus, most rendering plants will be exempt from this section.

5.2 Packaging and Materials Receiving Processes

Packaging materials are not used in most rendering plants because materials are handled in bulk, thus, most rendering plants will be exempt from this section.

Bulk storage and conveyances shall be constructed of materials verified to ensure product safety is not compromised and the material is fit for its intended purpose.

5.2.1 Receiving Processes for Packaging Materials

5.2.2 Receiving Processes for Raw Materials and Ingredients

For rendering plants, note these additional points:

- Raw material truck drivers or plant personnel are physically inspecting (visually and by smelling any off-odors) the material. If product is suspected of being contaminated it is removed from the food chain.
- Raw material contaminated by insecticides, pesticides, herbicides, fungicides, etc. are disposed of properly, and not placed into production.
- PCB sources at this facility that cannot be feasibly or economically removed or replaced are posted or marked. Possible sources of PCBs at this facility have been identified

(transformers, electrical equipment, etc.) and are included on a written list.

- Removal & Disposal of cattle material prohibited in animal feed (CMPAF) for facilities handling cattle 30 months of age and older:
 - The facility should have a written plan for separating renderable carcasses or tissues originating from cattle less than 30 months of age from carcasses or tissues originating from cattle 30 months and older and destined for disposal.
 - The facility should have a written SOP describing the removal and disposal of brains and spinal cord from cattle 30 months and older.
 - Records should be maintained that document the effective removal of brains and spinal cord from renderable material and that document the collection, marking, and disposal of CMPAF.
 - The facility should have a written SOP describing the collection of CMPAF removed during processing as well as during cleaning for disposal.
 - Labels carry the appropriate caution statements for compliance with the FDA Feed Rule 21CFR589.2000 and 2001.

5.2.3 Equipment at Receiving

Incoming raw materials for rendering are not yet finished feed ingredients and may have unpleasant odors and appearances. However, sometimes physical hazards can be observed or chemical hazards can be smelled. Inspection of incoming raw materials for rendering should be based on criteria appropriate for rendering plants which may be different from feed mills.

Incoming raw materials for rendering usually arrives at the rendering plant in specialized dedicated equipment. Seals for this type of equipment are not usually possible.

5.3 Manufacturing Processes

5.3.1 Process Control (M)

For rendering plants:

- The cooking process is most important in a rendering operation. The cooker must be operated to maintain proper temperature ranges when producing finished feed ingredients.
- Thermometers in fat works and/or tanks and thermocouples in cookers/evaporators are working properly and calibrated on a regular basis.
- Thermometer/thermocouple inspections and replacements are recorded.

5.3.2 Control of Raw Materials and Ingredients

Decomposition of animal tissues begins the moment slaughter takes place, and some time is needed to get these materials into the rendering process. Decomposition is not always a negative for product quality and food safety. The rendering process effectively “re-sets the clock” by processing raw materials including offal, outdated meat, and fallen animals that may be deemed filthy, putrid, or decomposed substances with respect to human food into safe, wholesome, and useful feed ingredients for animals.

The rendering industry uses truck driver checklists, investigations of unusual raw material variation, and supplier affidavits of compliance with “Animal Proteins Prohibited from Animal Feed,” the BSE feed regulation (21 CFR 589.2000 and 589.2001), among other effective ways, to minimize hazards.

Any rendering ingredients, additives, anti-foam products, denaturing agents, or cleaning compounds (if used in the facility or if in raw materials) must be handled properly. Any products that may result in residues remaining in rendered products shall be reviewed for GRAS /food grade status prior to use and approved by facility management.

Raw or in-process material or finished product that may be contaminated by spills or leaks of on-site fuel, antifreeze, solvents, oils, or degreaser must be disposed of properly, and not placed back into production.

5.3.3 Product Release (M)

5.4 Finished Products

5.4.1 Finished Products Specifications (M)

Renderers generally sell "what they make" rather than "make what they sell." Consequently, specifications may be fluid and are often arrived at when a contract is made between buyer and seller. Products labeled with Association of American Feed Control Officials (AAFCO) defined product names should meet the specifications within those definitions.

Labeling information for bulk materials such as rendered products should accompany shipments and must meet FDA requirements. For example, the BSE Feed Rule requires written procedures for ensuring that tallow meets the standard of "no more than 0.15% insoluble impurities" if it is to be used in feed for cattle. Any tallow that exceeds this standard should be labeled, "Do Not Feed to Cattle or Other Ruminants." Alternatively, a plant may choose not to test for impurities and simply label its tallow production with "Do Not Feed To Cattle or Other Ruminants." If testing, tallow impurities are measured by a lab using the AOCS Official Method Ca 3a-46, or an equivalent method (as the rule allows). Facilities that produce or handle "tallow" (any fat originating from cattle) would be expected to have a written compliance testing GMP for managing insoluble impurities.

5.4.2 Product Formulation (M)

Rendering plants do not typically formulate products or medicate ingredients, but do process rendered products by cooking, pressing, grinding, centrifuging, etc. Thus, rendering plants would be exempt from formulation and medication points.

Protein blenders do meet certain specifications by blending batches of rendered products with varying nutrient levels.

5.5 Customer Related Processes

5.5.1 Customer Requirements

In rendering, specifications are most often agreed upon after manufacture of the product at the time the sales contract is negotiated and written.

5.5.2 Customer Communication

5.6 Labeling (M)

5.7 Nonconforming Products and Materials (M)

5.8 Rework (M)

"Rework" material in a rendering plant may be handled differently than if it were a finished feed ingredient. Rendered products that are undercooked, become re-contaminated, or otherwise need to be processed may go back to raw material receiving. Traceability and recordkeeping are not necessary if these materials only need to be re-cooked.

5.9 Inventory Stock Rotation

5.10 Storage of Materials and Finished Products

Finished rendered materials are normally stored in bulk. While these storage areas must have separation from raw materials and other sources of cross contamination, these bulk storage and conveyances are different from those used for some feed ingredients and should be managed accordingly.

5.10.1 Storage of Raw Materials and Ingredients

Rendering raw materials should not be stored in dry areas of the processing room because they are high in moisture. The rendering process removes moisture so that finished products can be stored in dry areas.

Incoming raw materials for rendering will have subsequent kill steps, so cross contamination hazards in this area are not microbiological in nature. Renderers handling ruminant materials may need to have procedures in place to prevent ruminant materials from being mixed with raw materials without BSE restrictions.

5.10.2 Storage of Packaging

Finished rendered materials are normally stored and shipped in bulk. Hopper trailers, rail cars and tankers are the packaging materials. Truck drivers and loadout personnel should inspect each vessel and document before shipping.

5.10.3 Storage of Finished Products

5.10.4 Storage of Nonconforming Materials

Rendering plants are configured in a way to accept raw materials in bulk, and large areas are needed to mix and alternate materials fed into the cookers for efficient operation. Thus, it is common for rendering plants to store nonconforming products to be re-cooked with other raw materials. Non-conforming products destined for landfill or other disposal may be exposed to the elements as long as recontamination of finished products is prevented.

5.10.5 Bulk Storage of Ingredients and Finished Products

5.11 Storage of Hazardous Chemicals

5.11.1 Hazardous Chemical Storage Process (M)

5.11.2 Hazardous Chemical Storage Area (M)

5.12 Loading, Transport and Unloading Practices

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 53-56 for the following items, but in some cases these items may apply differently in rendering plants as described:

6 PURCHASING PROCESSES AND CONTROLS

6.1 Vendors for Incoming Goods and Services

6.1.1 Approved Vendors (M)

Requirements in FSC36 Safe Feed/Safe Food Guidance Document Version 6.0 for "vendors" are appropriate for sources of anti-caking agents, antioxidants, flocculants, and other products used in rendering. However, all sources of rendering raw materials should not be considered to be commercial vendors.

The materials entering the rendering stream may not have any value to the supplying firm or farm. Flexibility is very important, as there are alternative ways to mitigate hazards when raw materials are procured from suppliers not necessarily interested in or focused on the ultimate destination of a by-product. When hazards are dealt with otherwise, suppliers of raw materials for rendering need not be on a list of approved vendors.

The rendering industry uses truck driver checklists, investigations of unusual raw material variation, and supplier affidavits of compliance with "Animal Proteins Prohibited from Animal Feed" and the BSE feed regulation (21 CFR 589.2000), among other methods to mitigate hazards.

CMPAF removal certification forms from slaughter plants, lockers, and 4-D operators must be current and on file (annual renewal).

Disclosures /affidavits from slaughter plants, lockers, large livestock producers, confinement operations, and stock removal services must be current and on file affirming the material they supply to this facility does not include hazardous levels of insecticides, herbicide, fungicides, rodenticides, PCBs, PBBs, or heavy metals (renewed annually).

6.1.2 Unapproved Vendors or Temporary Sourcing

6.2 Material and Packaging Specifications (M)

- 6.3 Contract Service Providers
- 6.3.1 Specifications for Contract Service Providers
- 6.3.2 Contract Manufacturing

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 57-68 for the following items, but in some cases these items may apply differently in rendering plants as described:

7 VALIDATION AND VERIFICATION

7.1 Responsibility, Frequency and Methods

7.2 Validation Effectiveness

7.3 Equipment Calibration

Auditors should consider equipment appropriate for the plant. For example, rendering plants do not use mixers, but it is appropriate to calibrate thermocouples within the cooking operation.

7.4 Verification Schedule and Monitoring Activities

The rendering cooker must be operated within proper temperature ranges at all times when producing finished feed ingredients.

7.5 Product Sampling and Inspection

7.5.1 Processes for Product Sampling

Rendering samples will change in much less time than 12 months so that the sample is no longer representative of what was originally shipped, particularly with respect to microbial contamination and oxidation. Rendered products are typically used in feed rations within a month of processing. Holding samples less than 12 months may be appropriate in these cases.

7.5.2 Inspection and Analysis of Raw Materials and Ingredients

The rendering industry uses truck driver checklists, investigations of unusual raw material variation, and supplier affidavits of compliance with "Animal Proteins Prohibited from Animal Feed," the BSE feed regulation (21 CFR 589.2000 and 589.2001), among other effective ways to minimize hazards. However, microbiological testing of raw materials intended for rendering are not instructive ahead of the cooking operation.

7.5.3 Inspection and Analysis of Finished Products

Testing of finished products may be used as a verification of process control.

Supplier requirements could be different for each finished product customer and would be defined in the sales contract..

7.6 Internal Audits

Rendering plants and processes are less complicated than feed mills with few ingredients other than offal and meat industry by-products and no medications are added. Internal audits are not necessary if management and the organization are committed to providing quality and safe feed ingredients. The Practitioner must be qualified and empowered to ensure that the animal food safety plan is followed, corrective actions are taken when necessary, and required records are kept.

7.6.1 Internal Audit Process

7.6.2 Internal Auditors

7.6.3 Internal Audit Corrective Actions

7.7 Product Identification (M)

Renderers generally sell "what they make" rather than "make what they sell." Consequently, specifications may be fluid and often arrived at when a contract is made between buyer and seller. Products labeled with Association of American Feed Control Officials (AAFCO) defined product names should meet the specifications within those definitions.

Renderers are not feed manufacturers and pre-determined formulas do not exist for rendering. Protein blenders do meet certain specifications by blending batches of rendered products with varying nutrient levels.

- 7.8 Product Traceability (M)
Independent renderers pick up raw materials from thousands of dispersed small entities (up to 6000 for large plants). Materials can be traced to a collection route but not to an individual raw material source. After processing, materials are comingled in tanks, bins, or silos and can be traced to these large bulk lots, but not to specific small entities.
- 7.9 Animal Food Defense and Biosecurity Plan

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, pages 69-78 for these items:

- 8 ANIMAL FOOD SAFETY PLAN
 - 8.1 Animal Food Safety Fundamentals (M)
 - 8.2 Animal Food Safety Plan
 - 8.2.1 Animal Food Safety Plan Responsibility (M)
 - 8.2.2 Process Flow Diagram
 - 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)
 - 8.6 Waste Disposal
 - 8.7 Water and Air

Please see FSC36 Safe Feed/Safe Food Guidance Document Version 6.0, page 79 for these items, if you wish to seek certification in FSC36 Safe Feed/Safe in addition to the Rendering Code of Practice:

- 9 FSC36 SAFE FEED/SAFE FOOD SEAL REQUIREMENTS
 - 9.1 Compliance with Safe Feed/Safe Food Seal Licensing Agreement