

Facility Certification Institute

RESTRICTED USE PROTEIN PRODUCTS PROGRAM

I. Introduction

The Facility Certification Institute (FCI) partnered with the American Feed Industry Association (AFIA) to create the Certified Facility Program for Restricted Use Protein Products (RUPP) to enhance consumer confidence in the feed and food supply. This plan incorporates the FDA's inspection program for compliance with Title 21, CFR § 589.2000, Substances Prohibited in Ruminant Feed. Under the program independent certifying Agents visit facilities, which utilize restricted use protein products, as well as those establishments, which do not utilize restricted ruminant protein products. Agents review procedures and records, then issue interim certifications to those facilities that meet the program's requirements.

For the purposes of this program, the terms "restricted use mammalian protein products" or "restricted use (protein) products" (RUPP) mean those prohibited mammalian protein products used as feed ingredients within the meaning of the federal regulation governing their use (Title 21, Code of Federal Regulations § 589.2000).

This outline lays out the RUPP program for firms and facilities applying for and receiving facility certifications. The responsibilities of facilities in this program are listed in the certification application (Appendix A). Firms and facilities applying for certification agree to the requirements of this program as described on the application.

FCI reserves the right to alter this program and policies with 30 days notice to the certified facilities. However, changes to the federal regulation (21 CFR, § 589.2000) may necessitate an immediate change in the program. FCI will make every effort to accommodate such federal changes in the program as quickly as possible and notify all certified facilities.

II. Certified Facility Program

FCI's certified facility program includes:

- A. Facilities that do not receive, manufacture or distribute products that contain restricted-use proteins.

Facilities complying with AFIA's advocacy of removal of prohibited mammalian protein products within the meaning of FDA's 21 CFR 589.2000 final rule may apply for and, if certified, receive permission to utilize the FCI Certified Facility seal, logo and label statement for certified facilities. A Certified Facility seal is authorized for use by certified facilities, a certificate (Appendix B) and letter are issued to such facilities. Use of the seal, logo and label statements are governed by a licensing agreement in Appendix C.

- B. Facilities that do receive, manufacture or distribute products that contain restricted-use proteins.

Facilities that use restricted use protein products in compliance with the FDA's 21 CFR § 589.2000 may apply for and, if certified, utilize the FCI Certified Facility seal, logo and label statement for certified facilities. A Certified Facility seal is authorized for use by certified facilities, a certificate (Appendix B) and letter are issued to such facilities. Use of the seal, logo and label statement is governed by the licensing agreement in Appendix C.

If the certifying Agent finds the firm meets the requirements of the RUPP Program, then the facility will be issued the certification certificate (Appendix B), subject to annual recertification requirements as described below.

III. Fees for Service

Fees are based on a per plant cost. Discounts for multi-facility firms are available to AFIA members, provided such facilities utilize similar or the same procedures. FCI Agents will perform annual recertification inspections. Failure to remit payment may result in decertification and additional fees for reinstatement. Timely notification will be provided by FCI prior to recertification inspections.

AFIA Member Rate

Single Facility	\$1,200	per facility
2-10 Facilities	\$1,100	per facility (\$100 discount per facility)*
11+ Facilities	\$1,000	per facility(\$200 discount per facility)*

*Only applies to AFIA members and must have one billing address.

Non-AFIA Members

Single Facility	\$1,200	per facility
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Upon certification of a facility, a firm will be licensed to utilize a Certified Facility seal and logo and statements regarding certification under the licensing rules for use and placement of the Certified Facility seal (Appendix C). Failure to follow the seal and logo placement and use rules for certification may result in decertification.

A. Reinspections

Facilities not granted certification on the first inspection may request a reinspection. Additional fees may be assessed to cover the costs of the reinspection, but not to exceed the initial fee. The reinspection fee will be determined by the detail level and time resources necessary to reinspect the facility. However, the minimum reinspection fee is \$700.

IV. Certifying Inspections

FCI uses trained, professional Certifying Agents (“Agents”). Agents are authorized to determine whether a facility is in compliance with the program’s rules and grant an interim facility certification in writing at the end of the inspection, subject to review by FCI. Also, the Agent may withhold certification subject to such changes as are suggested by the Agent and agreed to by the firm, in which case, a reinspection may be necessary. Additional inspections may require additional fees, subject to the details and time, which the reinspection requires. FCI retains the final authority to grant or deny facility certification.

Facilities should comply with the following:

1. A quality assurance manual, which identifies critical checkpoints preventing restricted use protein products from entering a facility or identifies critical checkpoints for restricted proteins.
2. Where appropriate, written procedures to assure bulk shipments of all ingredients are inspected and free of restricted use protein products.
3. Where appropriate, written agreements from suppliers that ingredients are free of restricted use protein product residue.
4. Where appropriate, written agreements with transportation carriers and suppliers that containers are free of restricted use protein product residue.
5. A quality assurance-training program that provides direction and education regarding restricted use protein products.

A. Facilities that do not receive, manufacture or distribute restricted-use protein products Certification Inspection

A Certifying Agent will visit facilities requesting certification. The Agent will schedule an appointment with the facility's management. Attempts will be made to schedule the inspections expeditiously. The Agent will review facility records to document the firm is complying with the program.

Records for review will include, but not necessarily be limited to, the list stated in Section IV. A. Additionally, the Agent will review a representative number of distribution records to insure compliance with the program's objectives.

If one or more discrepancies or deficiencies are noted, the Agent will complete the form in Appendix E, Certification Inspection Deficiencies,

discuss the discrepancies with the facility management and leave a copy of the form. The Agent will also attempt to get a commitment to change the discrepancies, a specified time to do so, and schedule a reinspection. The Agent should also indicate the approximate costs associated with reinspection, which can be determined by contacting FCI.

B. Facilities that do receive, manufacture or distribute restricted-use protein products Certification Inspection

A Certifying Agent will visit facilities requesting certification. The Agent will schedule an appointment with the facility's management. Attempts will be made to schedule the inspections expeditiously. The Agent will review records to document the firm is complying with the program.

Records for review will include, but not necessarily limited to the list stated in Section IV. A. Additionally, the Agent will review a representative number of distribution records to insure compliance with the program's objectives.

If one or more discrepancies or deficiencies are noted, the Agent will complete the form in Appendix F, Certification Inspection Deficiencies, discuss the discrepancies with the facility management and leave a copy of the form. The Agent will also attempt to get a commitment to change the discrepancies, a specified time to do so, and schedule a reinspection. The Agent will also indicate the approximate costs associated with reinspection. Or this can be determined by contacting FCI.

After the inspection, the Agent will discuss with the firm the option of removing restricted use protein products from the plant in agreement with AFIA's advocated position.

V. Firm and Facility Responsibilities

In order for the certification program to be successful, full cooperation from firms and facilities must be accorded. By signing an application, a firm agrees to allow an Agent of FCI to inspect the firm's facility(ies) and agrees to comply with the provisions of the program detailed on the reverse (or page two) of the certification application.

VI. Responsibilities of FCI in the Program

To facilitate the program's operations proceed smoothly and to provide information to facilities about the program, FCI will fulfill these obligations:

- A. FCI agrees to operate this program with integrity and provide the most professional services and Agents available.
- B. FCI agrees to promote and market the Certified Facility program and develop a website to generate interest in the program and add value to the Certified Facility seal.
- C. FCI will add to the Certified Facility website the name of each facility certified within three business days following issuance of the certification certificate.
- D. FCI agrees to vigorously challenge and pursue legal action against any firm or person using the Certified Facility seal and logo, certificate, program statements or promotion in a way which brings disrepute on the

program, violates the licensing agreement, is false or misleading, and/or is used by firms not certified by FCI.

- E. FCI will provide periodic reports on the program to the certified facilities, government, and other interested parties.

VII. Confidentiality

FCI and its Agents agree all information provided to FCI for participation in this program, including, but not limited to, applications, reports, procedures, labels, and any other documents, conversations, e-mail or similar information is confidential and may not be disclosed to any other person or organization outside of FCI staff and Agents without the express written permission of the applicant or certified firm.

VIII. Internal Appeals Procedure

A. Commencing The Appeal

Should a facility disagree with a Certifying Agent who has rendered a decision after conducting a certifying inspection, the Agent will contact FCI and discuss the issue. If the issue cannot be resolved, FCI shall contact another Certifying Agent and arrange a reinspection of the facility.

As soon as possible, the second Certifying Agent shall inspect the facility using the same criteria as the initial inspecting Agent. The second Agent may allow the facility or the original Certifying Agent to provide any additional, relevant information.

The second Certifying Agent will report back to the Appeals Committee when all relevant information has been gathered, and shall turn over all relevant information.

B. The Appeals Committee

The Appeals Committee will be comprised of up to three members, including the Chairperson and, at least, one other Board Member.

Each member of the Appeals Committee shall be and remain independent of the parties involved in the appeals process.

C. Appeals Proceedings

The Appeals Committee may deliberate at whatever location it deems appropriate.

In all cases, the Appeals Committee will act fairly and impartially and ensure that each party has a reasonable opportunity to present its case.

The Appeals Committee shall proceed promptly as possible to render a final decision.

The Appeals Committee shall implement measures for protecting trade secrets and confidential information.

When satisfied that all relevant information has been presented, the Appeals Committee shall declare the proceedings closed. Thereafter, no further submission or argument may be advanced, or evidence produced, unless requested or authorized by the Appeals Committee.

D. Decisions

A decision is rendered by majority vote. If there is no majority, the decision shall be made by the chairman of the Appeals Committee. Every Decision shall be binding on the parties. The decision shall state the reasons upon which it is based. Once a judgment has been made, all parties shall be notified.

E. Miscellaneous

A party which proceeds with the appeals process without raising its objection to a failure to comply with any of these procedures or any direction given by the Appeals Committee, shall be deemed to have waived its right to object.

Neither the Appeals Committee, nor the FCI, shall be liable to any person for any act or omission in connection with the appeals process.

In all matters not expressly provided for in these procedures, the Appeals Committee shall act in the spirit of these procedures and shall make every effort to ensure that its action is legally enforceable.



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