Pork for the European Union Program

1 General

The Pork for the European Union (PFEU) Program is a voluntary, user-fee service, available to pork producers, which is designed to provide independent verification that hogs destined for harvest and subsequent shipment to European Union (EU) countries have not been fed ractopamine hydrochloride, a beta agonist banned in the EU. Pork products produced by suppliers approved under the PFEU Program are eligible for certification by the Food Safety and Inspection Service (FSIS) for export to the European Union (EU). This document provides policies and procedures for providing services under the PFEU Program.

PFEU Program services are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Poultry (LP) Program, Quality Assessment Division (QAD) under the authority of the Agricultural Marketing Act of 1946, as amended, and the Code of Federal Regulations (CFR), 7 CFR part 62. Services are available without regard to membership in any organization.

2 Scope

These policies and procedures apply to the auditing and approval of documented programs in place at production and harvest facilities, hereinafter referred to as suppliers, and other locations as referenced in the supplier's program documentation. QAD will conduct complete reviews of suppliers' documentation and hog finishing operations with regard to requirements described in the appropriate FSIS guidelines. QAD will also review program documentation for FSIS inspected pork harvest operations to ensure adequacy and continuity of product control and identification procedures.

3 Program Requirements

Program requirements are as set forth by the Food Safety and Inspection Service Guideline, Program for Certifying Pork Intended for Export to the European Union (PFEU Program),. Copies of this document may be obtained by contacting the Food Safety and Inspection Service (FSIS), Office of Policy and Program Development, Import-Export Program Development Staff at (202) 720-0082 or on the USDA FSIS: Export Requirements for the European Union website.

4 Requesting Service

Any person with a financial interest in hogs or pork products that have been raised in compliance with the FSIS guidelines may apply for service under this program. To apply, suppliers must:

a. Complete the *Application for Service* (LP-109) and mail to the Business Operations Branch (BOB) at the address shown on the form. For faster service, suppliers may submit the application to QAD.BusinessOps@usda.gov.

b. Submit a cover letter requesting a PFEU Program audit along with a complete copy of the supplier's program manual to: QAD.AuditService@usda.gov. To expedite service, suppliers should include the following information with their program manual:

- A copy of the most recent internal audit report. All programs should complete a satisfactory internal audit and record the findings before contacting USDA for review and approval services.

- Completed examples of all forms used in the program. These examples should be taken from actual records.

5 Document Reviews

The QAD will receive requests for service and program documentation and store a copy of the information in the supplier's file. If any information is missing, the QAD will contact the supplier to request additional information necessary. The QAD will hold the application until the necessary information is received. Properly prepared requests for service and accompanying program documentation will be forwarded to the assigned auditor.

Harvest facilities. QAD auditors will only conduct initial document reviews of harvest facilities to ensure documentation is complete and provides adequate traceability. If program documentation is adequate, QAD will forward the information to FSIS and publish the harvest facility's information approval as described in **Publication of Approval Status.** If documentation is not adequate, the QAD will return the documentation to the supplier with comments for further development.

Hog finishing operations. Auditors will conduct a detailed review of the program documentation to ensure all elements of the FSIS guidelines are met. If the program documentation is adequate, the auditor will arrange to conduct an onsite audit. If any element of the program documentation requires clarification, the auditor will contact the supplier and request any additional information necessary. If the supplier's program information is grossly deficient, the auditor will prepare and submit a memorandum to the QAD Branch Chief itemizing the deficiencies. The QAD Branch Chief will contact the supplier and determine whether to return the manual to the supplier for further development or retain the manual in anticipation of receiving revised or additional information. Suppliers may opt to withdraw from the application process at any time.

6 Company's Suppliers Listing

6.1 The company must maintain an approved suppliers listing.

6.2

The approved suppliers listing must:

a) Identify the supplier's name, address, and approval date; and

b) Be available to the USDA for review.

6.3 The company must also maintain the date that suppliers were removed from the suppliers listing.

7 Onsite Audits

QAD auditors will travel to the main management facility for each hog finishing operation and conduct a detailed onsite audit. For programs with multiple production locations working under the same management, the auditor will select a representative sample of production locations (2 to 5) for review. The actual number of sites selected for review will be determined with regard to the overall size of the program and animal health considerations. At each selected location, the auditor will:

a. Interview management personnel and employees with specific responsibilities relative to the program to verify their knowledge of program requirements, their role in the system, and the roles and responsibilities of other persons involved in the system.

b. Animals must not be administered antimicrobial medicinal products for growth promotion and/or yield increase during their lifetime.

c. Animals must not be administered antimicrobials reserved for the treatment of certain infections in humans, as laid down in Commission Implementing Regulation (EU) 2022/1255, during their lifetime. See Appendix 1.

d. The company must maintain sufficient records of antimicrobials used, under the discretion of the veterinarian, or purposes other than growth promotion and/or yield increase.

e. Review written working instructions and supporting documentation. The company must retain production records for three years.

f. Observe operations in process to ensure compliance with supplier's program manual and verify adequacy of testing and procedures.

g. Conduct reviews of suppliers' supporting businesses, such as nutritionists and feed suppliers, as necessary to ensure program compliance.

h. Verify that the operation has had regular veterinary visits (at least annually).

In order to reduce travel expenses and time required onsite, the auditor may elect to conduct phone interviews and request e-mail copies of specific program documentation or records prior to arrival onsite as part of the official audit.

7 Audit Reports

Upon completion of the onsite audit, the auditor will prepare a detailed report of the audit observations, findings, and recommendations to the QAD Program Manager. The report will include, at a minimum:

a. Organizational structure of the business

b. Scope of the operation

c. Animal and product identification

d. Animal or product segregation

e. Feed management and control

f. Traceability procedures

g. Training methods used

h. Involvement of other parties (veterinarians, feed suppliers, etc.)

i. Recommendation regarding approval

Auditors will itemize any significant findings of nonconformance in the findings section of the audit report and assign a tracking number to each nonconformance. Auditors will classify each itemized nonconformance as either a *continuous improvement point* or *hold point* according to the following definitions:

Continuous improvement point: a minor nonconformance that, although it needs to be corrected in a timely manner, does not compromise the integrity of the program. Isolated incidences of nonconformance should be considered continuous improvement points.

Hold point: a major nonconformance that compromises the integrity of the program to the extent that program approval should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown in a required element should be considered a hold point. An accumulation of continuous improvement points may also result in the assignment of a hold point for an audit.

All audit findings, including recommendations to be sent forward to the QAD Program Manager, will be provided as a working draft to the supplier at a closing meeting at the conclusion of the audit. Auditors will then submit the completed report to the QAD Program Manager for final review and disposition.

8 Approval Procedures

The QAD Program Manager will review the auditor's report and any other available information regarding the supplier's program and issue an approval decision according to the following criteria.

Approval. Suppliers that meet all requirements as referenced in this procedure will be issued approval valid for 1 year from the date of the approval letter. If approved, the QAD Program Manager will notify the AMS webmaster and request the supplier be added to the list of approved PFEU program suppliers as described in **Publication of Approval Status.**

Conditional Approval. If the onsite audit finds only minor nonconformances (continuous improvement points) to the supplier's stated procedures or PFEU program requirements, the QAD Program Manager may issue conditional approval and post the supplier on the list of approved PFEU program suppliers for a period not to exceed 6 months.

Denied approval. The QAD Program Manager may deny approval for any of the following reasons:

a. Failure to adequately address any program documentation requirement.

b. Failure to demonstrate capability to meet any program requirement during the onsite audit.

c. Failure to provide unlimited access to supplier's facilities and records within the scope of the requested approval.

d. Presenting false or misleading information to any QAD personnel at any point in the review or approval process.

e. Finding of any objective evidence of administration of ractopamine to hogs within the scope of the requested approval.

9 Certification

Upon reaching a decision, the QAD Program Manager will issue a letter to the program's management representative regarding the decision to approve, conditionally approve, or deny approval, stating any terms and conditions, as appropriate. The letter will include references to all audit memorandums and reports or other information on which the approval decision was based. Approved suppliers should retain the approval letter for their records.

Conditional approvals are issued with specific actions to be taken by the supplier within a specified time period. Suppliers must complete corrective actions and submit written responses within the time frames specified in the supplier's conditional approval letter to be considered for full approval.

After the conditional approval period, a QAD auditor will conduct a follow-up audit of the program of sufficient detail to ensure all program requirements are met. If the follow-up audit finds all nonconformances have been adequately addressed, and no new nonconformances raised, the QAD

Program Manager will issue approval as described above in Approval. If the follow-up audit finds all previously identified nonconformances have been adequately addressed, but new minor nonconformances are identified, the QAD Program Manager may issue conditional approval as described in Conditional Approval. If the follow-up audit finds previously identified nonconformances have not been corrected, the supplier will be removed from the list of approved suppliers until corrective actions are completed and confirmed by an additional audit.

10 Publication of Approval Status

Information about each approved producer or processing facility will be posted on the USDA AMS: Pork for the European Union website on the *Official Listing of Approved Finished Hog Suppliers to the PFEU.*

11 Maintaining Approved Programs

Suppliers are required to maintain approved programs as described in their system documentation. Any changes to the approved supplier's system that may potentially affect the integrity of program animals or products, must be submitted in writing to the QAD Program Manager and approved prior to implementation.

Depending upon the nature and extent of the changes, the QAD Program Manager may require a complete or partial onsite audit of the system prior to approval. In situations where an onsite audit is required, a new approval will be issued for an appropriate time period based on the findings of the audit.

12 Surveillance

All approved programs are subject to unannounced reviews by QAD representatives. The findings of unannounced reviews will be documented by the auditor in an official memorandum to the QAD Program Manager. Findings of unannounced reviews will be considered when determining compliance of the program for ongoing approval, or renewal, or may provide the basis for suspension.

13 Renewal of Certification

Harvest facilities. Harvest facility approvals do not require renewal and are valid until FSIS notifies the QAD that the local system documentation is no longer valid, and that the supplier should be removed from the list of approved harvest facilities.

Hog finishing operations. Suppliers should contact the QAD, at least 90 days before the expiration of their approval to request renewal. Upon request, the QAD Program Manager will arrange for a review of any manual revisions and an onsite audit to be conducted at a time as near the renewal date as possible. Each supplier must submit any revised copies of program documentation and be reassessed as described in this procedure to maintain approved status.

14 Suspending Approval

The QAD Program Manager may suspend approval and remove a supplier's program from the Official Listing for any of the following reasons:

a. Failure to follow supplier's approved policies and procedures.

b. Implementing significant changes to approved systems without prior written notification to the QAD.

c. Deliberate misrepresentation of the eligibility of hogs to be marketed in compliance with this program.

d. Confirmed finding of ractopamine residues in PFEU program animals or products. Upon confirmation of testing, QAD will suspend all approvals for suppliers in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.

15 Reinstatement of Suspended Approval

Approvals suspended for implementing changes to the supplier's system without the required advance notifications will be reinstated immediately upon receipt of appropriate corrective action.

Approvals for suppliers whose systems are within the chain of custody of animals or products testing positive for ractopamine will be reinstated only upon revalidation of the integrity of their program by QAD in cooperation with appropriate regulatory agencies.

Approvals for suppliers found to be responsible for the introduction of ractopamine into the affected animals or products will be suspended until such a time as the supplier provides objective evidence that their system has been completely purged of all potentially affected product and an onsite audit verifies that effective corrective action has been taken. Final decisions on the suitability of corrective action and the supplier's eligibility for reinstatement is at the discretion of the QAD Program Manager.

16 Appeals

Suppliers have the right to appeal any adverse audit findings or decisions issued by the QAD Program Manager. Appeals must be submitted in writing to the QAD Branch Chief, Washington, D.C., within 30 days of the date of the official report or letter rendering the findings or decisions. Requests for appeals must include:

a. the basis for the appeal, and

b. the requested alternative decision or actions.

The QAD Branch Chief will review the appeal and notify the supplier of the final decision within 30 working days of the receipt of the request. Any suspensions or denied approvals will remain in effect pending the outcome of the appeal.

17 Fees for Service

The cost of QAD document reviews, onsite compliance audits, and any follow-up or surveillance audits, including auditing and travel time, per diem, and related expenses, are the responsibility of the party requesting the service. Fees charged for service will be charged according to the approved hourly rate published in the *Federal Register* and can be found on the USDA, AMS website. Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments, and time required to complete all related travel.

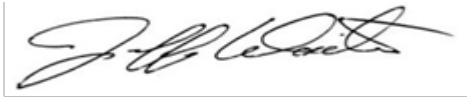
Audit preparation. Suppliers will be billed for official time spent preparing for quality system audits performed on their behalf. Official preparation time will include review of approved quality manuals and records from previous audits, and preparation of checklists.

Travel. Suppliers will be charged for travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide service to multiple suppliers, charges will be prorated between the suppliers.

18 Document Control and Retention

Records relating to services provided under the NHTC Program are stored and maintained as follows:

LP-109 *Application for Service*:	Original filed in the BOB Electronic version filed on QAD server. Copies retained until supplier withdraws request for service.
Audit Reports:	Electronic version filed on QAD server. One copy sent to supplier with approval letter. Copies retained for at least 3 years.
Approval letters:	Signed original sent to supplier. Electronic version filed on QAD server. Copies retained for at least 3 years.



Jeff Waite, Branch Chief
Quality Assessment Division
Livestock and Poultry Program

Appendix 1

Antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans per Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022

(1) Antibiotics

(a) Carboxypenicillins

(b) Ureidopenicillins

(c) Ceftobiprole

(d) Ceftaroline

(e) Combinations of cephalosporins with beta-lactamase inhibitors

(f) Siderophore cephalosporins

(g) Carbapenems

(h) Penems

(i) Monobactams

(j) Phosphonic acid derivates

(k) Glycopeptides

(l) Lipopeptides

(m) Oxazolidinones

(n) Fidaxomicin

(o) Plazomicin

(p) Glycylcyclines

(q) Eravacycline

(r) Omadacycline

(2) Antivirals

(a) Amantadine

(b) Baloxavir marboxil

(c) Celgosivir

(d) Favipiravir

(e) Galidesivir

(f) Lactimidomycin

(g) Laninamivir

(h) Methisazone/metisazone

(i) Molnupiravir

(j) Nitazoxanide

(k) Oseltamivir

(l) Peramivir

(m) Ribavirin

(n) Rimantadine

(o) Tizoxanide

(p) Triazavirin

(q) Umifenovir

(r) Zanamivir

(3) Antiprotozoals

(a) Nitazoxanide