FSIS Guideline - Program for Certifying Pork Intended for Export to the European Union (PFEU Program)

The Food Safety and Inspection Service (FSIS) is responsible for certifying that meat exported from the United States (US) to the European Union (EU) originates from animals that have never been treated with hormonal growth promotants[1].

Member states shall prohibit the importation of meat or products obtained from animals from third countries... to which products or substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and/or beta-agonists have been administered to animals by any means whatsoever (*Article 11*.)

> *Reference: Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC.*

Member states are authorized to import animals and animal products provided the third country submits a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I (*Article 29)*

> *Reference: Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.*

System Requirements

In order for FSIS, as the competent authority, to provide export certification for product produced without hormonal growth promotants, there must be assurances that there are effective controls in all applicable phases of production in growing the animal, as well as at the slaughter establishment. Though each phase or ownership stage will have to demonstrate that their system controls are adequate and are meeting the standard, emphasis will be placed on the finishing unit, which is where the compound is approved for use. An independent, third party must certify to compliance with the conditions outlined herein. The laboratory results from analyses of tissue samples collected at slaughter will help to verify the effectiveness of these controls.

Pork Production for the European Union

In December 1999, the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) approved the ß -agonist, ractopamine hydrochloride (hereafter referred to as ractopamine) as a swine feed ingredient[2]. This compound (Type A medicated article) is sold as a pre-mix without veterinary prescription over the counter (labeled as Paylean™), directly to feed mills and producers, to be incorporated in rations intended to be fed the last 90 pounds of the finishing period or roughly the final six weeks prior to slaughter. As a result of this approval and subsequent use by the swine industry, any pork intended for export to the European Union must be produced under a documented control system that will provide assurances that ractopamine has not been fed to the animal.

Production controls in feed mills

Animal feed manufacturers must provide feed produced-whether medicated or non-medicated-which meets the intended specifications and is not adulterated. The FDA established the Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds, which require medicated feed manufacturers to assure that their products meet these specifications. All manufacturers of medicated feed, including commercial manufacturers as well as on-farm mixing operations are subject to these requirements. The Federal Food, Drug, and Cosmetic Act provides that a medicated feed containing an animal drug is considered adulterated if not produced in conformance with CGMPs. Appropriate regulatory action is taken in the event that feeds are adulterated or mislabeled.

Animal feed manufacturers participating in the production of rations free of ractopamine will provide the pork production system with a letter of guarantee assuring that the feed has been prepared following standard operating procedures that assure the feed does not contain ractopamine (using the CGMP regulations specified in 21 CFR Part 225 as guidance). In addition, assurances will be made that all persons involved with the production of feed for this program are knowledgeable of the requirements of the program and have been adequately trained. The feed manufacturer shall keep appropriate records to demonstrate that the feed meets the required specifications. These records must be made available to both internal and external auditors upon request. Periodic assays are required to demonstrate that the feed meets the appropriate specifications. The feed manufacturer issuing the letter of guarantee will perform these assays. In addition, the pork production system will conduct internal audits of the feed manufacturer to assure compliance with the guarantees stated.

Production controls prior to finishing

Conditions of use for ractopamine restrict feeding a complete ration containing at least 16 percent protein to finishing swine from 150 to 240 pounds body weight (21 CFR 558.500). This product is not permitted for use in breeding swine. Suppliers that provide hogs to finishing operations that are participating in this program must provide written assurances, in the format of a producer affidavit[3], that ractopamine has not been fed during this production phase. Appropriate documentation and records must be maintained by the operation to validate this claim. These records must be made available to both internal and external auditors upon request. The pork production system will conduct internal audits of the operations supplying hogs to assure compliance with the guarantees stated.

Production controls in finishing operations

The pork production system finishing hogs for the production of meat intended for export to the EU must maintain a written program that describes procedures for maintaining identity of and segregating hogs, as well as the controls necessary to prevent the

administration of restricted compounds to each group of animals. The program must describe frequencies for monitoring and verifying that effective controls are in place. Corrective actions, with preventative measures in response to any deviations, should be included in the program. In addition, the plan must include record keeping activities. Appropriate records for each lot of animals presented to the EU-approved slaughter establishment must be maintained by the operator to validate every step in the process. These records must be made available to both internal and external auditors upon request.

Any pork production system interested in producing animals for slaughter and subsequent shipment to the EU must have their control programs approved prior to feeding hogs under this program. The control program must comply with the program requirements for traceability and identification. Emphasis will be placed on the ability to demonstrate and document sufficient identification of animals that have never been fed ractopamine. Producer affidavits are a component of the program supplied by the farrowing unit, nursery unit, growing unit, and/or finishing unit, as applicable, which will provide assurances that each lot of hogs presented for slaughter has not been fed ractopamine.

The documented program will be reviewed, audited, and approved by the USDA, Agricultural Marketing Service (AMS), Livestock and Seed Programs (LSP) or by an independent third party that has been accredited by AMS, to assure compliance with these conditions. These conditions are outlined in the "Components of the Program" provided with this document. Independent third party audit groups must be accredited by AMS in accordance with ISO Guide 65[4] requirements relative to providing certification services.

Production controls in slaughter establishments

All hogs must be slaughtered in a federally inspected slaughter establishment approved for export to the EU. If carcass meat is boned or stored in the United States, this process must be carried out in an EU approved cutting plant and/or cold storage facility. Each establishment must have a written control program and procedures in place that will assure the production and shipment of product derived from hogs that have not been fed ractopamine. The FSIS Inspector-in-charge (IIC) will review the establishment's written program to determine if it is adequate to maintain controls throughout the slaughter, fabrication, processing, packaging process, and subsequent storage. In addition, FSIS inspection personnel will be responsible for continuous monitoring of the program by performing random checks of these procedures and records throughout the EU production.

In order to assure continuity of product identification and traceability of the entire system's program, AMS will conduct an initial document review of the EU-approved establishment's written procedures for the control and segregation program. However, FSIS will maintain oversight in the establishment.

Analytical Verification Program

In addition to the audited documented system requirements, all slaughter establishments approved for export of meat and/or offals to the EU are required to participate in the EU Additional Residue Testing Program, which is administered by FSIS. In accordance with Directive 96/23/EC, a targeted number of samples are collected and analyzed for the presence of residues. These monitoring samples are tested at industry expense in independent laboratories participating in the Agricultural Marketing Service's European Meat Export Laboratory Program. The results, which are reported to both plant management and FSIS, provide verification of the effectiveness of the program to prevent use of hormones in meat intended for the EU. FSIS summarizes and reports these results to the EU annually.

In the event that a confirmed violative positive result is reported by the laboratory, FSIS will coordinate the appropriate follow-up, including notification to the Food and Drug Administration (FDA), AMS and FSIS District Enforcement Operations (DEO), depending upon which compound has been detected. AMS will immediately suspend all approvals for applicants in the product chain of custody pending a complete investigation. Suspension will remain in effect until objective evidence is provided that the system has been completely purged of all affected products and an on-site audit verifies that effective corrective action has been taken. FDA and FSIS/DEO will pursue regulatory action including criminal prosecution, where warranted. Each phase or ownership stage will independently have to demonstrate that their system requirements are adequate and are meeting the standard prior to reinstatement of the program, in accordance with AMS guidelines (MGC Instruction 710).

Components of the Program

I. Feed Manufacturers

A. Components

1. Adequate procedures will be established and maintained for identification, storage and inventory control of feeds not containing ractopamine (note: if no ractopamine is introduced into the system, identification, storage and inventory control of feeds will not be required);
2. Establish and maintain Standard Operating Procedures specific to preventing the contamination of feeds with ractopamine. Include specifications for sequencing, flushing and equipment clean out procedures.
3. A letter of guarantee that the feed does not contain ractopamine will be provided to the pork production system receiving the feed produced under this program.

B. Laboratory Assays

Feeds produced under this program will be assayed periodically (at minimum, 2 times per year) to demonstrate that ractopamine is not present.

C. Labeling

All feed must be properly labeled and handled in a manner that prevents mix-ups.

D. Record Keeping

Appropriate records must be maintained for all phases of production and distribution to support the controls and enable traceback to a specific batch if necessary.

II. Finishing Operations (verified by third party)

A. Written Program Manual

The pork production system finishing hogs for the production of meat intended for export to the EU shall prepare and maintain a program manual that contains, at minimum:

1. a description of the legal status of the supplier;
2. the names and positions of persons with responsibilities for operation under the program;
3. the names of all persons authorized to sign affidavits attesting to the non-hormone treatment of animals;
4. maps and/or legal descriptions of specific locations where hogs are maintained;
5. all operating policies and procedures or work instructions addressing controls specific to the site where the hogs are maintained (must be clear and sequential);
6. a list of all feeds and supplements and their sources;
7. completed examples of all forms, tags and labels used in operation and management of the program.
8. This program manual must be signed and dated by a responsible representative of the company.

B. On-farm Animal Identification

Each group of animals, as defined by the pork production system, must be identified with a unique identification to maintain segregation and to facilitate traceback throughout the system, in the event of a violation. The identification system must include:

1. records of the names and addresses of the places where animals for finishing originated, if different from the site where hogs are maintained for finishing;
    i. specifications for purchasing weaned or feeder hogs
    ii. letter of assurance (producer affidavit) that these hogs meets these specifications
    iii. first hand knowledge that these requirements have been met
2. type of system used to identify groups of animals (such as ear clips, ear tags, tattoos, ear notches) and at what point this identification is applied;
3. Each lot's identification must be listed in the supplier's records;
4. disposition of animals that are excluded or taken out of program;
5. procedures for ensuring each lot of hogs is traceable throughout the system;
6. Loss of identification. Written procedures must be maintained for ensuring animals with lost identification are correctly re-identified or excluded from the program.

C. Process Controls

Every step in the process where controls are needed to assure that only non-ractopamine fed hogs are presented for slaughter must be described, complete with frequencies for monitoring and means of verification that the controls are effective. These controls should include:

1. Identification of the type of operation (i.e. farrow/finish; wean/finish; grow/finish, etc.)
2. Feeds and feeding. Hogs must not have been fed ractopamine at any time during the life of the animal.
    i. records of all rations used to feed hogs to demonstrate program compliance, including the source of the feed and whether any supplements or additives are used;
    ii. maintain letter of guarantee for all sources of pre-mixed feeds;
    iii. conduct regular, detailed reviews of sources that process feeds containing ractopamine;
    iv. select weekly random samples of feed deliveries into the production system;
    v. feeds mixed on farm under this program will be assayed periodically (at minimum, 2 times per year) to demonstrate that ractopamine is not present.
3. Control and segregation.
    i. procedures to ensure program animals are not commingled with animals fed ractopamine;
    ii. procedures to ensure feed treated with ractopmamine does not cross contaminate with c. program feed that does not contain ractopamine;
    iii. identification of any ractopamine substances on premises.
4. Shipping.
    i. procedures for controlling animals during transport to slaughter establishment with affidavits
    ii. procedures for issuing and controlling the distribution of affidavits attesting to the non-ractopamine treatment for each shipment
    iii. all sales, movements or transport of hogs will be recorded in the supplier's records.
5. Records to verify procedures and evaluations have been performed.

D. Producer Affidavits

Signed statements from each production segment will attest to the non-hormone treatment of animals identified on the affidavit (see annex 2).

1. The affidavit must accompany the animals to the slaughter establishment. The affidavit must include the following information:
    i. FSIS inspected EU approved slaughter establishment where animals will be slaughtered;
    ii. provide sufficient description to permit identification and traceability of the lot of animals and total number of animals included in transport;

iii. statement attesting to full responsibility for the relevant practices applied to producing hogs that have never been fed ractopamine;

iv. AMS approval number;

v. date of dispatch;

vi. Warning statement: Persons willfully making false, fictitious, or fraudulent statements or entries are subject to fine or imprisonment or both as prescribed by Title 18 U.S. Code 1001.

2. Animals owned or under control of other persons or at other premises must have affidavits on file from each such owner
3. Must be signed by a person authorized and listed in the approved program manual
4. Affidavits must be maintained on file with other documents.

E. Educational Program

All employees involved in the program must be knowledgeable of the requirements, including but not limited to animal identification procedures, segregation procedures, and ineligible compounds. The educational programs should include:

1. procedures for ensuring all persons with program responsibilities are properly trained in relevant aspects of the program;
2. records supporting that suppliers are knowledgeable of the requirements of the program
3. records of persons trained and the scope of the training received.

F. Record Keeping

Appropriate records must be maintained for all phases of the operation to provide traceability and control of identity of the origin of the animals in addition to supporting the system of controlling banned substances.

1. Records must be maintained in a manner so as to prevent loss, damage, or alteration and be easily accessible.
2. Records should be maintained for a period projected to be one year after the export of the meat that is produced from such animals.
3. Records must be made available for inspection by AMS or other third party auditors.

G. Internal Audits

An internal assessment of the performance of the operation will be conducted periodically (at minimum 2 times per year) at every phase of the process. This assessment will be documented.

III. In-plant Slaughter and Processing Controls

A. Program Requirements

1. Written notification must be provided to the FSIS IIC prior to EU production;
2. System must ensure products received, processed, or shipped are identified and are traceable to AMS approved production system or supplier;
3. Animals received or shipped must be accompanied by a signed affidavit attesting to the to full responsibility for the relevant practices applied to producing hogs that have never been fed ractopamine;
4. All persons with responsibilities for program activities must have a complete understanding of program requirements relevant to their area of responsibility.

B. Written Program ManualAll operating procedures related to the control of and segregation of non-hormone treated animals through slaughter, cutting and packaging must be documented. These procedures must include:

1. a description of the legal status of the establishment;
2. the names and positions of persons in managerial responsibilities for operation of the certified program;
3. the names of all persons authorized to sign affidavits that the products originated from production systems not feeding ractopamine;
4. diagrams and/or descriptions of locations where products are stored or processed;
5. clear, sequential, operating policies and procedures or work instructions, specific to the establishment seeking approval, that address the entire process, from receiving animals for slaughter, transfer of carcasses into cooler, transfer of carcasses into the cutting room or to another cutting plant, transfer of cuts into the shipping carton and subsequent storage.
6. Completed examples of all forms, tags, and labels used by the supplier to track products or demonstrate program compliance;
7. This program manual must be signed and dated by a responsible representative of the company.

C. Identification

Documented procedures for identification, segregation and proper handling of product throughout the entire process to maintain segregation and to facilitate traceback throughout the system. The identification system must include:

1. Sufficient identification of each carcass component or container to provide cross referenced documentation from the identification of the animals at receiving (and the affidavit) to the identification system in-plant;
2. Record of the signed affidavit accompanying the lot of animals;
3. Method of identification clearly distinguishing EU product from non-EU product;
4. Loss of identification. Written procedures must be maintained for ensuring animals or product with lost identification are correctly re-identified or excluded from the program.

D. Production Controls

Every step in the process where controls are needed to assure that only non-hormone treated animals are slaughtered must be described, complete with frequencies for monitoring and means of verification that the controls are effective. These controls should include:

1. Segregation of non-hormone treated animals (carcasses/meat) from non-program animals (carcasses/meat)
2. Procedures that account for the disposition of animals and products excluded from the program
3. Records related to the number of animals presented for slaughter and the number of animals slaughtered for the EU
4. Storage and inventory control of the EU oval health mark (including labels and brands)
5. Records supporting control of product transferred to separate cutting facilities and cold storage warehouses

E. Educational Program

All employees involved in the production of non-hormone treated meat must be knowledgeable of the requirements of this program, including but not limited to animal/meat product identification procedures, segregation procedures, and laboratory sampling procedures. The educational programs should include:

1. Access to documented company procedures as well as access to the current version of the EU Export Requirements located in the FSIS Export Library
2. Record of communication of any changes to the program;
3. Procedures for ensuring all persons with program responsibilities are properly trained in relevant aspects of the program;
4. Records supporting that suppliers are knowledgeable of the requirements of the program;
5. Records of persons trained and the scope of the training received

F. Transfer Affidavits

Signed statements from each production segment will attest to the non-hormone treatment of animals identified on the affidavit (see annex 3). A copy of the affidavit accompanying the animals to the slaughter establishment will remain on file with other documents. The transfer affidavit will have sufficient description to permit identification and traceability of the meat products through the system back to the origin of the animals.

G. Internal Audits

An internal assessment of the performance of the operation will be conducted periodically (at minimum two times per year) at every phase of the process. This assessment will be documented.

H. Record Keeping

Appropriate records must be maintained for all phases of the operation to provide traceability and control of identity of the origin of the animals.

1. Records must be maintained in a manner so as to prevent loss, damage, or alteration and be easily accessible
2. Records must be maintained for a period of at least one year after the export of the meat that is produced from such animals.
3. Records must be made available for inspection by FSIS or other third party auditor.

Annex 1

These substances have thyrostatic, oestrogenic, androgenic or gestagenic action. They are used to increase feed efficiency, accelerate attainment of market weight and improve carcass quality. The compounds include drugs such as methylthiouracil, zeranol (Ralgro), melengestrol acetate (MGA), endogenous sex steroids (Synovex-S, Synovex-H, Compudose 200 and 400), trenbolone acetate (Revalor-S, H or G, Finapix-H, S) and ractopamine hydrochloride (Paylean).

GROUP A of Annex I - Substances having anabolic effect and unauthorized substances

1. Stilbenes, stilbene derivatives, and their salts and esters
    - Diethylstilbestrol (DES)
    - Hexoestrol
    - Dienoestrol
2. Anti-thyroid agents
    - Thyreostats (2 - thirouracil)
3. Steroids
    - Melengestrol acetate (MGA)
    - 19 Nortestosterone (17-? and 17-?)
    - Trenbolone acetate (17-?, 17-?)
4. Resorcylic acid lactones including zeranol
    - Zeranol/Taleranol
5. Beta-agonists
    - Clenbuterol

- Salbutamol
- Cimaterol
- Ractopamine hydrochloride

6. Compounds included in Annex IV to Council Regulation (EEC) No. 2377/90 of June 26, 1990
    - Nitrofurans
    - Chloramphenicol
    - Dimetridazole (hydroxy metabolite)

Note: The targeted number of samples for each compound included in the EU Additional Residue Testing Program can be found in the FSIS Export Requirement Library (www.fsis.usda.gov)

[1]Prohibited compounds are listed in Annex 1

[2] 21 CFR Part 556-Tolerances for residues of new animal drugs in food (§556.570 Ractopamine) and Part 558-New animal drugs for use in animal feeds (§ 558.500 Ractopamine).

[3] Terminology for producer affidavits is included in the sample affidavit presented in Annex 2.

[4] ISO (International Organization for Standardization), IEC (International Electrotechnical Commission) Guide 65: General requirements for bodies operating product certification systems. Copies can be obtained from American National Standards Institute, 11 West 42nd Street, New York, New York 10036. Tel (212) 642-4900, facsimile (212) 398-0023. Website: www.ansi.org.