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Food Safety and Inspection Service's Program for Certifying Non-Hormone Treated Beef to the European Union

Standard

The Food Safety and Inspection Service (FSIS) is responsible for certifying that the bovine 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.)*
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> *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.*
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> 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)*
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> *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

The Non-hormone Treated Cattle (NHTC) program has been in effect since 1989, when the EU and the US agreed to control measures to facilitate the trade of non-hormone treated bovine meat. There are three principal components of this program:

(1) Cattle are to be grown in approved farms/feedlots and delivered to the slaughter establishment with an affidavit from the grower attesting to their non-hormone treated condition.
(2) Non-treated cattle and beef are segregated at the slaughter establishment and handled in a fashion that ensures that they are not commingled with other animals or meat.
(3) Tissue samples from non-hormone treated cattle are collected at slaughter and analyzed by accredited independent laboratories for residual levels of restricted compounds.

In order for FSIS to provide export certification for this product, there must be assurances that there are effective controls in all phases of production in growing the animal, as well as at the slaughter establishment. Compliance with the conditions outlined herein must be certified by a third party. The laboratory results from analyses of tissue samples collected at slaughter will help verify the effectiveness of these controls.

The farm/feedlot operation must be documented in a written program or plan which describes procedures for maintaining identity of and segregating non-hormone treated cattle, as well as the controls necessary to prevent the administration of restricted compounds to the animals and documentation of regular veterinary visits. The program or plan must describe frequencies for monitoring and verifying that effective controls are in place.

[1] Prohibited compounds are listed in Annex 1

Corrective actions, with preventative measures in response to any deviations, should be included in the program or plan. In addition, the program or 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 maintained according to the record retention requirements defined in the AMS guidelines and made available to both internal and external auditors upon request.

Any origin premise, farm or feedlot interested in producing animals for slaughter and subsequent shipment to the EU must have their control systems approved in advance of shipment of animals to harvest. Each of these systems 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 treated with growth promotants from birth to point of slaughter. Producer affidavits and/ or shipping records are a component of the program supplied by the grower, producer, and feeder, which will provide assurances that each individual animal in the entire lot of cattle presented for slaughter has not been treated with hormones. The documented system will be audited by an independent, third party that has been accredited by the USDA, Agricultural Marketing Service (AMS), Livestock and Poultry Programs (LP) or by LP itself, to assure compliance with these conditions. AMS, LP has prepared guidelines describing the NHTC Program, based on the conditions outlined in this document. These are available on the AMS web site.

All cattle must be slaughtered in a federally inspected slaughter establishment approved for export to the EU. If carcass meat is boned or stored in the US, 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 non-hormone treated cattle. 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, inspection personnel will perform 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 program procedures for the controls, identification, and segregation program. However, FSIS will maintain operational oversight in the establishment.

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 an independent laboratory. 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 cattle intended for the EU. On an

annual basis, FSIS summarizes and reports these results to the EU.

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 Office of Field Operations and Office of Investigation, Enforcement, and Audit (OIEA), depending upon which compound has been detected. AMS will immediately suspendall 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/OFO and OIEA 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 NHTC program, in accordance with AMS guidelines (QAD 1013 Procedure).

Components of the Program

I. Farm/Feedlot

The farm/feedlot operation must maintain a written program or plan that describes procedures for maintaining identity of and segregating non-hormone treated cattle, as well as the controls necessary to prevent the administration of restricted compounds to the animals. The company must provide evidence of regular veterinary visits to the farm or ranch. The frequency of these visits should at minimum be annually. AMS LP has prepared guidelines describing the NHTC Program, based on the conditions outlined in this document. These are available on the AMS web site (https://www.ams.usda.gov/services/imports-exports/nhtc).

II. In-plant Slaughter and Processing Controls

Plant Management Responsibilities
Written notification must be provided to FSIS IIC prior to EU production in any FSIS establishment.

A. Approved Origin
Premises Animals must be sourced from an approved origin premises that has been certified by an accredited third party

B. Written Program
All operating procedures related to the control of and segregating non-hormone treated cattle 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 approved production systems;

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.
8. Relevant portions of this document must be readily available for reference by persons supporting the system.

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 cattle are slaughtered must be described, complete with frequencies for monitoring and means of verification that the controls are effective. These controls should include:

1. 100% palpation of ears for the presence of implants
2. Segregation of non-hormone treated cattle (beef) from other cattle (beef)
3. Records related to number of animals presented for slaughter and 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 beef 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 on 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. Record of training and the scope of training received

F. Transfer Affidavits

Signed statements from each production segment will attest to the non-hormone treatment of animals identified on the affidavit. A copy of the affidavit or shipping documents accompanying the cattle 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 cattle.

G. Internal Audits

An internal assessment of the performance of the operation will be conducted at every phase of the process periodically. 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), and trenbolone acetate (Revalor-S, H or G, Finapix-H, S).

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-alpha and 17-beta), Trenbolone acetate (17-alpha, 17-beta))

4. Resorcylic acid lactones including Zeranol/Taleranol
5. Beta-agonists (Clenbuterol, Salbutamol, Cimaterol, Ractopamine hydrochloride, zilpaterol)
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)