



NON-HORMONE TREATED CATTLE (NHTC) PROGRAM

General

The Non-Hormone Treated Cattle (NHTC) Program is a voluntary, user-fee service available to beef producers that is designed to provide independent verification that beef cattle and beef products have never been fed or treated with hormonal growth promotants. Cattle raised and fed by producers approved under the NHTC Program are eligible for certification by the Food Safety and Inspection Service (FSIS) for export to the European Union (EU) as non-hormone treated beef. This instruction sets forth revised policies and procedures for providing service under the NHTC Program.

NHTC services are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review, and Compliance (ARC) Branch, Quality Systems Verification (QSV) under the authority of the Agricultural Marketing Act of 1946, as amended, and the applicable Code of Federal Regulations. Services are available without regard to membership in any organization.

Scope

These policies and procedures apply to the auditing and approval of farms, ranches, and feedlots, hereinafter referred to as *producers*, and any other entity in the chain of custody of cattle to be certified under this program. Effective with the publication of this revision, slaughter facilities will be audited by AMS for initial approval only to ensure proposed procedures support the traceability of products to the farm or ranch of origin. Ongoing surveillance of slaughter and processing facilities will be maintained by FSIS.

Program Requirements

Program requirements for are as set forth by the LS Program's NHTC Program General Requirements for Live Animal Production, as revised April 30, 2001. This document is available on the USDA's Internet website at <http://www.ams.usda.gov/lsg/ARC/nhtc.htm>, or by contacting the ARC Branch office at (202) 720-1124.

Requesting Service

Any person with a financial interest in cattle that have been raised without the use of hormonal growth promotants may apply for service under this program. To apply, producers must:

- (1) Complete a LS 313, Application for Service, and send it to the ARC Branch Headquarters, LS Program, 1400 Independence Avenue, S.W., Room 2627- S, Washington, D.C., 20250-0248. For faster service, producers may fax the form to the Washington ARC Branch office at (202) 690-3428, but must send the form with the original signature to the address above.

"The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (VOICE and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer."



- (2) Submit a cover letter requesting an NHTC Program audit, along with a complete copy of the producer's program manual, as described in the appropriate General Requirements document, to the QSV Manager, ARC Branch, LS Program, 1400 Independence Avenue, S.W., Room 2627-S, Washington, D.C., 20250-0248. New applicants must include the following information with their program manual:
- Examples of all animal identification ear tags used in the program.
 - A copy of the most recent internal audit report. All programs must complete a satisfactory internal audit and record the findings before contacting USDA for review and approval services.
 - A letter from the producer's consulting veterinarian, who must be familiar with the NHTC program requirements, attesting to the non-use of hormonal growth promotants in any part of the producer's feeding and health care program.
 - A letter from the tag manufacturer attesting to the unique tag control system.
 - Completed examples of all forms used in the program. These examples should be taken from actual records.

Document Reviews

The ARC office will review applications for completeness and store a copy of the information in the producer's file. If any information is missing, the ARC office will contact the producer to request any additional information. The ARC office will hold the application until the necessary information is received.

Properly prepared requests for service and accompanying program documentation will be forwarded to an assigned auditor. The auditor will review the producer's NHTC documentation to ensure that each element of the general requirements has been appropriately addressed. If the program documentation is adequate, the auditor will arrange to conduct an onsite audit. If any element of the program documentation requires clarification that can be easily obtained by working directly with the producer, the auditor will contact the producer and request the necessary information. If the producer's program information is significantly deficient, the auditor will prepare and submit a memorandum itemizing the deficiencies to the QSV Manager. The QSV Manager will contact the producer and determine whether to return the manual to producer for further development or retain the manual in anticipation of receiving revised or additional information. Producers may opt to withdraw from the application process at any time; however, they are responsible for any fees incurred up to the time they withdraw their application.

Onsite Audits

AMS auditors will travel to each location and conduct a detailed audit. At each location, the auditor will:

- (1) 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.
- (2) Observe operations in process to ensure compliance with producer's program manual and verify adequacy of testing and procedures. If any aspect of the operation is not available for review



during the audit, the auditor may require additional onsite reviews if necessary to adequately evaluate the program.

- (3) Review written procedures and supporting documentation.
- (4) Establish positive traceability of cattle to the farm or ranch of birth.
- (5) Conduct reviews of producers' supporting businesses such as consulting veterinarians, feed producers, animal health product producers, as deemed necessary by the auditor to ensure compliance.

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

Audit Reports

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

- (1) Organizational structure of the business
- (2) Scope of the operation
- (3) Identification procedures
- (4) General feeding and healthcare information
- (5) Livestock or product segregation procedures
- (6) Traceability procedures
- (7) Training methods used
- (8) Involvement of other parties (veterinarians, feed producers, etc.)
- (9) 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 QSV Manager, will be discussed with the producer at the conclusion of the audit. Auditors will then submit a complete report to the QSV Manager for final review and disposition.

Approval Procedures



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

Approval. Producers that meet all program requirements will be issued approval valid for 1 year from the date of the onsite audit. If approved, the QSV Manager will notify the LS Program Internet webmaster and request the producer be added to the list of approved NHTC program producers as described in **Publication of Approval Status.**

Conditional Approval. If the onsite audit finds only minor nonconformances (continuous improvement points) to the producer's stated procedures or NHTC program requirements, the QSV Manager may issue approval with requirements for additional document and/or onsite reviews be conducted at the applicant's expense after 6 months.

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

- (1) Failure to adequately address any program documentation requirement.
- (2) Failure to demonstrate capability to meet any program requirement during the onsite audit.
- (3) Finding of a major nonconformance (hold point) to stated procedures during an onsite audit.
- (4) Denying access to producer's facilities and records within the scope of the requested approval.
- (5) Presenting false or misleading information to any ARC Branch official at any point in the review or approval process.
- (6) Finding of any objective evidence of administration of any hormonal growth promotant to cattle within the scope of the requested approval.

Certification

Upon reaching a decision, the QSV 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 producers should retain the approval letter for their records.

Approval may be issued with specified actions to be taken by the producer within a given time period. Producers must complete corrective actions and submit written responses within the time frames specified in the producer's approval letter. At the conclusion of the specified time period, the QSV Manager may require a document review or onsite 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 QSV 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 QSV Manager may issue conditional approval as described in **Conditional Approval.**

If the follow-up audit finds previously identified nonconformances have not been corrected, the producer will be removed from the list of approved producers until corrective actions are completed and confirmed by an additional audit.



Publication of Approval Status

Information about each approved farm, ranch, and feedlot will be posted on the USDA's Internet web site on the *Official Listing of Approved Producers of Non-Hormone Treated Cattle* located at <http://www.ams.usda.gov/lsg/arc/nhtc.htm>.

Maintaining Approved Programs

Producers are required to maintain approved programs as described in their system documentation. Any changes to the approved producer's system that may potentially affect the integrity of NHTC Program animals or products, must be submitted in writing to the QSV Manager and approved prior to implementation. Depending upon the nature and extent of the changes, the QSV 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.

Surveillance

All approved programs are subject to unannounced reviews by ARC Branch representatives. The findings of unannounced reviews will be documented by the auditor in an official memorandum to the QSV 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.

Renewal of Certification

Producers should contact the QSV office in Washington, D.C., at least 90 days before the expiration of their approval to request renewal. Upon request, the QSV Manager will arrange for a manual review and onsite audit to be conducted at a time as near the renewal date as possible while coordinating the audit with other audits in the area. Each producer must submit any revised copies of program documentation, and be reassessed as described in this instruction to maintain approved status.

Suspending Approval

The QSV Manager may suspend approval and remove a producer's program from the Internet posting for any of the following reasons:

- (1) Failure to follow producer's approved policies and procedures.
- (2) Implementing significant changes to approved systems without prior written notification to the ARC Branch.
- (3) Deliberate misrepresentation of the suitability of cattle to be marketed as non-hormone treated.
- (4) Confirmed finding of residues of any hormonal growth promotants in products from cattle raised, fed or marketed by the producer. Upon confirmation of testing, AMS will suspend all approvals for producers in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.
- (5) Failure to correct previously identified nonconformances as required.
- (6) Failure to pay required fees.



Reinstatement of Suspended Approval

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

Approvals suspended for failure to implement corrective actions within required timeframes, will be reinstated immediately upon verification that required actions have been implemented.

Approvals for producers whose systems are within the chain of custody of products identified with hormonal growth promotants will be reinstated only upon revalidation of the integrity of their program by AMS in cooperation with appropriate regulatory agencies.

Approvals for producers found to be responsible for the introduction of hormonal growth promotants into the affected cattle or products will be suspended until such a time as the producer 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 producer's eligibility for reinstatement is at the discretion of the QSV Manager.

Approvals suspended for failure to pay fees will be reinstated immediately upon payment of fees and any accrued interest.

Appeals, Complaints and Disputes

Producers have the right to question or appeal any adverse audit findings or decisions issued by the QSV Manager. Appeals, complaints, and disputes must be submitted in writing to the ARC 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:

- (1) the basis for the appeal, complaint, or dispute, and
- (2) the requested alternative decision or actions.

The ARC Branch Chief will review any request for action and notify the producer 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.

Fees for Service

The cost of QSV 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.

Fee rate. Fees for service will be charged according to the approved hourly rate published in the *Federal Register*.

Audit preparation. Producers 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. Producers 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 producers, charges will be prorated between the producers.

Recording hours charged. Hours of service to be charged to the producer will be documented on LS Form 5-3 (1-93), Agricultural Products Certificate, and submitted to the OFO for billing. Copies of the charge certificate will be maintained with the audit working papers.

Document Control and Retention

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

LS 313 - Requests for Service: Original filed in the ARC Branch.
 Electronic version filed in QSV office.
 Copies retained until the producer withdraws request for service.

Program manuals: Electronic or hard copy filed in QSV/QSV Auditor’s office.
 Copy of current version retained until the producer withdraws
 request for service.

Audit reports: Electronic version filed in QSV office.
 One copy sent to producer with approval letter.
 Copies retained for at least 3 years.

Approval letters: Signed original sent to producer.
 Electronic version filed in QSV office.
 Copies retained for at least 3 years.

Auditors

Auditors assigned to conduct document reviews and onsite audits must be qualified as ARC Branch lead auditors as described in ARC Instruction 1030, Training and Experience Requirements for Quality Systems Verification and Compliance Audits. Auditors must have signed conflict of interest statements and appropriate disclosure agreements on file with the ARC Branch prior to assignment to provide service to a specific producer.

James L Riva, Chief
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