# USDA EXPORT VERIFICATION (EV) PROGRAM SPECIFIED PRODUCT REQUIREMENTS NON-HORMONE TREATED CATTLE (NHTC) FOR THE EUROPEAN UNION

## 1 Purpose

This document provides the specified product requirements which are in addition to the USDA Food Safety and Inspection Service (FSIS) regulatory requirements for marketing U.S. bovine meat and meat products to the European Union (EU) produced from U.S. born and raised cattle.

## 2 Scope

These requirements apply to U.S. companies including cattle management groups, individual producers, stockers, and feedlots that supply cattle to approved harvest and processing facilities that are eligible for export to the EU as listed on the FSIS website. Suppliers who produce cattle that meet the specified product requirements, in addition to the USDA FSIS regulatory requirements, must produce the eligible cattle under an approved USDA Quality System Assessment (QSA) Program. The requirements for the QSA Program are defined in QAD 1002 Procedure: *USDA Quality System Assessment Program*. The QSA Program ensures that the specified product requirements are supported by a documented quality management system.

Alternatively, a supplier may produce the eligible cattle under an approved USDA Process Verified Program (PVP). The requirements of the PVP are defined in QAD 1001 Procedure: *USDA Process Verified Program*.

FSIS has developed guidelines for the industry, which provide the system requirements and components of the program (Program for Certifying Non-hormone Treated Beef to the European Union).

## 3 Reference Documents

QAD 1000 Procedure: *Quality Systems Verification Programs, General Policies and Procedures*

QAD 1001 Procedure: *USDA Process Verified Program*

QAD 1002 Procedure: *USDA Quality System Assessment (QSA) Program*

*GU0273AFA Additional Requirements for NHTC Program*

USDA AMS: Non-Hormone Treated Cattle (NHTC) Program website

USDA FSIS: Export Library - Requirements by country website

USDA FSIS: Program for Certifying Non-hormone Treated Beef to the European Union

## 4 Additions to QSA Program Requirements

The specified product requirements listed in Section 5 and Section 6 of this procedure must be met through an approved QSA Program. The QSA Program ensures that the specified product requirements are supported by a documented quality management system. In addition to the requirements listed in QAD 1002 Procedure, Section 7, *Program Requirements*, companies must also incorporate the following requirements into their QSA Program:

### 4.1 Internal Audit

4.1.1 The company must conduct internal audits at planned intervals.

4.1.2 The internal audit must determine whether the company's Quality Management System (QMS):

a) Conforms to the planned arrangements, to the requirements of this procedure, and to the QMS requirements established by the company; and

b) Is effectively implemented and maintained.

4.1.3 The company must have a documented procedure which defines:

a) The planning of an audit program, which must consider the status and importance of the processes and areas to be audited, as well as the results of the previous audit;

b) The audit criteria, scope, frequency, and methods;

c) The selection criteria of the auditors and conduct of auditors which must ensure objectivity and impartiality of the audit process (Auditors must not audit their own work.);

d) The responsibilities for planning and conducting audits;

e) The reporting of results;

f) The follow-up activities (Follow-up activities must include the verification of the actions taken and the reporting of the verification results.); and

g) The maintenance of records.

4.1.4 Within the area being audited, management must ensure that actions are taken without undue delay to eliminate detected non-conformances and their causes.

4.1.5 The company must maintain records of the internal audits.

## 4.2 Company's Suppliers Listing

4.2.1 When a company approves its own suppliers, the company must maintain an approved suppliers listing.

4.2.2 The approved suppliers listing must:

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

b) Be available to the USDA for review.

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

## 4.3 Supplier Evaluations and Re-evaluations

.The company must conduct an initial onsite evaluation of each supplier prior to approving the supplier under the program.

4.3.1 The company must take into consideration the risk associated with the supplier when determining the frequency of the onsite re-evaluation. At a minimum, the company must conduct an onsite re-evaluation of each approved supplier on an annual basis.

4.3.2 The company must ensure that the evaluator is independent and free from bias and conflict of interest.

4.3.3 The company must ensure that the final decision of approval is determined by someone other than the evaluator.

4.3.4 The findings and final decision must be based on the evidence gathered during the evaluations and re-evaluations.

## 4.4 Record Retention

4.4.1 Records must be retained for a period projected to be 1 year beyond the date of export of meat products to the EU. For each industry sector, the minimum requirement must be:

a) Cow/calf operations - 3 years from date of birth

b) Yearling stocker operations - 2 years from date of sale or transfer to feedlot

c) Auction markets - 30 months from date of sale

d) Feedlot operations - 18 months from date of harvest

## 5 Specified Product Requirements for Live Animals

5.1 Animals must not be administered hormonal growth promotants (HGPs) at any time during their lifetime.

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

5.3 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.

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

5.5 Animals must be traceable to their farm or ranch of birth using live animal production records. Verification activities for specified product requirements must be conducted at applicable levels as required by the submitted QSA Program.

5.6 Animals must be obtained from, and must be traceable to, approved companies that appear on the *Official Listing of Approved Sources of Non-Hormone Treated Cattle.*

5.7 Animals must be identified prior to leaving the place of birth with a program compliant ear tag. A Program compliant ear tag is a 1-time use, tamper-evident tag, which contains a non-repeatable, unique number. It may be an EID, RFID, or a visual tag. The company must provide evidence that the tag meets these requirements.

5.8 The company must maintain sufficient records of all rations fed to animals for the life span of the animal to demonstrate compliance. The records must identify the source and ingredients of pre-mixed feed and supplements.

5.9 When feed or supplements are obtained from sources that process feeds containing HGPs, the company must periodically test feeds to ensure procedures in place effectively prevent HGP-treated feeds from being fed to program animals. As an alternative, if the feed supplier has an additive-control program monitored by a State or Federal agency, the company may obtain a certificate of compliance or letter of guarantee stating that the feed to be used for program animals is free of HGPs.

5.10 If HGPs are used on the premises, the company must develop and maintain written procedures for accounting for the acquisition, inventory, use, and disposal of all HGP

used on the premises. The procedures must ensure that feeds treated with HGPs do not contaminate feed for program animals. Applicable records must be maintained.

5.11 The company must provide evidence of regular veterinary visits to the farm or ranch. The frequency of these visits should at minimum be annually.

5.12 Shipping documentation (bills of lading, shipping manifests, letters of guarantee, or electronic transmissions) must accompany each shipment of animals that occurs due to sale or transfer of custody. Shipping documentation must have the statement "Cattle Meet EV Program Requirements for the EU" and must clearly identify the animals and the quantity.

## 6 Listing of Approved Programs

6.1 U.S. companies who produce live animals that meet the specified product requirements for the European Union are listed on the *Official Listing of Approved Sources of Non-Hormone Treated Cattle.* The Official Listing is available on the NHTC Program website.

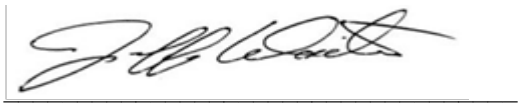
## 7 Audit Frequency

A company that does not approve suppliers under its program is audited at least once per fiscal year (October 1 to September 30). However more frequent audits may be conducted (1) if either numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners, or other financial interested parties; or (4) as directed by the QAD Branch Chief.

A company that does approve suppliers under its program is audited in accordance with the audit frequency outlined in QAD 1002 Procedure.

## 8 Responsibilities

U.S. companies must meet all policies and procedures outlined in this procedure, QAD 1000 Procedure: *Quality Systems Verification Programs, General Policies and Procedures,* QAD 1001 Procedure: *USDA Process Verified Program* and QAD 1002 Procedure: *Quality System Assessment (QSA) Program*.



Jeff Waite, Branch Chief
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# 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