



Guidance Number: GU0032AFA

Subject: Pork to the Russian Federation Guidance Document

Distribution: QSVF Customers and auditors

Instructions: Save this Operational Guidance document for further reference. A controlled copy is located on the QAD server.

1 Scope

This guidance is applicable to porcine. It is applicable to any U.S. companies that harvest, fabricate, and/or process pork and pork products for export to the Russian Federation and approved by USDA as a supplier to the QAD 1030V Procedure: *USDA EV Program: Specified Product Requirements for Pork to the Russian Federation*. This includes cold storages that package (re-box) pork products for export to the Russian Federation. It also includes any service provider who maintains an approved suppliers listing, in accordance with QAD 1030V Procedure, Section 4. These entities are referred to as "operations" for the remainder of this document. Approved operations must ensure that the requirements of this guidance are met, as applicable.

2 Responsibilities

2.1 The Quality Assessment Division (QAD) is responsible for the following:

- a) Conducting audits of approved operations in accordance with QAD 1000 Procedure and QAD 1030V Procedure. The audits verify conformance to the QAD 1030V Procedure.
- b) Verifying the operation's approved suppliers listing, product identification system, and associated procedures to ensure conformance to the QAD 1030V Procedure.
- c) Verifying the operation's testing protocols for the Tetracycline Group Testing Program and the Microbiological Testing Program to ensure conformance to the QAD 1030V Procedure.

2.2 Harvest facilities and service providers are responsible for the following:

- a) Developing and maintaining an approved suppliers listing. Documented procedures for approving suppliers must meet the requirements outlined in below in Section 2.2 b). Documented procedures for the removal of suppliers must meet the requirements outlined below in Section 2.2 c).

Note 1: An affidavit system alone is not an acceptable method of approving suppliers.

Note 2: As an alternative, harvest facilities may utilize a service provider's approved suppliers listing. If the harvest facility utilizes a service provider's approved suppliers listing, then it is exempt from this responsibility.



- b) Conducting supplier evaluations and re-evaluations. The USDA Process Verified Program and USDA Quality System Assessment (QSA) Program require supplier evaluations and re-evaluations as outlined in QAD 1001 Procedure, Section 4.5.1 Receiving Process and QAD 1002 Procedure, Section 4.2, respectively. Supplier evaluations and re-evaluations must meet the requirements as written. Additionally, these evaluations must meet the requirements of either Option 1 or Option 2 as outlined below.
- i) Option 1 (without on-going verification testing for tetracycline group residues for each producer):
- a. Person-to-Person interaction (face-to-face or telephone communications);
 - b. Review of production records, as appropriate, to ensure conformance;
 - c. Documented procedures, as appropriate, to ensure conformance;
 - d. Communication of the program requirements to ensure conformance; and
 - e. A detailed questionnaire appropriate to the claim and activities that occur at the location to ensure conformance.
- ii) Option 2 (with on-going verification testing for tetracycline group residues for each producer):
- a. Person-to-Person interaction (face-to-face or telephone communications);
 - b. Communication of the program requirements to ensure conformance; and
 - c. On-going verification testing for tetracycline group residues for each producer. Testing must occur at least semi-annually.

Note 1: Supplier evaluations and re-evaluations may also be called initial audits and surveillance audits, respectively, within an approved program.

Note 2: If the harvest facility utilizes a service provider's approved suppliers listing, then it is exempt from conducting supplier evaluations and re-evaluations.

- c) Developing and maintaining documented procedures for the removal of suppliers if the testing protocol indicates the presence of tetracycline group residues. If the operation re-approves such suppliers, then it must also develop and maintain documented procedures for the re-approval, including verification by the operation of implementation and effectiveness of corrective actions by the supplier.

Note: If the harvest facility utilizes a service provider's approved suppliers listing, then it is exempt from this responsibility.



- d) Developing and maintaining an approved testing protocol for the Tetracycline Group Testing Program in accordance with the requirements of QAD 1030V Procedure, Section 5.1.
- e) Developing and maintaining a product identification system, in accordance with the requirements of QAD 1030V, Section 4.3.1.

2.3 Harvest facilities, further processing facilities, and cold storages are responsible for the following:

- a) Developing and maintaining a Microbiological Testing Program in accordance with the requirements of QAD 1030V Procedure, Section 5.2.

Note 1: If the harvest facility retains ownership of the product, then the cold storage does not need to implement a Microbiological Testing Program. However, the cold storage must have procedures in place to ensure identification, traceability, and segregation of conforming product in accordance with the procedures of the harvest facility. The cold storage is audited under the harvest facility's program.

Note 2: If the cold storage takes ownership of the product, then the cold storage must implement a Microbiological Testing Program. The cold storage is audited under its own program.

- b) Developing and maintaining a product identification system, in accordance with the requirements of QAD 1030V, Section 4.3.1. Regardless of ownership, whoever's establishment number is on the box must maintain a product identification system, to ensure only conforming product is being used in the EV Program for Pork to the Russian Federation.

2.4 Further processing facilities and cold storages are responsible for the following:

- a) Developing and maintaining an approved suppliers listing. Operations must ensure they are purchasing product from USDA-approved harvest facilities as listed on the Official Listing.
- b) Ensuring conforming product is purchased and used within the approved program. Operations must have documented procedures addressing the purchase, verification, and identification of conforming product.
- c) Developing and maintaining a product identification system, in accordance with the requirements of QAD 1030V, Section 4.3.1. Regardless of ownership, whoever's establishment number is on the box must maintain a product identification system, to ensure only conforming product is being used in the EV Program for Pork to the Russian Federation.



2.5 Producers are responsible for the following:

- a) Adhering to the procedures and requirements of the harvest facility's approved program to maintain conformance to the 14-day withdrawal period for tetracycline group antibiotics.

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