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Subject:	Additional Requirements for verifying market claims for the USDA PVP and QSA Program
Distribution:	QSVP Customers and Auditors
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1 Scope

This guidance is applicable to any operation that is a supplier to an approved USDA Process Verified Program (PVP) or a USDA Quality System Assessment (QSA) Program where the marketing claims must be traceable to live animal production records. Approved USDA programs must ensure that the requirements of this guidance are met.

2 Definitions

The following definitions apply to this document.

- 2.1 Auction Market: An operation where animals are purchased and sold. Also includes video and web operations.
- 2.2 Backgrounder-Stocker: An operation where animals are maintained, often on pasture or rangeland, to increase weight and maturity before being placed into a feedyard.
- 2.3 Claim: A specified process verified point within a PVP or a specified product requirement within a QSA Program.
- 2.4 Company: The approved USDA PVP or QSA Program that must meet the requirements.
- 2.5 Dairy Calf Ranch: An operation that receives dairy calves from dairy farms to increase weight and maturity before being placed into a feedyard. May also be called a grow yard.
- 2.6 Farm/Ranch of Origin: The location where an animal is born.
- 2.7 Feedyard: An operation that receives animals for feeding in preparation for harvest.
- 2.8 Marketing Claims: One or more characteristics about a process, product, or service that has been verified by a USDA-Authorized Agent. (e.g., process verified points, grade marks).
- 2.9 Non-regulated Feed Mill: An operation that does not have an additive-control program monitored by a State or Federal agency.
- 2.10 Producer: A person who operates a farm or ranch where animals are born (e.g.: cow-calf operation).



NOTE: A producer may have an additional operation, such as a backgrounder-stocker operation or a feedyard. In such instance, if all animals within the operation are considered non-conforming, then the producer should be considered only as a producer. However, the activities at the additional operation(s) and the risks associated with those activities must be considered during the evaluation of the producer.

- 2.11 **Producer-Feeder:** An operation that feeds animals born at the operation for harvest.
- 2.12 **Regulated Feed Mill:** An operation that has an additive-control program monitored by a State or Federal agency.
- 2.13 **USDA-Approved Service Provider:** An entity that certifies or verifies that products and/or services meet specified requirements. In terms of the USDA PVP, a Service Provider verifies that products and/or services meet specified requirements.
- 2.14 **Specified Requirement:** A need or stated expectation.
- 2.15 **Service Provider Audits:** The accreditation, verification, and certification of an entity that provides products and/or services to an applicant of an Official USDA Audit Program.
- 2.16 **Supplier:** A source of materials (including animals), service, or information input provided to a process or program.
- 2.17 **Verification:** The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.
- 2.18 **Onsite evaluation:** Review of a potential supplier or location, conducted face to face on the physical location where program activities are to be conducted.

3 Supplier Evaluations and Re-evaluations

The USDA PVP and USDA QSA Programs 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 following requirements.

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



3.1 Producer (including producer-feeder)

3.1.1 Claims that may change over time or location require initial onsite evaluations of each producer. Therefore, any program that includes, but is not limited to health, feeding, and/ or management claims requires initial onsite evaluations of producers.

a. Annual onsite re-evaluations of each producer are required.

3.1.2 Claims that do not change over time or location, such as date of birth (age), source, and breed claims, do not require initial onsite evaluations of each producer. However, the evaluation must be sufficient to verify that animals conform to the claim. The risk associated with the producer must be considered and documented, when determining whether or not it is necessary to conduct an initial onsite evaluation.

NOTE: (For Export Verification Programs Only) If cattle or sheep are aged at the time of harvest using the dentition method in accordance with the FSIS reference document(s) *Using Dentition to Age Cattle, or Dentition to Age Ovine* the age claims are not required to be traceable to live animal production records. Annual onsite re-evaluations of producers are required at frequency of 10% or 2, whichever is greater.

a. Alternatively, annual onsite re-evaluations of producers may occur at a frequency of 5% or 2, whichever is greater, if the company conducts initial onsite evaluations of each producer.

b. If the company evaluates independent groups of animals, then annual onsite re-evaluations of producers may occur at a frequency of 3% or 2, whichever is greater.

3.1.3 Minimum requirements for evaluations and re-evaluations of producers include the following:

a. Person-to-Person interaction (face-to-face or telephone communications);

NOTE 1: Phone interviews conducted for evaluations or re-evaluations of producers can only be conducted by employees trained under the approved PVP or QSA Program. A list of these employees, along with their training, must be maintained by the approved company.

NOTE 2: Independent agents not directly employed by the approved company can only be utilized to conduct onsite evaluations or re-evaluations. USDA retains the right to determine whether these individuals are considered agents or employees.

b. A review of production records to ensure conformance must be conducted prior to final approval of the producer and animals. A record of this review must be maintained by the approved company.



- c. Documented procedures, as appropriate, to ensure conformance;
- d. Communication of the program requirements to ensure conformance;
- e. A detailed questionnaire appropriate to the claim and activities that occur at the location, (USDA must review and approve the questionnaire prior to use,); and
- f. Communicate to producer that USDA may visit his/her location(s) to verify the approved USDA PVP or QSA Program's activities.

3.2 Dairy Calf Ranch, Backgrounder, Stocker, Feedyard, Auction Market, and Non-regulated Feed Mill:

- 3.2.1 Initial onsite evaluations of each operation are required, regardless of the claim.
- 3.2.2 Annual onsite re-evaluations of each operation are required, regardless of the claim.

3.3 Regulated Feed Mill (For NHTC Program Only)

- 3.3.1 Evaluations and re-evaluations of regulated feed mills are not required. However, the company must ensure that the requirements outlined in Sections 4.2 and 5 are met.

4 Required Documentation and Records of Suppliers

4.1 Producer (including producer-feeder)

- 4.1.1 Each approved supplier must maintain documented procedures and records appropriate to the operation and necessary to provide evidence of conformance. Documents and records must be retained for the timeframe necessary to provide evidence of conformance.

NOTE: Depending upon a supplier's on-farm activities, the questionnaire (3.1.3e) may serve as a documented procedure. For example, a producer who has 2 calving seasons and does not receive calves from outside sources may use the questionnaire to document how the calves are identified, where they are located, and how dates of birth are assigned.

4.2 Regulated Feed Mills

- 4.2.1 When applicable based on the claim, each regulated feed mill must provide the company with a certificate of compliance or a letter of guarantee stating that the feed to be used for program animals meets the program requirements.

4.3 Backgrounder, Stocker, Feedyard, Auction Market, and Non-regulated Feed Mill

- 4.3.1 Each approved supplier must maintain documented procedures and records appropriate to the operation and necessary to provide evidence of conformance. These may include documented procedures and records that are standard to the approved program as well as



those that are unique to the operation. (For example: standard procedures for control of documents and records and supplier evaluations; and unique procedures for identification and traceability.)

4.3.2 The following requirements must be addressed:

- a. **Control of Documents:** The operation must control all documents required at the operation related to the program. Documents must be retained for the timeframe necessary to provide evidence of conformance or as defined by the specific program.
- b. **Control of Records:** The operation must establish and maintain records to provide evidence of conformance. Records must be retained for the timeframe necessary to provide evidence of conformance or as defined by the specific program.
- c. **Operation Representative:** The operation must have a designated representative who, irrespective of other responsibilities, must have responsibilities and authorities to ensure that processes needed for the program are established, implemented and maintained. The representative must have the authority to act on behalf of the operation at all locations where program activities are conducted.
- d. **Training:** Personnel with responsibilities for program activities must be appropriately trained. Records of training, including scope, must be maintained.
- e. **Receiving Process** (QAD 1001 Procedure *Section 4.5.1* or QAD 1002 Procedure *Section 4.2*): The requirements as written must be addressed.
- f. **Identification and Traceability** (QAD 1001 Procedure *Section 4.6.3* or QAD 1002 Procedure *Section 4.3*): The requirements as written must be addressed.
- g. **Preservation of Product** (QAD 1001 Procedure *Section 4.6.5* or QAD1002 Procedure *Section 4.4*): The requirements as written must be addressed. Additionally, the operation must have a documented shipping procedure and shipping records. Records must include the date, the number of animals in the shipment, animal identification, the name of the shipper, the name of the receiver, and the claim(s) to which the animals conform. **NOTE:** Animal identification may include individual identification, group identification, or other identification as appropriate.
- h. **Control of Non-conforming Product within the QMS** (QAD 1001 Procedure *Section 5.3* or QAD 1002 Procedure *Section 5.3*): The requirements as written must be addressed. **NOTE:** Non-conforming animals must be identified in a manner that clearly identifies them from conforming animals.



4.4 Dairy Calf Ranch

4.4.1 Each approved supplier must maintain documented procedures and records appropriate to the operation and necessary to provide evidence of conformance. These may include documented procedures and records that are standard to the approved program as well as those that are unique to the operation. (For example: standard procedures for control of documents and records and supplier evaluations; and unique procedures for identification and traceability.)

4.4.2 The requirements outlined in section 4.3.2 must be addressed in addition to the following requirements:

- a. A **dairy supplier list** from which calves are sourced. The list must contain the name of the dairy, an identification number (as applicable), the approval date, and the removal date.
- b. A **schedule** identifying when calves are picked up at each approved dairy and **supporting information**. The schedule may contain the name of the dairy or another code assigned to the dairy. Supporting information must include the number of calves collected on the scheduled date, the dairy of origin, and calf identification. **NOTE:** Each calf must be traceable to the dairy of origin. Therefore, appropriate animal identification must be used.
- c. **Documented criteria for visual verification of the age** of calves at pickup. (For example: 1 to 2 day old calves have wet navels, soft hooves, and thick, soft, lush coats.)
- d. **Documented method for assigning the date of birth** of the calves. This method must be consistent with the pick-up schedule. At a minimum, the calf's date of birth must be recorded as the date of the previous pick-up. (For example: Calves are picked up on the 1st and 15th of each month. Calves picked up on the 15th are assigned a date of birth of the 1st.) This methodology, along with the criteria for verifying the age, is used to ensure that the date of birth has been assigned properly.

5 Training of Suppliers

5.1 Suppliers must be trained only if they are personnel with responsibilities in the approved program. However, training of all suppliers is encouraged since the company must ensure that animals and products received from outside establishments and used in the program conform to specified receiving requirements.

5.2 The company must communicate the specified receiving requirements to suppliers. (QAD 1001 Procedure *Section 4.5.1* or QAD 1002 Procedure *Section 4.2*).



6 Evaluators of Suppliers

- 6.1 Evaluators, including the person making the final decision, must be independent of the supplier and free from bias and conflict-of-interest. This ensures that the evaluation findings and conclusions are based solely on the evidence collected, thereby making the evaluation an effective and reliable tool.
- 6.2 When there is an inherent conflict of interest, the supplier evaluation must include controls that limit the conflict-of-interest. (For example: The buyer may conduct the supplier evaluation of the producer, but the final decision is made by another person.)

7 Company's Approved Supplier Lists

- 7.1 Companies with an approved USDA PVP or QSA Program must make their supplier lists available to the Quality Assessment Division.

8 Program Compliant Tags (PCT)

- 8.1 The use of a PCT allows animals to retain claims that do not change over time or location, such as date of birth (age), source, and breed, regardless of movement between approved and unapproved locations. If animals move from an unapproved to an approved location, then the approved location must read the PCT and access the individual animal information from the approved USDA program that enrolled the animal.

NOTE: If the claim may change over time or location, such as health, feeding, and/or management claims, then animals with must move from one approved location to another approved location even if a PCT is used.

- 8.2 If the company requires the use of a PCT, then the following requirements must be met:
- a. A PCT is a one-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 PCT meets these requirements.
 - b. The PCT must be applied (1) under an approved USDA PVP or QSA Program and (2) at the farm or ranch of birth or at an alternative location as approved on a case-by-case basis.
 - c. The company must control the use of PCT, including a documented procedure for tag allocation and an inventory record. The PCT inventory record:
 - i) May be maintained by either the company or the producer.
 - ii) Must include the tag number, the producer, and the associated claim(s).



- iii) Should include dates of activity, the tag status, and changes of identify when a tag is replaced with another.

NOTE: Unused PCTs should be recorded within the company's program to strengthen inventory control.

- 8.3 Secondary tagging locations may be used to apply PCTs in the event the farm or ranch of origin does not have adequate facilities to apply PCTs to animals. The company must be approved to use secondary tagging locations prior to implementation. All secondary tagging locations must be audited onsite and approved by the company prior to use.

NOTE: Secondary tagging locations can only be used for claims that do not change over time, such as age, source, and breed.

- a. Animals may only be tagged with approved PCTs issued to the owner of the animals.
- b. The PCTs must be brought to the secondary tagging location with the animals to be tagged.
- c. PCTs must be applied immediately upon arrival of the untagged animals at the secondary tagging location.
- d. Each secondary tagging location must maintain documented procedures and records appropriate to the operation and necessary to produce evidence of conformance. Documents and records must be retained for the timeframe necessary to provide evidence of conformance.
 - i) Initial onsite evaluations of each operation are required, regardless of the claim.
 - ii) Annual onsite re-evaluations of each operation are required, regardless of the claim.

9 Back Verification

- 9.1 The verification of claims for animals that have left the farm or ranch of origin may occur only if the claim does not change over time or location, such as date of birth (age), source, and breed.
- 9.2 To use back verification, the company must include a documented procedure and records specific to the activity within the approved program. Documents and records must be maintained for the timeframe necessary to provide evidence of conformance.
- 9.3 The following requirements must be met.
- a. The producer must receive an evaluation. The evaluation must meet the requirements outlined in Section 3, as applicable.



- b. Animals must be identified (ear tag, brand, etc). The method must match the information collected during the evaluation of the producer.
- c. Animals must have moved directly from the farm or ranch of origin to the location where back verification occurs. The location must be approved by the company in accordance with Section 3 and Section 4, as applicable.
- d. Animals must be traceable to the farm or ranch of origin.
- e. A copy of the production record(s) supporting the claim(s) must be maintained by the company or approved location.
- f. The producer must maintain (1) shipping records that include the date, the number of animals in the shipment, animal identification, the name of the shipper, and the name of the receiver; and (2) a bill of sale, if applicable, including the date, the number of animals sold, animal identification, the name of the seller, and the name of the buyer.

NOTE: Companies that include back verification as an activity within the approved program are subject to increased audits to verify conformance to the requirements. Such audits may include verification activities at the producer level.

10 USDA Approved PVP Service Providers

USDA Approved PVP Service Providers are entities that assist with verifying and certifying that products, processes, or results meet specified requirements. Service Provider audits include the verification and certification of an entity that provides products and/or services to an applicant of an Official USDA Audit Program.

- 10.1 Applicants, including USDA Approved PVP Service Providers, of a USDA Audit Program that use marketing claims and/or process verified points on product labels and/or marketing materials associated with their approved audit program must ensure that marketing claims and/or process verified points are:
- a. Clearly defined in their audit program documents.
 - b. Approved by the appropriate regulatory body [e.g. Food Safety and Inspection Service (FSIS)] or adhere to the guidelines established by the appropriate regulatory body [e.g. Food and Drug Administration (FDA)].
 - c. Used only by the applicant approved by AMS. No other entity may perform conformity assessment services on an applicant's behalf, nor can applicants transfer the use of marketing claims and/or process verified points to another entity.



10.2 USDA-Approved Service Providers:

- a. May conduct activities as determined and defined by a USDA Audit Program (ex. USDA Process Verified Program).
- b. Shall not approve or otherwise issue USDA shields, marketing claims, or process verified points to entities that they audit.
- c. Shall not officially audit or approve any PVP applicant; this is done by the AMS Auditor/Program Manager.

10.3 USDA Audit Programs

- a. Official USDA Audits shall be performed by an AMS Auditor.
- b. Applicants who use the USDA PVP shield and/or terminology on products produced within and/or on marketing materials used in association with their approved audit program must be audited directly by an AMS Auditor.
- c. The AMS Auditor will audit annually the full scope of all approved PVP Programs. This includes all types of facilities and documented program manuals included in the applicant's program.

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