Animal and Plant Health Inspection Service

Veterinary Services

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Items to Consider for Autogenous Vaccines in Relation to VS Memo 800.69 and 9 CFR 113.113

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Items to Consider for Autogenous Vaccines in Relation to VS Memo 800.69 and 9 CFR 113.113

Source Documents: VS Memo 800.69 and 9 CFR 113.113

Background: The animal health and livestock industries indicated that isolates for autogenous vaccines are useful for up to 60 months from isolation. The CVB worked with industry to provide this flexibility, along with further regulatory flexibilities involving third party cold storage distribution facilities and common ownership allowances. This work instruction provides guidance to inspectors while on inspection or reviewing records that relate to these regulatory flexibilities from the updated VS Memo 800.69.

A. Isolate Expiration Date:

1. 9 CFR 113.113 (a)(4) states under normal circumstances microorganism(s) used for the production of autogenous biologics may not be older than 15 months from the date of isolation or 12 months from the date of harvest of the first serial of product produced from the microorganism(s), whichever comes first.

2. The 3-month difference in isolate expiration dating reflects the CVB's expectation that a firm use an isolate to produce the first serial in a timely manner to ensure the isolate remains relevant to the herd.

B. Isolate Extension of Use to 60 months:

1. Previously, the CVB allowed extending the use of an isolate to 24 months from the date of isolation with information on file at the manufacture. The only difference in the revised VSM 800.69 is the extension timeframe has moved from 24 months to 60 months from date of isolation.

2. The VSM does state the extension can be from 60 months from the first harvest and if the firm has a controlled process and the original dating was in line with the intent of the regulation, that can be considered. The difference between first harvest date and isolate date should not be more than three months. The firm must maintain record of the request for this extension by the attending veterinary/nonveterinary specialist, including justification for continued use.

3. The 60-month extension of use date is ONLY for isolates, NOT serials or bulk antigens.

4. The isolation extension of use date under IC authority is 60 months TOTAL, not 15 months plus 60 months. Extension of isolate use beyond 60 months from the date of isolation are submitted to PEL for consideration.

5. If an isolate has exceeded the date of use before the implementation of the updated VS Memo 800.69 on November 19, 2021, that isolate is NOT eligible for the 60-month extension.

6. The VS Memo 800.69 did NOT change the regulation that all isolates that have exceeded the date of use must NOT be stored on licensed premises. It is permissible that a firm moves these isolates to a building that is at an address not within the licensed premises. R&D that is separate and apart may be considered.

C. Third-party cold storage distribution facility:

The location of the third-party facility must be approved by the CVB-IC before use, and the documentation and approval must be on file with the CVB-IC and the firm. The licensee or permittee is ultimately responsible for all third-party adherence to the regulations and this privilege may revoked at any time based on cause.

Below is the outline of the CVB-IC expectations for third-party cold storage distribution facility:

1. The firm must submit a written request to the CVB-IC for each 3rd Party Facility prior to use. If conditions do not change, CVB-IC only needs to provide a one-time approval for each 3rd Party Facility. This permission does not transfer from licensee to licensee. Exceptions may be considered for establishment mergers. The request should address the following issues:

a. Temperature control during shipment to the 3rd Party Facility – including documentation

b. Temperature control at the 3rd Party Facility – including documentation

c. Temperature control during shipment to the herd/flock/veterinarian – including documentation

d. Tracking and distribution of serials at the 3rd Party Facility – including documentation

e. Permission for CVB to inspect the 3rd Party Facility

f. Quality agreement or process for notifying the firm regarding quality or issues impacting quality (The licensed firm may have routine audits of the 3rd party facility and have these available for CVB upon request.)

2. Shipment of autogenous products to the 3rd Party Facility may only occur after the serial is released, either 3-day release for first serials or CVB release for subsequent serials.

3. Once a 3rd Party Facility is approved, this approval is further documented in a Plot Plan Legend Addendum as a more centrally located source of information. The addendum should include the address for the 3rd party facility, the Mail Log number of the approval and permission to inspect the facility.

4. The licensed establishment is responsible for all compliance related to the maintenance and distribution of the autogenous serials by the 3rd Party Facility in accordance with the regulations. This includes, but is not limited to, 9 CFR 113.113(a)(2),(3) and (4), 114.11 and 116.2. Records confirming compliance should be available for review during inspection at the licensee and 3rd party facility.

5. All documents will be available and supplied for inspection. If the 3rd Party Facility refuses to supply documents, the privileges and regulatory flexibility of 3rd Party facility distribution will immediately be revoked for that distribution site.

6. Once approved 3rd Party Facility will be entered into LSRTIS

7. For recalled, returned, or expired autogenous serials:

a. If the testing of a first serial indicates contamination or safety issues after the 3rd day of observation, the serial may be quarantined at the 3rd Party Facility until a retest (if performed) has been done and a final determination has been made. This is only if the 3rd Party Facility has appropriate quarantine procedures.

b. If the serial has already been shipped to the herd, the unused inventory should be returned to the licensee, not the 3rd Party Facility.

c. Inventory of expired serials at the 3rd Party Facility can be destroyed by the 3rd Party Facility if processes and documentation is in place. If the 3rd Party Facility is not equipped to handle or do destruction, the serials will be shipped back to the firm for destruction. The firm shall be responsible for and maintain all documentation.

D. Common Ownership:

1. The flexibility of common ownership is for the same species owned by a common owner. Common ownership is usually regarded as animal ownership or a grow out facility, or similar facilities which are under contract with the owner to raise the animals.

2. Use of the common ownership flexibility REQUIRES inactivation kinetics for the virus type (by species) on file with CVB and must be in the Outline of Production prior to movement of the product. If an owner has multiple species, submission of inactivation kinetics is required for each species. This flexibility may be used in lieu of the regulations regarding adjacent and non-adjacent herd/flock use and, as an example, would allow for flexibility to take an isolate from the nursery or grow-out facility (herd of origin) and prepare a vaccine for the breeding facility.

3. Documentation must be maintained by the manufacturer to attest to common ownership of the herds the product is shipped to. It is the expectation of the CVB that firms ensure veterinarians and owners understand that vaccine is only to be distributed to sites noted under the common ownership.

4. Common ownership is a regulatory flexibility and may not be appropriate for all situations. Firms may continue to ship product under the adjacent and non-adjacent herds regulations cited in 9 CFR 113.113(a)(2) and (3). This documentation must be on file with the licensee before an autogenous product is shipped for use in a herd other than the herd of origin.

E. Autogenous Products for Export Only Distribution:

1. Manufacturers with an autogenous license are allowed to produce autogenous products for export only purposes. However, autogenous products containing isolates originating from outside the United States are not eligible for use or distribution within the United States, regardless of any potential epidemiological link with the foreign herd of origin. These autogenous products are only eligible for "export only" distribution. They are also not eligible for the 3rd party cold storage distribution facility flexibility.

2. The manufacturer must obtain a valid Organisms and Vector (Form 16-3) permit. This permit is obtained from Veterinary Services, Organisms and Vectors (OV) Permitting Unit.

3. Safeguards must be in place during the production, so these isolates do not contaminate other products or facilities. These safeguards may be reviewed on inspection.

Signature Manifest

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