

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Policy/Procedure

Product Destruction

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Product Destruction

1. Purpose and Scope

The purpose of this document is to describe the various methods for the destruction and/or disposal of unsatisfactory biological products, carcasses, refuse, or materials unsatisfactory for production or marketing purposes. In addition, this document describes the Center for Veterinary Biologics (CVB)-Inspection and Compliance's (IC) procedure for observing product destruction and processing of destruction records. This document does not cover disposal of known or suspected Transmissible Spongiform Encephalopathy (TSE) contaminated or infected materials.

2. Authority for Product Destruction

The Virus Serum Toxin Act (VSTA) makes it unlawful to prepare, ship, or deliver for shipment, any worthless, dangerous, contaminated or harmful products for use in domestic animals. The Code of Federal Regulations, Title 9 (9 CFR) Part 114.15 requires that "all biological products found to be unsatisfactory for marketing, all biological products which have become worthless subsequent to the expiration date, all refuse, other materials deemed unsatisfactory for production purposes, all carcasses (part or whole) of production or test animals, and any undesirable by-products of manufacture shall be disposed of as may be required by the Administrator."

3. Other Laws and Regulations

Disposal of destroyed materials are subject to all federal, state, and local laws and regulations pertaining to the disposal of waste and the maintenance of environmental quality in the final disposition of materials.

4. VS Memorandum 800.56

Veterinary Services (VS) Memorandum 800.56 contains guidance on product destruction. The decision to destroy such products can be made only by an authorized agent of the licensee. Once decided upon, destruction must be by approved methods.

5. Disposal Methods

The disposal method depends upon: 1) whether the product contains live agents or toxins or is inactivated or contains hazardous compounds (i.e. thimerosal), and 2) whether it has been found unsatisfactory by the CVB testing or by licensee testing.

Live agents or toxins may be potentially hazardous to the health of humans, or other animals, or the environment, and must be inactivated by approved procedures. Serials found contaminated

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are considered to contain live agents. The following approved destruction methods are described in VS Memorandum 800.56 unless otherwise noted.

5.1 Products Containing Live Agents or Toxins

5.1.1 Incineration

The application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state.

5.1.2 Dry Heat

The application of dry heat at a temperature of at least 160°C for a period of time, minimum of 1 hour, adequate to inactivate, detoxify, and/or sterilize the material involved (9 CFR 109.1[a]).

5.1.3 Autoclaving

The application of live steam at a temperature of at least 120°C for a period of time, not less than one-half hour, adequate to inactivate, detoxify, and/or sterilize the material involved (9 CFR 109.1[a]).

5.1.4 Chemical

The addition of chemicals such as sodium hypochlorite (bleach), formalin, phenol, cresol, beta-propiolactone, phenylmercuric nitrate, or equivalent inactivating agents at sufficient concentration for sufficient time and under proper conditions to inactivate, detoxify, and/or sterilize the material involved.

Note: Bleach is not listed in VS Memorandum 800.56 but may be approved by VS for use in appropriate situations.

5.2 Refuse, Carcasses, and Other Undesirable By-products Containing Live Agents or Toxins

The by-products of veterinary biologics manufacture (such as refuse, carcasses, contaminated disposable plastic-ware, etc.) may also contain live agents or toxins. The following methods are approved ways of disposal of these materials.

5.2.1 Rendering

The denaturing and cooking of carcasses or other organic material in closed tanks for a period of time sufficient to effectively destroy the material for human food purposes and to degrade to a noninfectious state.

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5.2.2 Burial

The internment of carcasses, contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.

5.2.3 Composting

The controlled aerobic biological decomposition of organic matter into an environmentally stable product called compost. It is used as an alternative method of managing manure and other organic wastes, such as poultry or livestock waste.

Note: Composting is not listed in VS Memorandum 800.56, but may be approved by VS for use in appropriate situations.

5.2.4 Incineration (see Section 5.1.1)

5.2.5 Tissue Digestion

The digestion and liquefaction of organic matter by alkaline hydrolysis in a heated sealed vessel under constant agitation. The alkali and water are added in precise proportion to the weight of tissue and the system is heated to a specified operating temperature for a specified period of time.

Note: Tissue digestion is not listed in VS Memorandum 800.56, but may be approved by VS for use in appropriate situations.

5.3 Products Containing Hazardous Compounds, including Thimerosal

Some veterinary biologics may contain hazardous compounds, including, but not limited to, Thimerosal/Merthiolate, that are used as preservatives, inactivants, etc. The improper treatment and disposal of products containing hazardous compounds may pose a substantial present or potential hazard to human health or the environment. Disposal of such products must comply with all applicable federal, state, and local regulations. Contractors and facilities used to dispose of hazardous waste should be registered with the Environmental Protection Agency (EPA) and have a United States EPA ID number.

6. Transport of Materials

The conveyances used to transport carcasses or other infectious materials are to be constructed so as to be leak-proof and equipped to permit thorough cleaning and disinfecting. Vehicles used for the transportation of hazardous waste should be properly placarded.

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7. Products Found Unsatisfactory by CVB

It is Animal and Plant Health Inspection Services (APHIS) policy to have VS personnel physically present at the firm to observe the destruction of product that has been found unsatisfactory as a result of CVB testing (9 CFR 114.15, VS Memorandum 800.56 III.C.3.).

Unsatisfactory testing is reported to the licensee by the CVB on the Biologics Test Report and is sent to the firm with the APHIS Form 2008 (Form 2008) submitted by the licensee or permittee (9 CFR 113.5[c]).

The Biologics Test Report details the CVB testing, indicating how the serial tested unsatisfactorily.

8. Documentation of Destruction

8.1 APHIS Form 2045

APHIS Form 2045 (Form 2045) is only to be used by APHIS personnel for recording the observation of destruction of serials.

The form is completed by the APHIS observer after destruction has been performed. All copies should be legible.

8.1.1 Processing the completed Form 2045

The completed Form 2045 is distributed as follows:

- The white copy (original) is filed with inspection notes.
- The yellow copy is forwarded to the Biologics Compliance Assistant (BCA) for entry into the LSRTIS database.
- The pink copy is left with the licensee or permittee (firm is to be given a legible copy).

Upon receipt of the yellow copy of the Form 2045, the BCA records the destruction in the LSRTIS as follows:

- Scan the Form 2045 and attach the electronic copy to the serial record in LSRTIS.

The Form 2045 is initialed and dated by the BCA to confirm data entry and attachment of the serial record.

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The processed Form 2045 (yellow copy) is filed in the firm's product file.

8.2 APHIS Form 2008

The licensee or permittee may request permission to destroy product found unsatisfactory by CVB without APHIS supervision. If authorized, the licensee reports the destruction of the serial(s) on a Form 2008. The method of destruction and date performed is reported in Block 11 or 12 of the Form 2008.

In cases where the licensee or permittee is authorized to dispose of a serial, the CVB will verify destruction records during an inspection of the establishment and refer to this verification in the inspection report.

9. Products Found Unsatisfactory by Licensee

The CVB does not require licensees to destroy products under APHIS supervision that have been found unsatisfactory by the licensee or permittee prior to the release of the serial(s) for distribution and sale.

Reporting on Form 2008

See the current version of **ICSOP0010** for procedures on processing the Form 2008.

The destruction of product by the firm is reported in Block 12, Disposition by Firm, Destroyed.

If not apparent from the test results reported on the Form 2008, the reason for determining the serial is unsatisfactory should be provided in Block 11, Remarks.

Note: The notice of destruction on a Form 2008 is not the intent to destroy but a certification of destruction. The Form 2008 should include the date of destruction.

10. Other Types of Products or By-products

Products or by-products not containing live agents or toxins are subject to applicable federal, state, or local laws and regulations pertaining to the treatment and disposal of waste and to environmental quality.

VS employees are to complete the Form 2045 for inactivated products after witnessing the destruction of such products found unsatisfactory as a result of CVB testing. If a sanitary landfill is used, the VS employee is to verify that the landfill is a state approved site and that the unsatisfactory product is destroyed.

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11. Disposal Routine

The firm is required to hold the unsatisfactory serial(s) on licensed premises until disposal is witnessed by APHIS or until other arrangements have been authorized. Storage at 2°- 7°C is not required.

Product destruction should be scheduled as part of an inspection or other visit to the establishment.

In unusual situations, arrangements may be made with the USDA Area-Veterinarian-In-Charge for a VS field veterinarian to witness the destruction. This option should be discussed with the Inspection Section Leader prior to making such arrangements.

12. VS Observer Responsibilities

The VS observer is responsible for the following:

- Review of production records and Form 2008 for each serial or subserial to be destroyed.
- Determine if the method of destruction the firm proposes to use is allowed in VS Memorandum 800.56.
- Ensure the entire inventory is presented for destruction. This should include all reserve and retention samples. To retain any portion of an unsatisfactory serial, the licensee must obtain permission from the CVB prior to presenting the serial for destruction.
- Perform an actual count of the serial or material presented for destruction.
- Maintain the inventory under observation and control until the destruction cycle has progressed enough to make all product unmarketable (i.e., until the maximum heat of the autoclave has been applied, or final containers have been dumped into barrels for hazardous waste disposal).
- Observe completion of cycle (i.e., removal from the autoclave or incinerator).
- Certify destruction by completing the Form 2045. Note on the form if any samples are retained. A legible pink copy is left with the licensee or permittee.
- **Offsite product destruction:** In addition to above, the VS observer is responsible for the following:

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- a. Ensure all cartons or containers are appropriately packed, sealed, and clearly identified as for destruction and labeled hazardous waste, if applicable.
- b. Render all barrels or pallets tamper-evident by the use of locking seals, shrink wrap, or other acceptable device/material.
- c. If the VS observer is present for the pick-up of product, after loading, ensure the vehicle transporting the product to the destruction site is locked. Render the lock tamper-evident.
- d. In addition to information required on the Form 2045, the form should also list the weight and corresponding identification of the barrel(s), pallet(s) or other containers.
- e. If the product(s) is to be picked up by a contractor at a later date, request a copy of the shipping manifest when available. The manifest should be traceable to the information listed on the Form 2045.
- f. Request that the firm provide a copy of the records from the contractor confirming destruction and the method of destruction, including landfill or burial. The records should be traceable to the information listed on the Form 2045.

13. Summary of Revisions

Version .03

- The Contact information has been updated.
- **8.1:** Changes have been made to reflect the process change from VBIS to LSRTIS system.

Version .02

- The Contact has been changed from Mark Pagala to Dennis Page.