



March 12, 2008

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.56

Animal and Plant
Health Inspection
Service

TO: VS Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

Veterinary Services

Washington, DC
20250

FROM: /s/ Andrea M. Morgan for John R. Clifford
Deputy Administrator

SUBJECT: Disposal of Unsatisfactory and Undesirable Materials

I. PURPOSE

This memorandum establishes procedures to comply with Title 9, Code of Federal Regulations (9 CFR) 114.15 for the disposal of unsatisfactory biological products, carcasses, refuse, or materials unsatisfactory for production purposes.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.56 dated September 7, 1999.

III. PROCEDURES

A. Inactivation - Carcasses, contaminated material and byproducts, and unsatisfactory products containing live agents or toxins must be treated by one of the following approved inactivation procedures prior to disposal:

1. *Incineration* - The application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state.
2. *Dry Heat* - The application of dry heat at a temperature of at least 160 °C for a period of time (not less than 1 hour) adequate to inactivate, detoxify, and/or sterilize the material involved.
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.
4. *Chemical Inactivation* - The addition of sodium hypochlorite (bleach),



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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.

5. *Rendering* - The application of sufficient heat for a period of time sufficient to effectively destroy carcasses for human food purposes and to degrade to a noninfectious state.
6. *Burial* - To bury carcasses, contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.
7. *Composting* - The controlled anaerobic 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.
8. *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 specific operating temperature for a specified period of time.

B. Disposal

1. *Hazardous Compounds* - 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.
2. *Live Agents and/or Toxins* - Treat materials containing live agents and/or toxins by an approved method listed in section III.A of this memorandum before disposal. Other materials may be discarded without such treatment.
3. *Other Laws and Regulations* - Comply with all applicable 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. *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.

C. Documentation

1. *Methods for Disposal* - Describe the method for disposal of material unsuitable for use in production in the Outline of Production. The citation of Veterinary Services Memorandum No. 800.56 is acceptable.
2. *Records* - Maintain records according to 9 CFR 116.2.
3. *Supervision of Disposal* - The disposal of biological products found satisfactory by the licensee or permittee but found unsatisfactory by the Center for Veterinary Biologics (CVB) should be conducted under the supervision of the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) or other APHIS official. Unless the CVB has authorized the licensee or permittee to dispose of such products without supervision, CVB personnel will witness the destruction. In cases where the licensee or permittee is authorized to dispose of a serial, the CVB will verify records during an inspection of the establishment and refer to this verification in the inspection report.
4. *Disposal by the Firm* - Submit final test summaries and disposition of serials or subserials found unsatisfactory by the licensee or permittee on an APHIS Form 2008, Veterinary Biologics Production and Test Report as described in Veterinary Services Memorandum 800.53. If CVB has authorized the licensee or permittee to dispose of such products without supervision, CVB personnel will verify the destruction of the product during inspection of the establishment.