



United States Department of Agriculture

Animal and Plant Health Inspection Service

Overview of the Center for Veterinary Biologics

Veterinary Biologics in the U.S.



**Kendall Graber – Section Leader, Inspection
Center for Veterinary Biologics
1920 Dayton Avenue
Ames, Iowa USA 50010**



United States Department of Agriculture

Animal and Plant Health Inspection Service

The Center for Veterinary Biologics

The Veterinary Biologics Program implements the provisions of the Virus-Serum-Toxin Act to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are not worthless, dangerous, contaminated, or harmful.



Virus Serum Toxin Act

- The Virus, Serum, Toxin Act (21 U.S.C. 151-159), assures the safe and effective supply of animal vaccines and other biological products.
- Enacted primarily in response to losses from the unregulated manufacture and distribution of [anti-hog cholera serum](#).
- The VSTA requires that a person who prepares, sells, barter, exchanges, or ships any virus, serum*, toxin, or analogous product do so in compliance with USDA regulations.

***serum in these references refers to serum for which immunogenicity claims are made**

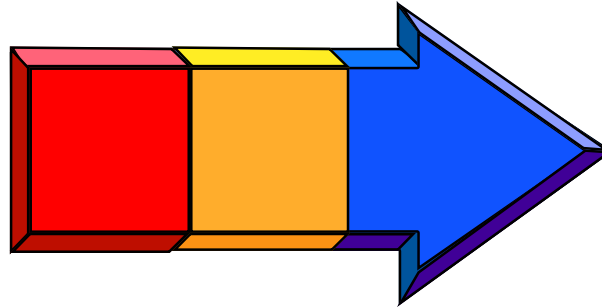


United States Department of Agriculture

Animal and Plant Health Inspection Service

Virus-Serum-Toxin Act of 1913

Worthless
Dangerous
Contaminated
Harmful



Pure
Safe
Potent
Efficacious



Authorities

- **Federal Law: Virus-Serum-Toxin Act (1913, 1985)**
- **Federal Regulations**
 - **Code of Federal Regulations, Title 9, Parts 101-122**
 - **Specifically 113.53 “Requirements for ingredients of animal origin used for production of biologics.”**
- **Policy (guidance documents)**
 - **Veterinary Services Memoranda - 800 Series**
- **Practice (guidance documents)**
 - **Veterinary Biologics Notices**
 - **Supplemental Assay Methods**
 - **Licensing Guidelines, Inspection & Compliance Manual**



Ensuring Quality of Veterinary Biologics

- **Licensing**
- **Quality Manufacturing**
- **Inspection**
- **Testing**
- **Serial (batch) Release**
- **Compliance Actions**
- **Pharmacovigilance**



USDA CVB Product Types

- **Vaccines**
- **Bacterins and Bacterial Extracts**
- **Toxoids**
- **Antitoxins**
- **Antiserum and Antibodies**
- **Diagnostics**
- **Immunomodulators and Immunostimulants**
- **Allergenic Extracts**
- **Autogenous and Autologous**
- **Platform**



Product Diversity

629 unique products for 278 animal diseases protecting 31 species (as of spring 2026)

- **Appropriate and adequate standards required**
- **Uniform and consistent application of the regulations**
- **Quality biologics must be available to the consumer**
 - **Quality product requires quality ingredients**
- **Assessment risks of each application**
 - **Species barrier is not a safeguard – species to species use can and does occur.**



Regulations – 9 CFR

113.50 Ingredients of Biological Products

All ingredients used in a licensed biological product shall meet accepted standards of purity and quality



Regulations – 9 CFR

113.53 Ingredients of Animal Origin

Each lot of ingredient of animal origin which is not subjected to heat sterilization or other sterilization methods acceptable to APHIS such as, but not limited to serum and albumin, used to prepare a biological products shall be tested as prescribed in this section by the licensee or a laboratory acceptable to APHIS.



Regulations – 9 CFR

113.53 Ingredients of Animal Origin

Results of all tests shall be recorded by the testing laboratory and made a part of the licensee's records.

A lot of ingredient found unsatisfactory by any prescribed test shall not be used to prepare a biological product.

Testing of Ingredients – 9 CFR

Sterility: 9CFR: 113.26 & 113.28

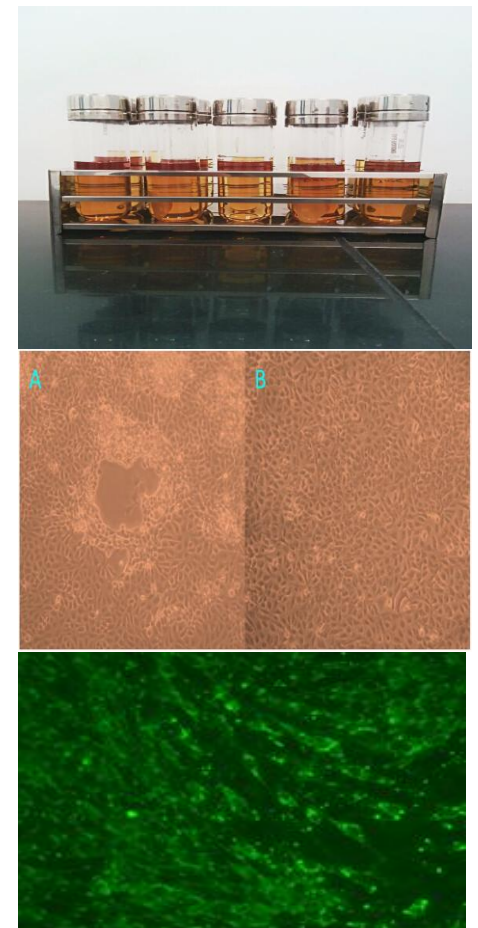
Mycoplasma, Bacteria, and Fungi

General Viral : 9 CFR 113.46

Cytopathic and Hemadsorbing agents

Specific Viral : 9 CFR 113.47

Bovine Virus Diarrhea Virus, Reovirus,
Rabies Virus, Bluetongue Virus,
Bovine Adenovirus, Bovine Parvovirus,
Bovine Respiratory Syncytial Virus.





Guidance Documents VS Memo 800.51

Additives in Administered Animal Biological Products

Each lot of ingredient additive of animal origin used to prepare an administered biological product must be sterilized or tested as prescribed in 9 CFR 113.53.

Ingredients of animal origin are sourced from the United States or countries considered free, low risk, or not affected with foreign animal diseases of concern according to APHIS' Animal Disease Status designations, which may be viewed at:

www.aphis.usda.gov/aphis/ourfocus/animalhealth/sa_import_into_us/ct_animal_disease_status/



Guidance Documents VS Memo 800.51

The foreign animal diseases of concern to the CVB are:

- *Foot-and-Mouth Disease (FMD),*
- *African Swine Fever (ASF),*
- *Classical Swine Fever (CSF),*
- *Highly Pathogenic Avian Influenza (HPAI),*
- *Newcastle Disease (ND).*



Guidance Documents VS Memo 800.51

If an outbreak of any of these diseases occurs in countries providing ingredients of animal origin, the CVB must be consulted for an assessment of risk.

A risk assessment, including an analysis of the risk of contamination to licensed biologics, must be submitted to the CVB for review to justify using an ingredient of animal origin from a country that has a foreign animal disease of concern.

This guidance does not abrogate any other import requirements; all Animal Product Imports restrictions apply.



Guidance Documents VS Memo 800.51

Manufacturers must maintain a comprehensive list of all ingredients of animal origin used in production of biological products.

This list should include the name of the material, the supplier, the country of origin, and the date of purchase of each lot.

This list may be reviewed and certification of materials required at the time of inspection by the CVB Inspection and Compliance (IC), or as requested by the CVB.



United States Department of Agriculture



Center for Veterinary Biologics (CVB), APHIS

National Animal Disease Center (NADC), ARS

National Veterinary Services Laboratories (NVSL), APHIS

**Together we meet the national needs for animal health research,
diagnosis, and product evaluation.**







United States Department of Agriculture

Animal and Plant Health Inspection Service

THANK YOU

QUESTIONS

