

**Virus-Serum-Toxin Act**  
**21 USC 151-159 et. seq.**

**CHAPTER 5. VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS**

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(37 Stat. 832-833; as amended December 23, 1985, Pub. L. 99-198, 99 Stat.1654-1655; 21 U.S.C. 151-159).

**151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments.**

It shall be unlawful for any person, firm or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as herein after authorized.

**152. Importation regulated and prohibited.**

The importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are hereby prohibited.

**153. Inspection of imports; denial of entry and destruction.**

The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

**154. Regulations for preparation and sale; licenses.**

The Secretary of Agriculture is hereby authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, or otherwise to carry out this paragraph, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

**154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria.**

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation--

- (1) solely for administration to animals of such person, firm, or corporation;
- (2) solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional practice of veterinary medicine by such person, firm, or corporation; or
- (3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet the criteria under which the State--
  - (A) may license virus, serum, toxin, and analogous products and establishments that produce such products;
  - (B) may review the purity, safety, potency, and efficacy of such products prior to licensure;
  - (C) may review product test results to assure compliance with applicable standards for purity, safety, and potency prior to release to the market;
  - (D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and
  - (E) exercises the authority referred to in subclauses (A) through (D) consistent with the

intent of this paragraph of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

**155. Permits for importation.**

The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

**156. Licenses conditioned on permitting inspection; suspension of licenses.**

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

**157. Same; inspection daytime or nighttime.**

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

**158. Offenses; punishment.**

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding \$1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

**159. Enforcement, penalties applicable. Congressional findings.**

The procedures on sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this chapter. The provisions (including penalties) of section chapter 675 of this title shall apply to the performance of official duties under this paragraph. Congress finds that (1) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof and (ii) regulations of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.

This section is effective on December 23, 1985, except that:

(1) Subject to subparagraphs (2) through (4), in the case of a person, firm or corporation preparing, selling, bartering, exchanging, or shipping a virus, serum, toxin, or analogous product during the 12 month period ending on the date of enactment of this Act solely for intrastate commerce or for exportation, such product shall not after such date of enactment, as a result of its not having been licensed or produced in a licensed establishment, be considered in violation of the eighth paragraph of the matter under the heading "BUREAU OF ANIMAL INDUSTRY" of the Act entitled "The Virus-Serum-Toxin Act."

An Act making appropriations for the Department of Agriculture for fiscal year ending June thirtieth, nineteen hundred and fourteen", approved March 14, 1913 (as amended by this section), until the 1st day of the 49th month following the date of enactment of this Act.

(2) The exemption granted by subparagraph (1) may be extended by the Secretary of Agriculture for a period up to 12 months in an individual case on a showing by a person, firm, or corporation of good cause and a good faith effort to comply with such eighth paragraph with due diligence.

(3) The exemption granted by subparagraph (1) must be claimed by the person, firm, or corporation preparing such product by the 1st day of the 13th month following the date of enactment of this Act, in the form and manner prescribed by the Secretary, unless the Secretary grants an extension of the time to claim such exemption in an individual case for good cause shown.

(4) On the issuance by the Secretary of a license to such person, firm, or corporation for such product prior to the 1st day of the 49th month following the date of enactment of this Act, or the end of an extension of the exemption granted by the Secretary, the exemption granted by subparagraph (1) shall terminate with respect to such product.