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The Virus-Serum-Toxin Act: A Brief History and Analysis

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Summary

The Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. 151-159), also known as the Virus-Serum-Toxin Act (VSTA), is intended to assure the safe and effective supply of animal vaccines and other biological products. The act and its applicable regulations are administered by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

The VSTA was enacted in 1913, and revised once in 1985. A 2002 law affected the VSTA by transferring border and import inspection functions from USDA to the Department of Homeland Security.

Origins in 1913 (62nd Congress)

The Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. 151-159) was enacted in 1913 (the Act of March 4, 1913, ch. 145, sec. 1) and is known commonly as the Virus-Serum-Toxin Act (VSTA).[1] It was enacted primarily in response to substantial losses from the unregulated manufacture and distribution of anti-hog cholera serum. The authority to license and regulate the production and trade of affected products is granted to the Secretary of Agriculture. The act states that:

> It shall be unlawful for any person, firm or corporation to prepare sell, barter, or exchange [in the United States], or ship or deliver for shipment in or from the United States ... any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals.[2]

[1] This report draws upon CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Viña, which discusses the VSTA in terms of regulating diagnostic tests.

[2] 21 U.S.C. 151.

In 1913, a USDA official testified that the bill was necessary "to protect the farmer and stock raiser from improperly made and prepared serums, toxins, and viruses."[3] The 1913 Senate report for the VSTA stated that the legislation would prevent:

> the introduction into the United States of dangerous and worthless viruses, serums and analogous products for use in the treatment of domestic animals, some of which products may be the means of introducing disease not now known in the United States, and also for the purpose of controlling the use, by preventing the interstate shipment, of similar dangerous and worthless products that may be manufactured within the United States.[4]

Revisions in 1985 (99th Congress)

After seven decades, the original provisions in the VSTA faced challenges from a modernized agricultural sector and a more complicated regulatory environment. Congress amended the VSTA in the Food Security Act of 1985 (P.L. 99-198, Title XVII, Sec.1768) to (1) authorize USDA regulate *intrastate*, as well as interstate, movement of biological products, (2) broaden the Secretary's authority to issue regulations, (3) enhance enforcement powers, and (4) recognize a congressional view that regulation is "necessary to prevent and eliminate burdens on commerce and to effectively regulate commerce."[5]

A Senate report cited the need for "national uniform standards" in the preparation and sale of biological products.[6] The same report refers to jurisdictional issues between USDA and the Food and Drug Administration (FDA) regarding the need to update the law and preserve USDA authorities:

> Two recent Federal court decisions have created confusion and concern among the producers of animal biological products and those who utilize them. The thrust of these decisions is that USDA has primary regulatory authority over finished products physically moving in interstate commerce, but all other products, such as those made and sold within a single State, are subject only to Food and Drug Administration jurisdiction. These "intrastate" products are not subject to USDA licensure, and FDA has, so far, not asserted its authority over them in a comprehensive manner. In the meantime, "interstate" products remain firmly under the jurisdiction of USDA.
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> The narrow "intrastate" versus "interstate" distinction found in the VSTA no longer exists for any class of comparable products. Federal laws make no such distinctions for human-use pharmaceuticals, animal drugs, food additives, color additives, medical devices, processed food, meat and poultry products, or pesticides; all are subject to uniform Federal regulatory standards, whether they cross state lines or not.[7]

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[3] Hearing before the Committee on Agriculture on the Estimates of Appropriations for the Fiscal Year Ending June 30, 1914 (H.R. 28283), 62nd Cong. 24 (1913) (statement of Dr. A. M. Farrington, Asst. Chief Bureau of Animal Industry, Dept. of Agriculture).

[4] S.Rept. 62-1288 (1913).

[5] 21 U.S.C. 151, 154, 159.

[6] S.Rept. 99-145, pp. 338-339.

[7] Ibid.

Transfer of Functions in 2002 (107th Congress)

The Homeland Security Act of 2002 (P.L. 107-296, Title IV, Sec. 421, 6 U.S.C. 231) transferred most major border inspection functions (immigration, customs, and agriculture) to the Department of Homeland Security (DHS). The VSTA was one of seven agricultural laws affected by this transfer. The law did not change provisions in VSTA, but only moved certain functions from one department to another. The purpose was to unify all major border inspection activities under the jurisdiction of one department after the terrorist attacks of September 11, 2001.

Although DHS now conducts the physical inspection of imports, USDA continues to have jurisdiction over VSTA regulations and policies, including setting such policies for imports. The Secretaries of USDA and DHS are to consult each other and coordinate their regulatory and inspection practices.

For more on border inspections, and the transfer of inspection functions to DHS, see CRS Report RL32399, *Border Security: Inspections Practices, Policies, and Issues*.

Analysis of Provisions and Regulatory Action[8]

Except as permitted in the act, the VSTA makes it unlawful for any person to prepare, sell, barter, or exchange anywhere in the United States, or to ship or deliver in or from the United States, any dangerous or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals.[9]

The VSTA further requires that a person who prepares, sells, barters, exchanges, or ships any virus, serum, toxin, or analogous product do so in compliance with USDA regulations through an establishment holding an unsuspended and unrevoked USDA license.[10] The VSTA authorizes the Secretary to issue, suspend, and revoke licenses for the maintenance of establishments that prepare viruses, serums, toxins, or analogous products for use in the treatment of domestic animals. In 21 U.S.C. 152, the VSTA also prohibits the importation of any virus, serum, toxin, or analogous product except under a permit from the Secretary of Agriculture.

The Secretary of Agriculture is also authorized to make and promulgate rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment of a dangerous virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out the VSTA. Consequently, the Animal and Plant Health Protection Service has issued a comprehensive set of regulations governing the licensing of viruses, serums, toxins, or analogous products (9 C.F.R. 101-124).

Regulations for the VSTA broadly catagorize viruses, serums, toxins, or analogous products as "biological products" at any stage of production intended for use in the

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[8] Drawn primarily from CRS Report RL32414, *The Private Testing of Mad Cow Disease: Legal Issues*, by Stephen R. Viña.

[9] 21 U.S.C. 151.

[10] Ibid.

treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. A "biological product" includes but is not limited to:

> vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.[11]

"Treatment" under the regulations means the prevention, diagnosis, management, or cure of diseases of animals.[12] "Prepare" or "preparation" is generally referred to as the manufacture or production of a biological product and has been defined as the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product. With respect to licensing, the regulations require every person who "prepares" biological products subject to the VSTA to have a valid U.S. Veterinary Biologics Establishment License and at least one valid U.S. Veterinary Biological Product License.[13] A USDA permit is also required for every person importing a biological product.[14]

The VSTA explicitly addresses preparation, sale, barter, exchange and shipment, but does not address use or distribution. However, USDA regulations authorize certain use and distribution restrictions. These include distribution of experimental products prior to licencing (9 C.F.R. 103.3), exemptions concerning USDA's use in emergencies and experimental programs (9 C.F.R. 106.1), packaging and labeling requirements (9 C.F.R. 112), and possession, use, and transfer of biological agents and toxins (9 C.F.R. 121).[15]

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[11] 9 C.F.R. 101.2.

[12] *Id.*

[13] *Id.* at 102.2.

[14] *Id.* at 104.1.

[15] Authority for 9 C.F.R. 121 concerning possession, use, and transfer of biological agents and toxins ("select agents") comes from the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188, sec. 211-213, June 12, 2002), but is directly applicable to the products covered by the VSTA.