

**Chapter 16-42 WAC  
BIOLOGICAL PRODUCTS**

**Last Update:** 6/18/08

**WAC**

16-42-005 Definitions.  
16-42-015 License.  
16-42-017 Permits required.  
16-42-023 Sale of licensed products.  
16-42-026 Restricted products.  
16-42-035 Reports.

**DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER**

16-42-001 Promulgation. [Order 578, Promulgation, effective 5/15/50.] Repealed by Order 896, effective 11/24/62.

16-42-00101 Promulgation. [Order 896, Promulgation, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-002 Promulgation. [Order 767, Promulgation, effective 12/30/57.] Repealed by Order 896, effective 11/24/62.

16-42-010 License. [Order 767, Regulation 1, effective 12/30/57.] Repealed by Order 896, effective 11/24/62.

16-42-01001 Definition. [Order 896, Regulation 1, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-020 Who administers. [Order 578, Regulation 2, effective 5/15/50.] Repealed by Order 896, effective 11/24/62.

16-42-02001 Vaccine outlets restricted. [Order 896, Regulation 3, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-022 Biologics. [Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-022, filed 7/10/85.] Repealed by WSR 00-17-072, filed 8/14/00, effective 9/14/00. Statutory Authority: RCW 16.36.040.

16-42-025 Purchasing and administering biologics limited. [Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-025, filed 7/10/85; Order 896, Regulation 4, effective 11/24/62.] Repealed by WSR 00-17-072, filed 8/14/00, effective 9/14/00. Statutory Authority: RCW 16.36.040.

16-42-030 Permit. [Order 578, Regulation 3, effective 5/15/50.] Repealed by Order 896, effective 11/24/62.

16-42-03001 Exempt vaccines. [Order 896, Regulation 5, filed 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-040 Report. [Order 578, Regulation 4, effective 5/15/50.] Repealed by Order 896, effective 11/24/62.

16-42-04001 Reports of disease outbreak by user. [Order 896, Regulation 7, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-045 Order is exclusive—Control of sales, etc. [Order 896, Regulation 8, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-050 Penalty. [Order 578, Penalty, effective 5/15/50.] Repealed by Order 896, effective 11/24/62.

16-42-05001 Penalty. [Order 896, Regulation 9, effective 11/24/62.] Repealed by WSR 85-15-024 (Order 1866), filed 7/10/85. Statutory Authority: Chapter 16.36 RCW.

16-42-060 Penalty. [Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-060, filed 7/10/85.] Repealed by WSR 00-17-072, filed 8/14/00, effective 9/14/00. Statutory Authority: RCW 16.36.040.

**WAC 16-42-005 Definitions.** "Department" means the Washington state department of agriculture (WSDA).

"Director" means the director of WSDA or the director's authorized representative.

"Veterinary biologic" means any virus, serum, toxin, and analogous product of natural or synthetic origin, or product prepared from any type of genetic engineering, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components intended for use in the diagnosis, treatment, or prevention of diseases in animals.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-005, filed 6/18/08, effective 7/19/08. Statutory Authority: RCW 16.36.040. WSR 00-17-072, § 16-42-005, filed 8/14/00,

effective 9/14/00. Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-005, filed 7/10/85.]

**WAC 16-42-015 License.** Only veterinary biologics that have been produced under a U.S. Veterinary Biological Product License may be imported into the state of Washington. The director may allow the importation of unlicensed veterinary biologics under special use permits.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-015, filed 6/18/08, effective 7/19/08. Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-015, filed 7/10/85; Order 896, Regulation 2, effective 11/24/62.]

**WAC 16-42-017 Permits required.** (1) Any person manufacturing veterinary biologics within the state for distribution within the state must first obtain a permit from the director. This permit may be revoked or suspended under chapter 34.05 RCW for any violation of this chapter.

(2) Written approval of the director is required before any newly licensed veterinary biologic is imported into the state for sale, use or distribution. The director may also require a special permit for the importation or distribution of prelicensed veterinary biologics into Washington state.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-017, filed 6/18/08, effective 7/19/08. Statutory Authority: RCW 16.36.040. WSR 00-17-072, § 16-42-017, filed 8/14/00, effective 9/14/00. Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-017, filed 7/10/85.]

**WAC 16-42-023 Sale of licensed products.** Veterinary biologics produced in accordance with WAC 16-42-015 or 16-42-017 may be sold over the counter as well as by persons or firms properly licensed under chapter 18.64 RCW and by any veterinarian licensed under chapter 18.92 RCW. Persons other than licensed veterinarians or state or federal veterinarians may purchase and administer veterinary biologics to their own animals, except for those veterinary biologics restricted in WAC 16-42-026.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-023, filed 6/18/08, effective 7/19/08. Statutory Authority: RCW 16.36.040. WSR 00-17-072, § 16-42-023, filed 8/14/00, effective 9/14/00.]

**WAC 16-42-026 Restricted products.** (1) All veterinary biologics now in existence or newly developed to diagnose, prevent, or combat the following diseases are declared by the director to be of such a nature that their control is necessary to protect animal health:

- (a) Avian influenza.
- (b) Anthrax.
- (c) Bluetongue.
- (d) Brucellosis.
- (e) Equine infectious anemia.

- (f) Equine viral arteritis.
- (g) Paratuberculosis.
- (h) Pseudorabies.
- (i) Rabies.
- (j) Tuberculosis.
- (k) Foot and mouth.
- (l) Vesicular stomatitis.
- (m) All conditionally approved vaccines.

(2) All veterinary biologics used to control or diagnose any of the diseases listed in subsection (1) of this section are restricted, and may only be purchased, administered, or otherwise used by or under the direct supervision of veterinarians licensed under chapter 18.92 RCW, or by state or federal veterinarians. The director may authorize others by written permit to purchase the veterinary biologics listed in subsection (1) of this section for research agencies or laboratories authorized by the department, for emergency disease control programs, or for other limited and controlled purposes.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-026, filed 6/18/08, effective 7/19/08. Statutory Authority: RCW 16.36.040. WSR 00-17-072, § 16-42-026, filed 8/14/00, effective 9/14/00.]

**WAC 16-42-035 Reports.** In the interest of public health and good cooperative disease control it is recommended that any person using any veterinary biologics immediately report to the department any suspected or actual disease outbreak that occurs in connection with use of the veterinary biologic.

[Statutory Authority: RCW 16.36.040 and chapter 34.05 RCW. WSR 08-13-103, § 16-42-035, filed 6/18/08, effective 7/19/08. Statutory Authority: RCW 16.36.040. WSR 00-17-072, § 16-42-035, filed 8/14/00, effective 9/14/00. Statutory Authority: Chapter 16.36 RCW. WSR 85-15-024 (Order 1866), § 16-42-035, filed 7/10/85; Order 896, Regulation 6, effective 11/24/62.]