



# RULE-MAKING ORDER

(RCW 34.05.360)

CR-103 (7/10/97)

Agency: Department of Agriculture

- Permanent Rule
- Emergency Rule
- Expedited Adoption
- Expedited Repeal

(1) Date of adoption: August 14, 2000

(2) Purpose: Chapter 16-42, "Biological Products" protects animal and public health by establishing rules for control of sale, distribution and use of biological products. Certain biologics are restricted to protect animal or human health, ensure accurate diagnosis of disease, prevent spread of diseases and ensure quality state-federal animal disease control and eradication programs.

(3) Citation of existing rules affected by this order: WAC 16-42, "Biological Products"

- Repealed: 16-42-022, 16-42-025 and 16-42-060
- Amended: 16-42-005, 16-42-017, 16-42-035
- Suspended: None

(4) Statutory authority for adoption: RCW 16.36.040

Other Authority: None

### PERMANENT RULE ONLY (Including EXPEDITED ADOPTION)

Adopted under notice filed as WSR 00-14-076 on July 5, 2000. Describe any changes other than editing from proposed to adopted version: No changes made from proposed to adopted version.

### EMERGENCY RULE ONLY

Under RCW 34.05.350 the agency for good cause finds:

- (a) That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- (b) That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding:

### EXPEDITED REPEAL ONLY

Under Preproposal Statement of Inquiry filed as WSR \_\_\_\_\_ on \_\_\_\_\_ (date)

(5.3) Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?:

- Yes     No    If Yes, explain:

(6) Effective date of rule:

Emergency Rules

Permanent Rules  
or Expedited Repeal

- 31 days after filing
- Other (specify) \_\_\_\_\_\*
- Immediately
- Later (specify) \_\_\_\_\_

\*(If less than 31 days after filing, specific finding in 5.3 under RCW 34.05.380(3) is required)

Name (Type or Print)

Jim Jesernig

Signature

Title

Director

Date

8/9/00

CODE REVISER USE ONLY

AUG 14 2000

8:41

00-17-072

**Note: If any category is left blank, it will be calculated as zero.  
No descriptive text.**

Count by whole WAC sections only, from the WAC number through the history note.  
A section may be counted in more than one category.

**The number of sections adopted in order to comply with:**

<b>Federal statute:</b>	New	-----	Amended	-----	Repealed	-----
<b>Federal rules or standards:</b>	New	-----	Amended	-----	Repealed	-----
<b>Recently enacted state statutes:</b>	New	-----	Amended	-----	Repealed	-----

**The number of sections adopted at the request of nongovernmental entity:**

New	-----	Amended	-----	Repealed	-----
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**The number of sections adopted in the agency's own initiative:**

New	2	Amended	3	Repealed	3
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**The number of sections adopted in order to clarify, streamline, or reform agency procedures:**

New	-----	Amended	-----	Repealed	-----
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**The number of sections adopted using:**

<b>Negotiated rule making:</b>	New	-----	Amended	-----	Repealed	-----
<b>Pilot rule making:</b>	New	-----	Amended	-----	Repealed	-----
<b>Other alternative rule making:</b>	New	-----	Amended	-----	Repealed	-----

AMENDATORY SECTION (Amending Order 1866, filed 7/10/85)

**WAC 16-42-005 Definitions.** (1) "Department" means the department of agriculture of the state of Washington.

(2) "Director" means the director of the department of agriculture of the state of Washington or his/her authorized representative.

(3) "Biologics," sometimes referred to as biologicals or biological products, means all bacteria, viruses, serums, toxins, and analogous products of natural or synthetic origin, or products prepared from any type of genetic engineering, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases in animals.

AMENDATORY SECTION (Amending Order 1866, filed 7/10/85)

**WAC 16-42-017 Permits required.** (1) Any person manufacturing biologics within the state for distribution within the state ~~((shall))~~ must first obtain a permit from the director. ~~((Such))~~ This permit may be revoked or suspended ~~((in the manner provided for))~~ under chapter ~~((34.04))~~ 34.05 RCW for any violation of this chapter.

(2) ~~((Prior to importation of))~~ Written approval of the director is required before any newly licensed biologic is imported into the state for sale, use or distribution ~~((within the state, the written approval of the director shall be required. When deemed necessary,)).~~ The director may also require a special permit for the importation or distribution of other biologics into the state.

NEW SECTION

**WAC 16-42-023 Sale of licensed products.** 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 pursuant to chapter 18.92 RCW. Persons other than licensed veterinarians or

state or federal veterinarians may purchase and administer biologics to their own animals, except for those biologics restricted in WAC 16-42-026.

#### NEW SECTION

**WAC 16-42-026 Restricted products.** (1) All 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 or human health and welfare, to ensure accurate diagnosis, to prevent the spread of infectious, contagious, communicable, and dangerous diseases affecting domestic animals within the state and/or to effectuate state-federal animal disease control and eradication programs:

- (a) Anaplasmosis.
- (b) Anthrax.
- (c) Bluetongue.
- (d) Brucellosis.
- (e) Equine infectious anemia.
- (f) Equine viral arteritis.
- (g) Paratuberculosis.
- (h) Pseudorabies.
- (i) Rabies.
- (j) Tuberculosis.
- (k) Swine erysipelas (Avirulent vaccine exempted).
- (l) Vesicular stomatitis.
- (m) All conditionally approved vaccines.

(2) All 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 pursuant to chapter 18.92 RCW, or by state or federal veterinarians. The director may authorize others by written permit to purchase 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 which are not likely to create a hazard to the public health or to the health of domestic animals. In issuing this permit, the director will consider:

- (a) The known effectiveness of the biologic;
- (b) Whether or not the disease for which the biologic is used or intended to be used is present in this state and to what extent it is present;
- (c) Degree of isolation of the animals and area, and availability of veterinary service; and
- (d) Any other factor which, having due regard for the properties of the biologic, may constitute a hazard to animal or

public health in this state.

AMENDATORY SECTION (Amending Order 1866, filed 7/10/85)

**WAC 16-42-035 Reports.** In the interest of public health and good cooperative disease control it is recommended that any person using any biologics (~~(, as defined in WAC 16-42-005,)~~) immediately report to the department any suspected or actual disease outbreak that occurs in connection with use of the biologic.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 16-42-022	Biologics.
WAC 16-42-025	Purchasing and administering biologics limited.
WAC 16-42-060	Penalty.