

FORM OF ORDER AND TRANSMITTAL BY AGENCY HAVING SINGLE HEAD

State of Washington

Department of Agriculture  
(agency name)

Administrative Order No. 1866

(1) I, C. Alan Pettibone, director of the Department of Agriculture

do promulgate and adopt at Olympia, Washington (place)

the annexed rules relating to:

Chapter 16-42 WAC Relating to the use of biological products in animal health care

(2) ALTERNATIVE A. Use only for Adoption of Permanent Rules.

This action is taken pursuant to Notice No. WSR 86-09-061, 85-12-025, 85-13-047 filed with the code reviser on 4-17, 5-31, 6-17-85. These rules shall take effect:
[X] thirty days after they are filed with the code reviser pursuant to RCW 34.04.040(2).
[ ] at a later date, such date being

(2) ALTERNATIVE B. Use only for Adoption of Emergency Rules.

I, find that an emergency exists and that this order is necessary for the preservation of the public health, safety, or general welfare and that observance of the requirements of notice and opportunity to present views on the proposed action would be contrary to public interest. A statement of the facts constituting the emergency is:

These rules are therefore adopted as emergency rules to take effect upon filing with the code reviser.

(3) Pursuant to the requirements of RCW 34.04.026 that "every agency shall incorporate the most specific, but in no case omit all, of the following language alternatives when adopting or amending rules" fill in statement (a), (b), or (c) as appropriate:

[X] (a) This rule is promulgated pursuant to RCW 16.36 and is intended to administratively implement that statute.

[ ] (b) This rule is promulgated pursuant to RCW which directs that the

(agency) has authority to implement the provisions of (name of act or RCW citation)

[ ] (c) This rule is promulgated under the general rule-making authority of the

(agency) as authorized in RCW

(4) The undersigned hereby declares that the agency has complied with the provisions of the Open Public Meetings Act (chapter 42.30 RCW), the Administrative Procedure Act (chapter 34.04 RCW) and the State Register Act (chapter 34.08 RCW) in the adoption of these rules.

(5) This order, after being first recorded in the order register of this agency, is herewith transmitted to the Code Reviser for filing pursuant to chapter 34.04 RCW and chapter 1-12 WAC.

APPROVED AND ADOPTED July 9, 1985

FILED

JUL 10 1985

By [Signature]

Deputy Director

Title

CODE REVISER'S OFFICE WSR 85-15-004

NEW SECTION

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.

(3) "Biologics," sometimes referred to as biologicals or biological products, means all 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 896, Regulation 2, effective 11/24/62)

WAC 16-42-015 LICENSE. (~~License or permit to manufacture biological products - all veterinary biological products imported into this state or manufactured within the state of Washington shall be~~) Only biologics which have been produced under a regular license issued by the ((animal inspection and quarantine division,)) United States Department of Agriculture((, or by a special permit issued by the)) may be imported into the state of Washington ((state department of agriculture)). The director may allow the importation of unlicensed biologics when the director determines it necessary for the protection of humans or domestic animals.

NEW SECTION

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

(2) Prior to importation of any newly licensed biologic 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 16-42-022 BIOLOGICS. Biologics produced under a regular license issued by the United States Department of Agriculture, or produced under a permit issued by the director may only be sold by persons or firms properly licensed under Chapter 18.64 RCW or any veterinarian licensed pursuant to chapter 18.92 RCW. Persons other than licensed veterinarians or state or federal veterinarians may administer biologics other than those listed under WAC 16-42-025 to their own domestic animals.

AMENDATORY SECTION (Amending Order 896, Regulation 4, effective 11/24/62)

WAC 16-42-025 PURCHASING AND ADMINISTERING (~~VACCINES~~) BIOLOGICS LIMITED. (1) All (~~live vaccines~~) 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 ((public)) animal or human health and welfare, to ((insure)) ensure accurate diagnosis, to prevent the spread of infectious, contagious, communicable, and dangerous diseases affecting domestic animals within the state of Washington and/or to effectuate state-federal animal disease control and eradication programs:

- (a) (( Anthrax
- (b) Anaplasmosis
- (c) Bluetongue
- (d) Brucellosis
- (e) Contagious eethyma
- (f) Distemper
- (g) Equine rhinopneumonitis
- (h) Foot & mouth disease
- (i) Hog cholera
- (j) Infectious hepatitis
- (k) Rabies
- (l) Rinderpest
- (m) Swine erysepelas (Avirulent vaccine exempted))) 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

(2) ((Such vaccines)) All biologics used to control or diagnose any of the diseases listed in subsection (1) of this section are hereby restricted, and may only be purchased ((and)) administered ((only)) , or otherwise used by or under the direct supervision of veterinarians licensed pursuant to chapter 18.92 RCW, or by state or federal ((veterinary personnel: PROVIDED, That)) veterinarians. The director may authorize, by written permit, others to purchase such ((vaccines)) biologics for((+

(a)) research agencies or laboratories authorized by the state department of agriculture, emergency disease control programs, or other limited and controlled purposes which are not likely to create a hazard to the public health or to the health of((+ives+eek, and

(b) PROVIDED FURTHER, That)) domestic animals. The director, in establishing((such a)) this permit shall consider:

- ((+)) (a) The known effectiveness of the ((vaccine or product, and)) biologic;
- ((+)) (b) Whether or not the disease for which the ((product)) biologic is used or intended to be used is present in this state and to what extent it is present((, and)) ;
- ((+)) (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 ((vaccine or product)) biologic, may constitute a hazard to animal or public health in this state.

AMENDATORY SECTION (Amending Order 896, Regulation 6, effective 11/24/62)

WAC 16-42-035 ((REQUIREMENTS FOR SALES RECORDS AND)) REPORTS. In the interest of public health and good cooperative disease control ((anyone selling live vaccines must maintain records of such sales for one year. These records must be open for the department's inspection at any time)) 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.

#### NEW SECTION

WAC 16-42-060 PENALTY. Any person, firm or corporation violating any of these rules shall be guilty of a gross misdemeanor as set forth in chapter 16.36 RCW, and each day the violation occurs constitutes a separate offense.

#### REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 16-42-00101 PROMULGATION.  
WAC 16-42-01001 DEFINITION.  
WAC 16-42-02001 VACCINE OUTLETS RESTRICTED.  
WAC 16-42-03001 EXEMPT VACCINES.  
WAC 16-42-04001 REPORTS OF DISEASE OUTBREAK BY USER.  
WAC 16-42-045 ORDER IS EXCLUSIVE--CONTROL OF SALES, ETC.  
WAC 16-42-05001 PENALTY.