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FOOD AND AGRICULTURAL CODE - FAC
DIVISION 5. ANIMAL AND POULTRY QUARANTINE AND PEST CONTROL [9101 - 11305]
(Division 5 enacted by Stats. 1967, Ch. 15.)
PART 1. DISEASED ANIMALS AND POULTRY [9101 - 9702]
(Part 1 enacted by Stats. 1967, Ch. 15.)
CHAPTER 1.5. Commercial Blood Banks for Animals and Biologics [9201 - 9272]
(Heading of Chapter 1.5 amended by Stats. 2010, Ch. 235, Sec. 1.)

ARTICLE 1. Definitions [9201 - 9206]
(Article 1 added by Stats. 1974, Ch. 776.)

9201.

Unless the context otherwise requires, the definitions in this article govern the construction of this chapter.
(Added by Stats. 1974, Ch. 776.)

9202.

"Animal" includes, but is not limited to, any domesticated fowl or nonhuman mammal and any wild fowl, bird, or mammal that is reduced to captivity.
(Amended by Stats. 2002, Ch. 822, Sec. 1. Effective January 1, 2003.)

9203.

"Biologics" means all viruses, serums, antibody products, toxins (excluding substances that are selectively toxic to microorganisms, for example, antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.
(Amended by Stats. 2010, Ch. 235, Sec. 2. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9204.

"Blood and blood component products" means whole blood collected directly from a donor animal for transfusion or the blood components for transfusion including packed red blood cells, platelet-rich plasma, platelet concentrates, fresh plasma,

fresh frozen plasma, frozen plasma, cryoprecipitate, and cryosupernatant. Antibody products like hyperimmune serums are considered "biologics" and are excluded from this definition of blood and blood component products.
(Added by Stats. 2010, Ch. 235, Sec. 3. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9205.

"Commercial blood bank for animals" means an establishment that produces animal blood or blood component products to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals.
(Repealed and added by Stats. 2010, Ch. 235, Sec. 6. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9206.

"Production" means collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for the purpose of transfusion.
(Added by renumbering Section 9204 by Stats. 2010, Ch. 235, Sec. 4. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 2. Animal Blood and Blood Component Products Production and Biologics Production [9210 - 9212]

(Article 2 heading repealed and added by Stats. 2010, Ch. 235, Sec. 8.)

9210.

No person shall engage in the production of animal blood and blood component products for retail sale and distribution except in a commercial blood bank for animals licensed by the secretary.
(Added by Stats. 2010, Ch. 235, Sec. 9. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9211.

No person shall engage in the production of biologics except as permitted under federal law.
(Amended by Stats. 2010, Ch. 235, Sec. 10. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9212.

The secretary shall license establishments as commercial blood banks for animals that meet all of the following:

(a) Operate under conditions, and use methods of production, to ensure that the animal blood and blood component products will not be contaminated, dangerous, or harmful.
(b) Produce animal blood and blood component products under the direct supervision of a person qualified in the field.
(c) Maintain onsite records containing information documenting how the animal was acquired and any history of blood draws or use of anesthesia on the animal.
(Amended by Stats. 2010, Ch. 235, Sec. 11. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 3. Licenses [9221- 9221.]
(Article 3 added by Stats. 1974, Ch. 776.)

9221.

An application for a license for any establishment that produces, or proposes to produce, animal blood and blood component products shall be made on forms issued by the secretary. The application shall contain all of the following:
(a) The name and address of the person who owns the place, establishment, or institution in which it is proposed to produce animal blood and blood component products.
(b) The name and address of the person who shall be in charge of the production of animal blood and blood component products.
(c) The type of animal blood and blood component products that shall be produced.
(d) A full description of the building, including its location, facilities, equipment, and apparatus to be used in the production of animal blood and blood component products.
(e) A written protocol that addresses all of the following:
(1) Maximum length of time for donation by animal donors, or minimum health parameters for animal donors.
(2) Frequency and volume of blood collected from animal blood donors.
(3) Socialization and exercise programs for animal blood donors.
(4) Method of identification of each animal, including microchip or tattoo.
(5) Ongoing veterinary care, including an annual physical exam and vaccination schedule for animals held in blood donor facilities.
(6) Husbandry standards for feeding, watering, sanitation, housing, handling, and care in transit, with minimums based on the standards set forth pursuant to the federal Animal Welfare Act in Part 3 (commencing with Section 3.1) of Subchapter A of Chapter 1 of Title 9 of the Code of Federal Regulations.
(7) Implementation of a permissive adoption program.
(f) An "oversight letter" identifying the oversight veterinarian who will be responsible for oversight of the facility. The letter shall be from the oversight veterinarian, and shall be maintained on file by the secretary. Oversight veterinarians shall be licensed to practice veterinary medicine in California. In the event of a change of the oversight veterinarian, it is the oversight veterinarian's responsibility to give notice to the secretary of the termination of the oversight

veterinarian within 30 days of the termination date of the oversight veterinarian. An oversight letter from the incoming oversight veterinarian shall be submitted to the secretary within 30 days of the termination date of the prior oversight veterinarian.
(g) Additional information that the secretary finds is necessary for the proper administration and enforcement of this chapter.
(Amended by Stats. 2010, Ch. 235, Sec. 12. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 4. License Fees [9231- 9231.]

(Article 4 added by Stats. 1974, Ch. 776.)

9231.

The license application fee and license renewal fee under this chapter for an establishment proposing to produce or producing animal blood and blood component products shall be as follows:
(a) The application and annual license fee shall be two hundred fifty dollars ($250) for each establishment, which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year. When an applicant is a city, county, state, or district, or an official thereof, no fee shall be required under this section.
(b) Licenses shall be renewed every year. The annual renewal fee shall be paid on or before the first day of July of each year.
(c) Fees may be increased by the department to cover the department's reasonable costs incurred in connection with performing the annual inspection required by Sections 9266 and 9268.
(d) The fees required by this section are maximum, and may be fixed by the secretary at a lesser amount for any fiscal year whenever he or she finds that the cost of administering this chapter can be defrayed from revenues derived from the lower fees.
(Amended by Stats. 2010, Ch. 235, Sec. 13. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 5. Blood or Blood Component Product Registration [9241 - 9245]

(Heading of Article 5 amended by Stats. 2010, Ch. 235, Sec. 14.)

9241.

No person shall offer for sale or use any of the following:
(a) Any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture.
(b) Any blood or blood component product unless it is produced in an establishment licensed by the secretary.
(Amended by Stats. 2010, Ch. 235, Sec. 15. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9242.

The secretary shall register blood or a blood component product that meets all of the following requirements:
(a) It is produced under acceptable procedures.
(b) It has been demonstrated to the secretary that the blood or blood component product is safe and noninjurious to animal health.
(c) It has been demonstrated to the secretary that the blood or blood component product is of value for the purpose intended.
(d) It is labeled for proper handling and use, and is not misrepresented.
(e) It is produced in an establishment that meets the requirements of Section 9210.
(Amended by Stats. 2010, Ch. 235, Sec. 16. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9244.

An application for registration of blood or a blood component product shall include both of the following:
(a) A protocol of the methods of production in detail that is followed in the production of the product.
(b) A sample of the label to be placed on the blood or blood component product.
(Amended by Stats. 2010, Ch. 235, Sec. 18. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9245.

The secretary may impose such conditions on the production or use of blood or blood component products as he or she deems necessary to accomplish the purposes of this chapter.
(Amended by Stats. 2010, Ch. 235, Sec. 19. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 6. Rules and Regulations [9251- 9251.]

(Article 6 added by Stats. 1974, Ch. 776.)

9251.

The secretary may adopt reasonably necessary rules and regulations for the administration and enforcement of this chapter.
(Amended by Stats. 2010, Ch. 235, Sec. 20. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

ARTICLE 7. Enforcement [9261 - 9269]

(Article 7 added by Stats. 1974, Ch. 776.)

9261.

License for any commercial blood bank for animals or registration of any blood or blood component product may be denied, suspended, or revoked by the secretary for failure to meet the requirements of this chapter or for the violation of any provision of this chapter, or of any rule or regulation adopted by the secretary under this chapter. The proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(Amended by Stats. 2010, Ch. 235, Sec. 21. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9262.

The biologics prepared prior to July 1, 1975, in laboratories licensed pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code, which have an expiration date of July 1, 1975, or later, are not subject to the provisions of this chapter.

(Added by Stats. 1974, Ch. 776.)

9263.

If the secretary finds that blood or blood component products do not conform to the requirements of Section 9242 or the use or continued use of such products constitutes an immediate danger to animals, the secretary may, after notice, suspend the registration of those blood or blood component products or license of an establishment producing those blood or blood component products pending a hearing and final decision.

(Amended by Stats. 2010, Ch. 235, Sec. 22. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9264.

(a) If the secretary finds blood or blood component products that do not meet the requirements of Section 9242, the secretary may order those blood or blood component products to be held on the premises where found or elsewhere until he or she has determined that the products may be safely released for the purposes intended.

(b) The secretary may order the destruction of any blood or blood component products under a hold order if the blood or blood component products cannot be made to meet the requirements of Section 9242.
(Amended by Stats. 2010, Ch. 235, Sec. 23. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9266.

The department, or humane officers under contract with the department, shall inspect commercial blood banks for animals licensed by the department at least once a year to ensure compliance with the protocols required by subdivision (e) of Section 9221.
(Added by Stats. 2002, Ch. 822, Sec. 5. Effective January 1, 2003.)

9267.

Notwithstanding Section 4827 of the Business and Professions Code, for commercial blood banks for animals licensed by the department, anesthesia shall be performed pursuant to Section 4826 of the Business and Professions Code.
(Amended by Stats. 2010, Ch. 235, Sec. 24. (AB 1709) Effective January 1, 2011. Became operative on January 1, 2013, pursuant to Sec. 28 of Ch. 235.)

9268.

The requirements set forth in subdivision (c) of Section 9212, subdivision (e) of Section 9221, subdivision (c) of Section 9231, and Sections 9266 and 9267:
(a) Shall not apply to those facilities required to be inspected by the United States Department of Agriculture in accordance with the Animal Welfare Act (Chapter 54 (commencing with Section 2131) of Title 7 of the United States Code).
(b) Shall apply to those facilities housing blood donor animals under contract with commercial blood banks for animals licensed by the department.
(Amended by Stats. 2018, Ch. 289, Sec. 4. (AB 3252) Effective January 1, 2019.)

9269.

(a) Except as provided in subdivision (b), all records held by the department relating to this chapter, including, but not limited to, records relating to applications, fees, or inspections required by this chapter, shall be confidential and not subject to disclosure under the California Public Records Act contained in Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.
(b) Notwithstanding subdivision (a), records held by the department relating to this chapter shall be accessible to law enforcement officers with jurisdiction over any matter covered by this chapter.
(Added by Stats. 2002, Ch. 822, Sec. 8. Effective January 1, 2003.)

ARTICLE 8. Exemptions [9272- 9272.]

(Article 8 added by Stats. 1974, Ch. 776.)

9272.

This chapter shall not apply (1) to licensed facilities primarily engaged in the collection, preparation, testing, processing, storage, or distribution of human blood or blood products, and any biologic as defined in Section 9203 produced by that facility is sold or distributed only to an establishment licensed by this chapter; (2) to clinical laboratories licensed pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code whose only biologics are autogenous bacterins prepared at the request of licensed veterinarians; or (3) to licensed private veterinarians who collect blood or blood products solely for use in their own practice.

(Amended by Stats. 2018, Ch. 289, Sec. 5. (AB 3252) Effective January 1, 2019.)