DEPARTMENT OF FOOD AND AGRICULTURE

PROPOSED REGULATORY TEXT – ANIMAL BLOOD BANKS

THIRD MODIFIED TEXT

Text proposed to be adopted is displayed in underline type.
Text proposed to be deleted is displayed in ~~strikethrough~~ type.
Modified proposed text to be adopted is displayed in double underline type.
Modified proposed text to be deleted is displayed in ~~double strikethrough~~ type.
Second proposed modified text to be adopted is displayed in ***bold underlined italics.***
Second proposed modified text to be deleted is displayed in ~~**bold strikethrough**~~.
Third proposed modified text to be adopted is displayed in **bold double underline** type**.**
Third proposed modified text to be deleted is displayed in ~~**bold double strikethrough**~~ type.

The Department of Food and Agriculture, Animal Blood Bank Program, proposes to adopt new Chapter 8 of Division 2 of Title 3 of the California Code of Regulations relating to animal blood bank provisions, to read as follows:

Chapter 8. Animal ~~Biologics [Repealed]~~ Blood Banks

Article 1. Definitions

§ 1303. Definitions.

(a) "Adverse event" means an event in which an animal is injured, sickened, rendered unconscious, or killed.

(b) "Animal" includes, but is not limited to, any domesticated fowl or nonhuman mammal or any wild fowl, bird, or mammal that is reduced to captivity.

(c) "Best clinical practice" means making clinical decisions that are based on up-to-date scientific knowledge. This includes, but is not limited to, guidelines and publications by the American Veterinary Medical Association (AVMA), AVMA-recognized specialty organizations, the Association of Veterinary Hematology and Transfusion Medicine, AVMA-accredited veterinary colleges, the Association for the Advancement of Blood and Biotherapies, and government organizations.

(~~c~~**d**) "Biologics" means all viruses, serums, antibody products, toxins (excluding substances that are selectively toxic to microorganisms, such as antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and that act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.

(~~d~~**e**) “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, cryosupernatant, lyophilized plasma, and albumin. Antibody products, such as hyperimmune serums, are excluded from this definition.

(~~e~~**f**) “Captive closed colony” means that an animal is kept, housed, or maintained in any way for the purpose of collecting its blood.

(~~f~~**g**) “Closed-colony blood bank” means a commercial blood bank for animals that produces animal blood or blood component products solely from animals held in a captive closed colony.

(~~g~~**h**) “Commercial blood bank for animals” means an establishment that produces animal blood or blood component products from captive closed-colony or community-sourced animals to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals~~. **This includes facilities that obtain blood or blood component products for additional processing, distribution, and resale**~~. **Facilities that obtain blood or blood component products for additional preparation, testing, processing, storage, or distribution to market and sell for the purpose of transfusion are considered commercial blood banks for animals.**

(~~h~~**i**) “Community blood bank” means a commercial blood bank for animals that produces animal blood or blood component products solely from community-sourced animals whose owners voluntarily consent to the donation.

(~~i~~**j**) “Community sourced animal” means that an animal is all of the following:

(1) Kept, housed, and maintained at the residence of its owner who is a person and not a partnership, association, corporation, or limited liability company.

(2) Brought by its owner ~~or caregiver~~ to a community blood bank to have its blood collected.

(3) Licensed in accordance with any pet licensing required by the pet owner’s state, county, or city of residence.

(~~j~~**k**) “Department” means the California Department of Food and Agriculture.

(~~k~~**l**) “Production” means collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for the purpose of transfusion.

(~~l~~**m**) “Quarterly reporting period” means a calendar year quarter. For reporting purposes these shall be January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.

(n) “Standards of care” means the level of care, skill, and treatment that, in the light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by

reasonably prudent licensed veterinarians. This includes, but is not limited to, guidelines published by the American Veterinary Medical Association, the American College of Veterinary Internal Medicine, the California Veterinary Medical Association, AVMA-accredited veterinary colleges, and government organizations.

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Section 9201, Food and Agricultural Code; and Section 4920, Business and Professions Code.

Article 2. Facility Licensing and Product Registration

§ 1304.1. Closed-Colony Facility Licensing.

An application for a license for any establishment that produces, or proposes to produce, animal blood and blood component products from a closed-colony blood bank shall contain all the following:

(a) The name and address of the person who owns the property, 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 oversee the production of animal blood and blood component products.

~~(c) The name and address of the person(s) who oversee properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank.~~

(~~d~~***c***) The type of animal blood and blood component products that shall be produced.

(~~e~~***d***) A full description of the building, including its address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products. This shall include ~~full descriptions of~~ the addresses of properties, establishments, or institutions that keep, house, or maintain animal blood donors used by the closed-colony blood bank.

(~~f~~***e***) Written protocols, consistent with current standards of care and practice for the field of veterinary transfusion medicine, that addresses all the following for each facility that keeps, houses, or maintains animal blood donors used by the closed-colony blood bank:

(1) Maximum length of time for donation by animal donors, or minimum health parameters for animal donors.

(2) Frequency and amount of blood collected from animal blood donors in estimated milliliters based on weight in grams.

(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~~ Sections 3.1 – 3.20)** of Subchapter A of Chapter 1 of Title 9 of the Code of Federal Regulations (CFR).

(7) Implementation of a permissive adoption program.

(8) Bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field, which may include the most recent Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine.

(~~g~~*f*) An oversight letter identifying the oversight veterinarian who will be responsible for oversight of each facility that keeps, houses, or maintains animal blood donors used by the closed-colony blood bank. 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 thirty (30) calendar days of the termination date of the oversight veterinarian. An oversight letter from the incoming oversight veterinarian shall be submitted to the secretary within thirty (30) calendar days of the termination date of the prior oversight veterinarian.

(~~h~~*g*) Any change in the information contained in the license application or license renewal application shall be reported to the Department within thirty (30) calendar days of such change.
NOTE: Authority cited: Sections 407, 9221(g), and 9251, Food and Agricultural Code. Reference: Section 9221, Food and Agricultural Code.

§ 1304.2. Discontinuation of Closed-Colony Licensing Program.

The Department shall discontinue its licensing program for commercial blood banks for animals that produce canine blood and blood component products sourced from captive closed-colony dogs within 18 months of making a finding and provision of notice as follows:

(a) Based on the quarterly reports required under Section 4920.6 of the Business and Professions Code, Section 9252(c) of the Food and Agricultural Code, and Section 9253(b) of the Food and Agricultural Code, every three months, the Secretary shall calculate the total estimated amount of canine blood sold in California that quarter by community blood banks and, separately, the total estimated amount of canine blood that closed-colony blood banks sold in the state during the same period. This information shall be publicly posted on the Department's internet website along with annual totals compiled each year.

(b) If the secretary finds that community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters, then the secretary shall provide notice on the Department's internet website that discontinues its licensing program for closed-colony blood banks for dogs within 18 months from the date of that notice.

(c) The calculation of canine blood pursuant to this section shall be done with whole blood, packed red blood cells, and fresh frozen plasma being measured as separate amounts in estimated milliliters based on weight in grams. Currently licensed closed-colony blood banks may continue to operate until each of these separate amounts meet the provisions in subsection (b).

~~(d) The calculation of canine blood required by this section can include additional blood component products if they meet all the following requirements:~~

~~(1) Product is registered with the Department;~~

~~(2) The amount of whole blood, packed red blood cells, or fresh frozen plasma required to create the product is clearly stated in protocols of the methods of production submitted to the Department at the time of product registration;~~

~~(3) The amount of the product sold in California in milliliters based on weight in grams, is stated in quarterly reports submitted to the Department. The amount of the product sold must be separate from the totals of whole blood, packed red blood cells, and fresh frozen plasma submitted to the Department on quarterly reports; and~~

~~(4) It has been demonstrated to the Department that the blood or blood component product is of value in veterinary transfusion medicine.~~

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Sections 9212.5, 9253(b), and 9252(c), Food and Agricultural Code; and Section 4920.6(a), Business and Professions Code.

~~§ 1304.3. Additional Facility Licensing.~~

~~A commercial blood bank for animals that is not a closed colony blood bank or otherwise registered as a community blood bank pursuant to Article 7 (commencing with section 4920) of Chapter 11 of Division 2 of the Business and Professions Code shall be licensed by the Department. This includes establishments that obtain blood or blood component products from a Community Blood Bank for additional processing, distribution, or resale of blood or blood component products.~~

~~(a) An application for a license for any such establishment shall contain all the following:~~

~~(1) The name and address of the person who owns the property, establishment, or institution in which it is proposed to produce animal blood and blood component products.~~

~~(2) The name and address of the person who shall oversee the production of animal blood and blood component products.~~

~~(3) The type of animal blood and blood component products that shall be produced.~~

~~(4) A full description of the building, including its address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products.~~

~~(5) A full list of the blood banks from which the facility will obtain blood or blood component products.~~

~~(6) A description of how the facility will document, in a traceable manner, the origins of the blood used in the creation of blood and blood component products.~~

~~(7) Any change in the information contained in the license application or license renewal application shall be reported to the Department within thirty (30) calendar days of such change.~~

~~(b) The license application fee and license renewal fee for an establishment described under this section shall be as follows:~~

~~(1) The application and annual license fee shall be five hundred dollars ($500) 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.~~

~~(2) Licenses shall be renewed every year. The annual renewal fee shall be paid on or before the first day of July of each year.~~

~~(3) The license application fee and licensee renewal fee under this chapter shall be adjusted annually for inflation to reflect changes in the California Consumer Price Index (CPI). The adjustments shall be rounded off to the nearest whole dollar.~~

~~(c) A facility operating under this section shall comply with blood or blood component product registration requirements under Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code.~~

~~NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Sections 9221, 9231, 9241-9245, Food and Agricultural Code; and Section 4920.4, Business and Professions Code.~~

§ 1304.~~4~~3. Change of Product Registration Information.

Any change in the information contained in the product registration application or product registration renewal application shall be reported to the Department within thirty (30) calendar days of such change.

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Section 9244, Food and Agricultural Code.

Article 3. Quarterly Reporting

§ 1305.1. Closed-Colony Blood Bank Quarterly Reporting.

(a) A closed-colony blood bank licensed under this chapter shall submit a quarterly report to the Department every three months including all the following:

(1) The number of donations from captive animals and separate total amount in milliliters of whole blood, packed red blood cells, and fresh frozen plasma sold in California during that quarter, by species of animal in estimated milliliters based on weight in grams.

~~(2) Additional products can be included in quarterly reports if they meet criteria specified in section 1304.2(d)(1) – (4).~~

(~~3~~2) The number of animals at each property, establishment, or institution that keeps, houses, or maintains animals that donate blood or blood component products used by the closed-colony blood bank.

(~~4~~3) The disposition records of any animals and the total number of animals released for adoption. This shall include records from each property, establishment, or institution that keeps, houses, or maintains animals for the closed-colony blood bank.

(~~5~~4) The number and species of animals experiencing adverse events, the total number of adverse events, and the nature of adverse events experienced by captive animals that donate blood.

(~~6~~5) The number and species of animal donors whose blood tested positive for known pathogens, in accordance with the best clinical practices in the veterinary field, which may include the most recent Consensus Statement for blood donor infectious disease screening by the American College of Veterinary Internal Medicine. This shall include the name of the pathogens detected in animal donor blood.

(b) A violation of this section, Food and Agricultural Code Section 9210, or Food and Agricultural Code Section 9212 shall constitute a cause for corrective action, suspension, restriction, or the nonrenewal or revocation of a license by the Department. The proceedings for the suspension or revocation of a license shall be conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The secretary shall have all the powers granted in that chapter.

(c) For purposes of this section, “disposition” means ~~the animal left the blood donor program for any reason including~~ adoption, euthanasia, ~~natural death,~~ transfer to another blood bank, breeding facility, farm, animal control agency, animal shelter, or rescue organization, or donation or sale for medical research or other purpose. Disposition records shall include all of the following:

(1) The species and breed of animal;

(2) The animal's registered name, license number, microchip, and tattoo, if present; ~~and~~

(3) The name and address of the individual or entity that received the animal and the purpose for which the animal was received; **and**

(4) The date of the animal's disposition.

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Sections 9253(b), Food and Agricultural Code.

§ 1305.2. Submission of Quarterly Reports.

Quarterly reports must be postmarked or electronically submitted to the Department no later than 45 calendar days after the end of the quarterly reporting period. **Mailed submissions shall be sent to:**

CDFA Animal Health and Food Safety Services
ATTN: California Animal Blood Banks Program
1220 N Street
Sacramento, CA 95814

Electronic submissions shall be submitted to CDFAbloodbanks@cdfa.ca.gov

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Sections 9253(b) and 9252(c), Food and Agricultural Code; and Section 4920.6(a), Business and Professions Code.

Article 4. Inspections ~~**and Fees**~~

§ 1306.1. Inspection of Facilities with Registered Products.

The Department, or humane officers under contract with the Department, shall inspect commercial blood banks with blood or blood component products registered with the Department at least once a year to ensure ~~**the product safety standards and**~~ compliance with protocols required by Section 9244(a) of the Food and Agricultural Code.

NOTE: Authority cited: Sections 407, 9245, and 9251, Food and Agricultural Code. Reference: Sections 9242 and 9244, Food and Agricultural Code.

§ 1306.2. Inspection of Closed-Colony Blood Banks and Contract Facilities.

The Department, or humane officers under contract with the Department, shall inspect commercial blood banks licensed by the Department and each facility that keeps, houses, or

maintains animals for the licensed blood bank at least once a year to ensure compliance with the protocols required by Section 9221(e) of the Food and Agricultural Code.
NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Section 9221(e) and 9266, Food and Agricultural Code.

§ 1306.~~5~~**3**. Inspections to Investigate Noncompliance.

The Department ~~**can at its discretion**~~ **will** investigate **substantiated** complaints of noncompliance**. The investigation may include** ~~**require**~~ additional inspections of commercial blood banks for animals.
NOTE: Authority cited: Sections 407, 9245, and 9251, Food and Agricultural Code. Reference: Sections 9241, 9242, 9244, and 9245, Food and Agricultural Code.

Article 5. Fees and Fee Adjustments

§ ~~**1306.3**~~ **1307.1**. **Additional Registration** Fees.

In addition to the registration application fee and annual renewal fee required by Food and Agricultural Code 9244, ~~C~~commercial blood banks **for animals** ~~**licensed**~~ ***with products registered*** by the Department shall pay a **registration** fee of $0.05 per milliliters (ml) blood and blood component products sold in this State, as reported on quarterly reports required under Section 4920.6 of the Business and Professions Code, Section 9252(c) of Food and Agricultural Code, and Section 9253(b) of the Food and Agricultural Code. These fees shall be paid to the Department **quarterly,** at the time of submission of quarterly reports. **This fee shall be adjusted annually for inflation, as described in section 1307.2(b).**
NOTE: Authority cited: Sections 407, 9231(d), 9244(b)(4), and 9251, Food and Agricultural Code. Reference: Sections 9244, 9252(c), and 9253(b), Food and Agricultural Code; and Section 4920.6, Business and Professions Code.

§ ~~**1306.4**~~ **1307.2**. Inflation Adjustments.

(a) Pursuant to ~~**The annual adjustment of fees for inflation required by**~~ Food and Agricultur~~**e**~~***al*** Code Sections 9231(c) and 9244(b)(3) ~~**shall be done according to the California Consumer Price Index**~~**, the annual adjustment of fees for inflation shall be based on the Consumer Price Index (CPI) – California, All Items, All Urban Consumers, as published by the California Department of Industrial Relations. The Department shall apply the percentage change in the CPI for February of the current year relative to the base CPI from February 2022. These adjustments shall be rounded to the nearest whole dollar. All recalculated fees shall take effect on July 1 each year**.

(~~a~~**1**) On ~~**or after Fiscal Year 2024/**~~**July 1,** 2025, the application and annual license fee for each establishment proposing to produce or producing animal blood and blood component products from a closed-colony blood bank shall be one thousand and ~~**fifty-four**~~ ***eighty-eight*** dollars ($~~1054~~1088), ~~**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**~~ **and shall be adjusted annually thereafter pursuant to (a).**

(~~b~~**2**) On ~~**or after Fiscal Year 2024/**~~**July 1,** 2025, the registration application fee and annual renewal fee for each blood and blood component product shall be five hundred and ~~**twenty-seven**~~ ***forty-four*** dollars ($~~527~~544), ~~**which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year**~~ **and shall be adjusted annually thereafter pursuant to (a).**

(b) For the additional registration fee established by Section 1307.1, the annual adjustment of fees for inflation shall be based on the Consumer Price Index (CPI) – California, All Items, All Urban Consumers, as published by the California Department of Industrial Relations. The Department shall apply the percentage change in the CPI for February of the current year relative to the base CPI from February 2025. This adjustment shall be rounded to the nearest cent. The recalculated fee shall take effect on July 1 each year.

NOTE: Authority cited: Sections 407 and 9251, Food and Agricultural Code. Reference: Sections 9231(c) and 9244(b)(3), Food and Agricultural Code.