

AMENDED IN ASSEMBLY AUGUST 1, 2002

AMENDED IN ASSEMBLY JULY 3, 2002

AMENDED IN SENATE APRIL 25, 2002

AMENDED IN SENATE APRIL 11, 2002

SENATE BILL

No. 1345

Introduced by Senator Kuehl

(Coauthors: Senators Bowen, Romero, and Vincent)

(Coauthors: Assembly Members Aroner, Longville, and
Strom-Martin)

February 4, 2002

An act to amend Sections 9202, 9212, 9221, and 9231 of, and to add Sections 9266, 9267, 9268, and 9269 to, the Food and Agricultural Code, relating to biologics.

LEGISLATIVE COUNSEL'S DIGEST

SB 1345, as amended, Kuehl. Biologics.

(1) Existing law provides for the licensure and regulation of persons engaging, or proposing to engage, in the production of biologics that are specified products used for the diagnosis and detection of, and for the prevention or treatment of, disease in animals other than ~~man~~ *humans*. Existing law defines "animal" to include, but not be limited to, any domesticated fowl and any wild fowl or bird which is reduced to captivity.

This bill would revise the definition of animal for the purposes of the provisions relating to biologics to also specifically include any domesticated nonhuman or wild mammal.

(2) Existing law provides that the Secretary of Food and Agriculture shall license biologic establishments that meet specified requirements.

This bill would provide, in addition, for the licensing of biologic commercial blood banks for animals licensed by the Department of Food and Agriculture that maintain onsite records containing information documenting how the animal was acquired and any history of blood draws or use of anesthesia on the animal.

(3) Existing law provides that an application for a license for any establishment that produces, or proposes to produce, biologics shall contain specified information.

This bill would provide that the application shall also contain a written protocol that addresses specified topics relating to animal blood donors.

(4) Existing law provides that the secretary may adopt reasonably necessary rules and regulations for the administration and enforcement of the provisions relating to biologics, and provides for that enforcement by the denial, suspension, or revocation of any license for any establishment or registration of any biologic that fails to meet specified requirements or that violates specified provisions. Existing law also provides for licensing fees that may be fixed at less than, but may not exceed, \$250.

This bill would, in addition, provide that for commercial blood banks for animals licensed by the department (a) the department, or humane officers under contract with the department, shall inspect the establishments at least once a year to ensure compliance with required protocols; (b) anesthesia shall be performed by a licensed veterinarian or a registered veterinary technician under the direct supervision of a licensed veterinarian, and ~~sedation or the determination of the correct dose of a prescribed injectable anesthetic or sedative shall be performed by a suitably trained person~~ *unregistered assistants may only perform auxiliary health care tasks, as specified, and either under the direct or indirect supervision of a licensed veterinarian or under the direct supervision of a registered veterinary technician*; and (c) existing fees may be increased by the department to cover the department's reasonable costs incurred in connection with required inspections.

(5) The bill would exempt certain federally inspected facilities and federal biologics licensees from its requirements, as well as private veterinarians who maintain their own, in-office blood donor animals for use in their own practice. The bill would also provide that all records held by the department relating to the provisions on biologics shall be



confidential and not subject to disclosure under the California Public Records Act, except that the records shall be accessible to specified law enforcement officers.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 9202 of the Food and Agricultural Code
2 is amended to read:

3 9202. "Animal" includes, but is not limited to, any
4 domesticated fowl or nonhuman mammal and any wild fowl, bird,
5 or mammal that is reduced to captivity.

6 SEC. 2. Section 9212 of the Food and Agricultural Code is
7 amended to read:

8 9212. The secretary shall license biologic establishments that
9 meet all of the following:

10 (a) Operate under conditions, and use methods of production,
11 to insure that the biologics will not be contaminated, dangerous,
12 or harmful.

13 (b) Produce biologics under the direct supervision of a person
14 qualified in the field of production of biologics.

15 (c) For those commercial blood banks for animals licensed by
16 the department, maintain onsite records containing information
17 documenting how the animal was acquired and any history of
18 blood draws or use of anesthesia on the animal.

19 SEC. 3. Section 9221 of the Food and Agricultural Code is
20 amended to read:

21 9221. An application for a license for any establishment that
22 produces, or proposes to produce, biologics shall be made on
23 forms to be issued by the secretary. The application shall contain
24 all of the following:

25 (a) The name and address of the person who owns the place,
26 establishment, or institution in which it is proposed to produce
27 biologics.

28 (b) The name and address of the person who shall be in charge
29 of biologics production.

30 (c) The type of biologics that shall be produced.



- 1 (d) A full description of the building, including its location,
- 2 facilities, equipment, and apparatus to be used in biologics
- 3 production.
- 4 (e) A written protocol for a commercial blood bank for animals
- 5 that addresses all of the following:
- 6 (1) Maximum length of time for donation by animal donors, or
- 7 minimum health parameters for animal donors.
- 8 (2) Frequency and volume of blood collected from animal
- 9 blood donors.
- 10 (3) Socialization and exercise programs for animal blood
- 11 donors.
- 12 (4) Method of identification of each animal, including
- 13 microchip or tattoo.
- 14 (5) Ongoing veterinary care, including an annual physical
- 15 exam and vaccination schedule for animals held in blood donor
- 16 facilities.
- 17 (6) Husbandry standards for feeding, watering, sanitation,
- 18 housing, handling, and care in transit with minimums based on the
- 19 standards set forth pursuant to the federal Animal Welfare Act in
- 20 Part 3 (commencing with Section 3.1) of Subchapter A of Chapter
- 21 1 of Title 9 of the Code of Federal Regulations.
- 22 (7) Implementation of a permissive adoption program.
- 23 (f) Additional information that the secretary finds is necessary
- 24 for the proper administration and enforcement of this chapter.
- 25 SEC. 4. Section 9231 of the Food and Agricultural Code is
- 26 amended to read:
- 27 9231. The license application fee and license renewal fee
- 28 under this chapter for an establishment proposing to produce or
- 29 producing biologics shall be as follows:
- 30 (a) The application and annual license fee shall be two hundred
- 31 fifty dollars (\$250) for each establishment, which shall be the fee
- 32 for the fiscal year, or portion thereof, ending June 30 of each year.
- 33 When an applicant is a city, county, state, or district, or an official
- 34 thereof, no fee shall be required under this section.
- 35 (b) Licenses shall be renewed every year. The annual renewal
- 36 fee shall be paid on or before the first day of July of each year.
- 37 (c) For commercial blood banks for animals licensed by the
- 38 department, fees may be increased by the department to cover the
- 39 department’s reasonable costs incurred in connection with



1 performing the annual inspection required by Sections 9266 and
2 9268.

3 (d) The fees required by this section are maximum, and may be
4 fixed by the secretary at a lesser amount for any fiscal year
5 whenever he or she finds that the cost of administering this chapter
6 can be defrayed from revenues derived from the lower fees.

7 SEC. 5. Section 9266 is added to the Food and Agricultural
8 Code, to read:

9 9266. The department, or humane officers under contract
10 with the department, shall inspect commercial blood banks for
11 animals licensed by the department at least once a year to ensure
12 compliance with the protocols required by subdivision (e) of
13 Section 9221.

14 SEC. 6. Section 9267 is added to the Food and Agricultural
15 Code, to read:

16 9267. Notwithstanding Section 4827 of the Business and
17 Professions Code, for commercial blood banks for animals
18 licensed by the department, the following requirements shall be
19 met:

20 (a) Anesthesia shall be performed by a licensed veterinarian or
21 ~~a licensed by a~~ registered veterinary technician under the direct
22 supervision of a licensed veterinarian.

23 ~~(b) Sedation or the determination of the correct dose of a~~
24 ~~prescribed injectable anesthetic or sedative shall be performed by~~
25 ~~a suitably trained person under the indirect supervision of a~~
26 ~~licensed veterinarian.~~

27 *(b) Subject to Section 2036.5 of Title 16 of the California Code*
28 *of Regulations, unregistered assistants may only perform auxiliary*
29 *animal health care tasks pursuant to the order, control, and full*
30 *professional responsibility of a licensed veterinarian and either*
31 *under the direct or indirect supervision of a licensed veterinarian*
32 *or under the direct supervision of a registered veterinary*
33 *technician.*

34 SEC. 7. Section 9268 is added to the Food and Agricultural
35 Code, to read:

36 9268. The requirements set forth in subdivision (c) of Section
37 9212, subdivision (e) of Section 9221, subdivision (c) of Section
38 9231, and Sections 9265, 9266, and 9267:

39 (a) Shall not apply to those facilities required to be inspected
40 by the United States Department of Agriculture in accordance with



1 the Animal Welfare Act (Chapter 54 (commencing with Section
2 2131) of Title 7 of the United States Code), or to federal biologics
3 licensees.

4 (b) Shall apply to those facilities housing blood donor animals
5 under contract with commercial blood banks for animals licensed
6 by the department.

7 (c) Shall not apply to private veterinarians who maintain their
8 own, in-office blood donor animals for use in their own practice.

9 SEC. 8. Section 9269 is added to the Food and Agricultural
10 Code, to read:

11 9269. (a) Except as provided in subdivision (b), all records
12 held by the department relating to this chapter, including, but not
13 limited to, records relating to applications, fees, or inspections
14 required by this chapter, shall be confidential and not subject to
15 disclosure under the California Public Records Act contained in
16 Chapter 3.5 (commencing with Section 6250) of Division 7 of
17 Title 1 of the Government Code.

18 (b) Notwithstanding subdivision (a), records held by the
19 department relating to this chapter shall be accessible to law
20 enforcement officers with jurisdiction over any matter covered by
21 this chapter.

