

AMENDED IN ASSEMBLY JANUARY 5, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1468

Introduced by Assembly Member Conway

February 27, 2009

An act to amend ~~Section 9211~~ of Sections 9211, 9241, 9266, 9267, 9268, 9269, and 9272 of, to amend the heading of Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of, to repeal Sections 9212, 9242, 9243, 9244, 9245, 9261, 9262, 9263, and 9264 of, and to repeal Article 3 (commencing with Section 9221), Article 4 (commencing with Section 9231), and Article 6 (commencing with Section 9251) of Chapter 1.5 of Part 1 of Division 5 of, the Food and Agricultural Code, relating to biologics.

LEGISLATIVE COUNSEL'S DIGEST

AB 1468, as amended, Conway. ~~Biologies.~~ *Biologics: licensure: registration.*

Existing law requires the Secretary of Food and Agriculture to license establishments, including commercial blood banks for animals, that produce, or propose to produce, biologics and that meet specified requirements, provides requirements relating to the application for a license, and requires a certain license application fee and license renewal fee.

This bill would delete the requirement that the secretary license those biologic establishments and would delete those related provisions regarding license applications and fees.

Existing law prohibits the offer for sale or use of any biologic unless it is registered by the secretary, except that registration is not required of any biologic manufactured pursuant to the terms of a valid license

issued by the United States Department of Agriculture unless the secretary finds that, due to local conditions, it is necessary that the biologic be registered.

This bill would, instead, prohibit the offer for sale or use of any biologic unless the person has a valid license or permit issued by the United States Department of Agriculture.

Existing law requires the secretary to register any biologic that meets certain requirements and a biologic that is produced in an establishment exempt from licensing and that meets certain requirements, provides requirements relating to the application for registration of a biologic, and authorizes the secretary to impose conditions on the production or use of biologics.

This bill would delete the requirement that the secretary register biologics and would delete those related provisions regarding the registration application and the imposition of conditions.

Existing law authorizes the secretary to adopt rules and regulations for the administration and enforcement of the provisions relating to biologics.

This bill would delete that authority.

Existing law provides various enforcement provisions that the secretary may undertake with respect to biologic licensees and registrants.

This bill would delete those enforcement provisions.

Existing law requires the Department of Food and Agriculture, or humane officers under contract with the department, to inspect commercial blood banks for animals licensed by the department at least once a year to ensure compliance with certain protocols.

This bill would, instead, authorize humane officers to inspect commercial blood banks for animals to ensure compliance with certain husbandry standards, written protocol requirements, and with a requirement for the maintenance of an affiliation with an identified oversight veterinarian for the facility.

This bill would also make various conforming changes and other technical changes.

~~Existing law prohibits a person from engaging in the production of biologics except as specified, including, among others, in an establishment licensed by the Secretary of Food and Agriculture.~~

~~This bill would make technical, nonsubstantive changes to those provisions.~~

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

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

1 *SECTION 1. Section 9211 of the Food and Agricultural Code*
2 *is amended to read:*

3 9211. No person shall engage in the production of biologics
4 except in any of the following:

5 ~~(a) In an establishment licensed by the United States~~
6 ~~Department of Agriculture.~~

7 ~~(b) In an establishment producing biologics only for use by the~~
8 ~~owner or operator of that establishment for animals owned by him~~
9 ~~or her. Biologics produced in such an establishment shall be~~
10 ~~registered by the director under this chapter.~~

11 ~~(c) In an establishment licensed by the director.~~

12 *SEC. 2. Section 9212 of the Food and Agricultural Code is*
13 *repealed.*

14 ~~9212. The secretary shall license biologic establishments that~~
15 ~~meet all of the following:~~

16 ~~(a) Operate under conditions, and use methods of production,~~
17 ~~to insure that the biologics will not be contaminated, dangerous,~~
18 ~~or harmful.~~

19 ~~(b) Produce biologics under the direct supervision of a person~~
20 ~~qualified in the field of production of biologics.~~

21 ~~(c) For those commercial blood banks for animals licensed by~~
22 ~~the department, maintain onsite records containing information~~
23 ~~documenting how the animal was acquired and any history of~~
24 ~~blood draws or use of anesthesia on the animal.~~

25 *SEC. 3. Article 3 (commencing with Section 9221) of Chapter*
26 *1.5 of Part 1 of Division 5 of the Food and Agricultural Code is*
27 *repealed.*

28 *SEC. 4. Article 4 (commencing with Section 9231) of Chapter*
29 *1.5 of Part 1 of Division 5 of the Food and Agricultural Code is*
30 *repealed.*

31 *SEC. 5. The heading of Article 5 (commencing with Section*
32 *9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and*
33 *Agricultural Code is amended to read:*

34
35 Article 5. ~~Biologic Registration~~ *Sale or Use of Biologics*

1 SEC. 6. Section 9241 of the Food and Agricultural Code is
2 amended to read:

3 9241. No person shall offer for sale or use any biologic unless
4 it is registered by the director pursuant to this article, except,
5 however, no such registration shall be required of any biologic
6 manufactured pursuant to the terms of the person has a valid
7 license or permit issued by the United States Department of
8 Agriculture unless the director finds that, due to local conditions,
9 it is necessary that the biologic be registered in order to assure that
10 it have value for the purpose intended and it is safe to use in this
11 state.

12 SEC. 7. Section 9242 of the Food and Agricultural Code is
13 repealed.

14 9242. The director shall register any biologic that meets all of
15 the following requirements:

16 (a) It is produced under acceptable procedures, which include
17 tests to insure its purity and safety.

18 (b) The production and use of such type of biologic has not
19 been specifically forbidden or disapproved by the director, the
20 United States Department of Agriculture, or the United States
21 Public Health Service.

22 (c) It has been demonstrated to the director that such a biologic
23 is safe and noninjurious to human or animal health.

24 (d) It has been demonstrated to the director that such a biologic
25 is of value for the purpose intended.

26 (e) It is labeled for proper handling and use, and is not
27 misrepresented.

28 (f) It is produced in an establishment that meets the
29 requirements of subdivision (a) or (c) of Section 9211.

30 SEC. 8. Section 9243 of the Food and Agricultural Code is
31 repealed.

32 9243. The director shall register a biologic, if it is produced in
33 an establishment exempt from licensing pursuant to subdivision
34 (b) of Section 9211 and meets the requirements of subdivisions
35 (a), (b), and (c) of Section 9242.

36 SEC. 9. Section 9244 of the Food and Agricultural Code is
37 repealed.

38 9244. An application for registration of a biologic shall include
39 both of the following:

1 ~~(a) A protocol of methods of production in detail which is~~
2 ~~followed in the production of the product.~~

3 ~~(b) A sample of the label to be placed on the biologic.~~

4 *SEC. 10. Section 9245 of the Food and Agricultural Code is*
5 *repealed.*

6 ~~9245. The director may impose such conditions on the~~
7 ~~production or use of biologics as he deems necessary to accomplish~~
8 ~~the purposes of this chapter.~~

9 *SEC. 11. Article 6 (commencing with Section 9251) of Chapter*
10 *1.5 of Part 1 of Division 5 of the Food and Agricultural Code is*
11 *repealed.*

12 *SEC. 12. Section 9261 of the Food and Agricultural Code is*
13 *repealed.*

14 ~~9261. License for any establishment or registration of any~~
15 ~~biologic may be denied, suspended, or revoked by the director for~~
16 ~~failure to meet the requirements of this chapter or for the violation~~
17 ~~of any provision of this chapter, or of any rule or regulation adopted~~
18 ~~by the director under this chapter. The proceedings shall be~~
19 ~~conducted in accordance with Chapter 5 (commencing with Section~~
20 ~~11500), Part 1, Division 3, Title 2 of the Government Code.~~

21 *SEC. 13. Section 9262 of the Food and Agricultural Code is*
22 *repealed.*

23 ~~9262. The biologics prepared prior to July 1, 1975, in~~
24 ~~laboratories licensed pursuant to Chapter 4 (commencing with~~
25 ~~Section 1600) of Division 2 of the Health and Safety Code, which~~
26 ~~have an expiration date of July 1, 1975, or later, are not subject to~~
27 ~~the provisions of this chapter.~~

28 *SEC. 14. Section 9263 of the Food and Agricultural Code is*
29 *repealed.*

30 ~~9263. If the director finds that biologics do not conform to the~~
31 ~~requirements of Section 9242 or 9243 or the use or continued use~~
32 ~~of such products constitutes an immediate danger to persons or~~
33 ~~animals, he may, after notice, suspend the registration of such~~
34 ~~biologics or license of an establishment producing such biologics~~
35 ~~pending a hearing and final decision.~~

36 *SEC. 15. Section 9264 of the Food and Agricultural Code is*
37 *repealed.*

38 ~~9264. If the director finds a serial or serials of a registered~~
39 ~~biologic which do not meet the requirements of Section 9242 or~~
40 ~~9243, he may order such serial or serials to be held on the premises~~

1 where found or elsewhere until he has determined that the products
2 may be safely released for the purposes intended.

3 ~~The director may order the destruction of any products under~~
4 ~~such a hold order if the products cannot be made to meet the~~
5 ~~requirements of Section 9242 or 9243.~~

6 *SEC. 16. Section 9266 of the Food and Agricultural Code is*
7 *amended to read:*

8 ~~9266. The department, or humane-Humane officers under~~
9 ~~contract with the department, shall may inspect commercial blood~~
10 ~~banks for animals licensed by the department at least once a year~~
11 ~~to ensure compliance with the protocols required by subdivision~~
12 ~~(e) of Section 9221. all of the following:~~

13 (a) *Husbandry standards for feeding, watering, sanitation,*
14 *housing, handling, and care in transit, with minimums based on*
15 *the standards set forth pursuant to the federal Animal Welfare Act*
16 *in Part 3 (commencing with Section 3.1) of Subchapter A of*
17 *Chapter I of Title 9 of the Code of Federal Regulations.*

18 (b) *Written protocols, established by, and to be followed by, the*
19 *commercial blood bank for animals, that address all of the*
20 *following:*

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

23 (2) *Frequency and volume of blood collected from animal blood*
24 *donors.*

25 (3) *Socialization and exercise programs for animal blood*
26 *donors.*

27 (4) *Method of identification of each animal, including microchip*
28 *or tattoo.*

29 (5) *Ongoing veterinary care, including an annual physical exam*
30 *and vaccination schedule for animals held in blood donor facilities.*

31 (6) *Implementation of a permissive adoption program.*

32 (c) *Maintenance of an affiliation with an identified oversight*
33 *veterinarian for the facility. Oversight veterinarians shall be*
34 *licensed to practice veterinary medicine in California. An*
35 *“oversight letter” identifying the oversight veterinarian shall be*
36 *maintained on the premises of the commercial animal blood bank.*

37 *SEC. 17. Section 9267 of the Food and Agricultural Code is*
38 *amended to read:*

39 9267. *Notwithstanding Section 4827 of the Business and*
40 *Professions Code, for commercial blood banks for animals licensed*

1 ~~by the department~~ that operate in California, anesthesia shall be
2 performed by a California licensed veterinarian or by a registered
3 veterinary technician under the direct supervision of a California
4 licensed veterinarian.

5 *SEC. 18. Section 9268 of the Food and Agricultural Code is*
6 *amended to read:*

7 9268. The requirements set forth in ~~subdivision (e) of Section~~
8 ~~9212, subdivision (e) of Section 9221, subdivision (e) of Section~~
9 ~~9231, and Sections 9265, 9266; and 9267:~~

10 (a) Shall not apply to those facilities required to be inspected
11 by the United States Department of Agriculture in accordance with
12 the Animal Welfare Act (Chapter 54 (commencing with Section
13 2131) of Title 7 of the United States Code), or to federal biologics
14 licensees.

15 (b) Shall apply to those *commercial animal blood banks and*
16 *facilities housing blood donor animals under contract with*
17 *commercial blood banks for animals licensed by the department.*

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

20 *SEC. 19. Section 9269 of the Food and Agricultural Code is*
21 *amended to read:*

22 9269. (a) Except as provided in subdivision (b), all records
23 held by the department relating to this chapter, including, but not
24 limited to, records relating to ~~applications~~ *state biologic*
25 *establishment licenses and registrations prior to January 1, 2011,*
26 *fees, or inspections required by this chapter, shall be confidential*
27 *and not subject to disclosure under the California Public Records*
28 *Act contained in Chapter 3.5 (commencing with Section 6250) of*
29 *Division 7 of Title 1 of the Government Code.*

30 (b) Notwithstanding subdivision (a), records held by the
31 department relating to this chapter shall be accessible to law
32 enforcement officers with jurisdiction over any matter covered by
33 this chapter.

34 *SEC. 20. Section 9272 of the Food and Agricultural Code is*
35 *amended to read:*

36 9272. The provisions of this chapter shall not apply ~~(1)~~ to
37 facilities primarily engaged in the collection, preparation, testing,
38 processing, storage, or distribution of human blood or blood
39 products, provided such facility is licensed pursuant to Section
40 ~~1601 or 1602~~ 1602.5 of the Health and Safety Code ~~and any~~

1 biologic as defined in Section 9203 produced by such facility is
2 sold or distributed only to an establishment licensed by this chapter
3 or (2) to clinical laboratories licensed pursuant to Chapter 3
4 (commencing with Section 1200) of Division 2 of the Business
5 and Professions Code whose only biologics are autogenous
6 bacterins prepared at the request of licensed veterinarians.

7 SECTION 1. Section 9211 of the Food and Agricultural Code
8 is amended to read:

9 9211. No person shall engage in the production of biologics
10 except in any of the following:

11 (a) In an establishment licensed by the United States Department
12 of Agriculture.

13 (b) In an establishment producing biologics only for use by the
14 owner or operator of that establishment for animals owned by him
15 or her. Biologics produced in such an establishment shall be
16 registered by the secretary under this chapter.

17 (c) In an establishment licensed by the secretary.