

ASSEMBLY BILL

No. 357

Introduced by Assembly Member Maienschein

February 1, 2023

An act to amend Section 1834.9 of the Civil Code, relating to animal testing.

LEGISLATIVE COUNSEL'S DIGEST

AB 357, as introduced, Maienschein. Animal test methods: alternatives.

Existing law prohibits manufacturers and contract testing facilities from using traditional animal test methods within the state for which an appropriate alternative test method has been scientifically validated and recommended by the Inter-Agency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and adopted, as specified. Existing law excepts certain animal tests from these provisions, including animal tests performed for the purpose of medical research. Existing law provides that the exclusive remedy for a violation of these provisions is a civil action for injunctive relief brought by, among others, the Attorney General and makes a violation of these provisions punishable by a specified civil penalty. Existing law defines various terms for purposes of these provisions.

This bill would instead prohibit manufacturers and contract testing facilities from using traditional animal test methods within this state for which an appropriate alternative test method or strategy exists, or a waiver has been granted by the agency responsible for regulating the specific product or activity for which the test is being conducted. The bill would define alternative test method or strategy as a test method that provides information of equivalent or better scientific quality and

relevance compared to traditional animal test methods, has been identified by a validation body, such as ICCVAM or the Organization for Economic Co-operation and Development, or accepted for use by a federal agency or program, as specified, and does not use animals or uses the fewest number of animals possible and reduces the level of pain, suffering, or stress of an animal used for testing to the greatest extent possible. The bill would except from these provisions animal tests performed for the purpose of biomedical research, as defined to not include testing done to assess the safety or efficacy of chemicals, ingredients, drugs, medical devices, vaccines, product formulations, or products, and make conforming changes.

The bill would also, starting January 1, 2025, and annually thereafter, require a manufacturer or contract testing facility that uses traditional animal test methods to report specified information to the Attorney General, and would require the Attorney General to make that information publicly available on its internet website.

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 1834.9 of the Civil Code is amended to
2 read:

3 1834.9. (a) Manufacturers and contract testing facilities shall
4 not use traditional animal test methods within this state for which
5 an appropriate alternative test method ~~has been scientifically~~
6 ~~validated and recommended by the Inter-Agency Coordinating~~
7 ~~Committee for the Validation of Alternative Methods (ICCVAM)~~
8 ~~and adopted by the relevant federal agency or agencies or program~~
9 ~~within an~~ or strategy exists, or a waiver has been granted by the
10 agency responsible for regulating the specific product or activity
11 for which the test is being conducted.

12 (b) ~~Nothing in this section shall~~ This section does not prohibit
13 the use of any ~~alternative~~ nonanimal test method or strategy for
14 the testing of any product, product formulation, chemical, drug,
15 medical device, vaccine, or ingredient that is not ~~recommended~~
16 ~~by ICCVAM. described in paragraph (1) of subdivision (g).~~

17 (c) ~~Nothing in this section shall~~ This section does not prohibit
18 the use of animal tests to comply with requirements of state
19 agencies. ~~Nothing in this section shall~~ This section does not prohibit

the use of animal tests to comply with requirements of federal agencies when the federal agency has approved an alternative nonanimal test *method or strategy* pursuant to subdivision (a) and the federal agency staff concludes that the alternative nonanimal test *method or strategy* does not assure the health or safety of consumers.

(d) Notwithstanding any other ~~provision of~~ law, the exclusive remedy for enforcing this section shall be a civil action for injunctive relief brought by the Attorney General, the district attorney of the county in which the violation is alleged to have occurred, or a city attorney of a city or a city and county having a population in excess of 750,000 and in which the violation is alleged to have occurred. If the court determines that the Attorney General or district attorney is the prevailing party in the enforcement action, the official may also recover costs, attorney fees, and a civil penalty not to exceed five thousand dollars (\$5,000) in that action.

(e) This section shall not apply to any animal test performed for the purpose of ~~medical~~ biomedical research.

(f) *Starting January 1, 2025, and annually thereafter, a manufacturer or contract testing facility in this state using traditional animal test methods shall report to the Attorney General the number and species of animals used, the type and number of alternative test methods or strategies used, the number of waivers used, and the purpose of the use of the traditional animal tests, alternative test methods or strategies, and waivers. The Attorney General shall make the results of this data collection publicly available on its internet website.*

~~(f)~~

(g) For the purposes of this section, ~~these terms have the following meanings:~~ the following terms apply:

(1) (A) “Alternative test method or strategy” means a test method, including a new or revised method, that fulfills all of the following criteria:

(i) *Provides information of equivalent or better scientific quality and relevance compared to traditional animal test methods.*

(ii) *Has been identified by a validation body, such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development, or accepted for use by a federal*

1 agency or program within an agency responsible for regulating
2 the specific product or activity for which the test is being
3 conducted.

4 (iii) Does not use animals, or in cases when there is no test
5 method available that does not use animals, uses the fewest number
6 of animals possible and reduces the level of pain, suffering, or
7 stress of an animal used for testing to the greatest extent possible.

8 (B) “Alternative test method or strategy” includes, but is not
9 limited to, computational toxicology and bioinformatics,
10 high-throughput screening methods, testing of categories of
11 chemical substances, tiered testing methods, in vitro studies, and
12 systems biology.

13 (H)

14 (2) “Animal” means vertebrate nonhuman animal.

15 (3) (A) Biomedical research means the investigation of the
16 biological processes and causes of disease or research conducted
17 to increase fundamental scientific knowledge, and to expand the
18 understanding about how processes in living organisms develop
19 and function.

20 (B) Notwithstanding subparagraph (A), “biomedical research”
21 shall not include testing done to assess the safety or efficacy of
22 chemicals, ingredients, drugs, medical devices, vaccines, product
23 formulations, or products.

24 (4) “Contract testing facility” means any partnership,
25 corporation, association, or other legal relationship that tests
26 chemicals, ingredients, drugs, medical devices, vaccines, product
27 formulations, or products in this state.

28 (2)

29 (5) “Manufacturer” means any partnership, corporation,
30 association, or other legal relationship that produces chemicals,
31 ingredients, drugs, medical devices, vaccines, product formulations,
32 or products in this state.

33 ~~(3) “Contract testing facility” means any partnership,~~
34 ~~corporation, association, or other legal relationship that tests~~
35 ~~chemicals, ingredients, product formulations, or products in this~~
36 ~~state.~~

37 ~~(4) “ICCVAM” means the Inter-Agency Coordinating~~
38 ~~Committee for the Validation of Alternative Methods, a federal~~
39 ~~committee comprised of representatives from 14 federal regulatory~~
40 ~~or research agencies, including the Food and Drug Administration,~~

1 Environmental Protection Agency, and Consumer Products Safety
2 Commission, that reviews the validity of alternative test methods.
3 The committee is the federal mechanism for recommending
4 appropriate, valid test methods to relevant federal agencies.

5 (5) “Medical research” means research related to the causes,
6 diagnosis, treatment, control, or prevention of physical or mental
7 diseases and impairments of humans and animals or related to the
8 development of biomedical products, devices, or drugs as defined
9 in Section 321(g)(1) of Title 21 of the United States Code. Medical
10 research does not include the testing of an ingredient that was
11 formerly used in a drug, tested for the drug use with traditional
12 animal methods to characterize the ingredient and to substantiate
13 its safety for human use, and is now proposed for use in a product
14 other than a biomedical product, medical device, or drug.

15 (6) “Traditional animal test method” means a process or
16 procedure using animals to obtain information on the characteristics
17 of a chemical or agent. Toxicological test methods generate
18 information regarding the ability of a chemical or agent to produce
19 a specific biological effect under specified conditions.

20 (7) “Validated alternative test method” means a test method
21 that does not use animals, or in some cases reduces or refines the
22 current use of animals, for which the reliability and relevance for
23 a specific purpose has been established in validation studies as
24 specified in the ICCVAM report provided to the relevant federal
25 agencies.

26 (8)
27 (6) “Person” means an individual with managerial control, or
28 a partnership, corporation, association, or other legal relationship.

29 (9) “Adopted by a federal agency” means a final action taken
30 by an agency, published in the Federal Register, for public notice.

31 (7) “Traditional animal test method” means a process or
32 procedure using animals to obtain information on the
33 characteristics of a chemical or agent and that generates
34 information regarding the ability of a chemical or agent to produce
35 a specific biological effect under specified conditions.