

SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

AB 357 (Maienschein)
Version: May 25, 2023
Hearing Date: June 27, 2023
Fiscal: Yes
Urgency: No
AM

SUBJECT

Animal test methods: alternatives

DIGEST

This bill makes changes to the existing statute that prohibits testing of consumer products on animals to address obsolete provisions. The bill also requires a manufacturer or contract testing facility in this state using traditional animal test methods, except as specified, to report specified information to the State Department of Public Health (DPH), and requires DPH to post that information on its website, as provided.

EXECUTIVE SUMMARY

California became the first state in the nation to enact a widespread prohibition on unnecessary testing of consumer products on animals in 2000 when the Legislature enacted SB 2082 (O'Connell, Ch. 476, Stats. 2000). SB 2082 prohibited animal testing if an alternative test was approved by the Interagency Coordinating Committee on the Validation of Alternative Methods, with certain exceptions for medical research. Since that bill was enacted, the Interagency Coordinating Committee on the Validation of Alternative Methods no longer validates alternatives to animal testing. This bill seeks to revise, recast, and update the existing statute enacted by SB 2082 to ensure that animals will not suffer needlessly due to outdated provisions. The bill also requires reporting to DPH regarding the use of traditional animal test methods, and requires DPH to post that information on its website, as provided.

The bill is sponsored by the Humane Society of the United States and is supported by a coalition of animal rights organizations. After recent amendments, there is no longer any opposition.

PROPOSED CHANGES TO THE LAW

Existing law:

- 1) Requires a depository of living animals to provide the animals with necessary and prompt veterinary care, nutrition, and shelter, and to treat them kindly, and provides that a failure to do so may result in civil penalties, as specified. (Civ. Code § 1834.)
- 2) Prohibits manufacturers and contract testing facilities from utilizing animal tests when an appropriate alternative test method has been scientifically validated and recommended by the Inter-Agency Coordinating Committee for the Validation of Alternative Methods, and the alternative test has been approved by the relevant federal agency or agencies or program within an agency responsible for regulating the specific product or activity for which the test is being conducted. (Civ. Code § 1834.9 (a).)
- 3) Specifies that nothing in 2), above, prohibits the use of any alternative nonanimal test method for the testing of any product, product formulation, chemical, or ingredient that is not recommended by the Inter-Agency Coordinating Committee for the Validation of Alternative Methods. (Civ. Code § 1834.9(b).)
- 4) Provides that nothing in 2), above, prohibits the use of animal tests to comply with requirements of federal agencies when the federal agency has approved an alternative nonanimal test, and federal agency staff concludes that the alternative nonanimal test does not assure the health or safety of consumers, or when an animal test is required by a state agency. (Civ. Code § 1834.9(c).)
- 5) Provides that this prohibition does not apply to medical research, as defined. (Civ. Code § 1834.9(e).)
- 6) Provides that a violation of this prohibition is exclusively enforced by 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. (Civ. Code § 1834.9(d).)
- 7) Prohibits a testing facility from conducting a canine or feline toxicological experiment in this state to achieve discovery, approval, maintenance of approval, notification, registration, or maintenance of a pesticide or chemical substance, except as specified. (Civ. Code § 1834.9.3(b).)
- 8) Prohibits a manufacturer from importing for profit, selling, or offering for sale in this state, any cosmetic, if the cosmetic was developed or manufactured using an

animal test that was conducted or contracted by the manufacturer, or any supplier of the manufacturer, as specified. (Civ. Code § 1834.9.5.)

- 9) Provides, pursuant to the California Constitution, that the people have the right of access to information concerning the conduct of the people's business, and, therefore, the meetings of public bodies and the writings of public officials and agencies are required to be open to public scrutiny. (Cal. const. art. I, § 3(b)(1).)
 - a) Requires a statute to be broadly construed if it furthers the people's right of access, and narrowly construed if it limits the right of access. (Cal. const. art. I, § 3(b)(1).)
 - b) Requires a statute that limits the public's right of access to be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest. (Cal. const. art. I, § 3(b)(1).)

- 10) Governs the disclosure of information collected and maintained by public agencies pursuant to the CPRA. (Gov. Code §§ 7920.000 et seq.)
 - a) States that the Legislature, mindful of the individual right to privacy, finds and declares that access to information concerning the conduct of the people's business is a fundamental and necessary right of every person in this state. (Gov. Code § 7921.000.)
 - b) Defines "public records" as any writing containing information relating to the conduct of the public's business prepared, owned, used, or retained by any state or local agency regardless of physical form or characteristics. (Gov. Code § 7920.530.)
 - c) Provides that all public records are accessible to the public upon request, unless the record requested is exempt from public disclosure. (Gov. Code § 7922.530.)

This bill:

- 1) Prohibits manufacturers and contract 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.
- 2) Specifies that, when there is no appropriate alternative test method or strategy available, manufacturers and contract testing facilities must use a traditional animal test method using the fewest number of animals possible and reduce the level of pain, suffering, and stress of an animal used for testing.
- 3) Specifies that these provisions do not prohibit the use of traditional animal test methods to comply with requirements of state or federal agencies.

- 4) Requires, on and after January 1, 2025, a manufacturer or contract testing facility in this state using traditional animal test methods, except for those performed for the purpose of medical research, to report to DPH 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.
 - a) Requires the department to develop and maintain a portal on its website to receive the above information and make the information collected publicly available on its internet website. The department must ensure that information made available to the public does not include personally identifiable information or proprietary information.
- 5) Defines “alternative test method or strategy” to mean a test method, including a new or revised method, that fulfills all of the following criteria:
 - a) does not use animals;
 - b) provides information of equivalent or better scientific quality and relevance compared to traditional animal test methods, and includes, but is not limited to, computational toxicology and bioinformatics, high-throughput screening methods, testing of categories of chemical substances, tiered testing methods, in vitro studies, and systems biology; and
 - c) has been identified and accepted for use by a federal agency or program within an agency responsible for regulating the specific product or activity for which the test is being conducted.
- 6) Defines “department” to mean the State Department of Public Health.
- 7) Makes various conforming changes.

COMMENTS

1. Stated need for the bill

The author writes:

California is a scientific and technological leader in non-animal alternatives. Science is rapidly moving away from outdated animal tests as many faster, less expensive, and more human-relevant alternative methods become available. This legislation would ensure that companies in California are taking advantage of these new testing strategies as soon as they are available and appropriate for use.

AB 357 would require companies and their contract testing facilities to use test methods that replace animal testing when they are available and provide information of equivalent or better scientific quality and relevance for the intended purpose. The bill would also require a manufacturer or contract testing facility using

traditional animal testing methods to report annually to the Attorney General information regarding their use of animal testing.

2. California has a long history of prohibiting the testing on animals unnecessarily

California has a long history of passing legislation to address the issue of testing on animals unnecessarily. As noted above, California became the first state in the nation to enact a widespread prohibition on unnecessary testing of consumer products on animals when the Legislature enacted SB 2082 in 2000. In 2014, the California Legislature passed the Cruelty Free Cosmetics Resolution, SJR 22 (Block, Res. Ch. 73, Stats. 2014), urging Congress to prohibit animal testing for cosmetics and to phase out marketing animal-tested cosmetics.

As detailed in SJR 22, animals have been used in tests to assess the safety of chemicals used in cosmetic products for over 50 years. However, modern alternatives to animal testing exist. In fact, in 2013 the European Union prohibited the importation and sale of cosmetics that have been tested on animals. India, Israel, Norway, Iceland, Switzerland and Mexico followed suit enacting similar laws. California continued building on this legacy in 2018 by prohibiting the use of animal testing in the development of cosmetic products starting in 2020 (SB 1249 (Galgiani, Ch. 899, Stats. 2018.)), and last year prohibited unnecessary toxicological testing on dogs and cats. (SB 879 (Wiener, Ch. 551, Stats. 2022.))

3. Bill makes changes to update obsolete provisions and account for new technologies

This bill is intended to update the statute that prohibits testing of consumer products on animals to address obsolete provisions and address new technologies. Proponents of the bill point to various studies showing the lack of evidence that animal testing is warranted and effective.

As one study noted:

Despite the deeply rooted assumption that animal models accurately predict human toxicity, even cursory examination of the concordance of animal and human trials raises concerns. A 2006 review of 76 animal studies, for example, found that approximately 20% were contradicted in humans and only 37% were ever replicated in humans. A review of 221 animal experiments found agreement in human studies just 50% of the time – essentially randomly. [...]

About 12% of pharmaceuticals pass preclinical testing to enter clinical trials. Of those, only 60% successfully complete phase I trials. Overall, approximately 89% of novel drugs fail human clinical trials, with approximately one-half of those failures due to unanticipated human toxicity. If animal tests accurately predict human

toxicity, then why are toxicity-related failure rates in human clinical trials so high?
(footnotes omitted)¹

The bill modernizes the existing statute in several ways. First, it removes reference to approval of alternatives by the Interagency Coordinating Committee on the Validation of Alternative Methods and instead provides that if an appropriate alternative test method or strategy exists then manufacturers and contracting testing facilities are prohibited from using traditional animal test methods in the state. This is defined as a method that does not use animals, provides information of equivalent or better scientific quality and relevance compared to traditional animal test methods, and has been identified and accepted for use by a federal agency or program within an agency responsible for regulating the specific product or activity for which the test is being conducted. The bill specifically does not prohibit the use of traditional animal test methods to comply with requirements of state or federal agencies. Recent amendments to the bill maintain the existing exemption for tests performed for the purpose of medical research.

The bill also implements a new reporting requirement where a manufacturer of a consumer product or contract testing facility in this state that uses traditional animal test methods must report to the DPH the number and species of animals used, the type and number of alternative tests, methods or strategies used, the number of waivers issued, and the purpose served by the traditional animal tests, alternative test methods or strategies, and waivers beginning January 1, 2025. The bill requires the Department to develop and maintain a portal on its website to receive that information and make it publicly available on the website.

In recognition of the fact that information required to be reported to DPH could be proprietary or include information that may be personally identifiable, the bill provides that DPH must ensure that the information it posts publically on its website does not include personally identifiable information or proprietary information. California generally recognizes that public access to information concerning the conduct of the people's business is a fundamental and necessary right. At the same time, the state recognizes that this right must be balanced against the right to privacy. The general right of access to public records may, therefore, be limited where records include personal information. In light of the nature of information that may be submitted to the DPH, the potential limiting of access to public records in this bill seems warranted.

¹ Gail Van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials: Is it Time to Rethink Our Current Approach?* (November 2019) *JACC: Basic to Translational Science*, at p. 849, available at <https://www.sciencedirect.com/science/article/pii/S2452302X1930316X>.

4. Statements in support

A coalition of organizations, including the sponsor of the bill The Humane Society of the United States, writes in support stating:

Animal testing is costly, time-consuming, and often poorly predictive of toxicity in humans. Nonanimal alternatives can provide more efficient as well as more effective chemical safety assessments. Human cell-based tests and advanced computer models, for example, deliver human-relevant results in hours or days, unlike some animal tests that can take months or years.

By minimizing animal testing and focusing on the use of faster, cost effective, and more reliable testing methods, companies can save lives, time, and money. This legislation would ensure companies take advantage of those new testing strategies as soon as they are approved for use.

SUPPORT

The Humane Society of the United States (sponsor)
American Society for the Prevention of Cruelty to Animals
Animal Legal Defense Fund
Cruelty Free International
GATC Health Corp.
Humane Society of the United States; the
Humane Society Veterinary Medical Association
Marin Humane
National Anti-Vivisection Society
Physicians Committee for Responsible Medicine
Rise for Animals
San Diego Humane Society
Social Compassion in Legislation

OPPOSITION

None known

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

SB 879 (Wiener, Ch. 551, Stats. 2022, *see* Comment 2, above).

SB 1249 (Galgiani, Ch. 899, Stats. 2018), *see* Comment 2, above.

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SJR 22 (Block, Res. Ch. 73, Stats. 2014), see Comment 2, above.

SB 2082 (O'Connell, Ch. 476, Stats. 2000, *see* Comment 2, above.

PRIOR VOTES:

Assembly Floor (Ayes 68, Noes 2)

Assembly Appropriations Committee (Ayes 12, Noes 2)

Assembly Judiciary Committee (Ayes 8, Noes 0)
