

Department of Legislative Services  
Maryland General Assembly  
2025 Session

FISCAL AND POLICY NOTE  
First Reader

Senate Bill 536 (Senator Kramer)  
Education, Energy, and the Environment

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**Research Facilities and Testing Facilities That Use Animals - Regulation**

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This bill establishes requirements and prohibitions applicable to a “research facility” or “testing facility” in the State that uses animals, including (1) a prohibition against the use of certain dogs or cats for research or testing purposes and (2) a prohibition against the use of traditional animal test methods under certain circumstances, except as specified. The bill also (1) establishes penalties; (2) requires specified reporting; and (3) requires regulations to be adopted.

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**Fiscal Summary**

**State Effect:** The bill is expected to be implemented with existing resources, as discussed below. The bill’s penalty provisions are not expected to materially affect State finances.

**Local Effect:** The bill is not expected to significantly affect local government finances.

**Small Business Effect:** Potential meaningful.

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**Analysis**

**Bill Summary:**

*Research Facilities and Testing Facilities – Requirements and Prohibitions*

“Research facility” means any facility in the State that uses animals for research, education, or experimentation. “Research facility” does not include (1) a partnership, a corporation, an association, an institution, an organization, or any other entity in the State that provides

only beneficial services to an animal, such as spaying or neutering, or (2) a school or an institution of higher education.

“Testing facility” means a public or private partnership, corporation, association, organization, or any other entity in the State – including one owned, leased, or operated by a public or private entity – that uses animals for the testing of (1) chemical substances; (2) ingredients; (3) drugs; (4) vaccines; (5) products; or (6) product formulations. “Testing facility” does not include (1) a partnership, a corporation, an association, an institution, an organization, or any other entity in the State that provides only beneficial services to an animal, such as spaying or neutering, or (2) a school or an institution of higher education.

Each research facility and testing facility must ensure that the number of dogs and cats used for research or testing purposes not otherwise prohibited under Title 15 of the Agriculture Article (Research Facilities and Testing Facilities That Use Animals), as modified by the bill, is reduced to the smallest number possible by using scientifically reliable and relevant methods that do not involve the use of dogs or cats. A research facility or testing facility may not use for research or testing purposes:

- a dog sold by a Class B dealer licensed under the federal Animal Welfare Act;
- a dog or cat obtained from a person that did not breed and raise the dog or cat, including a dog or cat obtained from an auction, a flea market, or an animal shelter; or
- a dog or cat that has undergone a devocalization surgery.

A research facility or testing facility may not perform a devocalization surgery on a dog or a cat. A dog or a cat at a research facility or testing facility may be euthanized only by a lethal injection of sodium pentobarbital administered by, or under the direct supervision of, a veterinarian licensed in the State.

A research facility or testing facility may not use a traditional animal test method if the agency responsible for regulating the specific product or activity for which a test method is being used has (1) approved an appropriate alternative test method or (2) granted the research facility or testing facility a waiver from using a traditional animal test method. If there is no alternative test method available or waiver granted, a research facility or testing facility may use a traditional animal test method if the research facility or testing facility uses the fewest number of animals possible and minimizes the level of pain, suffering, and stress of an animal used for testing.

A traditional animal test method may be used to comply with federal or State requirements if the appropriate federal or State agency has approved the use of an alternative test method but determined that the alternative test method does not ensure the health or safety of the public or the environment.

Except for biomedical research, a research facility or testing facility may not conduct a canine or feline toxicological experiment in the State for discovery, approval, maintenance of approval, notification, registration, or maintenance of a chemical substance unless the canine or feline toxicological experiment is conducted to:

- satisfy an express requirement imposed by the U.S. Environmental Protection Agency (EPA) under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act or the federal Toxic Substances Control Act;
- satisfy an express requirement imposed by the U.S. Food and Drug Administration (FDA) under the authority of the Federal Food, Drug, and Cosmetic Act if the research facility or testing facility (1) submits a pre-investigational new drug application meeting request to FDA to receive guidance on whether all proposed canine or feline toxicological experiments are necessary to support the research facility's or testing facility's planned clinical trials and (2) is not expressly directed by FDA to use an alternative test method;
- support an application to EPA for a waiver from the use of a canine or feline toxicological experiment if the experiment is conducted solely for the purpose of reducing the total number of animals needed for experiments to achieve discovery, approval, maintenance of approval, notification, registration, or maintenance of a chemical substance; or
- develop, manufacture, or market a product intended for the beneficial use of dogs or cats.

### *Reporting Requirements*

By January 31 of each year, each research facility and testing facility must submit to the Secretary of Agriculture the following information regarding the immediately preceding 12-month period: (1) the number of each species of animals owned and used by the research facility or testing facility; (2) the number of dogs or cats released to animal rescue organizations and the names of the organizations to which the dogs or cats were released; (3) the type and number of alternative test methods and traditional animal test methods used; (4) the number of traditional animal test method waivers and canine or feline toxicological experiment waivers used; and (5) the purpose of any tests conducted using alternative test methods or traditional animal test methods.

The Secretary must prepare an annual report aggregating the information submitted pursuant to the above requirement and post the annual report on the department's website.

*Adoption of Dogs or Cats No Longer Needed for Scientific Research Purposes – Applicability to Testing Facilities and Change in Definition of “Research Facilities”*

The bill makes existing provisions – requiring a research facility located in the State in which dogs or cats are used for scientific research purposes to take specified reasonable steps to provide for the adoption of a dog or cat no longer needed for scientific research purposes – applicable to testing facilities as defined under the bill. Also, while these provisions still apply to “research facilities,” that term is modified by the bill. Among other things, this means that higher education research facilities are no longer subject to these provisions.

*Penalties*

A research facility or testing facility that violates the provisions of the bill or the existing provisions relating to adoption of dogs or cats used for scientific research is subject to (1) for a first offense, a fine of up to \$1,000 and (2) for a second or subsequent offense, a fine of up to \$5,000.

*Regulations*

The Maryland Department of Agriculture (MDA) must adopt regulations to (1) carry out the bill and the existing provisions relating to adoption of dogs or cats used for scientific research and (2) ensure the humane treatment and care of dogs and cats that are used for research, education, or testing consistent with the federal Animal Welfare Act and corresponding regulations.

*Additional Definitions*

“Alternative test method” means a test method, including a new or revised method, that (1) does not use animals; (2) produces information of equivalent or better scientific quality and relevance compared to traditional animal test methods; and (3) has been identified and accepted for use by the federal agency or program within the federal agency responsible for regulating the specific product or activity for the test being conducted.

“Biomedical research” means (1) the investigation of the biological processes and causes of disease or (2) research conducted to increase fundamental scientific knowledge and expand the understanding of how processes in living organisms develop and function. The term does not include testing done to assess the safety or efficacy of (1) chemical substances; (2) ingredients; (3) drugs; (4) vaccines; (5) products; or (6) product formulations.

“Traditional animal test method” means a process, an experiment, or a procedure that (1) uses animals to obtain information on the characteristics of a chemical substance, an ingredient, a drug, a vaccine, a product formulation, or a product and (2) generates information regarding the ability of the chemical substance, ingredient, drug, vaccine, product formulation, or product to produce a specific biological effect under specified conditions.

“Chemical substance” means any organic or inorganic substance, including a drug, a pesticide, a chemical substance, and a food additive, as those terms are defined in specified federal law.

### **Current Law:**

#### *Title 15 of the Agriculture Article – Research Facilities That Use Dogs or Cats*

A research facility located in the State in which dogs or cats are used for scientific research purposes must take reasonable steps to provide for the adoption of a dog or cat that, in the determination of the research facility, is no longer needed for scientific research purposes by (1) establishing a private placement process to provide for the adoption of a dog or cat; (2) establishing a list of animal rescue organizations that are approved by the research facility and are willing to take a dog or cat from the research facility; and (3) offering the dog or cat to the animal rescue organizations identified in the list if the research facility is unable to place the dog or cat through its private placement process. “Research facility” includes (1) a higher education facility; (2) a scientific research facility; (3) a medical research facility; and (4) a product testing facility.

#### *Federal Regulation*

Under the federal Animal Welfare Act, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regulates commercial animal dealers, exhibitors (circuses, zoos, etc.), research facilities, and commercial businesses that transport animals. Research facilities that use or intend to use live animals in research, tests, or experiments must be registered with USDA and are inspected by APHIS. A facility must also appoint an Institutional Animal Care and Use Committee (IACUC) consisting of at least three members, including a veterinarian and one person who is not in any way affiliated with the facility. IACUC is responsible for, among other things, reviewing the facility’s program for humane care and use of animals and inspecting the research facility’s animal facilities.

Research facilities must submit an annual report to APHIS providing information that includes the types and numbers of animals used for teaching, testing, experiments, research, or surgery, by specified categories, and the types and numbers of animals being

bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

In addition, the Office of Laboratory Animal Welfare within the National Institutes of Health administers the Public Health Service [Policy on Humane Care and Use of Laboratory Animals](#).

**State Expenditures:** The bill is expected to be implemented with existing resources by MDA, assuming the bill’s requirements and prohibitions are enforced only on the basis of any complaints received and information reported by the facilities pursuant to the bill. MDA may also be able to coordinate with APHIS, to at least a limited extent, to enforce the bill. The federal Animal Welfare Act authorizes the U.S. Secretary of Agriculture to cooperate with State or local officials to carry out the purposes of the Act and any State or local law on the same subject.

**Small Business Effect:** To the extent any small businesses fall under the definition of “research facility” or “testing facility,” they may be meaningfully affected by costs to comply with the bill.

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### Additional Information

**Recent Prior Introductions:** Similar legislation has not been introduced within the last three years.

**Designated Cross File:** None.

**Information Source(s):** Anne Arundel, Baltimore, Cecil, and Frederick counties; Maryland Association of Counties; City of Frederick; Maryland Municipal League; University System of Maryland; Morgan State University; St. Mary’s College of Maryland; Maryland Department of Agriculture; Maryland Department of Health; Wicomico County Public Schools; National Institutes of Health; Department of Legislative Services

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Analysis by: Scott D. Kennedy

Direct Inquiries to:  
(410) 946-5510  
(301) 970-5510