

Department of Legislative Services
 Maryland General Assembly
 2024 Session

FISCAL AND POLICY NOTE
 First Reader

Senate Bill 761 (Senator Kramer, *et al.*)
 Education, Energy, and the Environment

Testing Facilities That Use Animals - Licensing and Regulation

This bill requires each “testing facility” in the State to be licensed by the Maryland Department of Agriculture (MDA) to use animals in research, education, or testing. Among other things, the bill (1) establishes the position of State Inspector of Animal Welfare (State Inspector) to inspect testing facilities; (2) prohibits the use of certain dogs or cats for research or testing purposes; (3) prohibits the use of traditional animal test methods under certain circumstances, except as specified; (4) establishes penalties for violations; (5) requires specified reporting; and (6) establishes the Animals in Research Fund, primarily funded by licensing fees that must be set to cover MDA’s implementation costs.

Fiscal Summary

State Effect: Special fund revenues and expenditures both increase by at least \$142,500 in FY 2025, reflecting licensing fees set at a level to cover MDA’s implementation costs, as discussed below. Future years reflect annualization, inflation, and minimum ongoing costs as well as ongoing licensing fee revenue. Special fund revenues may increase further from any interest earned and penalties assessed for violations.

| (in dollars) | FY 2025 | FY 2026 | FY 2027 | FY 2028 | FY 2029 |
|----------------|-----------|-----------|-----------|-----------|-----------|
| SF Revenue | \$142,500 | \$126,400 | \$132,100 | \$137,900 | \$144,000 |
| SF Expenditure | \$142,500 | \$126,400 | \$132,100 | \$137,900 | \$144,000 |
| Net Effect | \$0 | \$0 | \$0 | \$0 | \$0 |

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

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

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Licensing of Testing Facilities

Each testing facility must be licensed by MDA to use animals in research, education, or testing. The department must issue a license to a testing facility that (1) passes an inspection conducted by the State Inspector and (2) agrees to comply with the inspection and reporting requirements under the bill. MDA must charge a licensing fee to (1) a testing facility that uses vertebrates *not* covered under the federal Animal Welfare Act and (2) cover the costs of implementing the bill.

“Research facility” means any facility in the State that uses live vertebrates 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 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 institution of higher education.

State Inspector of Animal Welfare

The State Inspector must inspect (1) each testing facility applying for a license; (2) at least once every year, each testing facility that has an active license but is *not* registered by the U.S. Department of Agriculture (USDA) under the federal Animal Welfare Act; and (3) at least once every other year, each testing facility for which a license has been issued under the bill and that *is* registered by USDA under the federal Animal Welfare Act. The department may enter into an agreement with an animal welfare organization, a local animal control agency, or another similar entity to conduct the inspections.

A testing facility must notify the State Inspector within 30 days after receipt of any violation notification received for a violation under the federal Animal Welfare Act or the regulations adopted under the Act. Within 30 days of receipt of a notification, the State Inspector must inspect the testing facility that is in violation.

Testing Facilities – Requirements and Prohibitions

Each 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 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 testing facility may not perform a devocalization surgery on a dog or a cat. A dog or a cat at a 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 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 testing facility a waiver from using a traditional animal test method. If there is no alternative test method available or waiver granted, a testing facility may use a traditional animal test method if the 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 testing for biomedical research, a 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 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 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 pesticide or 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 testing facility that uses live animals for research, education, or testing must submit to the Secretary the following information regarding the immediately preceding 12-month period: (1) the number of each species of vertebrate animals owned and used by the 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.

By December 31 of each year, a school or an institution of higher education that uses animals for the same purpose as a research facility or testing facility must report to the General Assembly on the results of any inspection of the school or institution of higher education performed by the agency that regulates the use of animals by the school or institution of high education. The report must include any violations found during an inspection.

Animals in Research Fund

The stated purpose of the Animals in Research Fund, administered by MDA, is to cover the costs associated with the statutory and regulatory duties of the State Inspector, and the fund may only be used for that purpose. The fund consists of (1) licensing fees charged by MDA under the bill; (2) penalties collected under the bill; (3) money appropriated in the SB 761/ Page 4

State budget to the fund; (4) interest earnings; and (5) any other money from any other source accepted for the benefit of the fund.

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 testing facility that violates the provisions of the bill 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

MDA must adopt regulations to (1) carry out the bill 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, 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 Fiscal Effect:

Maryland Department of Agriculture

Special fund expenditures from the Animals in Research Fund increase by at least \$142,534 in fiscal 2025, which accounts for the bill’s October 1, 2024 effective date. This estimate reflects the cost of hiring one agriculture inspector to act as the State Inspector (and handle inspections and other compliance activities) and one office secretary to handle administrative work associated with licensing, reporting, and enforcement. MDA indicates that these responsibilities cannot be handled by existing staff. The estimate includes salaries, fringe benefits, one-time start-up costs (including the purchase of a vehicle), and ongoing operating expenses.

| | |
|---|------------------|
| Positions | 2.0 |
| Salaries and Fringe Benefits | \$95,522 |
| Vehicle Purchase | 32,500 |
| Operating Expenses | <u>14,512</u> |
| Minimum FY 2025 MDA Expenditures | \$142,534 |

Future year expenditures – which also reflect minimum costs – reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

MDA advises that the number of testing facilities that will need to be licensed under the bill cannot readily be determined because APHIS – and not MDA – currently oversees these facilities. To the extent the additional workload generated by the bill cannot be handled with the two additional staff estimated above, expenditures increase further.

The bill contemplates that licensing fee revenue will cover the costs MDA incurs under the bill. Specifically, the bill requires MDA to charge a licensing fee to (1) testing facilities that use vertebrates not covered under the federal Animal Welfare Act and (2) cover the costs of implementing the bill. Therefore, it is assumed that special fund revenues to the Animals in Research Fund increase correspondingly to the expenditures described above, as MDA sets licensing fees to fully cover its costs. Special fund revenues may increase further from any interest earned and any penalties assessed for violations of the bill.

However, the Department of Legislative Services notes that there are likely at least some facilities that need to be licensed but are not subject to the licensing fee. MDA estimates

that there may be between six to eight facilities subject to the licensing fee. *For illustrative purposes only*, based on that information, and the estimated costs described above, the licensing fee would need to be between about \$18,000 and \$24,000 in fiscal 2025 to cover MDA’s minimum anticipated costs in that year. Because it may be unrealistic to set a licensing fee at that level, to the extent fee revenues are not sufficient to cover MDA’s costs, general funds may be needed.

Public Institutions of Higher Education

It is assumed that the bill’s changes do not materially affect the operations or finances of public institutions of higher education.

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

Additional Information

Recent Prior Introductions: Similar legislation has been introduced within the last three years. See SB 495 of 2023.

Designated Cross File: None.

Information Source(s): Baltimore, Charles, Garrett, and Howard counties; University System of Maryland; Morgan State University; Maryland Independent College and University Association; Maryland Department of Agriculture; Maryland Department of Health; U.S. Department of Agriculture; National Institutes of Health; Department of Legislative Services

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