

Department of Legislative Services
 Maryland General Assembly
 2023 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 495 (Senator Kramer, *et al.*)
 Education, Energy, and the Environment

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

This bill requires each research facility and 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 research and testing facilities; (2) prohibits the use of certain dogs or cats for research or testing purposes; (3) requires alternative testing methods to be used under certain circumstances; (4) establishes criminal penalties for violations; (5) requires specified reporting; and (6) establishes the Animals in Research Fund, primarily funded by license fees that must be set to cover implementation costs.

Fiscal Summary

State Effect: Special fund revenues and expenditures both increase by \$456,100 in FY 2024, reflecting licensing fees set at a level to cover MDA’s implementation costs. Future years reflect annualization and inflation and ongoing licensing fee revenue. Special fund revenues may increase further due to the bill’s penalty provisions. Higher education expenditures may increase beginning in FY 2024, as discussed below.

| (in dollars) | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
|----------------|-----------|-----------|-----------|-----------|-----------|
| SF Revenue | \$456,100 | \$375,100 | \$391,400 | \$408,800 | \$430,300 |
| SF Expenditure | \$456,100 | \$375,100 | \$391,400 | \$408,800 | \$430,300 |
| Higher Ed Exp. | - | - | - | - | - |
| Net Effect | (-) | (-) | (-) | (-) | (-) |

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

Each research facility and testing facility must be licensed by MDA to use animals in research, education, or testing. The department must issue a license to a research or testing facility that (1) passes an inspection conducted by the State Inspector and (2) agrees to comply with inspection and reporting requirements. The department must charge a licensing fee to cover the costs of implementing the bill.

“Research facility” means a public or private partnership, corporation, association, school, institution, organization, or other entity in the State – including one owned, leased or operated by a public or private entity – that uses animals for (1) research, including biomedical research, or (2) education. “Research facility” does not include facilities that only provide beneficial services to animals, such as spaying and neutering.

“Testing facility” means a public or private partnership, corporation, association, school, institution, 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) medical devices; (5) vaccines; (6) products; or (7) product formulations.

State Inspector of Animal Welfare

The State Inspector must inspect (1) each research and testing facility applying for a license; (2) at least once every year, each research and testing facility with an active license; and (3) at least once every other year, each research and testing facility for which a license has been issued under the bill and that is registered by the U.S. Department of Agriculture (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 research or 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 research or testing facility that is in violation.

Research and Testing Facilities

Each research and testing facility must ensure that the number of dogs and cats used for research or testing purposes 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 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 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 testing facility must use an alternative test method instead of a traditional test method if the alternative test method has been (1) approved by the Interagency Coordinating Committee on the Validation of Alternative Methods, the Organization for Economic Co-operation and Development, or another similar validation and standard-setting organization or (2) adopted by a federal agency, or a program within a federal agency, that is responsible for regulating the specific product or activity for which the test is being conducted.

With the exception of testing for biomedical research, a testing facility may not use a traditional animal test method if (1) an appropriate alternative test method is available or (2) the appropriate federal agency has waived the requirement to use the traditional animal test method.

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.

With the exception of 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 pesticide or 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.

Adoption of Dogs or Cats No Longer Needed for Scientific Research Purposes

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 research and testing facilities as they are defined under the bill.

Penalties

An owner, operator, employee, or agent of a research or testing facility that violates the provisions of the bill is guilty of a misdemeanor and subject to (1) for a first offense, a fine of up to \$1,000 and/or imprisonment for up to 90 days and (2) for a second or subsequent offense, a fine of up to \$5,000 and/or imprisonment for up to 180 days.

Additional Definitions

“Alternative test method” means a test method that (1) produces information of equivalent or better scientific quality and relevance than information produced from test methods performed on animals and (2) does not use animals, or, for instances in which a test method that does not use animals is not available, uses the fewest number of animals possible and reduces, to the greatest extent possible, the level of suffering and stress caused to the animal being used for testing.

“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.

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

“Chemical substance” has the meaning stated in 15 United States Code § 2602, which defines chemical substance as any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.

Reporting Requirements

Each research facility conducting biomedical research must report to the State Inspector on how the animals will be used in the research and provide the State Inspector a justification for the use of the animals in the research. The justification must address (1) whether another suitable model is available, such as in vitro, nonhuman in vitro, or other models; (2) whether the research, education, or testing can be performed ethically on human subjects; and (3) whether animals are necessary to accelerate prevention, control, or treatment of potentially life-threatening or debilitating conditions.

By January 31 each year, each research facility or 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 research facility or testing facility and (2) the number of dogs or cats released to animal rescue organizations and the names of the animal rescue organizations to which the dogs or cats were released.

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 type and number of alternative test methods and traditional animal test methods used; (2) the number of traditional animal test method waivers and canine or feline toxicological experiment waivers used; and (3) 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 by research facilities and testing facilities each year and post the annual report on the department’s website.

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

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, educational, and testing purposes.

Current Law: 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.

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:

Special Fund Impact

Special fund (Animals in Research Fund) expenditures increase by \$456,116 in fiscal 2024, which accounts for the bill’s October 1, 2023 effective date. This estimate reflects the cost of MDA hiring (1) four agriculture inspectors, one to act as State Inspector and three additional inspectors to handle inspections required under the bill and other compliance efforts and (2) two office secretaries to handle administrative work associated with licensing, inspections, and reporting, and other compliance efforts. MDA indicates that these responsibilities cannot be handled by existing staff. The estimate includes salaries, fringe benefits, one-time start-up costs (including additional vehicles), and ongoing operating expenses.

| | |
|---------------------------------------|------------------|
| Positions | 6.0 |
| Salaries and Fringe Benefits | \$273,162 |
| Vehicles | 130,000 |
| Operating Expenses | <u>52,954</u> |
| Total FY 2024 MDA Expenditures | \$456,116 |

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

Special fund revenues increase correspondingly (by \$456,116 in fiscal 2024 and ongoing amounts in future years) from licensing fees MDA is required to charge to cover the costs of implementing the bill. Special fund revenues may increase further from any criminal penalties collected under the bill.

Higher Education Impact

Higher education expenditures may increase, beginning in fiscal 2024, for at least some higher education institutions, those that fall under the definition of “research facility” or “testing facility,” for costs such as the licensing fee and personnel costs to manage reporting and other administrative work associated with complying with the bill. The extent of any overall increase in higher education expenditures cannot be reliably estimated at this time.

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.

Additional Information

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

Designated Cross File: None.

Information Source(s): Maryland Municipal League; Maryland State Department of Education; University System of Maryland; Morgan State University; Maryland Independent College and University Association; Maryland Department of Agriculture; Maryland Department of the Environment; Maryland Department of Health; Department of Natural Resources; Department of Legislative Services

Fiscal Note History: First Reader - March 1, 2023
km/sdk

Analysis by: Brandon Stouffer

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