

SENATE BILL 536

M4
SB 761/24 – EEE

5lr1395

By: **Senator Kramer**

Introduced and read first time: January 23, 2025

Assigned to: Education, Energy, and the Environment

A BILL ENTITLED

1 AN ACT concerning

2 **Research Facilities and Testing Facilities That Use Animals – Regulation**

3 FOR the purpose of establishing requirements for the use and treatment of dogs or cats by
4 a research facility or testing facility; prohibiting a research facility and testing
5 facility from using certain dogs and cats for research or testing purposes and
6 performing certain procedures on dogs or cats; prohibiting a research facility and
7 testing facility from using traditional animal test methods under certain
8 circumstances; prohibiting a research facility and testing facility from conducting a
9 canine or feline toxicological experiment under certain circumstances; applying
10 certain provisions of law regarding the adoption of dogs and cats used for scientific
11 research purposes to testing facilities; and generally relating to research facilities
12 and testing facilities that use animals in research, education, or testing.

13 BY adding to

14 Article – Agriculture
15 Section 15–101 through 15–103 and 15–105 through 15–107
16 Annotated Code of Maryland
17 (2016 Replacement Volume and 2024 Supplement)

18 BY repealing and reenacting, with amendments,

19 Article – Agriculture
20 Section 15–101 to be under the amended title “Title 15. Research Facilities and
21 Testing Facilities That Use Animals”
22 Annotated Code of Maryland
23 (2016 Replacement Volume and 2024 Supplement)

24 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
25 That the Laws of Maryland read as follows:

26 **Article – Agriculture**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



Title 15. Research Facilities [that] **AND TESTING FACILITIES THAT Use [Dogs or Cats]
ANIMALS.**

15–101.

**(A) IN THIS TITLE THE FOLLOWING WORDS HAVE THE MEANINGS
INDICATED.**

**(B) (1) “ALTERNATIVE TEST METHOD” MEANS A TEST METHOD,
INCLUDING A NEW OR REVISED METHOD, THAT:**

(I) DOES NOT USE ANIMALS;

**(II) PRODUCES INFORMATION OF EQUIVALENT OR BETTER
SCIENTIFIC QUALITY AND RELEVANCE COMPARED TO TRADITIONAL ANIMAL TEST
METHODS; AND**

**(III) 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 WHICH THE TEST IS BEING
CONDUCTED.**

(2) “ALTERNATIVE TEST METHOD” INCLUDES:

(I) COMPUTATIONAL TOXICOLOGY AND BIOINFORMATICS;

(II) HIGH–THROUGHPUT SCREENING METHODS;

(III) TESTING CATEGORIES OF CHEMICAL SUBSTANCES;

(IV) TIERED TESTING METHODS;

(V) IN VITRO STUDIES; AND

(VI) SYSTEMS BIOLOGY.

(C) (1) “BIOMEDICAL RESEARCH” MEANS:

**(I) THE INVESTIGATION OF THE BIOLOGICAL PROCESSES AND
CAUSES OF DISEASE; OR**

(II) RESEARCH CONDUCTED TO INCREASE FUNDAMENTAL SCIENTIFIC KNOWLEDGE AND EXPAND THE UNDERSTANDING OF HOW PROCESSES IN LIVING ORGANISMS DEVELOP AND FUNCTION.

(2) "BIOMEDICAL RESEARCH" DOES NOT INCLUDE TESTING DONE TO ASSESS THE SAFETY OR EFFICACY OF:

(I) CHEMICAL SUBSTANCES;

(II) INGREDIENTS;

(III) DRUGS;

(IV) VACCINES;

(V) PRODUCTS; OR

(VI) PRODUCT FORMULATIONS.

(D) "CANINE OR FELINE TOXICOLOGICAL EXPERIMENT" MEANS A TEST OR STUDY USED TO DETERMINE THE EFFECT OF THE APPLICATION OR EXPOSURE, WHETHER INTERNAL OR EXTERNAL AND INCLUDING ORAL INGESTION, SKIN OR EYE CONTACT, AND INHALATION, OF ANY AMOUNT OF A CHEMICAL SUBSTANCE ON A DOG OR CAT.

(E) "CHEMICAL SUBSTANCE" MEANS ANY ORGANIC OR INORGANIC SUBSTANCE INCLUDING:

(1) A DRUG AS DEFINED IN 21 U.S.C. § 321(G);

(2) A PESTICIDE AS DEFINED IN 7 U.S.C. § 136(U);

(3) A CHEMICAL SUBSTANCE AS DEFINED IN 15 U.S.C. § 2602(2); AND

(4) A FOOD ADDITIVE AS DEFINED IN 21 U.S.C. § 321(S).

(F) (1) "RESEARCH FACILITY" MEANS ANY FACILITY IN THE STATE THAT USES ANIMALS FOR RESEARCH, EDUCATION, OR EXPERIMENTATION.

(2) "RESEARCH FACILITY" DOES NOT INCLUDE:

(I) A PARTNERSHIP, A CORPORATION, AN ASSOCIATION, AN INSTITUTION, AN ORGANIZATION, OR ANY OTHER ENTITY IN THE STATE THAT

1 PROVIDES ONLY BENEFICIAL SERVICES TO AN ANIMAL SUCH AS SPAYING AND
2 NEUTERING; OR

3 (II) A SCHOOL OR AN INSTITUTION OF HIGHER EDUCATION.

4 (G) (1) "TESTING FACILITY" MEANS A PUBLIC OR PRIVATE
5 PARTNERSHIP, CORPORATION, ASSOCIATION, ORGANIZATION, OR ANY OTHER
6 ENTITY IN THE STATE THAT USES ANIMALS FOR THE TESTING OF:

7 (I) CHEMICAL SUBSTANCES;

8 (II) INGREDIENTS;

9 (III) DRUGS;

10 (IV) VACCINES;

11 (V) PRODUCTS; OR

12 (VI) PRODUCT FORMULATIONS.

13 (2) "TESTING FACILITY" INCLUDES A PARTNERSHIP, A
14 CORPORATION, AN ASSOCIATION, AN ORGANIZATION, OR ANY OTHER ENTITY IN THE
15 STATE THAT IS OWNED, LEASED, OR OPERATED BY A PUBLIC OR PRIVATE ENTITY.

16 (3) "TESTING FACILITY" DOES NOT INCLUDE:

17 (I) A PARTNERSHIP, A CORPORATION, AN ASSOCIATION, AN
18 INSTITUTION, AN ORGANIZATION, OR ANY OTHER ENTITY IN THE STATE THAT
19 PROVIDES ONLY BENEFICIAL SERVICES TO AN ANIMAL SUCH AS SPAYING AND
20 NEUTERING; OR

21 (II) A SCHOOL OR AN INSTITUTION OF HIGHER EDUCATION.

22 (H) "TRADITIONAL ANIMAL TEST METHOD" MEANS A PROCESS, AN
23 EXPERIMENT, OR A PROCEDURE THAT:

24 (1) USES ANIMALS TO OBTAIN INFORMATION ON THE
25 CHARACTERISTICS OF A CHEMICAL SUBSTANCE, AN INGREDIENT, A DRUG, A
26 VACCINE, A PRODUCT FORMULATION, OR A PRODUCT; AND

27 (2) GENERATES INFORMATION REGARDING THE ABILITY OF THE
28 CHEMICAL SUBSTANCE, INGREDIENT, DRUG, VACCINE, PRODUCT FORMULATION, OR

PRODUCT TO PRODUCE A SPECIFIC BIOLOGICAL EFFECT UNDER SPECIFIED
CONDITIONS.

15-102.

(A) EACH RESEARCH FACILITY AND TESTING FACILITY SHALL ENSURE THAT
THE NUMBER OF DOGS AND CATS USED FOR RESEARCH OR TESTING PURPOSES NOT
OTHERWISE PROHIBITED UNDER THIS TITLE IS REDUCED TO THE SMALLEST
NUMBER POSSIBLE BY USING SCIENTIFICALLY RELIABLE AND RELEVANT METHODS
THAT DO NOT INVOLVE THE USE OF DOGS OR CATS.

(B) A RESEARCH FACILITY OR TESTING FACILITY MAY NOT USE FOR
RESEARCH OR TESTING PURPOSES:

(1) A DOG SOLD BY A CLASS B DEALER LICENSED UNDER THE
FEDERAL ANIMAL WELFARE ACT;

(2) 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

(3) A DOG OR CAT THAT HAS UNDERGONE A DEVOCALIZATION
SURGERY.

(C) A RESEARCH FACILITY OR TESTING FACILITY MAY NOT PERFORM A
DEVOCALIZATION SURGERY ON A DOG OR CAT.

(D) A DOG OR CAT AT A RESEARCH FACILITY OR TESTING FACILITY MAY BE
EUTHANIZED ONLY BY A LETHAL INJECTION OF SODIUM PENTOBARBITAL
ADMINISTERED:

(1) BY A VETERINARIAN LICENSED IN THE STATE; OR

(2) UNDER THE DIRECT SUPERVISION OF A VETERINARIAN LICENSED
IN THE STATE.

15-103.

(A) (1) SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, 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 (I) APPROVED AN ALTERNATIVE TEST METHOD; OR

2 (II) GRANTED THE RESEARCH FACILITY OR TESTING FACILITY
3 A WAIVER FROM USING A TRADITIONAL ANIMAL TEST METHOD.

4 (2) IF THERE IS NO ALTERNATIVE TEST METHOD AVAILABLE OR
5 WAIVER GRANTED, A RESEARCH FACILITY OR TESTING FACILITY MAY USE A
6 TRADITIONAL ANIMAL TEST METHOD IF THE RESEARCH FACILITY OR TESTING
7 FACILITY USES THE FEWEST NUMBER OF ANIMALS POSSIBLE AND MINIMIZES THE
8 LEVEL OF PAIN, SUFFERING, AND STRESS OF AN ANIMAL USED FOR TESTING.

9 (3) NOTHING IN THIS SUBSECTION MAY BE CONSTRUED TO PROHIBIT
10 THE USE OF A TRADITIONAL ANIMAL TEST METHOD TO COMPLY WITH FEDERAL OR
11 STATE REQUIREMENTS IF THE APPROPRIATE FEDERAL OR STATE AGENCY HAS
12 APPROVED THE USE OF AN ALTERNATIVE TEST METHOD BUT DETERMINED THAT
13 THE ALTERNATIVE TEST METHOD DOES NOT ENSURE THE HEALTH OR SAFETY OF
14 THE PUBLIC OR THE ENVIRONMENT.

15 (B) (1) THIS SUBSECTION DOES NOT APPLY TO BIOMEDICAL RESEARCH.

16 (2) A RESEARCH FACILITY OR TESTING FACILITY MAY NOT CONDUCT
17 A CANINE OR FELINE TOXICOLOGICAL EXPERIMENT IN THE STATE FOR DISCOVERY,
18 APPROVAL, MAINTENANCE OF APPROVAL, NOTIFICATION, REGISTRATION, OR
19 MAINTENANCE OF A CHEMICAL SUBSTANCE UNLESS THE CANINE OR FELINE
20 TOXICOLOGICAL EXPERIMENT IS CONDUCTED TO:

21 (I) SATISFY AN EXPRESS REQUIREMENT IMPOSED BY THE U.S.
22 ENVIRONMENTAL PROTECTION AGENCY UNDER THE AUTHORITY OF THE FEDERAL
23 INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT OR THE FEDERAL TOXIC
24 SUBSTANCES CONTROL ACT;

25 (II) SATISFY AN EXPRESS REQUIREMENT IMPOSED BY THE U.S.
26 FOOD AND DRUG ADMINISTRATION UNDER THE AUTHORITY OF THE FEDERAL
27 FOOD, DRUG, AND COSMETIC ACT IF THE RESEARCH FACILITY OR TESTING
28 FACILITY:

29 1. SUBMITS A PRE-INVESTIGATIONAL NEW DRUG
30 APPLICATION MEETING REQUEST TO THE U.S. FOOD AND DRUG ADMINISTRATION
31 TO RECEIVE GUIDANCE ON WHETHER ALL PROPOSED CANINE OR FELINE
32 TOXICOLOGICAL EXPERIMENTS ARE NECESSARY TO SUPPORT THE RESEARCH
33 FACILITY'S OR TESTING FACILITY'S PLANNED CLINICAL TRIALS; AND

1 **2. IS NOT EXPRESSLY DIRECTED BY THE U.S. FOOD AND**
2 **DRUG ADMINISTRATION TO USE AN ALTERNATIVE TEST METHOD;**

3 **(III) SUPPORT AN APPLICATION TO THE U.S. ENVIRONMENTAL**
4 **PROTECTION AGENCY FOR A WAIVER FROM THE USE OF A CANINE OR FELINE**
5 **TOXICOLOGICAL EXPERIMENT IF THE EXPERIMENT IS CONDUCTED SOLELY FOR THE**
6 **PURPOSE OF REDUCING THE TOTAL NUMBER OF ANIMALS NEEDED FOR**
7 **EXPERIMENTS TO ACHIEVE DISCOVERY, APPROVAL, MAINTENANCE OF APPROVAL,**
8 **NOTIFICATION, REGISTRATION, OR MAINTENANCE OF A CHEMICAL SUBSTANCE; OR**

9 **(IV) DEVELOP, MANUFACTURE, OR MARKET A PRODUCT**
10 **INTENDED FOR THE BENEFICIAL USE OF DOGS OR CATS.**

11 **[15–101.] 15–104.**

12 (a) (1) In this section the following words have the meanings indicated.

13 (2) “Animal rescue organization” includes:

14 (i) A nonprofit organization incorporated for the purpose of rescuing
15 animals in need and finding permanent adoptive homes for the animals; and

16 (ii) A government–operated animal control unit that provides
17 animals for adoption.

18 (3) [“Research facility” includes:

19 (i) A higher education research facility;

20 (ii) A scientific research facility;

21 (iii) A medical research facility; and

22 (iv) A product testing facility.

23 (4)] “Scientific research purposes” includes:

24 (i) Investigation;

25 (ii) Experimentation;

26 (iii) Instruction; and

27 (iv) Testing.

(b) This section applies to a dog or cat that, in the determination of an attending veterinarian, is suitable for adoption.

(c) A research facility **OR TESTING FACILITY** located in the State in which dogs or cats are used for scientific research purposes shall take reasonable steps to provide for the adoption of a dog or cat that, in the determination of the research facility **OR TESTING 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 **OR TESTING FACILITY** and are willing to take a dog or cat from the research facility **OR TESTING FACILITY**; and

(3) Offering the dog or cat to the animal rescue organizations identified in the list established under item (2) of this subsection if the research facility **OR TESTING FACILITY** is unable to place the dog or cat through its private placement process.

(d) A research facility **OR TESTING FACILITY** may enter into a collaborative agreement with an animal rescue organization for the purpose of carrying out the provisions of this section.

15-105.

(A) ON OR BEFORE JANUARY 31 EACH YEAR, EACH RESEARCH FACILITY AND TESTING FACILITY SHALL SUBMIT TO THE SECRETARY 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 UNDER § 15-104 OF THIS TITLE AND THE NAMES OF THE ANIMAL RESCUE 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.

(B) THE SECRETARY SHALL:

**(1) PREPARE AN ANNUAL REPORT AGGREGATING THE INFORMATION
SUBMITTED UNDER SUBSECTION (A) OF THIS SECTION; AND**

(2) POST THE ANNUAL REPORT ON THE DEPARTMENT'S WEBSITE.

15-106.

**A RESEARCH FACILITY OR TESTING FACILITY THAT VIOLATES THIS TITLE IS
SUBJECT TO:**

(1) FOR A FIRST OFFENSE, A FINE NOT EXCEEDING \$1,000; AND

**(2) FOR A SECOND OR SUBSEQUENT OFFENSE, A FINE NOT
EXCEEDING \$5,000.**

15-107.

THE DEPARTMENT SHALL ADOPT REGULATIONS TO:

(1) CARRY OUT THIS TITLE; 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.**

**SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
October 1, 2025.**