SENATE BILL 536

M4 SB 761/24 – EEE

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

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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 certain provisions of law regarding the adoption of dogs and cats used for scientific 10 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
- 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:

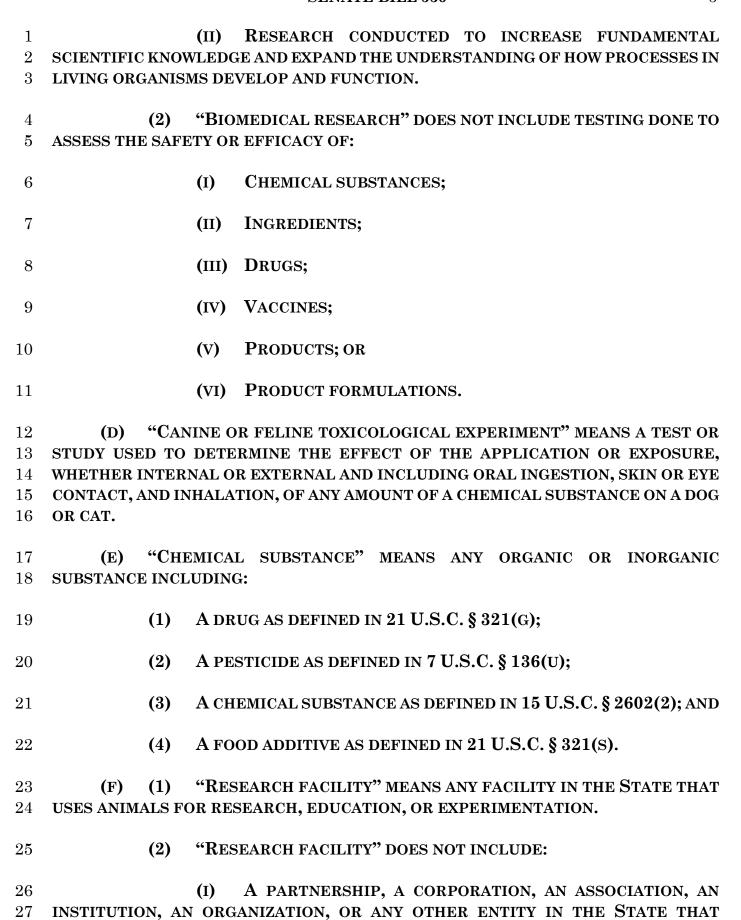
Article – Agriculture

 ${\bf EXPLANATION: Capitals\ indicate\ matter\ added\ to\ existing\ law}.$

[Brackets] indicate matter deleted from existing law.



$\frac{1}{2}$	Title 15. Research Facilities [that] AND TESTING FACILITIES THAT Use [Dogs or Cats] ANIMALS.						
3	15–101.						
4 5	(A) IN THIS TITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.						
6 7	(B) (1) "ALTERNATIVE TEST METHOD" MEANS A TEST METHOD, INCLUDING A NEW OR REVISED METHOD, THAT:						
8	(I) DOES NOT USE ANIMALS;						
9 10 11	(II) PRODUCES INFORMATION OF EQUIVALENT OR BETTER SCIENTIFIC QUALITY AND RELEVANCE COMPARED TO TRADITIONAL ANIMAL TEST METHODS; AND						
12 13 14 15							
16	(2) "ALTERNATIVE TEST METHOD" INCLUDES:						
17	(I) COMPUTATIONAL TOXICOLOGY AND BIOINFORMATICS;						
18	(II) HIGH-THROUGHPUT SCREENING METHODS;						
19	(III) TESTING CATEGORIES OF CHEMICAL SUBSTANCES;						
20	(IV) TIERED TESTING METHODS;						
21	(V) IN VITRO STUDIES; AND						
22	(VI) SYSTEMS BIOLOGY.						
23	(C) (1) "BIOMEDICAL RESEARCH" MEANS:						
2425	(I) THE INVESTIGATION OF THE BIOLOGICAL PROCESSES AND CAUSES OF DISEASE; OR						



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- PROVIDES ONLY BENEFICIAL SERVICES TO AN ANIMAL SUCH AS SPAYING AND 1 2 **NEUTERING**; OR A SCHOOL OR AN INSTITUTION OF HIGHER EDUCATION. 3 (II)"TESTING FACILITY" 4 (G) **(1)** MEANS \mathbf{A} PUBLIC OR **PRIVATE** PARTNERSHIP, CORPORATION, ASSOCIATION, ORGANIZATION, OR ANY OTHER 5 ENTITY IN THE STATE THAT USES ANIMALS FOR THE TESTING OF: 6 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, 14 CORPORATION, AN ASSOCIATION, AN ORGANIZATION, OR ANY OTHER ENTITY IN THE STATE THAT IS OWNED, LEASED, OR OPERATED BY A PUBLIC OR PRIVATE ENTITY. 15 "TESTING FACILITY" DOES NOT INCLUDE: 16 **(3)** A PARTNERSHIP, A CORPORATION, AN ASSOCIATION, AN 17 **(I)** INSTITUTION, AN ORGANIZATION, OR ANY OTHER ENTITY IN THE STATE THAT 18 PROVIDES ONLY BENEFICIAL SERVICES TO AN ANIMAL SUCH AS SPAYING AND 19 20 **NEUTERING; OR** 21A SCHOOL OR AN INSTITUTION OF HIGHER EDUCATION. (II)"TRADITIONAL ANIMAL TEST METHOD" MEANS A PROCESS, AN 2223 EXPERIMENT, OR A PROCEDURE THAT: 24 **(1) USES** \mathbf{TO} ANIMALS OBTAIN INFORMATION \mathbf{ON} THE 25CHARACTERISTICS OF A CHEMICAL SUBSTANCE, AN INGREDIENT, A DRUG, A
- 27 (2) GENERATES INFORMATION REGARDING THE ABILITY OF THE 28 CHEMICAL SUBSTANCE, INGREDIENT, DRUG, VACCINE, PRODUCT FORMULATION, OR

VACCINE, A PRODUCT FORMULATION, OR A PRODUCT; AND

- 1 PRODUCT TO PRODUCE A SPECIFIC BIOLOGICAL EFFECT UNDER SPECIFIED
- 2 CONDITIONS.
- 3 **15–102.**
- 4 (A) EACH RESEARCH FACILITY AND TESTING FACILITY SHALL ENSURE THAT
- 5 THE NUMBER OF DOGS AND CATS USED FOR RESEARCH OR TESTING PURPOSES NOT
- 6 OTHERWISE PROHIBITED UNDER THIS TITLE IS REDUCED TO THE SMALLEST
- 7 NUMBER POSSIBLE BY USING SCIENTIFICALLY RELIABLE AND RELEVANT METHODS
- 8 THAT DO NOT INVOLVE THE USE OF DOGS OR CATS.
- 9 (B) A RESEARCH FACILITY OR TESTING FACILITY MAY NOT USE FOR
- 10 RESEARCH OR TESTING PURPOSES:
- 11 (1) A DOG SOLD BY A CLASS B DEALER LICENSED UNDER THE
- 12 FEDERAL ANIMAL WELFARE ACT;
- 13 (2) A DOG OR CAT OBTAINED FROM A PERSON THAT DID NOT BREED
- 14 AND RAISE THE DOG OR CAT, INCLUDING A DOG OR CAT OBTAINED FROM AN
- 15 AUCTION, A FLEA MARKET, OR AN ANIMAL SHELTER; OR
- 16 (3) A DOG OR CAT THAT HAS UNDERGONE A DEVOCALIZATION
- 17 SURGERY.
- 18 (C) A RESEARCH FACILITY OR TESTING FACILITY MAY NOT PERFORM A
- 19 DEVOCALIZATION SURGERY ON A DOG OR CAT.
- 20 (D) A DOG OR CAT AT A RESEARCH FACILITY OR TESTING FACILITY MAY BE
- 21 EUTHANIZED ONLY BY A LETHAL INJECTION OF SODIUM PENTOBARBITAL
- 22 ADMINISTERED:
- 23 (1) By A VETERINARIAN LICENSED IN THE STATE; OR
- 24 (2) UNDER THE DIRECT SUPERVISION OF A VETERINARIAN LICENSED
- 25 IN THE STATE.
- 26 **15–103.**
- 27 (A) (1) SUBJECT TO PARAGRAPH (3) OF THIS SUBSECTION, A RESEARCH
- 28 FACILITY OR TESTING FACILITY MAY NOT USE A TRADITIONAL ANIMAL TEST
- 29 METHOD IF THE AGENCY RESPONSIBLE FOR REGULATING THE SPECIFIC PRODUCT
- 30 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	2. IS NOT EXPRESSLY DIRECTED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO USE AN ALTERNATIVE TEST METHOD;				
3 4 5 6 7 8	TOXICOLOGIC PURPOSE O EXPERIMENT	CALI F R TS TO	ENCY EXPEREDUC ACH	SUPPORT AN APPLICATION TO THE U.S. ENVIRONMENTAL FOR A WAIVER FROM THE USE OF A CANINE OR FELINE RIMENT IF THE EXPERIMENT IS CONDUCTED SOLELY FOR THE ING THE TOTAL NUMBER OF ANIMALS NEEDED FOR IEVE DISCOVERY, APPROVAL, MAINTENANCE OF APPROVAL, PRATION, OR MAINTENANCE OF A CHEMICAL SUBSTANCE; OR	
9 10	INTENDED FO	OR TI	(IV) HE BE	DEVELOP, MANUFACTURE, OR MARKET A PRODUCT NEFICIAL USE OF DOGS OR CATS.	
11	[15–101.] 15–104.				
12	(a) (1)	In thi	s section the following words have the meanings indicated.	
13	(2)	"Anin	nal rescue organization" includes:	
14 15	animals in ne	ed an	(i) d find	A nonprofit organization incorporated for the purpose of rescuing ing permanent adoptive homes for the animals; and	
16 17	animals for ac	doptio	(ii) on.	A government-operated animal control unit that provides	
18	(3)	["Res	earch 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)]	"Scien	ntific research purposes" includes:	
24			(i)	Investigation;	
25			(ii)	Experimentation;	
26			(iii)	Instruction; and	
27			(iv)	Testing.	

- 1 (b) This section applies to a dog or cat that, in the determination of an attending 2 veterinarian, is suitable for adoption.
- 3 (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
- 5 the adoption of a dog or cat that, in the determination of the research facility **OR TESTING**
- 6 FACILITY, is no longer needed for scientific research purposes by:
- 7 (1) Establishing a private placement process to provide for the adoption of 8 a dog or cat;
- 9 (2) Establishing a list of animal rescue organizations that are approved by 10 the research facility **OR TESTING FACILITY** and are willing to take a dog or cat from the 11 research facility **OR TESTING FACILITY**; and
- 12 (3) Offering the dog or cat to the animal rescue organizations identified in 13 the list established under item (2) of this subsection if the research facility **OR TESTING** 14 **FACILITY** is unable to place the dog or cat through its private placement process.
- 15 (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.
- 18 **15–105.**
- 19 (A) ON OR BEFORE JANUARY 31 EACH YEAR, EACH RESEARCH FACILITY 20 AND TESTING FACILITY SHALL SUBMIT TO THE SECRETARY THE FOLLOWING 21 INFORMATION REGARDING THE IMMEDIATELY PRECEDING 12-MONTH PERIOD:
- 22 (1) THE NUMBER OF EACH SPECIES OF ANIMALS OWNED AND USED BY 23 THE RESEARCH FACILITY OR TESTING FACILITY;
- 24 (2) THE NUMBER OF DOGS OR CATS RELEASED TO ANIMAL RESCUE 25 ORGANIZATIONS UNDER § 15–104 OF THIS TITLE AND THE NAMES OF THE ANIMAL 26 RESCUE ORGANIZATIONS TO WHICH THE DOGS OR CATS WERE RELEASED;
- 27 (3) THE TYPE AND NUMBER OF ALTERNATIVE TEST METHODS AND TRADITIONAL ANIMAL TEST METHODS USED;
- 29 (4) THE NUMBER OF TRADITIONAL ANIMAL TEST METHOD WAIVERS 30 AND CANINE OR FELINE TOXICOLOGICAL EXPERIMENT WAIVERS USED; AND
- 31 (5) THE PURPOSE OF ANY TESTS CONDUCTED USING ALTERNATIVE 32 TEST METHODS OR TRADITIONAL ANIMAL TEST METHODS.

- 1 (B) THE SECRETARY SHALL:
- 2 (1) PREPARE AN ANNUAL REPORT AGGREGATING THE INFORMATION
- 3 SUBMITTED UNDER SUBSECTION (A) OF THIS SECTION; AND
- 4 (2) POST THE ANNUAL REPORT ON THE DEPARTMENT'S WEBSITE.
- 5 **15–106.**
- A RESEARCH FACILITY OR TESTING FACILITY THAT VIOLATES THIS TITLE IS SUBJECT TO:
- 8 (1) FOR A FIRST OFFENSE, A FINE NOT EXCEEDING \$1,000; AND
- 9 (2) FOR A SECOND OR SUBSEQUENT OFFENSE, A FINE NOT 10 EXCEEDING \$5,000.
- 11 **15–107.**
- 12 THE DEPARTMENT SHALL ADOPT REGULATIONS TO:
- 13 (1) CARRY OUT THIS TITLE; AND
- 14 (2) Ensure the humane treatment and care of dogs and cats
- 15 THAT ARE USED FOR RESEARCH, EDUCATION, OR TESTING CONSISTENT WITH THE
- 16 FEDERAL ANIMAL WELFARE ACT AND CORRESPONDING REGULATIONS.
- 17 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
- 18 October 1, 2025.