

116TH CONGRESS
1ST SESSION

S. _____

To prohibit the use of animal testing for cosmetics and the sale of cosmetics tested on animals.

IN THE SENATE OF THE UNITED STATES

Ms. MCSALLY (for herself, Mr. BOOKER, Mr. PORTMAN, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To prohibit the use of animal testing for cosmetics and the sale of cosmetics tested on animals.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Humane Cosmetics
5 Act of 2019”.

6 **SEC. 2. ANIMAL TESTING.**

7 (a) PROHIBITION ON ANIMAL TESTING.—Beginning
8 1 year after the date of enactment of this Act, it shall
9 be unlawful for any person, whether private or govern-

1 mental, to knowingly conduct or contract for cosmetic ani-
2 mal testing that occurs in the United States.

3 (b) PROHIBITION ON SALE OR TRANSPORT.—It shall
4 be unlawful to sell, offer for sale, or knowingly transport
5 in interstate commerce in the United States any cosmetic
6 that was developed or manufactured using cosmetic ani-
7 mal testing that was conducted or contracted for by any
8 person in the cosmetic product’s supply chain after the
9 date that is 1 year after the date of enactment of this
10 Act.

11 (c) DATA USE.—

12 (1) IN GENERAL.—No evidence derived from
13 animal testing conducted after the effective date
14 specified in subsection (a) may be relied upon to es-
15 tablish the safety of a cosmetic, cosmetic ingredient,
16 or non-functional constituent under the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
18 seq.), unless—

19 (A) in the case of such testing on an ingre-
20 dient or non-functional constituent, there is no
21 non-animal alternative method or strategy rec-
22 ognized by any Federal agency or the
23 Organisation for Economic Co-operation and
24 Development for the relevant safety endpoints

1 for such ingredient or non-functional con-
2 stituent; and

3 (B)(i) such animal testing is subject to an
4 exemption under paragraph (2) or (3) of sub-
5 section (d); or

6 (ii)(I) such animal testing is subject to an
7 exemption under paragraph (4) of subsection
8 (d);

9 (II) there is documented evidence of the
10 non-cosmetic intent of the test; and

11 (III) there is a history of use of the ingre-
12 dient outside of cosmetics at least 1 year prior
13 to the reliance on such data.

14 (2) LIMITATION.—This section shall not be con-
15 strued to prohibit any entity from reviewing, assess-
16 ing, or retaining evidence generated from animal
17 testing.

18 (d) EXEMPTIONS.—Subsections (a) and (b) shall not
19 apply with respect to animal testing—

20 (1) conducted outside the United States in
21 order to comply with a requirement from a foreign
22 regulatory authority;

23 (2) requested, required, or conducted by the
24 Secretary, following—

1 (A) a written finding by the Secretary
2 that—

3 (i) there is no non-animal alternative
4 method or strategy recognized by any Fed-
5 eral agency or the Organisation for Eco-
6 nomic Co-operation and Development for
7 the relevant safety endpoints for the cos-
8 metic ingredient or non-functional con-
9 stituent;

10 (ii) the cosmetic ingredient or non-
11 functional constituent poses a risk of caus-
12 ing serious adverse health consequences or
13 death; and

14 (iii) the cosmetic ingredient or non-
15 functional constituent is in wide use and,
16 in the case of a cosmetic ingredient, cannot
17 be replaced by another cosmetic ingredient
18 capable of performing a similar function;

19 (B) publication by the Secretary of the
20 written finding required by subparagraph (A)
21 on the internet website of the Food and Drug
22 Administration together with a notice that the
23 Secretary intends to request, require, or con-
24 duct new animal testing, and provides a period

1 of not less than 60 calendar days for public
2 comment; and

3 (C) a written determination by the Sec-
4 retary, after review of all public comments re-
5 ceived pursuant to subparagraph (B), that no
6 previously generated data that could be sub-
7 stituted for, or otherwise determined sufficient
8 to replace, the data expected to be produced
9 through new animal testing is available for re-
10 view by the Secretary;

11 (3) conducted for any product or ingredient
12 that is subject to regulation under chapter V of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 351 et seq.); or

15 (4) conducted for non-cosmetic purposes pursu-
16 ant to a requirement of a Federal, State, or foreign
17 regulatory authority.

18 (e) **RULE OF CONSTRUCTION.**—With the exception of
19 records or other information demonstrating compliance
20 with subsection (c)(1)(B)(ii), nothing in this section shall
21 be construed to authorize the Secretary to impose any new
22 recordkeeping requirements relating to cosmetic animal
23 testing.

24 (f) **CIVIL PENALTIES.**—

1 (1) IN GENERAL.—In addition to any other
2 penalties applicable under law, the Secretary shall
3 assess whoever violates any provision of this section
4 a civil penalty of not more than \$10,000 for each
5 such violation.

6 (2) MULTIPLE VIOLATIONS.—Each violation of
7 this section with respect to a separate animal, and
8 each day that a violation of this Act continues, con-
9 stitutes a separate offense.

10 (g) RECORDS ACCESS.—

11 (1) IN GENERAL.—The Secretary may request
12 any records or other information from a cosmetic
13 manufacturer that such manufacturer relied upon to
14 meet the criteria in subsection (c)(1)(B)(ii). Such
15 manufacturer shall, upon such request of the Sec-
16 retary in writing, provide to the Secretary such
17 records or other information, within a reasonable
18 timeframe, within reasonable limits, and in a reason-
19 able manner, and in either electronic or physical
20 form, at the expense of such manufacturer. The Sec-
21 retary's request shall include a sufficient description
22 of the records requested and reference this sub-
23 section.

24 (2) CONFIRMATION OF RECEIPT.—Upon receipt
25 of the records requested under paragraph (1), the

1 Secretary shall provide to the manufacturer con-
2 firmation of receipt.

3 (3) INSPECTION AUTHORITY.—Nothing in this
4 subsection supplants the authority of the Secretary
5 to conduct inspections otherwise permitted under the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 301 et seq.).

8 (h) STATE AUTHORITY.—No State or political sub-
9 division of a State may establish or continue in effect any
10 prohibition relating to cosmetic animal testing, or to the
11 regulation of data use, labeling, and packaging related to
12 animal testing, that is not identical to the prohibitions set
13 forth in subsections (a), (b), (c), and (k) and that does
14 not include the exemptions contained in subsections (c),
15 (d), and (k). No State or political subdivision of a State
16 may require any entity to perform cosmetic animal testing
17 that is not permitted by subsection (a).

18 (i) FDA STRATEGIC PLAN FOR NON-ANIMAL TEST
19 METHODS.—

20 (1) SCIENTIFIC INNOVATION.—To promote the
21 development and provide for expedited review and
22 acceptance of new scientifically valid test methods
23 and strategies that are not based on vertebrate ani-
24 mals, the Secretary shall—

1 (A) not later than 1 year after the date of
2 enactment of this Act, develop and publish on
3 the internet website of the Food and Drug Ad-
4 ministration a strategic plan to promote the de-
5 velopment and implementation of alternative
6 test methods and strategies to replace
7 vertebrate animal testing for assessing the safe-
8 ty of cosmetics;

9 (B) provide a period of not less than 60
10 calendar days for public comment regarding
11 such strategic plan;

12 (C) include in the strategic plan developed
13 under subparagraph (A) a list, which the Sec-
14 retary shall update on a regular basis, of sci-
15 entifically reliable and relevant non-animal test
16 methodology as alternatives to animal testing
17 that have been recognized by any Federal agen-
18 cy or an international regulatory agency, which
19 also includes next generation risk assessment
20 methods, and a list of examples of alternative
21 methods and strategies that have been accepted
22 by the Secretary (such lists shall be for infor-
23 mation purposes and shall not be deemed to
24 constitute a list of the only acceptable non-ani-
25 mal test methods); and

1 (D) to the maximum extent practicable
2 with available resources, prioritize and carry
3 out performance assessment, validation, and
4 translational studies to accelerate the develop-
5 ment of scientifically valid test methods and
6 strategies that replace the use of vertebrate ani-
7 mals.

8 (2) PUBLIC MEETINGS.—

9 (A) INITIAL MEETING.—No later than 90
10 days after the date of enactment of this Act,
11 the Secretary shall convene a public meeting re-
12 garding the strategic plan described in para-
13 graph (1)(A).

14 (B) SUBSEQUENT ANNUAL MEETINGS.—
15 No later than 1 year after the date of the pub-
16 lic meeting under subparagraph (A), and annu-
17 ally thereafter, the Secretary shall convene a
18 public meeting to inform the Secretary's ad-
19 vancement of alternative test methods and
20 strategies to replace vertebrate animal testing
21 for assessing the safety of cosmetics. The Sec-
22 retary shall include in such meetings scientific
23 and academic experts, animal and consumer ad-
24 vocacy groups, and the regulated industry.

1 (3) RULE OF CONSTRUCTION.—Nothing in this
2 subsection shall be construed to limit the authority
3 of the Secretary to address other tools to promote
4 the development and implementation of alternative
5 test methods and strategies to replace vertebrate
6 animal testing for assessing the safety of cosmetics
7 as part of the strategic plan described in paragraph
8 (1)(A).

9 (j) DEFINITIONS.—

10 (1) COSMETIC.—The term “cosmetic” has the
11 meaning given such term in section 201(i) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 321(i)).

14 (2) COSMETIC ANIMAL TESTING.—The term
15 “cosmetic animal testing” means the internal or ex-
16 ternal application or exposure of any cosmetic prod-
17 uct, or any cosmetic ingredient or non-functional
18 constituent, to the skin, eyes, or other body part
19 (organ or extremity) of a live non-human vertebrate
20 for the purpose of evaluating the safety or efficacy
21 of a cosmetic product or a cosmetic ingredient or
22 non-functional constituent for use in a cosmetic
23 product.

1 (3) LABEL.—The term “label” has the meaning
2 given such term in section 201(k) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 321(k)).

4 (4) NON-FUNCTIONAL CONSTITUENT.—The
5 term “non-functional constituent” means any inci-
6 dental ingredient as defined in section 701.3(1) of
7 title 21, Code of Federal Regulations, on the date of
8 enactment of this section.

9 (5) SECRETARY.—The term “Secretary” means
10 the Secretary of Health and Human Services.

11 (k) CONSUMER INFORMATION RELATED TO ANIMAL
12 TESTING.—

13 (1) IN GENERAL.—A cosmetic product manu-
14 facturer shall not include on the label of a cosmetic
15 product or any of the product’s containers or wrap-
16 pers a claim that such cosmetic product was not
17 tested on animals, including any claim or logo of
18 “cruelty free” if—

19 (A) such cosmetic product or any ingre-
20 dient or non-functional constituent contained in
21 such cosmetic product was tested on an animal
22 after the effective date specified in subsection
23 (a); and

24 (B)(i) the testing was conducted by or con-
25 tracted for by the cosmetic product manufac-

1 turer or another person in the supply chain at
2 the direction or request of the cosmetic product
3 manufacturer; or

4 (ii) the cosmetic product manufacturer re-
5 lied upon evidence from such testing, pursuant
6 to subsection (c)(1)(B)(ii), to establish the safe-
7 ty of such product, ingredient, or nonfunctional
8 constituent under chapter VI of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 361
10 et seq.).

11 (2) EXCEPTIONS.—Notwithstanding paragraph
12 (1), a cosmetic product manufacturer may include a
13 claim described in such paragraph on the label of a
14 cosmetic product described in such paragraph or any
15 of the product’s containers or wrappers if—

16 (A) such testing qualifies for the exemp-
17 tion under subsection (d)(4); and

18 (B)(i) in the case of animal testing con-
19 ducted by or contracted for by the cosmetic
20 product manufacturer or another person in the
21 supply chain at the direction or request of the
22 cosmetic product manufacturer, the cosmetic
23 manufacturer did not rely upon evidence from
24 such testing for the purpose of establishing the
25 safety of the product, ingredient, or nonfunc-

1 tional constituent under chapter VI of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 361 et seq.); or

4 (ii) in the case of animal testing conducted
5 by or contracted for by a person that is not de-
6 scribed in clause (i), evidence from which the
7 cosmetic product manufacturer relied upon,
8 pursuant to subsection (c)(1)(B)(ii), to estab-
9 lish the safety of such product, ingredient, or
10 nonfunctional constituent under chapter VI of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 361 et seq.), the cosmetic product man-
13 ufacturer includes on the label a disclosure de-
14 scribing the circumstances surrounding the use
15 of the exemption under subsection (c)(1)(B)(ii)
16 by such manufacturer that includes a reference
17 to the specific Federal, State, or foreign re-
18 quirement under which the animal testing was
19 conducted or a reference to a publicly available
20 internet website of such manufacturer that pro-
21 vides such disclosure.

22 (l) REPORT.—Beginning 2 years after the date of en-
23 actment of this Act, the Secretary shall biennially submit
24 to the Committee on Health, Education, Labor, and Pen-
25 sions of the Senate and the Committee on Energy and

1 Commerce of the House of Representatives, and make
2 available on the internet website of the Food and Drug
3 Administration, a report that includes, with respect to the
4 previous 2 fiscal years—

5 (1) updates on the Secretary’s implementation
6 of this section, including developments implementing
7 the strategic plan under subsection (i)(1)(A);

8 (2) the number of times the Secretary re-
9 quested animal test data as set forth in subsection
10 (d)(2), the ingredients involved, and the animal tests
11 performed; and

12 (3) based on the data reviewed by the Secretary
13 under subsection (g)(1), the number of times manu-
14 facturers relied upon data pursuant to the exemp-
15 tion under subsection (d)(4) to establish the safety
16 of a cosmetic under chapter VI of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.).