

117TH CONGRESS
1ST SESSION

S. 3357

To substantially restrict the use of animal testing for cosmetics.

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2021

Mr. BOOKER (for himself, Mr. PORTMAN, Mr. HICKENLOOPER, Ms. COLLINS, and Ms. ROSEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To substantially restrict the use of animal testing for cosmetics.

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 2021”.

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

7 (a) PROHIBITION ON ANIMAL TESTING.—Beginning
8 on the date that is 1 year after the date of enactment
9 of this Act, it shall be unlawful for any person, whether
10 private or governmental, to knowingly conduct or contract

1 for cosmetic animal testing that occurs in the United
2 States.

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

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 nonfunctional 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 nonfunctional constituent, there is no
21 non-animal alternative method or strategy rec-
22 ognized by any Federal agency, the Interagency
23 Coordinating Committee on the Validation of
24 Alternative Methods, or the Organisation for
25 Economic Co-operation and Development for

1 the relevant safety endpoints for such ingre-
2 dient or nonfunctional constituent; 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, the Interagency Coordinating
6 Committee on the Validation of Alternative
7 Methods, or the Organisation for Economic
8 Co-operation and Development for the rel-
9 evant safety endpoints for the cosmetic in-
10 gredient or nonfunctional constituent;

11 (ii) there is a reasonable probability
12 that the ingredient or nonfunctional con-
13 stituent poses a specific and serious ad-
14 verse human health risk and the need to
15 conduct an animal test is justified and
16 supported by a detailed research protocol
17 that is proposed for the basis for evalua-
18 tion of the cosmetic ingredient or nonfunc-
19 tional constituent; and

20 (iii) the cosmetic ingredient or non-
21 functional constituent is in wide use and,
22 in the case of a cosmetic ingredient, cannot
23 be replaced by another cosmetic ingredient
24 capable of performing a similar function;

1 (B) publication by the Secretary, on the
2 website of the Food and Drug Administration,
3 of the written finding under subparagraph (A)
4 together with a notice that the Secretary in-
5 tends to request, require, or conduct new ani-
6 mal testing, and providing a period of not less
7 than 60 calendar days for public comment; and

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

16 (3) conducted for any product or ingredient
17 that is subject to regulation under chapter V of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 351 et seq.); or

20 (4) conducted for non-cosmetic purposes pursu-
21 ant to a requirement of a Federal, State, or foreign
22 regulatory authority.

23 (e) RULE OF CONSTRUCTION.—With the exception of
24 records or other information demonstrating compliance
25 with subsection (c)(1)(B)(ii), nothing in this section shall

1 be construed to authorize the Secretary to impose any new
2 recordkeeping requirements relating to cosmetic animal
3 testing.

4 (f) CIVIL PENALTIES.—

5 (1) IN GENERAL.—In addition to any other
6 penalties under applicable law, any person who vio-
7 lates this section may be subject to a civil penalty
8 in an amount of not more than \$10,000 for each
9 such violation, as determined by the Secretary.

10 (2) MULTIPLE VIOLATIONS.—Each violation of
11 this section with respect to a separate animal, and
12 each day that a violation of this Act continues, con-
13 stitutes a separate offense.

14 (g) RECORDS ACCESS.—

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

1 of the records requested and reference this sub-
2 section.

3 (2) CONFIRMATION OF RECEIPT.—Upon receipt
4 of the records requested under paragraph (1), the
5 Secretary shall provide to the manufacturer con-
6 firmation of receipt.

7 (3) INSPECTION AUTHORITY.—Nothing in this
8 subsection supplants the authority of the Secretary
9 to conduct inspections otherwise permitted under the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 301 et seq.).

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

22 (i) FDA STRATEGIC PLAN FOR NON-ANIMAL TEST
23 METHODS.—

24 (1) SCIENTIFIC INNOVATION.—To promote the
25 development of, and provide for expedited review and

1 acceptance of, new scientifically valid test methods
2 and strategies that are not based on vertebrate ani-
3 mals, the Secretary shall—

4 (A) not later than 1 year after the date of
5 enactment of this Act, develop and publish on
6 the website of the Food and Drug Administra-
7 tion a strategic plan to promote the develop-
8 ment and implementation of alternative test
9 methods and strategies to replace vertebrate
10 animal testing for assessing the safety of cos-
11 metics;

12 (B) provide a period of not less than 60
13 calendar days for public comment regarding
14 such strategic plan;

15 (C) include in the strategic plan developed
16 under subparagraph (A) a list (which the Sec-
17 retary shall update on a regular basis, and
18 which shall be for informational purposes and
19 shall not be deemed to constitute a list of the
20 only acceptable non-animal test methods) of—

21 (i) scientifically reliable and relevant
22 non-animal test methodology as alter-
23 natives to animal testing that have been
24 recognized by any Federal agency or an
25 international regulatory agency;

1 (ii) next generation risk assessment
2 methods; and

3 (iii) examples of alternative methods
4 and strategies that have been accepted by
5 the Secretary; and

6 (D) to the maximum extent practicable
7 given available resources, prioritize and carry
8 out performance assessment, validation, and
9 translational studies to accelerate the develop-
10 ment of scientifically valid test methods and
11 strategies that replace the use of vertebrate ani-
12 mals.

13 (2) PUBLIC MEETINGS.—

14 (A) INITIAL MEETING.—Not later than 90
15 days after the date of enactment of this Act,
16 the Secretary shall convene a public meeting re-
17 garding the strategic plan described in para-
18 graph (1)(A).

19 (B) SUBSEQUENT ANNUAL MEETINGS.—
20 Not later than 1 year after the date of the pub-
21 lic meeting under subparagraph (A), and annu-
22 ally thereafter, the Secretary shall convene a
23 separate public meeting or add as an agenda
24 item to an already existing meeting, in-person
25 or virtually, to inform the Secretary's advance-

1 ment of alternative test methods and strategies
2 to replace vertebrate animal testing for assess-
3 ing the safety of cosmetics. The Secretary shall
4 include in such meetings scientific and aca-
5 demic experts, animal and consumer advocacy
6 groups, and the regulated industry.

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

15 (j) CONSUMER INFORMATION RELATED TO ANIMAL
16 TESTING.—

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

23 (A) such cosmetic product or any ingre-
24 dient or nonfunctional constituent contained in
25 such cosmetic product was tested on an animal

1 after the effective date specified in subsection
2 (a); and

3 (B)(i) the testing was conducted by or con-
4 tracted for by the cosmetic product manufac-
5 turer or another person in the supply chain at
6 the direction or request of the cosmetic product
7 manufacturer; or

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

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

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

22 (B)(i) in the case of animal testing con-
23 ducted by or contracted for by the cosmetic
24 product manufacturer or another person in the
25 supply chain at the direction or request of the

1 cosmetic product manufacturer, the cosmetic
2 manufacturer did not rely upon evidence from
3 such testing for the purpose of establishing the
4 safety of the product, ingredient, or nonfunc-
5 tional constituent under chapter VI of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
7 361 et seq.); or

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

1 (k) REPORT.—Beginning 2 years after the date of en-
 2 actment of this Act, the Secretary shall biennially submit
 3 to the Committee on Health, Education, Labor, and Pen-
 4 sions of the Senate and the Committee on Energy and
 5 Commerce of the House of Representatives, and make
 6 available on the website of the Food and Drug Administra-
 7 tion, a report that includes, with respect to the previous
 8 2 fiscal years—

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

12 (2) the number of times the Secretary re-
 13 quested animal test data under subsection (d)(2),
 14 the ingredients involved, and the animal tests per-
 15 formed; and

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

22 (l) DEFINITIONS.—

23 (1) COSMETIC.—The term “cosmetic” has the
 24 meaning given such term in section 201(i) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 321(i)).

3 (2) COSMETIC ANIMAL TESTING.—The term
4 “cosmetic animal testing” means the internal or ex-
5 ternal application or exposure of any cosmetic prod-
6 uct, or any cosmetic ingredient or nonfunctional con-
7 stituent, to the skin, eyes, or other body part (organ
8 or extremity) of a live non-human vertebrate for the
9 purpose of evaluating the safety or efficacy of a cos-
10 metic product or a cosmetic ingredient or nonfunc-
11 tional constituent for use in a cosmetic product.

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

15 (4) NONFUNCTIONAL CONSTITUENT.—The term
16 “nonfunctional constituent” means any incidental in-
17 gredient as defined in section 701.3(l) of title 21,
18 Code of Federal Regulations, on the date of enact-
19 ment of this section.

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

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