

117TH CONGRESS
1ST SESSION

H. R. 6207

To substantially restrict the use of animal testing for cosmetics.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2021

Mr. BEYER (for himself, Mr. BUCHANAN, Mr. CÁRDENAS, Mr. CALVERT, Mr. TONKO, Mr. RUPPERSBERGER, Mr. LOWENTHAL, Mr. MALINOWSKI, Mr. QUIGLEY, Ms. CLARKE of New York, Mr. COURTNEY, Ms. TITUS, Ms. SCANLON, Ms. KAPTUR, Mr. GRIJALVA, Mr. CONNOLLY, Mr. MICHAEL F. DOYLE of Pennsylvania, Mr. GARAMENDI, Mrs. NAPOLITANO, Mr. KILMER, Mr. JOHNSON of Georgia, Mrs. MCBATH, Mr. CARBAJAL, Mrs. AXNE, Mr. LANGEVIN, Mr. BRENDAN F. BOYLE of Pennsylvania, Ms. BROWNLEY, Ms. SHERRILL, Mr. KRISHNAMOORTHY, Ms. LEE of California, Mr. FOSTER, Mrs. CAROLYN B. MALONEY of New York, Mr. POCAN, Mr. DEFazio, Ms. ROYBAL-ALLARD, Ms. BONAMICI, Ms. DELBENE, Ms. NORTON, Mrs. MURPHY of Florida, Mr. WALTZ, Ms. STEVENS, Mr. SARBANES, Mrs. WATSON COLEMAN, Ms. ADAMS, Ms. HOULAHAN, Mr. BLUMENAUER, Mr. FITZPATRICK, Mr. SCHWEIKERT, Mr. KHANNA, Mr. TAKANO, Mr. LYNCH, Mr. COOPER, Ms. LOIS FRANKEL of Florida, Mr. PRICE of North Carolina, Mr. KATKO, Mr. ALLRED, Mr. SOTO, Mr. LIEU, Ms. JAYAPAL, Mr. CICILLINE, Ms. MCCOLLUM, Ms. SÁNCHEZ, Mr. LARSON of Connecticut, Ms. BLUNT ROCHESTER, Mr. NADLER, Ms. UNDERWOOD, Miss RICE of New York, Mr. LAMB, Mr. NEGUSE, Ms. CHU, Ms. MALLIOTAKIS, Mrs. LURIA, Ms. DAVIDS of Kansas, Ms. LOFGREN, and Mrs. TRAHAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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
11 for cosmetic animal testing that occurs in the United
12 States.

13 (b) PROHIBITION ON SALE OR TRANSPORT.—Begin-
14 ning on the date that is 1 year after the date of enactment
15 of this Act, it shall be unlawful to sell, offer for sale, or
16 knowingly transport in interstate commerce in the United
17 States any cosmetic product that was developed or manu-
18 factured using cosmetic animal testing that was conducted
19 or contracted for by any person in the cosmetic product’s
20 supply chain after such date.

21 (c) DATA USE.—

22 (1) IN GENERAL.—No evidence derived from
23 animal testing conducted after the effective date
24 specified in subsection (a) may be relied upon to es-
25 tablish the safety of a cosmetic, cosmetic ingredient,

1 or nonfunctional constituent under the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
3 seq.), unless—

4 (A) in the case of such testing on an ingre-
5 dient or nonfunctional constituent, there is no
6 non-animal alternative method or strategy rec-
7 ognized by any Federal agency, the Interagency
8 Coordinating Committee on the Validation of
9 Alternative Methods, or the Organisation for
10 Economic Co-operation and Development for
11 the relevant safety endpoints for such ingre-
12 dient or nonfunctional constituent; and

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

16 (ii)(I) such animal testing is subject to an
17 exemption under paragraph (4) of subsection
18 (d);

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

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

24 (2) LIMITATION.—This section shall not be con-
25 strued to prohibit any entity from reviewing, assess-

1 ing, or retaining evidence generated from animal
2 testing.

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

5 (1) conducted outside the United States in
6 order to comply with a requirement from a foreign
7 regulatory authority;

8 (2) requested, required, or conducted by the
9 Secretary, following—

10 (A) a written finding by the Secretary
11 that—

12 (i) there is no non-animal alternative
13 method or strategy recognized by any Fed-
14 eral agency, the Interagency Coordinating
15 Committee on the Validation of Alternative
16 Methods, or the Organisation for Economic
17 Co-operation and Development for the rel-
18 evant safety endpoints for the cosmetic in-
19 gredient or nonfunctional constituent;

20 (ii) there is a reasonable probability
21 that the ingredient or nonfunctional con-
22 stituent poses a specific and serious ad-
23 verse human health risk and the need to
24 conduct an animal test is justified and
25 supported by a detailed research protocol

1 that is proposed for the basis for evalua-
2 tion of the cosmetic ingredient or nonfunc-
3 tional constituent; and

4 (iii) the cosmetic ingredient or non-
5 functional constituent is in wide use and,
6 in the case of a cosmetic ingredient, cannot
7 be replaced by another cosmetic ingredient
8 capable of performing a similar function;

9 (B) publication by the Secretary, on the
10 website of the Food and Drug Administration,
11 of the written finding under subparagraph (A)
12 together with a notice that the Secretary in-
13 tends to request, require, or conduct new ani-
14 mal testing, and providing a period of not less
15 than 60 calendar days for public comment; and

16 (C) a written determination by the Sec-
17 retary, after review of all public comments re-
18 ceived pursuant to subparagraph (B), that no
19 previously generated data that could be sub-
20 stituted for, or otherwise determined sufficient
21 to replace, the data expected to be produced
22 through new animal testing is available for re-
23 view by the Secretary;

24 (3) conducted for any product or ingredient
25 that is subject to regulation under chapter V of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 351 et seq.); or

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

6 (e) RULE OF CONSTRUCTION.—With the exception of
7 records or other information demonstrating compliance
8 with subsection (c)(1)(B)(ii), nothing in this section shall
9 be construed to authorize the Secretary to impose any new
10 recordkeeping requirements relating to cosmetic animal
11 testing.

12 (f) CIVIL PENALTIES.—

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

18 (2) MULTIPLE VIOLATIONS.—Each violation of
19 this section with respect to a separate animal, and
20 each day that a violation of this Act continues, con-
21 stitutes a separate offense.

22 (g) RECORDS ACCESS.—

23 (1) IN GENERAL.—The Secretary may request
24 any records or other information from a cosmetic
25 manufacturer that such manufacturer relied upon to

1 meet the criteria in subsection (c)(1)(B)(ii). Such
2 manufacturer shall, upon such request of the Sec-
3 retary in writing, provide to the Secretary such
4 records or other information, within a reasonable
5 timeframe, within reasonable limits, and in a reason-
6 able manner, and in either electronic or physical
7 form, at the expense of such manufacturer. The Sec-
8 retary's request shall include a sufficient description
9 of the records requested and reference this sub-
10 section.

11 (2) CONFIRMATION OF RECEIPT.—Upon receipt
12 of the records requested under paragraph (1), the
13 Secretary shall provide to the manufacturer con-
14 firmation of receipt.

15 (3) INSPECTION AUTHORITY.—Nothing in this
16 subsection supplants the authority of the Secretary
17 to conduct inspections otherwise permitted under the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 301 et seq.).

20 (h) STATE AUTHORITY.—No State or political sub-
21 division of a State may establish or continue in effect any
22 prohibition relating to cosmetic animal testing, or to the
23 regulation of data use, labeling, and packaging related to
24 animal testing, that is not identical to the prohibitions set
25 forth in subsections (a), (b), (c), and (j) and that does

1 not include the exemptions contained in subsections (c),
2 (d), and (j). No State or political subdivision of a State
3 may require any entity to perform cosmetic animal testing
4 that is not permitted by subsection (a).

5 (i) FDA STRATEGIC PLAN FOR NON-ANIMAL TEST
6 METHODS.—

7 (1) SCIENTIFIC INNOVATION.—To promote the
8 development of, and provide for expedited review and
9 acceptance of, new scientifically valid test methods
10 and strategies that are not based on vertebrate ani-
11 mals, the Secretary shall—

12 (A) not later than 1 year after the date of
13 enactment of this Act, develop and publish on
14 the website of the Food and Drug Administra-
15 tion a strategic plan to promote the develop-
16 ment and implementation of alternative test
17 methods and strategies to replace vertebrate
18 animal testing for assessing the safety of cos-
19 metics;

20 (B) provide a period of not less than 60
21 calendar days for public comment regarding
22 such strategic plan;

23 (C) include in the strategic plan developed
24 under subparagraph (A) a list (which the Sec-
25 retary shall update on a regular basis, and

1 which shall be for informational purposes and
2 shall not be deemed to constitute a list of the
3 only acceptable non-animal test methods) of—

4 (i) scientifically reliable and relevant
5 non-animal test methodology as alter-
6 natives to animal testing that have been
7 recognized by any Federal agency or an
8 international regulatory agency;

9 (ii) next generation risk assessment
10 methods; and

11 (iii) examples of alternative methods
12 and strategies that have been accepted by
13 the Secretary; and

14 (D) to the maximum extent practicable
15 given available resources, prioritize and carry
16 out performance assessment, validation, and
17 translational studies to accelerate the develop-
18 ment of scientifically valid test methods and
19 strategies that replace the use of vertebrate ani-
20 mals.

21 (2) PUBLIC MEETINGS.—

22 (A) INITIAL MEETING.—Not later than 90
23 days after the date of enactment of this Act,
24 the Secretary shall convene a public meeting re-

1 garding the strategic plan described in para-
2 graph (1)(A).

3 (B) SUBSEQUENT ANNUAL MEETINGS.—

4 Not later than 1 year after the date of the pub-
5 lic meeting under subparagraph (A), and annu-
6 ally thereafter, the Secretary shall convene a
7 separate public meeting or add as an agenda
8 item to an already existing meeting, in-person
9 or virtually, to inform the Secretary’s advance-
10 ment of alternative test methods and strategies
11 to replace vertebrate animal testing for assess-
12 ing the safety of cosmetics. The Secretary shall
13 include in such meetings scientific and aca-
14 demic experts, animal and consumer advocacy
15 groups, and the regulated industry.

16 (3) RULE OF CONSTRUCTION.—Nothing in this
17 subsection shall be construed to limit the authority
18 of the Secretary to address other tools to promote
19 the development and implementation of alternative
20 test methods and strategies to replace vertebrate
21 animal testing for assessing the safety of cosmetics
22 as part of the strategic plan described in paragraph
23 (1)(A).

24 (j) CONSUMER INFORMATION RELATED TO ANIMAL
25 TESTING.—

1 (1) IN GENERAL.—A cosmetic product manu-
2 facturer shall not include on the label of a cosmetic
3 product or any of the product’s containers or wrap-
4 pers a claim that such cosmetic product was not
5 tested on animals, including any claim or logo of
6 “cruelty free” if—

7 (A) such cosmetic product or any ingre-
8 dient or nonfunctional constituent contained in
9 such cosmetic product was tested on an animal
10 after the effective date specified in subsection
11 (a); and

12 (B)(i) the testing was conducted by or con-
13 tracted for by the cosmetic product manufac-
14 turer or another person in the supply chain at
15 the direction or request of the cosmetic product
16 manufacturer; or

17 (ii) the cosmetic product manufacturer re-
18 lied upon evidence from such testing, pursuant
19 to subsection (c)(1)(B)(ii), to establish the safe-
20 ty of such product, ingredient, or nonfunctional
21 constituent under chapter VI of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 361
23 et seq.).

24 (2) EXCEPTIONS.—Notwithstanding paragraph
25 (1), a cosmetic product manufacturer may include a

1 claim described in such paragraph on the label of a
2 cosmetic product described in such paragraph or any
3 of the product's containers or wrappers if—

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

6 (B)(i) in the case of animal testing con-
7 ducted by or contracted for by the cosmetic
8 product manufacturer or another person in the
9 supply chain at the direction or request of the
10 cosmetic product manufacturer, the cosmetic
11 manufacturer did not rely upon evidence from
12 such testing for the purpose of establishing the
13 safety of the product, ingredient, or nonfunc-
14 tional constituent under chapter VI of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 361 et seq.); or

17 (ii) in the case of animal testing conducted
18 by or contracted for by a person that is not de-
19 scribed in clause (i), evidence from which the
20 cosmetic product manufacturer relied upon,
21 pursuant to subsection (c)(1)(B)(ii), to estab-
22 lish the safety of such product, ingredient, or
23 nonfunctional constituent under chapter VI of
24 the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 361 et seq.), the cosmetic product man-

1 ufacturer includes on the label a disclosure de-
2 scribing the circumstances surrounding the use
3 of the exemption under subsection (c)(1)(B)(ii)
4 by such manufacturer that includes a reference
5 to the specific Federal, State, or foreign re-
6 quirement under which the animal testing was
7 conducted or a reference to a publicly available
8 internet website of such manufacturer that pro-
9 vides such disclosure.

10 (k) REPORT.—Beginning 2 years after the date of en-
11 actment of this Act, the Secretary shall biennially submit
12 to the Committee on Health, Education, Labor, and Pen-
13 sions of the Senate and the Committee on Energy and
14 Commerce of the House of Representatives, and make
15 available on the website of the Food and Drug Administra-
16 tion, a report that includes, with respect to the previous
17 2 fiscal years—

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

21 (2) the number of times the Secretary re-
22 quested animal test data under subsection (d)(2),
23 the ingredients involved, and the animal tests per-
24 formed; and

(3) based on the data reviewed by the Secretary under subsection (g)(1), the number of times manufacturers relied upon data pursuant to the exemption under subsection (d)(4) to establish the safety of a cosmetic under chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.).

(l) DEFINITIONS.—

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

(2) COSMETIC ANIMAL TESTING.—The term “cosmetic animal testing” means the internal or external application or exposure of any cosmetic product, or any cosmetic ingredient or nonfunctional constituent, to the skin, eyes, or other body part (organ or extremity) of a live non-human vertebrate for the purpose of evaluating the safety or efficacy of a cosmetic product or a cosmetic ingredient or nonfunctional constituent for use in a cosmetic product.

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

(4) NONFUNCTIONAL CONSTITUENT.—The term “nonfunctional constituent” means any incidental in-

1 gradient as defined in section 701.3(l) of title 21,
2 Code of Federal Regulations, on the date of enact-
3 ment of this section.

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

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