

116TH CONGRESS  
1ST SESSION

# H. R. 5141

To substantially restrict the use of animal testing for cosmetics.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2019

Mr. BEYER (for himself, Mr. BUCHANAN, Mr. CÁRDENAS, Mr. TONKO, and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 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 verte-  
7 brate animal testing for assessing the safety of  
8 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.).

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