

118TH CONGRESS  
1ST SESSION

# H. R. 3622

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the supply chain transparency needed for companies to make safe cosmetics, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 24, 2023

Ms. SCHAKOWSKY (for herself, Ms. NORTON, Ms. TLAIB, Ms. VELÁZQUEZ, Mr. GRIJALVA, Mr. JOHNSON of Georgia, and Ms. MENG) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the supply chain transparency needed for companies to make safe cosmetics, and for other purposes.

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 “Cosmetic Supply Chain  
5 Transparency Act of 2023”.

1 **SEC. 2. COSMETIC REGULATION.**

2 Chapter VI of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 361 et seq.) is amended—

4 (1) by inserting before section 601 the fol-  
5 lowing:

6 **“Subchapter A—Adulterated and Misbranded**  
7 **Cosmetics”;**

8 and

9 (2) by adding at the end the following:

10 **“Subchapter B—Supply Chain Transparency**

11 **“SEC. 621. DEFINITIONS.**

12 “In this subchapter:

13 “(1) BRAND OWNER.—The term ‘brand owner’  
14 means the entity responsible for bringing a cosmetic  
15 to market.

16 “(2) FLAVOR OR FRAGRANCE COMPANY.—The  
17 term ‘flavor or fragrance company’ means an entity  
18 that makes or supplies fragrance or flavor ingredi-  
19 ents or fragrance or flavor formulations.

20 “(3) FORMULATING LABORATORY.—The term  
21 ‘formulating laboratory’ means an entity that sup-  
22 plies a finished cosmetic product to a retailer or cos-  
23 metic company to sell under the retailer or cosmetic  
24 company’s brand name.

25 “(4) HARMFUL TO HUMAN HEALTH OR THE  
26 ENVIRONMENT.—The phrase ‘harmful to human

1 health or the environment’ means, with respect to a  
2 nonfunctional constituent—

3 “(A) being—

4 “(i) a reproductive or developmental  
5 toxicant;

6 “(ii) persistent, bioaccumulative, and  
7 toxic;

8 “(iii) an allergen; or

9 “(iv) an endocrine disruptor, car-  
10 cinogen, or mutagen; and

11 “(B) present on the most recent version in  
12 effect of any of the following lists:

13 “(i) Chapter 6.6 of the California  
14 Safe Drinking Water and Toxic Enforce-  
15 ment Act of 1986 (sections 25249.5  
16 through 25249.14 of the California Health  
17 and Safety Code), List of Reproductive  
18 and Developmental Toxicants and Carcino-  
19 gens.

20 “(ii) Chemicals classified as ‘Per-  
21 sistent, Bioaccumulative and Toxic’ by the  
22 Toxics Release Inventory published by the  
23 Environmental Protection Agency pursuant  
24 to section 313 of the Emergency Planning

1 and Community Right-to-Know Act of  
2 1986.

3 “(iii) European Union Regulation  
4 1223/2009/EC on Cosmetic Products, as  
5 amended by Regulation (EU) 2020/1683,  
6 Annex II–Prohibited Substances.

7 “(iv) Annex III of European Union  
8 Cosmetics Regulation No. 1223/2009, as  
9 required to be disclosed pursuant to Euro-  
10 pean Union Detergents Regulation No.  
11 21648/2004.

12 “(v) Chemicals included in the Euro-  
13 pean Union Candidate List of Substances  
14 of Very High Concern in accordance with  
15 Article 59 of the REACH Regulation (EC)  
16 No. 1907/2006 on the basis of fulfilling  
17 the criteria defined in Article 57(f) for en-  
18 docrine-disrupting properties.

19 “(vi) Substances classified as carcino-  
20 gens, mutagens, or reproductive toxicants  
21 in Appendices 1–6 of Annex XVII to Regu-  
22 lation (EC) No. 1907/2006 of the Euro-  
23 pean Union’s Registration, Evaluation,  
24 Authorisation, and Restriction of Chemi-  
25 cals (REACH) law, as revised by the Com-

1 mission Regulation (EU) 2020/2096 of  
2 December 15, 2020.

3 “(vii) Group 1, 2A, or 2B carcinogens  
4 identified by the International Agency for  
5 Research on Cancer of the World Health  
6 Organization.

7 “(viii) Any other list the Secretary de-  
8 termines appropriate for purposes of this  
9 subchapter.

10 “(5) INGREDIENT.—The term ‘ingredient’  
11 means an intentionally added chemical in a cosmetic  
12 that has a technical or functional effect, including—

13 “(A) the breakdown products of an inten-  
14 tionally added chemical that also have a func-  
15 tional or technical effect in the cosmetic;

16 “(B) a fragrance, flavor, preservative, or  
17 colorant (and the components thereof); and

18 “(C) any individual component that the  
19 Secretary deems to be an ingredient for pur-  
20 poses of this subchapter.

21 “(6) INCIDENTAL COMPONENT.—The term ‘in-  
22 cidental component’ means—

23 “(A) a chemical added during the manu-  
24 facturing process at any point in a cosmetic’s,  
25 or an ingredient’s, supply chain, but which has

1 no functional or technical effect in the finished  
2 cosmetic; or

3 “(B) a chemical present in the environ-  
4 ment which was introduced into a cosmetic, or  
5 into an ingredient, at any point in the supply  
6 chain for the cosmetic or ingredient.

7 “(7) MANUFACTURER.—The term ‘manufac-  
8 turer’ means any entity that—

9 “(A) produces an ingredient; or

10 “(B) combines one or more ingredients to  
11 produce a cosmetic.

12 “(8) NONFUNCTIONAL CONSTITUENT.—The  
13 term ‘nonfunctional constituent’ means a chemical  
14 that has no functional or technical effect on the  
15 product or ingredient and is present—

16 “(A) as an incidental component of an in-  
17 tentionally added ingredient;

18 “(B) as a breakdown product of an inten-  
19 tionally added ingredient;

20 “(C) as a byproduct of the manufacturing  
21 process;

22 “(D) due to storage of primary substances;

23 or

24 “(E) due to instability of the packaging.

1           “(9) RAW MATERIAL.—The term ‘raw material’  
2 means a substance or mixture of substances that—

3           “(A) is used in the manufacture of a cos-  
4 metic for commercial distribution; and

5           “(B) is supplied to a cosmetic manufac-  
6 turer, packer, or distributor by a cosmetic raw  
7 material manufacturer or supplier.

8           “(10) SUPPLIER.—The term ‘supplier’—

9           “(A) means an entity that supplies a cos-  
10 metic, cosmetic packaging, or an ingredient or  
11 raw material of a cosmetic or cosmetic pack-  
12 aging; and

13           “(B) includes any such entity that is a  
14 manufacturer, a formulating laboratory, or a  
15 fragrance or flavor company.

16 **“SEC. 622. COSMETIC AND INGREDIENT SAFETY INFORMA-**  
17 **TION.**

18           “‘At the request of a brand owner of a cosmetic, a  
19 supplier of the cosmetic or any ingredient therein shall,  
20 not later than 90 days after receipt of such request, pro-  
21 vide to the brand owner, with respect to the cosmetic or  
22 ingredient, any of the following information:

23           “(1)(A) Functions and uses.

24           “(B) The human health and environmental haz-  
25 ards.

1           “(C) The physical and chemical properties.

2           “(D) The Chemical Abstracts Services Registry  
3 number of any such ingredient.

4           “(E) Environmental exposure and fate informa-  
5 tion.

6           “(F) Heavy metal testing results.

7           “(G) Safety data sheets.

8           “(H) Manufacturing flow charts.

9           “(I) Composition statement.

10          “(J) Fragrance allergen statement.

11          “(K) International Fragrance Association  
12 (IFRA) standards conformity certificate.

13          “(L) Any other information used to substan-  
14 tiate the safety of such ingredient.

15          “(2) A full and complete listing of ingredients  
16 in fragrance or flavor formulations, preservative sys-  
17 tems, or other ingredient formulations, including the  
18 presence of any allergens.

19          “(3) A full and complete listing of ingredients  
20 in a finished cosmetic presented in descending order  
21 of predominance by weight, except that ingredients  
22 present in amounts of 1 percent or less by weight  
23 can be placed in any order at the end of the ingre-  
24 dient statement.

25          “(4) A certificate of analysis for the ingredient.



1 **“SEC. 623. PROCESS FOR ESTABLISHING AN FDA LIST OF**  
2 **NONFUNCTIONAL CONSTITUENTS KNOWN OR**  
3 **REASONABLY EXPECTED TO BE PRESENT IN**  
4 **COSMETICS AND INGREDIENTS.**

5 “(a) IN GENERAL.—The Secretary shall create and  
6 maintain a list of nonfunctional constituents to guide test-  
7 ing under this subchapter conducted by suppliers of cos-  
8 metics and ingredients.

9 “(b) CONTENTS.—The list under subsection (a) shall  
10 consist of nonfunctional constituents that are—

11 “(1) known or reasonably expected to be  
12 present in cosmetics or ingredients; and

13 “(2) subject to subsection (e)(2), harmful to  
14 human health or the environment.

15 “(c) IDENTIFICATION OF INGREDIENTS AND COS-  
16 METICS.—For each nonfunctional constituent on the list  
17 under subsection (a), the Secretary shall identify the spe-  
18 cific ingredient or cosmetic, or category of ingredients or  
19 cosmetics, in which the nonfunctional constituent is known  
20 or reasonably expected to be present.

21 “(d) INITIAL LIST.—

22 “(1) IN GENERAL.—In creating the initial list  
23 under subsection (a), the Secretary shall—

24 “(A) publish a proposed list and provide  
25 an opportunity for public comment on such pro-  
26 posed list for a period of 60 days; and

1           “(B) not later than 18 months after the  
2 date of enactment of the Cosmetic Supply  
3 Chain Transparency Act of 2023, finalize and  
4 publish the list.

5           “(2) ADVISORY COMMITTEE.—

6           “(A) IN GENERAL.—Not later than 9  
7 months after the date of enactment of the Cos-  
8 metic Supply Chain Transparency Act of 2023,  
9 the Secretary shall convene an advisory com-  
10 mittee to advise the Secretary on—

11                   “(i) creating the initial list under sub-  
12 section (a); and

13                   “(ii) best practices related to analyt-  
14 ical testing for nonfunctional constituents  
15 in cosmetics and ingredients.

16           “(B) MEMBERSHIP.—The membership of  
17 the advisory committee convened under sub-  
18 paragraph (A) shall consist of an equal number  
19 of—

20                   “(i) representatives from industry;

21                   “(ii) representatives from the non-  
22 profit community;

23                   “(iii) representatives from the sci-  
24 entific community; and

1                   “(iv) representatives from the medical  
2                   and public health community.

3                   “(C) TERMINATION.—The Secretary shall  
4                   terminate the advisory committee convened  
5                   under this paragraph upon the finalization of  
6                   the initial list pursuant to paragraph (1).

7                   “(e) UPDATES.—Not less than annually after the fi-  
8                   nalization pursuant to subsection (d) of the initial list  
9                   under subsection (a), and not less than annually there-  
10                  after, the Secretary shall—

11                  “(1) review the list under subsection (a);

12                  “(2) after providing a period of at least 30 days  
13                  for public comment, update the list by adding non-  
14                  functional constituents that are known or reasonably  
15                  expected to be present in a cosmetic or ingredient as  
16                  specified in subsection (b)(1) and—

17                  “(A) are determined by the Secretary to  
18                  meet the standard specified in section  
19                  621(4)(A) based on existing and emerging  
20                  science; or

21                  “(B) have been added to one of the lists in  
22                  section 621(4)(B); and

23                  “(3) update the list by adding any nonfunc-  
24                  tional constituent whose addition was approved pur-  
25                  suant to a petition under subsection (f).

1       “(f) PETITION PROCESS FOR ADDING NONFUNC-  
2 TIONAL CONSTITUENTS OR NEW LISTS.—

3               “(1) IN GENERAL.—Any person may petition,  
4 in accordance with paragraph (3), to add—

5                       “(A) a nonfunctional constituent to the list  
6 under subsection (a); or

7                       “(B) a new list to the lists specified in sec-  
8 tion 621(4)(B).

9               “(2) DEVELOPMENT OF PROCESS.—The Sec-  
10 retary—

11                       “(A) not later than 24 months after the  
12 date of enactment of the Cosmetic Supply  
13 Chain Transparency Act of 2023, shall develop  
14 and publish the process for submitting a peti-  
15 tion under this subsection; and

16                       “(B) may periodically review and update  
17 such process.

18               “(3) REQUIREMENTS FOR PROCESS.—The proc-  
19 ess developed and updated by the Secretary under  
20 paragraph (2) shall be consistent with the following:

21                       “(A) Such process shall specify the nec-  
22 essary scientific justification that must be in-  
23 cluded in a petition.

24                       “(B) The Secretary shall—

1                   “(i) provide a 30-day period for public  
2                   comment on a petition; and

3                   “(ii) not later than 90 days after the  
4                   close of such public comment period, ap-  
5                   prove or deny the petition.

6                   “(C) If the Secretary approves a petition,  
7                   the Secretary shall provide notice in the Federal  
8                   Register of each addition made pursuant to  
9                   such approval.

10                  “(D) In denying a petition, the Secretary  
11                  shall provide a written justification to the peti-  
12                  tioner for the denial.

13                  “(g) GUIDANCE.—The Secretary—

14                  “(1) shall, concurrently with the publication of  
15                  the initial list under subsection (a), and upon adding  
16                  any nonfunctional constituent pursuant to subsection  
17                  (e) or (f) to the list under subsection (a), issue guid-  
18                  ance for industry on best practices related to—

19                  “(A) analytical testing for nonfunctional  
20                  constituents in cosmetics and ingredients; and

21                  “(B) detection limits; and

22                  “(2) may periodically review and update such  
23                  guidance.

1 **“SEC. 624. TREATMENT OF NONFUNCTIONAL CONSTITU-**  
2 **ENTS.**

3 “A supplier of an ingredient or cosmetic shall—

4 “(1) not later than 1 year after a nonfunctional  
5 constituent is added to the list under section 623(a)  
6 pursuant to subsection (d), (e), or (f) of section 623,  
7 conduct testing for such nonfunctional constituent;  
8 and

9 “(2) prior to the sale of the ingredient or cos-  
10 metic to the brand owner, provide the brand owner  
11 a certificate of analysis that includes—

12 “(A) the levels of each such nonfunctional  
13 constituent present;

14 “(B) any analytical test used;

15 “(C) the detection limits of any analytical  
16 test used to detect each such nonfunctional con-  
17 stituent; and

18 “(D) heavy metal testing results.

19 **“SEC. 625. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
20 **OF ADULTERATED OR MISBRANDED COS-**  
21 **METICS.**

22 “(a) SUPPLY CHAIN INFORMATION.—In the case of  
23 a cosmetic that the Secretary has reason to believe is adul-  
24 terated, misbranded, or otherwise in violation of this Act,  
25 the Secretary shall request that the brand owner named

1 on the label of such cosmetic submit to the Secretary all  
2 of the following information:

3           “(1) The name and place of business of the  
4           manufacturer of the cosmetic and any supplier of an  
5           ingredient or raw material used in the manufacture  
6           of the cosmetic.

7           “(2) The name and place of business of any en-  
8           tity (including any retailer) to which the brand  
9           owner provided the cosmetic.

10          “(b) COLLECTION OF ADDITIONAL SUPPLY CHAIN  
11 INFORMATION.—In the case of a cosmetic that the Sec-  
12 retary has reason to believe is adulterated, misbranded,  
13 or otherwise in violation of this Act, to the extent nec-  
14 essary to protect the safety of the public, the Secretary  
15 may request that any entity in the supply chain of such  
16 cosmetic submit to the Secretary information that is simi-  
17 lar to the information described in paragraphs (1) and (2)  
18 of subsection (a).

19          “(c) MAINTENANCE OF RECORDS.—Any entity in the  
20 supply chain of a cosmetic (including the brand owner  
21 named on the label of a cosmetic) shall—

22           “(1) maintain records sufficient to provide the  
23           information described in paragraphs (1) and (2) of  
24           subsection (a); and

1           “(2) provide such information to the Secretary  
2           upon the request of the Secretary.

3 **“SEC. 626. CIVIL PENALTIES.**

4           “Any person that violates section 622, 624, or 625  
5 shall be liable to the United States for a civil penalty in  
6 an amount up to \$10,000 for each day on which such vio-  
7 lation continues.”.

○