

118TH CONGRESS  
1ST SESSION

# H. R. 3621

To amend title VI of the Federal Food, Drug, and Cosmetic Act to provide for greater transparency with respect to fragrance and flavor ingredients in cosmetics, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 24, 2023

Ms. SCHAKOWSKY (for herself, Ms. MATSUI, 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 provide for greater transparency with respect to fragrance and flavor ingredients in 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 Fragrance  
5 and Flavor Ingredient Right to Know Act of 2023”.

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

2 (a) DEFINITION.—Section 201(i) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 321(i)) is  
4 amended by adding at the end the following: “Such term  
5 includes such an article that is intended for consumer sale  
6 or professional use (as defined in section 617).”.

7 (b) REGULATION.—Chapter VI of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-  
9 ed—

10 (1) by inserting before section 601 the fol-  
11 lowing:

12 **“Subchapter A—Adulterated and Misbranded**  
13 **Cosmetics”;**

14 (2) in section 602, by adding at the end the fol-  
15 lowing:

16 “(g) If the fragrance and flavor ingredient informa-  
17 tion required to be disclosed pursuant to sections 615 and  
18 616 is not disclosed in accordance with such sections.

19 “(h) If its packaging fails to include any fragrance  
20 or flavor ingredient present in such cosmetic or the  
21 website of the brand owner of such cosmetic fails to dis-  
22 close any such fragrance or flavor ingredient.”; and

23 (3) by adding at the end the following:

1       **“Subchapter B—Fragrances and Flavors**

2       **“SEC. 615. WEBSITE DISCLOSURE OF INGREDIENTS.**

3           “(a) IN GENERAL.—Effective beginning on the date  
4 that is 1 year after the date of the enactment of the Cos-  
5 metic Fragrance and Flavor Ingredient Right to Know Act  
6 of 2023, a brand owner shall disclose in an electronically  
7 readable format on the website of the brand owner, and  
8 make available to any relevant internet vendor, with re-  
9 spect to each cosmetic sold or offered for sale in interstate  
10 commerce by such brand owner, the following information:

11           “(1) A full listing of each ingredient present in  
12 such cosmetic, including each fragrance or flavor in-  
13 gredient present in such cosmetic, in descending  
14 order of predominance.

15           “(2) Any fragrance or flavor ingredient present  
16 in such cosmetic that is specified in section 616(b),  
17 listed in descending order of predominance, followed  
18 by a link to the URL of any list on which such in-  
19 gredient appears.

20           “(3) In the case of a fragrance allergen in such  
21 cosmetic that meets the criteria specified in section  
22 616(c), the following statement: ‘This product con-  
23 tains the following fragrance allergens.’.

24           “(4) The functional purpose served by each  
25 such fragrance or flavor ingredient.

1           “(5) A link to the hazard communication safety  
2       data sheet for any such cosmetic intended for profes-  
3       sional use.

4           “(b) UPDATES.—In the case of an update to any of  
5       the lists specified in subsection (b) or (c) of section 616  
6       with respect to a cosmetic sold or offered for sale in inter-  
7       state commerce by a brand owner, the brand owner shall  
8       revise the disclosure made under subsection (a) to reflect  
9       such update not later than 7 months after the date on  
10      which such update is formally noticed by the authoritative  
11      body who administers the list.

12   **“SEC. 616. COSMETIC INGREDIENT PRODUCT LABEL DIS-**  
13                           **CLOSURE.**

14           “(a) IN GENERAL.—Effective beginning on the date  
15      that is 2 years after the date of the enactment of the Cos-  
16      metic Fragrance and Flavor Ingredient Right to Know Act  
17      of 2023, for purposes of section 602(h), the packaging or  
18      labeling of a cosmetic shall include—

19           “(1) A full listing of each ingredient present in  
20      such cosmetic (including each fragrance or flavor in-  
21      gredient), listed in descending order of predomi-  
22      nance.

23           “(2) In the case of a cosmetic in which any in-  
24      gredient specified in subsection (b) is present, the  
25      following statement: ‘For health impacts related to

1 the fragrance or flavor ingredients in this product,  
2 visit: www.\_\_\_\_\_.’ The uniform resource locator  
3 of the website of the brand owner shall be placed in  
4 the space identifying the website.’.

5 “(3) In the case of a fragrance allergen in such  
6 cosmetic that meets the criteria specified in section  
7 616(c), the following statement: ‘This product con-  
8 tains the following fragrance allergens.’.

9 “(4) Not later than 18 months after the date  
10 on which an update to any of the lists referred to  
11 in subsection (b) or (c) with respect to an ingredient  
12 or allergen present in such cosmetic are formally no-  
13 ticed by the authoritative body who administers the  
14 list, any necessary revisions with respect to such in-  
15 gredient or fragrance allergen to reflect such update.

16 “(b) INGREDIENTS SPECIFIED.—The ingredients  
17 specified in this subsection are the following chemicals (in-  
18 cluding chemicals included in any list specified in this sub-  
19 section after the date of the enactment of this subchapter):

20 “(1) Chemicals for which a reference dose or  
21 reference concentration has been developed based on  
22 neurotoxicity in the Environmental Protection Agen-  
23 cy’s Integrated Risk Information System.

24 “(2) Chemicals that are identified as carcino-  
25 genic to humans, likely to be carcinogenic to hu-

1       mans, or as group A, B1, or B2 carcinogens, in the  
2       Environmental Protection Agency’s Integrated Risk  
3       Information System.

4               “(3) Persistent, bioaccumulative, and toxic Pri-  
5       ority Chemicals identified by the Environmental Pro-  
6       tection Agency’s National Waste Minimization Pro-  
7       gram as of February 22, 2016.

8               “(4) Chemicals that are identified in volumes 1  
9       through 4 of the Reports on Human Exposure to  
10      Environmental Chemicals issued by the Centers for  
11      Disease Control and Prevention (and any updates to  
12      such reports).

13              “(5) Toxic pollutants listed under section 20  
14      307(a)(1) of the Federal Water Pollution Control  
15      Act and priority pollutants identified in appendix A  
16      to part 423 of title 40, Code of Federal Regulations  
17      (or successor regulations).

18              “(6) Chemicals classified as ‘Persistent, Bio-  
19      accumulative and Toxic’ by the Toxics Release In-  
20      ventory published by the Environmental Protection  
21      Agency pursuant to section 313 of the Emergency  
22      Planning and Community Right-to-Know Act of  
23      1986.

1           “(7) Chemicals that are identified in the Agen-  
2           cy for Toxic Substances and Disease Registry’s  
3           Toxic Substances Portal.

4           “(8) Chemicals that are hazardous substances,  
5           as such term is defined in section 101(14) of the  
6           Comprehensive Environmental Response, Compensa-  
7           tion, and Liability Act of 1980.

8           “(9) Reproductive and developmental toxicants  
9           identified by monographs issued by the National  
10          Toxicology Program Center for the Evaluation of  
11          Risks to Human Reproduction.

12          “(10) Chemicals that are identified as known to  
13          be, or reasonably anticipated to be human carcino-  
14          gens by the most recent Report on Carcinogens pre-  
15          pared by the National Toxicology Program pursuant  
16          to section 301(b)(4) of the Public Health Service  
17          Act.

18          “(11) Chemicals identified as persistent, bio-  
19          accumulative, and toxic (PBT) chemicals by the De-  
20          partment of Ecology of the State of Washington  
21          (WAC 173–333 (2006)).

22          “(12) Chemicals specified in Chapter 6.6 of the  
23          California Safe Drinking Water and Toxic Enforce-  
24          ment Act of 1986 (sections 25249.5 through  
25          25249.14 of the California Health and Safety Code),

1 List of Reproductive and Developmental Toxicants  
2 and Carcinogens.

3 “(13) Chemicals for which primary maximum  
4 contaminant levels have been established and adopt-  
5 ed under section 64431, 64444, or 64444.5 of divi-  
6 sion 22 of title 26 of the California Code of Regula-  
7 tions and chemicals for which notification levels, as  
8 defined in section 116455 of the California Health  
9 and Safety Code, have been established by the Cali-  
10 fornia State Water Resources Control Board.

11 “(14) Chemicals identified as toxic air contami-  
12 nants under section 93000 or 93001 of title 17 of  
13 the California Code of Regulations.

14 “(15) Substances classified as carcinogens,  
15 mutagens or reproductive toxicants in Appendices 1  
16 through 6 of Annex XVII to Regulation (EC) No.  
17 1907/2006 of the European Union’s Registration,  
18 Evaluation, Authorisation and Restriction of Chemi-  
19 cals (REACH) law, as revised by the Commission  
20 Regulation (EU) 2020/2096 of 15 December 2020.

21 “(16) Chemicals included in the European  
22 Union Candidate List of Substances of Very High  
23 Concern in accordance with Article 59 of the  
24 REACH Regulation (EC) No. 1907/2006 on the



1 basis of fulfilling the criteria defined in Article 57(f)  
2 for endocrine disrupting properties.

3 “(17) Chemicals included in such European  
4 Chemicals Agency Candidate List of Substances of  
5 Very High Concern on the basis of fulfilling the cri-  
6 teria defined in Article 57(d), Article 57(e), or Arti-  
7 cle 57(f) for persistent, bioaccumulative and toxic, or  
8 very persistent and very bioaccumulative, properties.

9 “(18) Chemicals classified by the European  
10 Union in Annex VI to Regulation (EC) No. 1272/  
11 2008 as respiratory sensitizer category 1.

12 “(19) Chemicals that are identified as per-  
13 sistent, bioaccumulative, and inherently toxic to the  
14 environment by the Canadian Environmental Protec-  
15 tion Act Environmental Registry Domestic Sub-  
16 stances List pursuant to subsection 66(1) of the Ca-  
17 nadian Environmental Protection Act, 1999.

18 “(20) Group 1, 2A, or 2B carcinogens identi-  
19 fied by the International Agency for Research on  
20 Cancer of the World Health Organization.

21 “(21) Chemicals that are identified on Part A  
22 of the list of Chemicals for Priority Action prepared  
23 by the Oslo and Paris Conventions for the Protec-  
24 tion of the Marine Environment of the North-East  
25 Atlantic.

1           “(22) Chemicals that are skin sensitizers and  
2           irritants classified by Regulation (EC) No 1272/  
3           2008 of the European Parliament and of the Council  
4           of 16 December 2008 on classification, labelling and  
5           packaging of substances and mixtures, amending  
6           and repealing Directives 67/548/EEC and 1999/45/  
7           EC, and amending Regulation (EC) No 1907/2006.

8           “(c) FRAGRANCE ALLERGENS.—A fragrance allergen  
9           specified in this subsection is an allergen that is—

10           “(1) included in Annex III of European Union  
11           Cosmetics Regulation No. 1223/2009, as required to  
12           be disclosed pursuant to European Union Deter-  
13           gents Regulation No. 21648/2004 (including any  
14           subsequent updates to those regulations); and

15           “(2) present in—

16                   “(A) a rinse-off cosmetic at a concentra-  
17                   tion at or above 0.01 percent; or

18                   “(B) a leave-on cosmetic product at a con-  
19                   centration at or above 0.001 percent.

20           “(d) MASTER LIST.—

21           “(1) IN GENERAL.—Not later than 6 months  
22           after the date of the enactment of the Cosmetic Fra-  
23           grance and Flavor Ingredient Right to Know Act of  
24           2023, the Secretary shall—

1           “(A) establish a master list of the chemi-  
2 cals that appear on the lists specified in sub-  
3 sections (b) and (c);

4           “(B) post such master list on a publicly  
5 available website of the Food and Drug Admin-  
6 istration; and

7           “(C) establish a voluntary electronic dis-  
8 tribution list to which cosmetic manufacturers  
9 and other interested parties may subscribe to  
10 receive a copy of the master list and any subse-  
11 quent updates.

12           “(2) UPDATES.—

13           “(A) IN GENERAL.—The Secretary shall  
14 maintain the master list established under para-  
15 graph (1) and make updates to such list as nec-  
16 essary.

17           “(B) NOTIFICATION.—Not later than 30  
18 days after making an update pursuant to sub-  
19 paragraph (A), the Secretary shall notify sub-  
20 scribers to the electronic distribution list re-  
21 ferred to in paragraph (1)(C) of that update.

22           “(C) SEMI-ANNUAL UPDATES.—Not less  
23 frequently than twice per year, the Secretary  
24 shall publish on a publicly available website of  
25 the Food and Drug Administration a list of up-

1 dates to the master list made during the pre-  
2 ceding 6-month period that includes summaries  
3 of any chemicals added to or removed from the  
4 lists specified in subsections (b) and (c).

5 **“SEC. 617. DEFINITIONS.**

6 “In this subchapter:

7 “(1) BRAND OWNER.—The term ‘brand owner’  
8 means the entity responsible for bringing a cosmetic  
9 to market for retail consumer sale or professional  
10 use.

11 “(2) ELECTRONICALLY READABLE FORMAT.—  
12 The term ‘electronically readable format’ means,  
13 with respect to information, that the information  
14 provided—

15 “(A) is machine readable by automated  
16 systems, including, web browsers, accessibility  
17 software to aid the disabled, automated scripts,  
18 and other software programs or applications;

19 “(B) is not restricted from access by  
20 search engines;

21 “(C) is not restricted from access by a re-  
22 quirement for registration, the provision of per-  
23 sonally identifiable information, or the use of  
24 CAPTCHA or similar challenge response test

1 technologies, whether visual, auditory, or other-  
2 wise; and

3 “(D) conforms to the most current version  
4 of the Web Content Accessibility Guidelines  
5 adopted by the Web Content Accessibility  
6 Guidelines Working Group of the World Wide  
7 Web Consortium.

8 “(3) FLAVOR INGREDIENT.—The term ‘flavor  
9 ingredient’ means, with respect to a cosmetic, any  
10 intentionally added substance or complex mixture of  
11 aroma chemicals, flavor chemicals, natural essential  
12 oils, and other functional ingredient or ingredients,  
13 including the constituent ingredients of botanicals,  
14 for which the purpose is to impart a flavor or taste,  
15 or to counteract a flavor or taste.

16 “(4) FRAGRANCE INGREDIENT.—The term ‘fra-  
17 grance ingredient’ means, with respect to a cosmetic,  
18 any intentionally added substance or complex mix-  
19 ture of aroma chemicals, natural essential oils, and  
20 other functional ingredient or ingredients for which  
21 the purpose is to impart an odor or scent, or to  
22 counteract an odor.

23 “(5) INGREDIENT.—The term ‘ingredient’  
24 means a chemical in a cosmetic, including—

1           “(A) a chemical that has a technical or  
2 functional effect in the cosmetic, including the  
3 breakdown products of an intentionally added  
4 chemical that also have a functional or technical  
5 effect in the cosmetic;

6           “(B) a substance that is present by reason  
7 of having been added to a cosmetic during proc-  
8 essing for the substance’s technical or func-  
9 tional effect;

10           “(C) a fragrance, flavor, preservative, or  
11 colorant (and the components thereof); and

12           “(D) any individual component that the  
13 Secretary deems to be an ingredient for pur-  
14 poses of this subchapter.

15           “(6) PROFESSIONAL USE.—The term ‘profes-  
16 sional use’ means—

17           “(A) the application of a cosmetic to a  
18 human customer or client that is intended only  
19 for use by an employee or contractor, in set-  
20 tings such as cosmetology, nail care, barbering,  
21 esthetics, spa, and other professions as deter-  
22 mined by the Secretary through regulation; or

23           “(B) the use by, or application to, a  
24 human of a cosmetic purchased from a hair  
25 salon, nail salon, beauty salon, spa, or other es-

- 1           tablishment that provides cosmetic treatment
- 2           services for humans.”.

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