

117TH CONGRESS
1ST SESSION

H. R. 5538

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.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2021

Ms. SCHAKOWSKY (for herself and Ms. MATSUI) introduced the following bill;
which was referred to the Committee on Energy and Commerce

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 2021”.

6 **SEC. 2. COSMETIC REGULATION.**

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

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

3 **“Subchapter A—Adulterated and Misbranded**
4 **Cosmetics”;**

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

7 “(g) If the ingredient information required to be dis-
8 closed pursuant to section 611 is not disclosed in accord-
9 ance with such section.

10 “(h) If it contains ingredients specified in a list in-
11 cluded in section 612 and its packaging or labeling fails
12 to include any such ingredient.”; and

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

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

15 **“SEC. 611. WEBSITE LABELING OF FRAGRANCE AND FLA-**
16 **VOR INGREDIENTS.**

17 “(a) IN GENERAL.—Effective beginning on the date
18 that is one year after the date of the enactment of the
19 Cosmetic Fragrance and Flavor Ingredient Right to Know
20 Act of 2021, a brand owner shall disclose in an electroni-
21 cally readable format on the website of the brand owner,
22 and make available to any relevant internet vendor, with
23 respect to each cosmetic sold or offered for sale in inter-
24 state commerce by such brand owner, the following infor-
25 mation:

1 “(1) any fragrance or flavor ingredient present
2 in such cosmetic at a concentration that equals or
3 exceeds .01 percent;

4 “(2) any fragrance or flavor ingredient present
5 in such cosmetic included on a list specified in sec-
6 tion 612(b);

7 “(3) any fragrance allergen in such cosmetic if
8 the fragrance allergen meets the criteria specified in
9 section 612(c);

10 “(4) the functional purpose served by each such
11 fragrance or flavor ingredient;

12 “(5) a link to the URL of the list referred to
13 in paragraph (2) on which the fragrance or flavor
14 ingredient present in such cosmetic appears (includ-
15 ing a cosmetic intended for retail consumer sale or
16 professional use); and

17 “(6) a link to the hazard communication safety
18 data sheet for any such cosmetic intended for profes-
19 sional use.

20 “(b) UPDATES.—In the case of an update to any of
21 the lists specified in subsection (b) or (c) of section 612
22 with respect to a cosmetic sold or offered for sale in inter-
23 state commerce by a brand owner, the brand owner shall
24 revise the disclosure made under subsection (a) to reflect
25 such update not later than seven months after the date

1 on which such update is formally noticed by the authori-
2 tative body who administers the list.

3 **“SEC. 612. COSMETIC INGREDIENT LABEL DISCLOSURE.**

4 “(a) IN GENERAL.—Effective beginning on the date
5 that is 2 years after the date of the enactment of the Cos-
6 metic Fragrance and Flavor Ingredient Right to Know Act
7 of 2021, for purposes of section 602(h), in the case of
8 a cosmetic in which any of the ingredients specified in sub-
9 section (b) or fragrance allergens specified in subsection
10 (c) is present, the packaging or labeling of such cosmetic
11 shall—

12 “(1) list each such ingredient; and

13 “(2) not later than 18 months after the date on
14 which an update to any of the lists referred to in
15 subsection (b) or (c) with respect to an ingredient or
16 allergen present in such cosmetic are formally no-
17 ticed by the authoritative body who administers the
18 list, include any necessary revisions with respect to
19 such ingredient or fragrance allergen to reflect such
20 update.

21 “(b) INGREDIENTS SPECIFIED.—The ingredients
22 specified in this subsection are the following chemicals (in-
23 cluding chemicals included in any list specified in this sub-
24 section after the date of the enactment of this subchapter):

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

5 “(2) Chemicals that are identified as carcino-
6 genic to humans, likely to be carcinogenic to hu-
7 mans, or as group A, B1, or B2 carcinogens, in the
8 Environmental Protection Agency’s Integrated Risk
9 Information System.

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

14 “(4) Chemicals that are identified in volumes 1
15 through 4 of the Reports on Human Exposure to
16 Environmental Chemicals issued by the Centers for
17 Disease Control and Prevention (and any updates to
18 such reports).

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

24 “(6) Chemicals classified as ‘Persistent, Bio-
25 accumulative and Toxic’ by the Toxics Release In-

1 ventory published by the Environmental Protection
2 Agency pursuant to section 313 of the Emergency
3 Planning and Community Right-to-Know Act of
4 1986.

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

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

12 “(9) Reproductive and developmental toxicants
13 identified by monographs issued by the National
14 Toxicology Program Center for the Evaluation of
15 Risks to Human Reproduction.

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

22 “(11) Chemicals identified as persistent, bio-
23 accumulative, and toxic (PBT) chemicals by the De-
24 partment of Ecology of the State of Washington
25 (WAC 173–333 (2006)).

1 “(12) Chemicals specified in Chapter 6.6 of the
2 California Safe Drinking Water and Toxic Enforce-
3 ment Act of 1986 (sections 25249.5 through
4 25249.14 of the California Health and Safety Code),
5 List of Reproductive and Developmental Toxicants
6 and Carcinogens.

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

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

18 “(15) Substances classified as carcinogens,
19 mutagens or reproductive toxicants in Appendices 1
20 through 6 of Annex XVII to Regulation (EC) No.
21 1907/2006 of the European Union’s Registration,
22 Evaluation, Authorisation and Restriction of Chemi-
23 cals (REACH) law, as revised by the Commission
24 Regulation (EU) 2020/2096 of 15 December 2020.

1 “(16) Chemicals included in the European
2 Union Candidate List of Substances of Very High
3 Concern in accordance with Article 59 of the
4 REACH Regulation (EC) No. 1907/2006 on the
5 basis of fulfilling the criteria defined in Article 57(f)
6 for endocrine disrupting properties.

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

13 “(18) Chemicals classified by the European
14 Union in Annex VI to Regulation (EC) No. 1272/
15 2008 as respiratory sensitizer category 1.

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

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

1 “(21) Chemicals that are identified on Part A
2 of the list of Chemicals for Priority Action prepared
3 by the Oslo and Paris Conventions for the Protec-
4 tion of the Marine Environment of the North-East
5 Atlantic.

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

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

13 “(2) present in—

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

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

18 “(d) MASTER LIST.—

19 “(1) IN GENERAL.—Not later than 6 months
20 after the date of the enactment of the Cosmetic Fra-
21 grance and Flavor Ingredient Right to Know Act of
22 2021, the Secretary shall—

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

1 “(B) post such master list on a publicly
2 available website of the Food and Drug Admin-
3 istration; and

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

9 “(2) UPDATES.—

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

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

19 “(C) SEMI-ANNUAL UPDATES.—Not less
20 frequently than twice per year, the Secretary
21 shall publish on a publicly available website of
22 the Food and Drug Administration a list of up-
23 dates to the master list made during the pre-
24 ceding 6-month period that includes summaries

1 of any chemicals added to or removed from the
2 lists specified in subsections (b) and (c).

3 **“SEC. 613. GENERAL PROVISIONS.**

4 “(a) TREATMENT OF CONFIDENTIAL COMMERCIAL
5 INFORMATION AND TRADE SECRETS.—Notwithstanding
6 any other provision of law, for purposes of applying section
7 552(b)(4) of title 5, United States Code, or section 1905
8 of title 18, United States Code—

9 “(1) an ingredient required to be listed on a
10 cosmetic packaging or labeling or on the website of
11 a brand owner (or other entity) under this section
12 shall not be treated as a trade secret; and

13 “(2) the concentration of any such ingredient
14 shall be treated as confidential commercial informa-
15 tion.

16 “(b) DEFINITIONS.—In this subchapter:

17 “(1) BRAND OWNER.—The term ‘brand owner’
18 means the entity responsible for bringing a cosmetic
19 to market for retail consumer sale or professional
20 use.

21 “(2) ELECTRONICALLY READABLE FORMAT.—
22 The term ‘electronically readable format’ means,
23 with respect to information, that the information
24 provided is—

1 “(A) is machine readable by automated
2 systems, including, web browsers, accessibility
3 software to aid the disabled, automated scripts,
4 and other software programs or applications;

5 “(B) is not restricted from access by
6 search engines;

7 “(C) is not restricted from access by a re-
8 quirement for registration, the provision of per-
9 sonally identifiable information, or the use of
10 CAPTCHA or similar challenge response test
11 technologies, whether visual, auditory, or other-
12 wise; and

13 “(D) conforms to the most current version
14 of the Web Content Accessibility Guidelines
15 adopted by the Web Content Accessibility
16 Guidelines Working Group of the World Wide
17 Web Consortium.

18 “(3) FLAVOR INGREDIENT.—The term ‘flavor
19 ingredient’ means, with respect to a cosmetic, any
20 intentionally added substance or complex mixture of
21 aroma chemicals, flavor chemicals, natural essential
22 oils, and other functional ingredient or ingredients,
23 including the constituent ingredients of botanicals,
24 for which the purpose is to impart a flavor or taste,
25 or to counteract a flavor or taste.

1 “(4) FRAGRANCE INGREDIENT.—The term ‘fra-
2 grance ingredient’ means, with respect to a cosmetic,
3 any intentionally added substance or complex mix-
4 ture of aroma chemicals, natural essential oils, and
5 other functional ingredient or ingredients for which
6 the purpose is to impart an odor or scent, or to
7 counteract an odor.

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

10 “(A) a chemical that has a technical or
11 functional effect in the cosmetic, including the
12 breakdown products of an intentionally added
13 chemical that also have a functional or technical
14 effect in the cosmetic;

15 “(B) a substance that is present by reason
16 of having been added to a cosmetic during proc-
17 essing for the substance’s technical or func-
18 tional effect;

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

21 “(D) any individual component that the
22 Secretary deems to be an ingredient for pur-
23 poses of this subchapter.

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

1 “(A) the application of a cosmetic to a
2 human customer or client that is intended only
3 for use by an employee or contractor, in set-
4 tings such as cosmetology, nail care, barbering,
5 esthetics, spa, and other professions as deter-
6 mined by the Secretary through regulation; or

7 “(B) the use by, or application to, a
8 human of a cosmetic purchased from a hair
9 salon, nail salon, beauty salon, spa, or other es-
10 tablishment that provides cosmetic treatment
11 services for humans.”.

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