

111<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5786

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 20, 2010

Ms. SCHAKOWSKY (for herself, Mr. MARKEY of Massachusetts, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of 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 “Safe Cosmetics Act  
5 of 2010”.

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

2 (a) IN GENERAL.—Chapter VI of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-  
4 ed—

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

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

9 and

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

11 **“Subchapter B—Regulation of Cosmetics**

12 **“SEC. 611. DEFINITIONS.**

13 “In this subchapter:

14 “(1) INGREDIENT.—The term ‘ingredient’  
15 means a chemical in a cosmetic, including—

16 “(A) chemicals that provide a technical or  
17 functional effect;

18 “(B) chemicals that have no technical or  
19 functional effect in the cosmetic but are present  
20 by reason of having been incorporated into the  
21 cosmetic as an ingredient of another cosmetic  
22 ingredient;

23 “(C) processing aids that are present by  
24 reason of having been added to a cosmetic dur-  
25 ing the processing of such cosmetic;

1           “(D) substances that are present by reason  
2 of having been added to a cosmetic during proc-  
3 essing for their technical or functional effect;

4           “(E) contaminants present at levels above  
5 technically feasible detection limits;

6           “(F) contaminants that may leach from  
7 container materials or form via reactions over  
8 the shelf life of a cosmetic and that may be  
9 present at levels above technically feasible de-  
10 tection limits;

11           “(G) the components of a fragrance, fla-  
12 vor, or preservative declared individually by  
13 their appropriate label names; and

14           “(H) any individual component of a botan-  
15 ical, petroleum-derived, animal-derived, or other  
16 ingredient that the Secretary determines be  
17 considered an ingredient.

18           “(2) PROFESSIONAL USE.—The term ‘profes-  
19 sional use’ means the use of any cosmetic—

20           “(A) by an employee (within the scope of  
21 the employment of such employee) of; or

22           “(B) purchased by a consumer in,  
23 a hair salon, nail salon, beauty salon, spa, or other  
24 establishment that provides cosmetic treatment serv-  
25 ices for humans.

1           “(3) REASONABLE CERTAINTY.—The term ‘rea-  
2           sonable certainty’, when used in establishing a safety  
3           standard (as defined in paragraph (5)) for an ingre-  
4           dient or cosmetic—

5                   “(A) means that no harm will be caused by  
6                   aggregate exposure for a member of a vulner-  
7                   able population to that ingredient or cosmetic;  
8                   and

9                   “(B) corresponds to the lower dose derived  
10                  from—

11                           “(i) data demonstrating that exposure  
12                           to all sources of the ingredient or cosmetic  
13                           present not more than a 1 in a million risk  
14                           for any adverse effect in the population of  
15                           concern, at the lower 95th percentile con-  
16                           fidence bound; or

17                           “(ii) the amount of an ingredient or  
18                           cosmetic shown to produce no adverse ef-  
19                           fects, incorporating an uncertainty factor  
20                           of at least 1,000 and considering all  
21                           sources of exposure.

22           “(4) REPRODUCTIVE AND DEVELOPMENTAL  
23           TOXICITY.—With respect to an ingredient or cos-  
24           metic, the term ‘reproductive and developmental tox-  
25           icity’ means that the ingredient or cosmetic causes

1 biologically adverse effects on the reproductive sys-  
2 tems of female or male humans or animals, includ-  
3 ing alterations to the female or male reproductive  
4 system development, the related endocrine system,  
5 fertility, pregnancy, pregnancy outcomes, or modi-  
6 fications in other functions that are dependent on  
7 the integrity of the reproductive system.

8 “(5) SAFETY STANDARD.—

9 “(A) IN GENERAL.—The term ‘safety  
10 standard’ means—

11 “(i) with respect to an ingredient,  
12 when the route of exposure is directly rel-  
13 evant to a particular cosmetic use, a stand-  
14 ard that—

15 “(I) provides a reasonable cer-  
16 tainty that no harm will result from  
17 aggregate exposure to the cosmetic or  
18 ingredient, including impacts on vul-  
19 nerable populations, taking into ac-  
20 count possible harmful effects from  
21 low dose exposures to the cosmetic or  
22 ingredient or from additive effects,  
23 where such evidence exists; and

24 “(II) is requisite to protect the  
25 public welfare from any known or an-

1            anticipated adverse effects associated  
2            with the cosmetic or ingredient; and

3            “(ii) with respect to a cosmetic, when  
4            the route of exposure is directly relevant to  
5            the use of the cosmetic, a standard that a  
6            cosmetic fails to meet if—

7                    “(I) the cosmetic would fail to  
8                    meet the standard under clause (i) if  
9                    the cosmetic was treated in the same  
10                   the manner as an ingredient under such  
11                   clause; or

12                   “(II) one or more ingredients in  
13                   the cosmetic fail to meet such stand-  
14                   ard.

15            “(B) DETERMINATION OF SAFETY.—A  
16            cosmetic or ingredient shall fail to meet the  
17            safety standard under subparagraph (A)—

18                    “(i) unless the Secretary determines  
19                    that there is a reasonable certainty that no  
20                    harm will result from aggregate exposure  
21                    to the ingredient or cosmetic, including im-  
22                    pacts on highly exposed or vulnerable pop-  
23                    ulations, taking into account, where evi-  
24                    dence exists, possible harmful effects  
25                    from—

1 “(I) low dose exposures to the  
2 cosmetic or ingredient; or

3 “(II) additive effects; or

4 “(ii) if the Secretary determines nec-  
5 essary to protect the public welfare from  
6 any known or anticipated adverse effects  
7 associated with the cosmetic or ingredient.

8 “(6) VULNERABLE POPULATIONS.—The term  
9 ‘vulnerable populations’ includes pregnant women,  
10 infants, children, the elderly, people with com-  
11 promised immune systems, and highly exposed popu-  
12 lations, including workers employed by establish-  
13 ments listed under paragraph (2) and cosmetic man-  
14 ufacturing plants.

15 **“SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REG-  
16 ISTRATION FEES.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) DOMESTIC ESTABLISHMENT.—The term  
19 ‘domestic establishment’ means an establishment lo-  
20 cated in any State that manufactures, packages, or  
21 distributes cosmetics.

22 “(2) FOREIGN ESTABLISHMENT.—

23 “(A) IN GENERAL.—The term ‘foreign es-  
24 tablishment’ means an establishment that man-  
25 ufactures, packages, or distributes cosmetics

1 that are exported to the United States without  
2 further processing or packaging outside the  
3 United States.

4 “(B) NOT CONSIDERED TO HAVE UNDER-  
5 GONE FURTHER PROCESSING OR PACKAGING.—  
6 A cosmetic may not be considered to have un-  
7 dergone further processing or packaging for  
8 purposes of subparagraph (A) solely on the  
9 basis that labeling was added or that any simi-  
10 lar activity of a de minimis nature was carried  
11 out with respect to the cosmetic.

12 “(b) REGISTRATION.—The Secretary shall require  
13 that any establishment engaged in manufacturing, pack-  
14 aging, or distributing cosmetics for use in the United  
15 States register annually with the Secretary. To be reg-  
16 istered—

17 “(1) as a domestic establishment, the owner,  
18 operator, or agent in charge of the domestic estab-  
19 lishment shall submit a registration to the Secretary;  
20 or

21 “(2) as a foreign establishment, the owner, op-  
22 erator, or agent in charge of the foreign establish-  
23 ment—

24 “(A) shall submit a registration to the Sec-  
25 retary; and



1           “(B) shall include with the registration the  
2           name of the United States agent for the foreign  
3           establishment.

4           “(c) SUBMISSION OF REGISTRATION.—

5           “(1) IN GENERAL.—An establishment (referred  
6           to in this section as the ‘registrant’) shall submit a  
7           registration under subsection (b) to the Secretary  
8           containing, with respect to any cosmetics that the  
9           establishment manufactures, packages, or distrib-  
10          utes—

11           “(A) any information necessary to notify  
12           the Secretary of the name and address of each  
13           establishment at which, and all trade names  
14           under which, the registrant manufactures,  
15           packages, or distributes cosmetics;

16           “(B) a description of the establishment’s  
17           activities with respect to cosmetics;

18           “(C) the number of workers employed at  
19           the establishment;

20           “(D) the gross receipts of sales; and

21           “(E) the name and address of any com-  
22           pany that supplies the establishment, if the es-  
23           tablishment manufactures cosmetics, with any  
24           ingredient (including preservatives, fragrances,  
25           or any other chemical component of a finished

1 cosmetic product) and the name of the ingre-  
2 dient supplied to such establishment by such  
3 supplier.

4 “(2) NOTIFICATION OF CHANGES.—

5 “(A) IN GENERAL.—The registrant shall  
6 notify the Secretary in a timely manner of  
7 changes to the information described in para-  
8 graph (1).

9 “(B) DEADLINE FOR CERTAIN  
10 CHANGES.—The registrant shall notify the Sec-  
11 retary of any change in the products, function,  
12 or legal status of each establishment at which  
13 the registrant manufactures, packages, or dis-  
14 tributes cosmetics (including cessation of busi-  
15 ness activities) not later than 60 days after the  
16 date of such change.

17 “(d) PROCEDURE.—Upon receipt of a completed reg-  
18 istration submitted under subsection (b), the Secretary  
19 shall notify the registrant of the receipt of such registra-  
20 tion and assign a registration number to each registered  
21 establishment.

22 “(e) LIST OF REGISTERED ESTABLISHMENTS.—

23 “(1) MAINTENANCE OF LIST.—The Secretary  
24 shall compile and maintain an up-to-date list of es-  
25 tablishments that are registered under this section.

1           “(2) REMOVAL AND SUSPENSION.—The Sec-  
2           retary shall remove from the list under paragraph  
3           (1) the name of any establishment that fails to re-  
4           register in accordance with this section and shall  
5           treat such removal as a suspension of the establish-  
6           ment’s registration.

7           “(3) APPLICATION OF FOIA.—

8           “(A) LIST.—The list under paragraph (1)  
9           shall be subject to disclosure under section 552  
10          of title 5, United States Code.

11          “(B) REGISTRATION DOCUMENTS.—Any  
12          registration documents submitted pursuant to  
13          this section shall not be subject to disclosure  
14          under section 552 of title 5, United States  
15          Code.

16          “(C) OTHER INFORMATION.—Information  
17          derived from—

18                  “(i) the list under paragraph (1); or

19                  “(ii) registration documents submitted  
20                  pursuant to this section,

21          shall not be subject to disclosure under section  
22          552 of title 5, United States Code, except to the  
23          extent that such information discloses the iden-  
24          tity or location of a specific registrant.

1       “(f) FEE SCHEDULE.—A schedule of fees shall be de-  
2 veloped by the Secretary to provide for oversight and en-  
3 forcement of this subchapter. The fee structure shall—

4               “(1) be prorated based on the establishment’s  
5 gross receipts or sales; and

6               “(2) only be assessed on companies with annual  
7 gross receipts or sales of more than \$1,000,000.

8       “(g) REGISTRATION CANCELLATION.—The Secretary  
9 may cancel the registration of any establishment under  
10 this section—

11               “(1) if the information submitted by the estab-  
12 lishment for such registration is incomplete, inac-  
13 curate, or out-of-date; or

14               “(2) if a registered establishment fails to up-  
15 date such information promptly when there is a  
16 change in such information.

17 **“SEC. 613. INGREDIENTS LABELS ON COSMETICS.**

18       “(a) IN GENERAL.—The Secretary shall require the  
19 label on each package of cosmetics, including cosmetics  
20 distributed for retail sale and professional use, to bear a  
21 declaration of the name of each ingredient in such cos-  
22 metic in descending order of predominance. The Secretary  
23 may allow that the declaration of an ingredient present  
24 as a contaminant is not required if the contaminant is  
25 present at levels below technically feasible detection limits.

1       “(b) LABELING OF INGREDIENTS IN COSMETICS  
2 SOLD THROUGH INTERNET COMMERCE.—Subject to sub-  
3 section (d), the Secretary shall require—

4           “(1) in the case of a cosmetic sold on the Web  
5 site of an Internet vendor, that the manufacturers  
6 and distributors of such cosmetic provide to such  
7 Internet vendor a list of the ingredients of the cos-  
8 metic; and

9           “(2) each Internet vendor to display the list of  
10 ingredients of each cosmetic sold by such vendor on  
11 the Web site of the vendor.

12       “(c) TRADE SECRETS.—Notwithstanding any other  
13 provision of law, an ingredient required to be listed or la-  
14 beled under this section shall not have protection as a  
15 trade secret.

16       “(d) DEADLINE.—Not later than one year after the  
17 date of the enactment of the Safe Cosmetics Act of  
18 2010—

19           “(1) all cosmetics that are available for retail  
20 sale shall be labeled in a manner that complies with  
21 the requirements under subsection (a); and

22           “(2) manufacturers, distributors, and Internet  
23 vendors shall comply with the applicable require-  
24 ments of subsection (b).

1 **“SEC. 614. COSMETIC AND INGREDIENT TESTING AND SAFE-**  
2 **TY.**

3 “(a) PUBLICLY AVAILABLE COSMETIC AND INGRE-  
4 DIENT TEST DATA.—

5 “(1) SUBMISSION OF INFORMATION.—

6 “(A) INITIAL SUBMISSION.—Not later than  
7 1 year after the date of the enactment of the  
8 Safe Cosmetics Act of 2010, manufacturers and  
9 distributors of cosmetics and ingredients shall  
10 submit to the Secretary (in an electronic format  
11 that the Secretary shall determine) all reason-  
12 ably available information in the possession or  
13 control of the manufacturer or distributor that  
14 has not previously been submitted to the Sec-  
15 retary regarding the physical, chemical, and  
16 toxicological properties of single or multiple  
17 chemicals listed on the cosmetic labels under  
18 section 613, including—

19 “(i) functions and uses;

20 “(ii) exposure and fate information;

21 “(iii) tests of finished cosmetics; and

22 “(iv) any other information used to  
23 substantiate the safety of such cosmetics  
24 or ingredients.

25 “(B) NEW OR UPDATED INFORMATION.—

26 Not later than 60 days after the date on which

1 new or updated information that is required  
2 under subparagraph (A) becomes available to a  
3 manufacturer or distributor, such manufacturer  
4 or distributor shall submit such information to  
5 the Secretary in the same form and manner as  
6 information submitted under subparagraph (A).

7 “(2) AVAILABILITY OF INFORMATION.—The  
8 Secretary shall require that any manufacturer, dis-  
9 tributor, or marketer of a cosmetic or ingredient (in-  
10 cluding a fragrance or preservative) make available  
11 to any entity purchasing the cosmetic or ingredient  
12 (excluding an individual who is a consumer and who  
13 is purchasing the cosmetic or ingredient for personal  
14 use) all available information in the possession or  
15 control of the manufacturer, distributor, or marketer  
16 described in paragraph (1), within 90 days of receipt  
17 of the request from such entity.

18 “(3) DATABASE.—

19 “(A) INITIAL PUBLICATION.—Not later  
20 than 12 months after the date of the enactment  
21 of the Safe Cosmetics Act of 2010, the Sec-  
22 retary shall publish a comprehensive, publicly  
23 accessible database containing all non-confiden-  
24 tial information submitted under paragraph (1).

1           “(B) UPDATES.—Not later than 90 days  
2           after the Secretary receives new or updated in-  
3           formation under paragraph (1)(B), the Sec-  
4           retary shall update the database described in  
5           subparagraph (A) with such information.

6           “(b) LISTS OF INGREDIENTS.—

7           “(1) PROHIBITED AND RESTRICTED INGREDI-  
8           ENTS.—

9           “(A) LIST OF INGREDIENTS THAT ARE  
10           PROHIBITED OR RESTRICTED.—Not later than  
11           2 years after the date of the enactment of the  
12           Safe Cosmetics Act of 2010, the Secretary shall  
13           issue, by regulation, a list of ingredients that  
14           are identified by the Secretary as—

15                   “(i) prohibited ingredients; or

16                   “(ii) restricted ingredients.

17           “(B) UPDATES.—The Secretary shall con-  
18           tinually update the list under subparagraph  
19           (A), including when—

20                   “(i) determinations under paragraph  
21                   (3)(D) are made; or

22                   “(ii) new information becomes avail-  
23                   able demonstrating that an ingredient fails  
24                   to meet the safety standard.

25           “(C) INFORMATION SOURCES.—



1           “(i) USE OF AUTHORITATIVE INFOR-  
2           MATION.—The list under subparagraph  
3           (A) shall contain ingredients that are  
4           known to be carcinogenic, mutagenic, or  
5           have reproductive and developmental tox-  
6           icity, based on information from the Envi-  
7           ronmental Protection Agency, the Inter-  
8           national Agency for Research on Cancer,  
9           the National Toxicity Program through the  
10          National Institutes of Health, the Cali-  
11          fornia Environmental Protection Agency,  
12          and other authoritative international, Fed-  
13          eral, and State entities (as determined by  
14          the Secretary).

15          “(ii) USE OF OTHER INFORMATION  
16          SOURCES.—In identifying ingredients for  
17          purposes of the list under subparagraph  
18          (A), the Secretary shall use all reasonably  
19          available information, including new sci-  
20          entific information and submissions from  
21          manufacturers and distributors of cos-  
22          metics.

23          “(D) PROHIBITED INGREDIENTS.—Ingre-  
24          dients that are listed as prohibited under sub-  
25          paragraph (A) shall include all ingredients that

1 the Secretary determines are unsafe for use in  
2 cosmetics in any amount because such ingredi-  
3 ents fail to meet the safety standard defined in  
4 section 611(5).

5 “(E) RESTRICTED INGREDIENTS.—Ingre-  
6 dients that are listed as restricted under sub-  
7 paragraph (A) shall include all ingredients for  
8 which the Secretary determines that limits on  
9 use or concentration are necessary to satisfy the  
10 safety standard defined in section 611(5).

11 “(F) INGREDIENTS AND COSMETICS  
12 FOUND TO INDUCE CANCER OR BIRTH DEFECTS  
13 OR HAVE REPRODUCTIVE OR DEVELOPMENTAL  
14 TOXICITY.—

15 “(i) PRESUMPTION.—The Secretary  
16 shall presume that any ingredient or cos-  
17 metic that induces cancer or birth defects  
18 or has reproductive or developmental tox-  
19 icity when ingested by, inhaled by, or  
20 dermally applied to a human or an animal  
21 has failed to meet the safety standard (as  
22 defined in section 611(5)).

23 “(ii) REBUTTAL.—The presumption  
24 under clause (i) may be rebutted only if  
25 the Secretary determines that the ingre-

1           dient or cosmetic meets such safety stand-  
2           ard.

3           “(iii) PUBLIC COMMENT.—The Sec-  
4           retary shall solicit public comment before  
5           making a determination under clause (ii).

6           “(2) SAFE WITHOUT LIMITS.—

7           “(A) IN GENERAL.—Not later than 2 years  
8           after the date of the enactment of the Safe Cos-  
9           metics Act of 2010, the Secretary shall issue,  
10          by regulation, a list of ingredients that the Sec-  
11          retary has determined are safe without limits  
12          for use in cosmetics.

13          “(B) STANDARD FOR INCLUSION IN  
14          LIST.—The Secretary may only include an in-  
15          gredient on the list under subparagraph (A) if  
16          the Secretary determines that such ingredient  
17          meets the safety standard (as defined in section  
18          611(5)) regardless of—

19                 “(i) the type and form of cosmetic the  
20                 ingredient is used in; or

21                 “(ii) the concentration of the ingre-  
22                 dient that is used in a cosmetic.

23          “(C) UPDATE.—The Secretary shall up-  
24          date the list under subparagraph (A) when new  
25          information becomes available.

1           “(D) CONSULTATIONS.—In determining  
2 whether a cosmetic or ingredient is safe, the  
3 Secretary shall consult hazard listings and as-  
4 sessments from authoritative international,  
5 Federal, and State entities, including the enti-  
6 ties listed in paragraph (1)(C)(i).

7           “(E) REDETERMINATIONS.—The Secretary  
8 may redetermine whether a cosmetic or ingre-  
9 dient distributed in commerce meets the safety  
10 standard if, in the judgment of the Secretary,  
11 new information raises a credible question as to  
12 whether the cosmetic or ingredient continues to  
13 meet the safety standard.

14           “(3) PRIORITY ASSESSMENT LIST.—

15           “(A) IN GENERAL.—Not later than 18  
16 months after the date of the enactment of the  
17 Safe Cosmetics Act of 2010, the Secretary shall  
18 develop a priority assessment list of not less  
19 than 300 ingredients—

20                   “(i) which cannot be included on the  
21 restricted and prohibited list under para-  
22 graph (1) or the safe without limits list  
23 under paragraph (2) because of a lack of  
24 authoritative information on the safety of  
25 the ingredient; and

1                   “(ii) for which safety determinations  
2                   under subparagraph (D) shall be made.

3                   “(B) ADDITIONAL INGREDIENTS.—The  
4                   Secretary shall add not less than 100 ingredi-  
5                   ents to the priority assessment list under sub-  
6                   paragraph (A) annually until all ingredients  
7                   that are used in the formulation or manufac-  
8                   ture of cosmetics have been added to the pri-  
9                   ority assessment list, the safe without limits  
10                  list, or the prohibited and restricted list.

11                  “(C) CONSIDERATIONS.—In developing or  
12                  updating the priority assessment list under this  
13                  paragraph, the Secretary shall take into ac-  
14                  count all relevant data with respect to ingredi-  
15                  ents including whether the ingredients—

16                         “(i) react to form harmful byproducts;

17                         “(ii) are found to be present in the  
18                         body through biomonitoring;

19                         “(iii) are found in drinking water or  
20                         indoor or outdoor air;

21                         “(iv) are a known or suspected neuro-  
22                         logical or immunological toxicant, res-  
23                         piratory asthmagens, or endocrine  
24                         disruptor, or have other toxicological con-  
25                         cerns; or

1 “(v) persist in the environment or bio-  
2 accumulate.

3 “(D) DETERMINATION OF WHETHER IN-  
4 GREDIENT MEETS SAFETY STANDARD.—

5 “(i) IN GENERAL.—Not later than 24  
6 months after the date on which an ingre-  
7 dient is placed on the priority assessment  
8 list under subparagraph (A), the Secretary  
9 shall issue, by rule, a determination of—

10 “(I) whether the ingredient meets  
11 the safety standard (as defined in sec-  
12 tion 611(5)) and can be placed on the  
13 safe without limits list under para-  
14 graph (2); or

15 “(II) whether to include the in-  
16 gredient in the prohibited and re-  
17 stricted ingredients list under para-  
18 graph (1), to ensure that the safety  
19 standard is not violated.

20 “(ii) RULEMAKING.—Before issuing  
21 final regulations under clause (ii), the Sec-  
22 retary shall issue a notice of proposed rule-  
23 making and provide a period of not less  
24 than 60 days for public comment on the  
25 proposed regulation, except that a shorter

1 period for comment may be provided if the  
2 Secretary—

3 “(I) finds that it would be in the  
4 public interest to have a shorter pe-  
5 riod; and

6 “(II) states the reasons for such  
7 finding in the notice of proposed rule-  
8 making.

9 “(c) MANUFACTURER INFORMATION AND SAFETY  
10 TESTING.—

11 “(1) PROVISION OF INFORMATION.—A manu-  
12 facturer of an ingredient or cosmetic shall provide to  
13 the Secretary, through a statement under paragraph  
14 (3), all information required to determine if an in-  
15 gredient or cosmetic meets the safety standard.

16 “(2) MINIMUM DATA REQUIREMENTS AND TEST  
17 PROTOCOLS.—Not later than 1 year after the date  
18 of the enactment of the Safe Cosmetics Act of 2010,  
19 the Secretary shall establish minimum data require-  
20 ments and test protocols to be used by manufactur-  
21 ers to assess the safety of cosmetic ingredients that  
22 would ensure that statements under paragraph  
23 (3)(A) regarding compliance with the safety stand-  
24 ard are based on sufficient and reliable data.

25 “(3) STATEMENTS.—

1           “(A) IN GENERAL.—Not later than 18  
2 months after the date of the enactment of the  
3 Safe Cosmetics Act of 2010, each manufacturer  
4 or marketer of a cosmetic shall submit to the  
5 Secretary a statement signed by the chief execu-  
6 tive officer of such manufacturer or marketer,  
7 based on available information after a good  
8 faith inquiry, that—

9                   “(i) the cosmetic and its ingredients  
10 meet the safety standard; or

11                   “(ii) there is insufficient data to de-  
12 termine whether the cosmetic and its in-  
13 gredients meet the safety standard.

14           “(B) UPDATES.—Each manufacturer or  
15 marketer of a cosmetic shall update the state-  
16 ment under subparagraph (A) when there be-  
17 comes available significant new information re-  
18 garding the safety, or lack thereof, of a cos-  
19 metic or its ingredients.

20           “(4) AUDIT.—The Secretary shall perform an  
21 annual comprehensive data audit on a statistically  
22 significant number of the statements submitted by  
23 manufacturers or marketers under paragraph (3).

24           “(d) NANOMATERIALS IN COSMETICS.—The Sec-  
25 retary shall—



1           “(1) monitor developments in the scientific un-  
2           derstanding of any adverse health effects related to  
3           the use of nanotechnology in the formulation of cos-  
4           metics; and

5           “(2) consider scale specific hazard properties of  
6           ingredients when conducting or reviewing safety sub-  
7           stantiation of cosmetic ingredients.

8           “(e) **PRODUCT TESTING AND REVIEW AUDIT.**—The  
9           Secretary shall conduct annual audits of random samples  
10          of cosmetic products to assess or test for acute negative  
11          reactions, pathogen hazards, contaminants, or leaching of  
12          packaging additives, mislabeling, or other relevant issues  
13          of concern (as determined by the Secretary).

14          **“SEC. 615. MARKET RESTRICTIONS.**

15          “(a) **FAILURE TO PROVIDE DATA OR MEET SAFETY**  
16          **STANDARD.**—No person shall manufacture, import, dis-  
17          tribute, or market in commerce a cosmetic or an ingre-  
18          dient for use in a cosmetic if the Secretary determines  
19          that—

20                 “(1) the person failed to provide information to  
21                 the Secretary as required under this subchapter; or

22                 “(2) beginning 180 days after the date on  
23                 which the Secretary places an ingredient on a list  
24                 under section 614(b)(1)—

25                         “(A) the ingredient—

1                   “(i) is on the list under section  
2                   614(b)(1)(A)(i); or

3                   “(ii) is a cosmetic containing an in-  
4                   gredient on such list;

5                   “(B) the ingredient is on the list under  
6                   section 614(b)(1)(A)(ii) and is being used in a  
7                   cosmetic in a manner that violates the limit on  
8                   use or concentration of such ingredient under  
9                   section 614(b)(1)(E).

10                  “(b) FAILURE OF SECRETARY TO ACT.—

11                   “(1) ISSUANCE OF PENDING NOTIFICATION.—If  
12                   the Secretary fails to act by an applicable deadline  
13                   under section 614, a manufacturer or marketer of  
14                   an ingredient affected by the failure to act shall  
15                   issue to the Secretary, the public, and each known  
16                   customer of the ingredient a written notice that a  
17                   determination by the Secretary of the safety of the  
18                   ingredient for use in cosmetics is pending.

19                   “(2) PROHIBITED USE.—If, by the last day of  
20                   the 5 year period beginning on the date on which an  
21                   ingredient is placed on the priority assessment list  
22                   under section 614(b)(3), the Secretary has not made  
23                   a determination under such section concerning  
24                   whether such ingredient meets the safety standard,  
25                   the ingredient may not be—

1                   “(A) used in cosmetics; or

2                   “(B) manufactured, imported, distributed,  
3                   or marketed for use in cosmetics.

4 **“SEC. 616. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
5 **OF ADULTERATED OR MISBRANDED COS-**  
6 **METICS.**

7                   “(a) NOTIFICATION, NONDISTRIBUTION, AND RE-  
8 CALL OF ADULTERATED OR MISBRANDED COSMETICS.—

9                   “(1) IN GENERAL.—A responsible party that  
10                  has reason to believe that a cosmetic, when intro-  
11                  duced into or while in interstate commerce, or while  
12                  held for sale (regardless of whether such sale is the  
13                  first sale of such cosmetic) after shipment in inter-  
14                  state commerce, is adulterated or misbranded in a  
15                  manner that presents a reasonable probability that  
16                  the use or exposure to the cosmetic (or an ingredient  
17                  or component used in any such cosmetic) will cause  
18                  a threat of serious adverse health consequences or  
19                  death to humans shall, as soon as practicable, notify  
20                  the Secretary of the identity and location of the cos-  
21                  metic.

22                  “(2) MANNER OF NOTIFICATION.—Notification  
23                  under paragraph (1) shall be made in such manner  
24                  and by such means as the Secretary may require by  
25                  regulation or guidance.

1           “(3) RESPONSIBLE PARTY DEFINED.—For pur-  
2           poses of this subsection, the term ‘responsible party’  
3           means a manufacturer, packager, retailer, or dis-  
4           tributor of the cosmetic.

5           “(b) VOLUNTARY RECALL.—The Secretary may re-  
6           quest that any person who distributes a cosmetic that the  
7           Secretary has reason to believe is adulterated, misbranded,  
8           or otherwise in violation of this Act voluntarily—

9           “(1) recall such cosmetic; and

10           “(2) provide for notice, including to individuals  
11           as appropriate, to persons who may be affected by  
12           the recall.

13           “(c) ORDER TO CEASE DISTRIBUTION.—

14           “(1) IN GENERAL.—If the Secretary has reason  
15           to believe that—

16           “(A) the use of, or exposure to, a cosmetic  
17           may cause serious adverse health consequences  
18           or death to humans;

19           “(B) the cosmetic is misbranded; or

20           “(C) the cosmetic is manufactured, pack-  
21           aged, or distributed by an unregistered facility;  
22           the Secretary shall have the authority to issue an  
23           order requiring any person who distributes such cos-  
24           metic to immediately cease distribution of such cos-  
25           metic.

1           “(2) ACTION FOLLOWING ORDER.—Any person  
2           who is subject to an order under paragraph (1) shall  
3           immediately cease distribution of such cosmetic and  
4           provide notification as required by such order, and  
5           may appeal such order to the Secretary within 24  
6           hours of the issuance of such order. Such appeal  
7           may include a request for an informal hearing and  
8           a description of any efforts to recall such cosmetic  
9           undertaken voluntarily by the person, including after  
10          a request under subsection (b). Except as provided  
11          in subsection (e), an informal hearing shall be held  
12          as soon as practicable, but not later than 5 calendar  
13          days, or less as determined by the Secretary, after  
14          such an appeal is filed, unless the parties jointly  
15          agree to an extension. After affording an oppor-  
16          tunity for an informal hearing, the Secretary shall  
17          determine whether the order should be amended to  
18          require a recall of such cosmetic. If, after providing  
19          an opportunity for such a hearing, the Secretary de-  
20          termines that inadequate grounds exist to support  
21          the actions required by the order, the Secretary shall  
22          vacate the order.

23          “(d) ORDER TO RECALL.—

24                 “(1) AMENDMENT.—Except as provided under  
25                 subsection (e), if after providing an opportunity for

1 an informal hearing under subsection (c)(2), the  
2 Secretary determines that the order should be  
3 amended to include a recall of the cosmetic with re-  
4 spect to which the order was issued, the Secretary  
5 shall amend the order to require a recall.

6 “(2) CONTENTS.—An amended order under  
7 paragraph (1) shall—

8 “(A) specify a timetable in which the recall  
9 will occur;

10 “(B) require periodic reports to the Sec-  
11 retary describing the progress of the recall; and

12 “(C) provide for notice, including to indi-  
13 viduals as appropriate, to persons who may be  
14 affected by the recall.

15 In providing for such notice, the Secretary may  
16 allow for the assistance of health professionals, State  
17 or local officials, or other individuals designated by  
18 the Secretary.

19 “(3) NONDELEGATION.—An amended order  
20 under this subsection shall be ordered by the Sec-  
21 retary or an official designated by the Secretary. An  
22 official may not be so designated unless the official  
23 is the director of the district under this Act in which  
24 the cosmetic involved is located, or is an official sen-  
25 ior to such director.

1 “(e) EMERGENCY RECALL ORDER.—

2 “(1) IN GENERAL.—If the Secretary has cred-  
3 ible evidence or information that a cosmetic subject  
4 to an order under subsection (c) presents an immi-  
5 nent threat of serious adverse health consequences  
6 or death to humans, the Secretary may issue an  
7 order requiring any person who distributes such cos-  
8 metic—

9 “(A) to immediately recall such cosmetic;  
10 and

11 “(B) to provide for notice, including to in-  
12 dividuals as appropriate, to persons who may be  
13 affected by the recall.

14 “(2) ACTION FOLLOWING ORDER.—Any person  
15 who is subject to an emergency recall order under  
16 this subsection shall immediately recall such cos-  
17 metic and provide notification as required by such  
18 order, and may appeal within 24 hours after  
19 issuance such order to the Secretary. An informal  
20 hearing shall be held as soon as practicable but not  
21 later than 5 calendar days, or less as determined by  
22 the Secretary, after such an appeal is filed, unless  
23 the parties jointly agree to an extension. After af-  
24 fording an opportunity for an informal hearing, the  
25 Secretary shall determine whether the order should

1 be amended pursuant to subsection (d)(1). If, after  
2 providing an opportunity for such a hearing, the  
3 Secretary determines that inadequate grounds exist  
4 to support the actions required by the order, the  
5 Secretary shall vacate the order.

6 “(3) NONDELEGATION.—An order under this  
7 subsection shall be issued by the Commissioner of  
8 Food and Drugs, the Principal Deputy Commis-  
9 sioner, or the Associate Commissioner for Regu-  
10 latory Affairs of the Food and Drug Administration.

11 “(f) NOTICE TO CONSUMERS AND HEALTH OFFI-  
12 CIALS.—The Secretary shall, as the Secretary determines  
13 to be necessary, provide notice of a recall order under this  
14 section to consumers to whom the cosmetic was, or may  
15 have been, distributed and to appropriate State and local  
16 health officials.

17 “(g) SAVINGS CLAUSE.—Nothing contained in this  
18 section shall be construed as limiting the authority of the  
19 Secretary to issue an order to cease distribution of, or to  
20 recall, a cosmetic under any other provision of this Act.

21 **“SEC. 617. PETITIONS.**

22 “(a) IN GENERAL.—The Secretary shall complete  
23 and publish a review, and, if appropriate, immediately re-  
24 vise related, relevant information, including ingredient  
25 lists, ingredient restrictions or prohibitions, or ingredient



1 or cosmetic safety determinations, not later than 180 days  
2 after the date on which the Secretary receives from any  
3 individual or entity a reasonable petition—

4 “(1) to prohibit or restrict an ingredient for use  
5 in cosmetics and list such ingredient on the list  
6 under section 614(b)(1);

7 “(2) to remove an ingredient from the list of in-  
8 gredients that are safe without limits under section  
9 614(b)(2); or

10 “(3) to add an ingredient to the priority assess-  
11 ment list under section 614(b)(3).

12 “(b) REASONABLE PETITION.—Not later than one  
13 year after the date of the enactment of this Act, the Sec-  
14 retary shall issue rules specifying the criteria which the  
15 Secretary will use to determine if a petition submitted  
16 under this section is a reasonable petition.

17 **“SEC. 618. COSMETIC AND INGREDIENT STATEMENTS.**

18 “(a) IN GENERAL.—Each establishment engaged in  
19 the manufacture of a cosmetic intended to be marketed  
20 in the United States shall submit electronically to the Sec-  
21 retary for each cosmetic manufactured in the establish-  
22 ment that is intended to be marketed in the United States  
23 a statement containing—

24 “(1) the registration number of the manufac-  
25 turing establishment where the cosmetic is manufac-

1       tured or, if the same cosmetic is manufactured in  
2       more than 1 establishment, the registration number  
3       of each establishment where it is manufactured;

4               “(2) the registration number of the establish-  
5       ment responsible for distributing the cosmetic;

6               “(3) the brand name and the product name for  
7       the cosmetic;

8               “(4) the applicable use for the cosmetic;

9               “(5) the ingredient list as it appears on the cos-  
10      metic label or insert, including the particle size of  
11      any nanoscale cosmetic ingredients;

12              “(6) any warnings and directions for use from  
13      the cosmetic label or insert; and

14              “(7) the title and full contact information for  
15      the individual responsible for submitting and main-  
16      taining such statement.

17      “(b) NOTIFICATION OF CHANGES.—The establish-  
18      ment shall notify the Secretary in a timely manner of any  
19      change to the information required under subsection (a).

20      “(c) PROCEDURE.—Upon receipt of a completed  
21      statement described under subsection (a), the Secretary  
22      shall notify the establishment of the receipt of such state-  
23      ment and assign a cosmetic statement number.

1       “(d) LIST.—The Secretary shall compile and main-  
2       tain an up-to-date list of cosmetics for which statements  
3       are submitted under this section.

4       “(e) LABELING OF NANOMATERIALS IN COS-  
5       METICS.—The Secretary may require that—

6               “(1) minerals and other particulate ingredients  
7       be labeled as ‘nano-scale’ on a cosmetic ingredient  
8       label or list if not less than 1 dimension is 100  
9       nanometers or smaller for not less than 1 percent of  
10      the ingredient particles in the cosmetic; and

11              “(2) other ingredients in a cosmetic be des-  
12      ignated with scale-specific information on a cosmetic  
13      ingredient label or list if such ingredients possess  
14      scale-specific hazard properties.

15      “(f) ACCESS TO SAFETY INFORMATION.—The cos-  
16      metic and ingredient statements collected under this sec-  
17      tion shall be added to the publicly accessible database cre-  
18      ated by the Secretary under section 614(a)(3).

19      “(g) EFFECTIVE DATES.—

20              “(1) IN GENERAL.—The provisions of this sec-  
21      tion shall take effect 1 year after the date of the en-  
22      actment of the Safe Cosmetics Act of 2010.

23              “(2) APPLICATION TO NEW COSMETICS.—An  
24      establishment that begins to manufacture a cosmetic  
25      after the date of the enactment of the Safe Cos-

1       metics Act of 2010 shall comply with the require-  
2       ments of subsections (a) and (b) not later than 6  
3       months after beginning to manufacture such cos-  
4       metic.

5       **“SEC. 619. MANDATORY REPORTING OF ADVERSE HEALTH**  
6                                   **EFFECTS.**

7           “(a) SUBMISSION OF REPORT ON ADVERSE HEALTH  
8       EFFECTS.—The Secretary shall require that the manufac-  
9       turer, packager, or distributor of a cosmetic whose name  
10      appears on the label of a cosmetic marketed in the United  
11      States submit to the Secretary a report containing infor-  
12      mation received concerning any serious adverse event asso-  
13      ciated with the use of the cosmetic.

14          “(b) TIMING OF REPORT.—A report under subsection  
15      (a) shall be submitted to the Secretary not later than 15  
16      business days after information concerning the adverse  
17      event is received at the place of business of the manufac-  
18      turer, packager, or distributor.

19          “(c) CONTENT OF REPORT.—A report under sub-  
20      section (a) shall include the following information to the  
21      extent to which the manufacturer, packager, or distributor  
22      submitting the report has been able to verify the informa-  
23      tion:

24                   “(1) An identifiable patient.

25                   “(2) An identifiable report.

1           “(3) A suspect cosmetic.

2           “(4) A serious and unexpected adverse event.

3           “(d) PUBLIC AVAILABILITY AND PRIVACY.—

4           “(1) PUBLIC AVAILABILITY.—Subject to para-  
5 graph (2), the adverse health effects reports col-  
6 lected by the Secretary under this section shall be  
7 submitted electronically and shall be made accessible  
8 to the public.

9           “(2) PRIVACY.—

10           “(A) PERSONALLY IDENTIFIABLE INFOR-  
11 MATION.—Notwithstanding any other provision  
12 of law, personally identifiable information in ad-  
13 verse event reports provided to the Secretary  
14 under this section, shall not—

15           “(i) be made publicly available pursu-  
16 ant to any State or other law requiring dis-  
17 closure of information or records; or

18           “(ii) otherwise be disclosed or distrib-  
19 uted to any party without the written con-  
20 sent of the Secretary and the person sub-  
21 mitting such information to the Secretary.

22           “(B) TREATMENT OF INFORMATION  
23 UNDER PRIVACY ACT AND FOIA.—An adverse  
24 event report submitted to the Secretary under  
25 this section, shall be considered to be a record

1 about an individual under section 552a of title  
2 5, United States Code (commonly referred to as  
3 the “Privacy Act of 1974”) and a medical or  
4 similar file the disclosure of which would con-  
5 stitute a violation of section 552 of such title 5  
6 (commonly referred to as the “Freedom of In-  
7 formation Act”), and shall not be publicly dis-  
8 closed unless all personally identifiable informa-  
9 tion is redacted.

10 **“SEC. 620. NONCONFIDENTIAL INFORMATION.**

11 “(a) IN GENERAL.—Subject to subsection (b) and  
12 section 619(d)(2), all nonconfidential information sub-  
13 mitted pursuant to this subchapter shall be made available  
14 to the public. The name, identity, and structure of a chem-  
15 ical substance, contaminant, or impurity that is an ingre-  
16 dient and all information concerning function, exposure,  
17 health hazards, and environmental hazards, and the func-  
18 tions of ingredients in cosmetics shall not be considered  
19 to be confidential business information under this sub-  
20 chapter. Fragrance, flavor, and colorants shall not be con-  
21 sidered confidential business information under this sub-  
22 chapter. The concentration of cosmetic ingredients used  
23 in a finished cosmetic shall be considered confidential busi-  
24 ness information except as otherwise required in section  
25 613.

1       “(b) PETITION FOR INFORMATION TO REMAIN CON-  
2 FIDENTIAL.—

3               “(1) IN GENERAL.—The Secretary shall create  
4 a process for an entity to petition for nonconfidential  
5 information described in subsection (a) to remain  
6 confidential if the entity shows that there would be  
7 serious commercial harm to such entity if such infor-  
8 mation were disclosed publicly.

9               “(2) LIMITATION.—The Secretary may not ap-  
10 prove a petition under paragraph (1) to the extent  
11 that such petition would prevent the public disclo-  
12 sure of—

13                       “(A) the name, identity, and structure of  
14 any substance referred to in subsection (a);

15                       “(B) all health and safety data related to  
16 that substance; or

17                       “(C) any data used to substantiate the  
18 safety of that substance.

19 **“SEC. 621. SAVINGS CLAUSE.**

20       “Nothing in this subchapter shall affect the right of  
21 a State, political subdivision of a State, or tribe to adopt  
22 or enforce any regulation, requirement, liability, or stand-  
23 ard of performance that is more stringent than a regula-  
24 tion, requirement, liability, or standard of performance es-

1 tablished by this subchapter, including requiring the provi-  
2 sion of a warning of risk, illness, or injury.

3 **“SEC. 622. ANIMAL TESTING ALTERNATIVES.**

4 “(a) IN GENERAL.—To minimize the use of animal  
5 testing of ingredients, the Secretary shall—

6 “(1) require, where practicable, alternative test-  
7 ing methods that—

8 “(A) do not involve the use of an animal  
9 to test the chemical substance;

10 “(B) provide information that is equivalent  
11 or superior in scientific quality to the animal  
12 testing method; and

13 “(C) use fewer animals than conventional  
14 animal-based tests when non-animal methods  
15 are impracticable, including the use of tests  
16 that combine multiple endpoints; and

17 “(2) encourage, where practicable—

18 “(A) estimation of toxicological properties  
19 of a chemical through the use of testing infor-  
20 mation for 1 or more structurally similar chemi-  
21 cals where such estimates provide information  
22 of sufficient scientific quality;

23 “(B) the formation of industry consortia to  
24 conduct testing to avoid duplication of tests;  
25 and



1                   “(C) funding for research and validation of  
2                   alternative test methods, in accordance with  
3                   this subsection.

4                   “(b) LIST OF ALTERNATIVE TESTING METHODS.—  
5 Not later than 1 year after the date of the enactment of  
6 the Safe Cosmetics Act of 2010, and triennially thereafter,  
7 the Secretary shall publish a list of the alternative testing  
8 methods described in subsection (a).

9                   **“SEC. 623. INTERAGENCY COOPERATION AND FUNDING.**

10                   “‘There is established an Interagency Council on Cos-  
11 metic Safety for the purpose of sharing data and pro-  
12 moting collaboration on cosmetic safety among and be-  
13 tween the Food and Drug Administration, the National  
14 Institute of Environmental Health Sciences, the Centers  
15 for Disease Control and Prevention, the Occupational  
16 Safety and Health Administration, and the Environmental  
17 Protection Agency.

18                   **“SEC. 624. AUTHORIZATION OF APPROPRIATIONS.**

19                   “‘There are authorized to be appropriated such sums  
20 as may be necessary to carry out this subchapter for each  
21 of the fiscal years 2011 through 2015.’”.

22                   (b) ADULTERATED AND MISBRANDED COSMETICS.—

23                   (1) ADULTERATED COSMETICS.—Section 601 of  
24 the Federal Food, Drug, and Cosmetic Act (21  
25 U.S.C. 361) is amended—

1           (A) in subsection (a), by striking “, except  
2           that this provision shall not apply to coal-tar  
3           hair dye” and all that follows through “or eye-  
4           brow dyes”; and

5           (B) by adding at the end the following:

6           “(f) If it—

7                 “(1) was manufactured, packaged, or distrib-  
8                 uted by an entity that failed to register as required  
9                 under section 612;

10                “(2) was sold by an Internet vendor that failed  
11                to comply with the requirements of section 613(b);

12                “(3) the person who manufactures, imports,  
13                distributes, or markets the cosmetic, or an ingre-  
14                dient in the cosmetic, fails to comply with the appli-  
15                cable requirements of section 615 (including failure  
16                to issue a notice required under section 615(b)(1));

17                “(4) is manufactured, packaged, distributed, or  
18                sold in retail by a manufacturer, packager, dis-  
19                tributor, or retailer, respectively, who fails to notify  
20                the Secretary as required under section 616(a);

21                “(5) is distributed in violation of an order  
22                under section 616(c);

23                “(6) is not recalled as required by an order  
24                under subsection (d) or (e) of section 616;

1           “(7) is manufactured in a manner that fails to  
2           comply with good manufacturing practices for cos-  
3           metics, as determined (and periodically updated), by  
4           the Secretary; or

5           “(8) is manufactured by a manufacturer who  
6           fails to submit the statement required under section  
7           618 or notify the Secretary of changes to informa-  
8           tion contained in such statement as required by such  
9           section.”.

10           (2) MISBRANDED COSMETICS.—Section 602 of  
11           the Federal Food, Drug, and Cosmetic Act (21  
12           U.S.C. 362) is amended in subsection (a), by insert-  
13           ing “, fails to meet the requirements of section  
14           613(a), or fails to meet any requirements under sec-  
15           tion 618(e)” before the period.

16 **SEC. 3. WORKER ISSUES.**

17           (a) IN GENERAL.—The Secretary of Labor shall pro-  
18           mulgate an occupational safety and health standard under  
19           section 6 of the Occupational Safety and Health Act of  
20           1970 (29 U.S.C. 655) that requires the following:

21           (1) MANUFACTURERS AND IMPORTERS.—

22                   (A) IN GENERAL.—Each manufacturer or  
23           importer selling any cosmetic for professional  
24           use shall—

1 (i) obtain or develop an expanded ma-  
2 terial safety data sheet described in sub-  
3 section (b) for each such cosmetic or per-  
4 sonal care product that—

5 (I) the manufacturer or importer  
6 produces or imports; and

7 (II) includes a hazardous chem-  
8 ical, or product ingredient associated  
9 with any chemical hazard, that has  
10 been indicated by authoritative bodies  
11 or scientific studies to be linked to  
12 health hazards including mutation, re-  
13 productive or developmental toxicity,  
14 neurotoxicity, endocrine disruption,  
15 asthma, or other immunological tox-  
16 icity; and

17 (ii) make the expanded material safety  
18 data sheet available to distributors and  
19 employers, including salon owners, in  
20 English and, upon request, in other lan-  
21 guages, including Spanish and Vietnamese.

22 (B) PROFESSIONAL USE DEFINED.—In  
23 this paragraph, the term “professional use” has  
24 the meaning given such term in section 611 of  
25 the Federal Food, Drug, and Cosmetic Act.

1           (2) DISTRIBUTORS.—Each distributor of a cos-  
2           metic or personal care product for professional use  
3           shall distribute and provide expanded material safety  
4           data sheets described in subsection (b) in the same  
5           manner as a distributor of a chemical hazard is re-  
6           quired to distribute and provide material safety data  
7           sheets under section 1910.1200(g) of title 29, Code  
8           of Federal Regulations, or any successor regulations.

9           (3) EMPLOYERS.—Each employer, including  
10          any operator of a salon, shall—

11                (A) have an expanded material safety data  
12                sheet in the workplace for each cosmetic or per-  
13                sonal care product for professional use that is  
14                used in the course of the employer’s business;

15                (B) make such expanded material safety  
16                data sheet available to all employees of the em-  
17                ployer who are exposed or use the product to  
18                the same extent and in the same manner as  
19                material safety data sheets are required to be  
20                made available under section 1910.1200(g) of  
21                title 29, Code of Federal Regulations, or any  
22                successor regulations; and

23                (C) upon request, provide employees with  
24                translations of such expanded material safety

1 data sheet in other languages, including Span-  
2 ish and Vietnamese.

3 (b) CONTENTS OF EXPANDED MATERIAL SAFETY  
4 DATA SHEET.—An expanded material safety data sheet  
5 for a cosmetic or personal care product for professional  
6 use described in this section shall—

7 (1) contain the information required in a mate-  
8 rial safety data sheet under section 1910.1200(g) of  
9 title 29, Code of Federal Regulations, or any suc-  
10 cessor regulations, for each hazardous chemical, or  
11 product ingredient associated with any chemical haz-  
12 ard, described in subsection (a)(1)(A)(i)(II); and

13 (2) include the following statement: “This ex-  
14 panded material safety data sheet is also available in  
15 multiple languages by contacting the manufacturer,  
16 using the contact information provided on this  
17 sheet.”.

18 **SEC. 4. FDA SAFETY STANDARD AS IT RELATES TO OTHER**  
19 **ADMINISTRATIVE AGENCIES.**

20 (a) USE OF DATA FROM FEDERAL SOURCES.—The  
21 Secretary shall request and utilize ingredient toxicity, use,  
22 and exposure data from other Federal agencies as appro-  
23 priate, to assist with developing the priority assessment  
24 list under section 614(b)(3) of the Federal Food, Drug,

1 and Cosmetic Act, and for reaching safety determinations  
2 under section 614(b)(3)(E) of such Act.

3 (b) USE OF OTHER FEDERAL STANDARDS.—If any  
4 Federal agency has promulgated a standard for an ingre-  
5 dient that satisfies the safety standard under section 611  
6 of the Federal Food, Drug, and Cosmetic Act, the Sec-  
7 retary may adopt it for purposes of this Act or an amend-  
8 ment made by this Act.

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