
Safe Cosmetics and Personal Care Products Act – H.R. 4296

REPRESENTATIVE JAN SCHAKOWSKY (D-IL)

SECTION BY SECTION SUMMARY

SEC. 1—SHORT TITLE AND TABLE OF CONTENTS.

SEC. 2— COSMETIC REGULATION

“Sec. 611. Definitions.

- Defines brand owner; contaminant; domestic establishment; foreign establishment; ingredient; manufacturer; microbusiness; professional use product; reasonable certainty of no harm; reproductive or developmental toxicity; serious adverse event; supplier; and vulnerable populations, including highly exposed populations such as salon workers and women of color.

“Sec. 612. Registration of establishments and registration fees.

- All brand owners, both foreign and domestic, that receive more than \$1 million in gross receipts must register with the Department of Health and Human Services (HHS) and provide the name, location, list of cosmetics products, their function, and gross sales receipts.
- For those brands that receive over \$10 million in sales, the HHS Secretary will establish a registration fee system.
- A registration may be suspended for submitting incomplete, inaccurate, or out-of-date information; not submitting required changes; not paying required fees; or any other violation. If the brand has not corrected the issue that caused suspension after 30 days, the Secretary can cancel the registration.
- Brands must submit registration every year and make necessary changes to the information. The Secretary will publish this up-to-date list of cosmetic manufacturers on the Food and Drug Administration (FDA) website and note any brands that have been suspended or cancelled.
- The information submitted to the Secretary through registration are not subject to the Freedom of Information Act.
- New brands will have 60 days after their product has been on the market to register with the Secretary.

“Sec. 613. Ingredients labels and website disclosure for cosmetics.

- Requires ingredient disclosure on the product labels of both retail and professional salon products.
- Requires disclosure of toxic fragrance and flavor chemicals on product labels (to be defined by whether the chemical is present on one of 23 hazard lists referenced by the bill or the EU fragrance allergens list) and full ingredient disclosure (including fragrance, flavor, colorants, contaminants, nanoparticles) on the fragrance manufacturer’s website.
- For cosmetics sold online, requires manufacturer to list ingredients on their own website and share ingredient list with any internet vendor to publish on the vendor’s website.
- All labeling must comply 18 months after the date of enactment.

“Sec. 614. Safety standard and good manufacturing practices.

- Requires the Secretary to establish a safety standard that provides a “reasonable certainty of no harm” and good manufacturing practices.

“Sec. 615. Cosmetic and ingredient safety information.

- Requires brands to electronically submit safety information on their cosmetics and ingredients to HHS; brands must update data annually and report adverse events within 60 days.
 - If the cosmetic/ingredient was on the market before the date of enactment, the brand has one year to submit data.
 - If the cosmetic/ingredient is not on the market on the date of enactment, the brand must submit data within 14 months.
 - If any cosmetic/ingredient comes to market 14 months after enactment, the brand has six months to submit data.
- Requires the Secretary to publish a database of this safety information alongside chemicals data gathered from state, national, and international hazards lists and authoritative bodies within one year and to update the database within 90 days of receiving additional information.
- Supports “manufacturer right to know” by requiring suppliers to provide manufacturers with safety data within 90 days of receiving such request.
- Requires the Secretary to promulgate regulations to provide for the content of the foreign supplier verification program.

“Sec. 616. Lists of ingredients and required responses.

- Requires HHS Secretary to place all ingredients on one of four lists to be updated annually: 1) Prohibited; 2) Restricted; 3) Safe Without Limits; or 4) Priority Assessment.
 - On the date of enactment, 12 ingredients that peer-reviewed research has proven to be toxic must immediately be added to the Prohibited List: 1) Benzophenones; 2) Octinoxate; 3) BHA and BHT; 4) Coal tar dyes; 5) Cocamide Diethanolamine; 6) Phthalates DBP, DEHP Bis(2-ethylhexyl); 7) Toluene; 8) Styrene or Styrene acrylates; 9) Formaldehyde and Formaldehyde-releasing preservatives; 10) Triclosan; 11) Lead acetate or other lead compounds; and 12) Parabens.
 - Within two years of the date of enactment, the Secretary must issue the Safe Without Limits list, a list of ingredients that are determined to be safe for use in cosmetics; this list must be updated annually.
 - The Secretary must place 20 ingredients on the Priority Assessment list within the first year of enactment. An ingredient may be placed on this list because of a lack of evidence that the ingredient is safe or should be restricted. Every year, the Secretary must evaluate a minimum of 10 additional ingredients until all ingredients used in the formulation or manufacture of cosmetics have been evaluated for safety and added to either the Prohibited, Restricted, or Safe Without Limits lists.
 - The Secretary must specifically consider communities disproportionately impacted by products marketed to them because of their particular race, ethnicity, or occupation while determining priority assessment list.

“Sec. 617. Treatment of cosmetics based on ingredient lists.

- Allows only cosmetics with ingredients that meet the safety standard to be sold in the U.S.

“Sec. 618. Treatment of contaminants.

- Requires all contaminants that have health risks to be placed on lists as described in Section 616.

- Requires all contaminants present at or above one half of one percent of the content of the product by weight to be listed on the label of a cosmetic.

“Sec. 619. Cosmetic and ingredient statements.

- Requires brands to submit to the Secretary the brand registration number, name of the cosmetic, the use of the cosmetic, the ingredient list (including fragrance and flavor ingredients), any warnings or directions for use, and the brand contact information within one year of enactment.
- Each brand is responsible to annually submit any changes to this information
- This information will publicly available.

“Sec. 620. Notification, non-distribution, and recall of adulterated or misbranded cosmetics.

- Gives the Secretary the authority to issue voluntary recalls of adulterated, misbranded, or otherwise harmful cosmetics.
- Gives the Secretary the authority to issue a cease of distribution if the cosmetic may cause a serious adverse event or is distributed by an unregistered brand.
- Gives the Secretary authority to issue a mandatory recall if a cosmetic poses an immediate threat of a serious adverse event.
- The Secretary must provide public notice of the recall and brands can appeal these determinations.

“Sec. 621. Petitions.

- Allows a person or entity to submit a reasonable petition to the Secretary to challenge a determination of an ingredient.
- The Secretary must review and publish reasonable petitions and take any subsequent actions.

“Sec. 622. Mandatory reporting of serious adverse events.

- Requires brands to submit to the Secretary reports of all serious adverse events related to use of their products within 15 business days of occurrence.
- These reports will be made publicly available without any personally identifiable information.

“Sec. 623. Nonconfidential information.

- Requires the Secretary to make all nonconfidential information submitted in this bill publicly available, including: contaminants; health hazards, toxicity data, environmental hazards, and exposure data; functions of ingredients in cosmetics; and fragrance, flavors, and colorants in cosmetics.
- The concentrations of cosmetic ingredients are considered confidential business information and will not be publicly available.
 - The Secretary will establish a process to allow an entity to petition to keep additional data confidential.

“Sec. 624. Ban on use of animal testing.

- Bans animal testing to determine the safety of a finished cosmetic.
- No animal testing data can be taken into account if it was conducted after the date of enactment.
- Establishes an exception if there are no alternative non-animal models as validated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) that can show that an ingredient meets the safety standard.

- Requires the Secretary to annually publish a list of non-animal tests that are validated by ICCVAM and must be used; creates grants to develop additional non-animal models.

“Sec. 625. Product Testing and Review Audit.

- Requires the Secretary to conduct annual audits of random samples to confirm the composition of the cosmetic.

“Sec. 626. Resources for small businesses.

- Requires the Secretary to provide technical assistance for small businesses.

“Sec. 627. Interagency cooperation.

- Creates an Interagency Council on Cosmetics Safety to share data between FDA, the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, the Occupational Safety and Health Administration, and the Environmental Protection Agency.

“Sec. 628. Savings clause.

- Allows states to enact stronger laws that they feel will better protect their residents.
- This bill acts as a floor, not a ceiling.

“Sec. 629. Authorization of appropriations.”

- Authorizes such sums as necessary to carry out the functions of this bill.

SEC. 3—ADULTERATED AND MISBRANDED COSMETICS

- Aligns existing statute around cosmetics with the provisions enacted through this bill.

SEC. 4—SUPPORT FOR CREATING SAFE ALTERNATIVES

- Creates a new grants program to be administered by FDA in consultation with Environmental Protection Agency (EPA) to support the creation of safer alternatives to chemicals of concern in professional use products and products marketed to women of color.

SEC. 5— SUPPORT BY NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES FOR RESEARCH ON HEALTH DISPARITIES IMPACTING COMMUNITIES OF COLOR.

- Creates a new grants program within the National Institutes for Environmental Health Sciences to provide support for research and public outreach on the marketing and sale of harmful cosmetics to women of color and the use of these products by women and girls of color.

SEC. 6—WORKER ISSUES

- Requires the Secretary of Labor to develop rules that require cosmetic manufacturers and importers to obtain or develop material safety data sheets for each cosmetic.
 - Data sheets must be made available on the manufacturer or importer’s website in English, Spanish, Vietnamese, Chinese, Korean, and any language upon request.
 - Data sheets must be distributed to employers and salon owners in English, Spanish, Vietnamese, Chinese, Korean, and any language upon request.
 - Employers must make the material safety data sheet for each cosmetic available to employees in the workplace.