

# The Campaign for Safe Cosmetics

## SAFE COSMETICS ACT OF 2010

H.R. 5786

Introduced by Representatives Schakowsky, Markey and Baldwin

### Section-by-Section Analysis

(August 10, 2010)

#### Sec. 611 – Definitions

*Provides definitions for key elements of the Act including:*

- Ingredient: defined as any chemical component of cosmetics, including contaminants, components of fragrance and flavors, and incidental ingredients.
- Safety standard: The term safety standard means, with respect to an ingredient, when route of exposure is directly relevant to a particular cosmetics use, a standard that -provides a reasonable certainty that no harm will result from aggregate exposure to the cosmetic or ingredient, including impacts on vulnerable populations taking into account possible harmful effects from low dose exposures to the cosmetic or ingredient or from additive effects.
- Reasonable certainty: With respect to the safety standard, a level sufficient to ensure that no harm will be caused by aggregate exposure for a member of a vulnerable population as determined by the Secretary AND corresponding to the lower dose defined by not more than a 1 in 1 million risk for any adverse effect in the population of concern, at the lower 95<sup>th</sup> percentile confidence bound; or the amount of an ingredient or cosmetic shown to produce no adverse effects, incorporating an uncertainty factor of at least 1,000 and considering all sources of exposure.
- Reproductive and developmental toxicity: means biologically adverse effects on the reproductive systems of female or male humans or animals including alternations to the reproductive system, endocrine system, fertility, pregnancy, etc.
- Vulnerable populations: includes pregnant women, infants, children, the elderly, people with compromised immune systems and highly exposed populations including workers employed by professional salons and cosmetic manufacturing plants.

## **Sec. 612 – Registration of Establishments and Registration Fees**

*Requires companies that manufacture, package or distribute cosmetics to register with FDA and pay a sliding scale registration fee.*

- FDA will assign a unique registration number and keep an up-to-date list of registered companies, which will allow FDA to link the company with required product and testing data.
- The registration must include the name, address and trade names of the manufacturers or packaging companies, a description of the cosmetics-related activities, the number of employees, gross receipt of sales (for calculating the fee schedule) and name and address of any company that supplies the manufacturer with cosmetic ingredients including fragrance.
- The Secretary maintains an up-to-date list of registered facilities. Companies are responsible for informing the FDA of changes in products, function or legal status within 60 days and other changes “in a timely manner.”
- A sliding scale fee schedule to be developed by FDA to provide for oversight and enforcement of the program will be prorated based on the establishment’s gross receipts of sales and will exempt registrants making less than \$1,000,000 from paying the fee.

## **Sec. 613 – Ingredients Labels on Cosmetics**

*One year after enactment, requires the label on each package of cosmetics to list the name of each ingredient in descending order of predominance.*

- This requirement includes fragrance and products for retail sale and professional salon use.
- All Internet vendors are required to display a list of ingredients of cosmetics sold on their websites to be provided by the manufacturer.
- An ingredient may be excluded from a label at the HHS Secretary’s discretion if it is in the product at an amount lower than 10 parts per billion and lower than 1/10<sup>th</sup> the safety standard.
- Contaminants can also be excluded from labeling if present at levels below technically feasible detection limits.

## **Sec. 614 – Cosmetic and Ingredient Testing and Safety**

*Requires FDA to establish a list of ingredients prohibited from being used in cosmetics including carcinogens and reproductive and developmental toxins, a list of restricted ingredients and a “Safe Without Limits” list.*

- Within one year all manufacturers and distributors of products and ingredients must submit all reasonably available information regarding physical, chemical and toxicological properties of ingredients to the FDA.
- Suppliers of cosmetics or ingredients are required to make available to any entity purchasing the cosmetic or ingredient (including fragrance and preservatives) any information in their possession or

control regarding the toxicological properties, safety tests and constituent ingredients of the cosmetic or ingredients.

- Within one year the Secretary will publish a comprehensive publicly accessible database containing the safety testing data collected from manufacturers and distributors of cosmetics and ingredients.
- Not later than two years after enactment, the FDA will consult hazard listings and assessments from authoritative international, federal and state bodies to develop a “CMR list” of carcinogens, mutagens, reproductive and developmental toxins prohibited or restricted from cosmetics.
- This “prohibited list” will include cosmetic ingredients determined to be unsafe for use in cosmetics because they fail to meet the safety standard. The Secretary shall presume that an ingredient that induces cancer or birth defects or has repro or developmental toxicity when ingested, inhaled or dermally applied to a human or animal fails to meet the safety standard.
- This presumption can be rebutted only if the Secretary determines the ingredient meets the safety standard as defined in Section 611.
- The Secretary shall also publish a “restricted list” including ingredients where the Secretary determines that limits on use or concentration are necessary to satisfy the safety standard.
- Within two years HHS will produce and publish a list of “Safe Without Limits” (SWL) List of cosmetic ingredients, which meet the safety standard in any type and form of cosmetic and at any concentration.
- Not later than 18 months after the date of enactment, the Secretary shall develop, by regulation, a priority assessment list(PAL) of not less than 300 ingredients which can’t be included on the prohibited, restricted or SWL lists for which safety determinations shall first be made.
- The Secretary shall add not less than 100 ingredients to the priority list annually until all ingredients used in the formulation of cosmetics have been substantiated for safety and added to the priority assessment list, the safe without limits list or the prohibited, restricted lists until all chemicals used in cosmetics are added to one of these lists.
- The FDA has 24 months after an ingredient is placed on the priority assessment list to determine whether or not the ingredient meets the safety standard in whole or part and should be placed on the SWL or prohibited and restricted list, subject to a proposed rulemaking period of not less than 60 days.
- Within one year FDA will establish minimum data requirements and test protocols to be used by manufacturers to assess the safety of cosmetic ingredients.
- Within 18 months, manufacturers must submit to FDA a signed statement based on available information and a good faith inquiry establishing that their cosmetics and ingredients meet the safety standard or that there is insufficient data to determine whether the cosmetics and its ingredients meet the safety standard.
- The FDA will perform an annual audit of safety statements.

- Secretary shall monitor developments in the scientific understanding of any adverse health effects related to the use of nanomaterials in cosmetics and consider scale specific hazard properties of ingredients when conducting or reviewing safety substantiation of cosmetic ingredients.
- The FDA shall conduct periodic audits of random samples of cosmetic products to assess or test for acute negative reactions, pathogen hazards, contaminants or leaching of packaging additives, mislabeling or other relevant issues of concern to the agency.

### **Sec. 615 – Market Restrictions**

*Provides FDA with recall authority for products that are misbranded, adulterated, or otherwise fail to meet the safety standard.*

- A cosmetic product or ingredient cannot be manufactured, imported, distributed or marketed if the required data is not provided or if the product or ingredient does not meet the safety standard.
- A cosmetic ingredient, the cosmetic or ingredient cannot be manufactured, imported, distributed or marketed beginning 180 days after the Secretary places an ingredient on the prohibited or restricted list.
- If FDA fails to complete an ingredient safety assessment within 5 years of listing, the ingredient cannot be used, manufactured, imported or distributed for use in cosmetics.

### **Sec. 616 – Notification, Nondistribution, and Recall of Adulterated or Misbranded Cosmetics**

*Provides FDA with the authority to request a voluntary recall or order the ceasing of distribution of an adulterated or misbranded cosmetic.*

- If the Secretary believes a cosmetic is adulterated, misbranded or somehow violates this Act, the Secretary may request a voluntary recall.
- The Secretary also may order distribution ceased if use of or exposure to a cosmetic may cause serious adverse health consequences or death, the cosmetic is misbranded or the cosmetic is manufactured, packaged or distributed in an unregistered facility.
- If after hearing an appeal and an informal hearing the order can be vacated or amended to order a recall. The Secretary may also order an immediate, emergency recall if a cosmetic presents an imminent threat of serious adverse health consequences or death.

### **Sec. 617 – Petitions**

*Establishes a deadline of 180 days by which the Secretary must act on a petition to prohibit or restrict a cosmetic ingredient, add an ingredient to the priority assessment list or remove an ingredient from the SWL (Safe Without Limits) list.*

### **Sec. 618 – Cosmetics and Ingredient Statements**

*Requires companies to electronically submit ingredient statements for every product they manufacture to the FDA within one year after enactment for products already on the market and within 6 months after beginning manufacture of a new product.*

- Information in the statement includes: the facility registration number of the manufacturing and distribution establishment, which will allow FDA to link this information to the facility registration database; brand names(s) and product name(s); applicable cosmetics category(s); the ingredient list; warnings and directions for use; and the title and full contact information for the individual(s) responsible for submitting the statement.
- The Secretary may require cosmetic ingredients be labeled as nano scale if at least one dimension is 100 nanometers or smaller for not less than 1 percent of the ingredient particles in the cosmetic and may require that other ingredients in a cosmetic be designated with scale-specific information on the label.
- This information shall also be entered into the publicly accessible database created by the Secretary in Section 614.

### **Sec. 619 – Mandatory Reporting of Adverse Health Effects**

*Requires the manufacturer, packager, or distributor whose name appears on a label of a cosmetic marketed in the US to submit electronically to the FDA a report containing information received concerning any serious adverse event associated with the use of the cosmetic.*

- The report must be submitted to the FDA within 15 business days of the manufacturer, packager or distributor learning of the event and the FDA must make the report public.
- The report must include an identifiable patient, an identifiable report, a suspect cosmetic and the adverse event.
- The adverse health reports collected by the FDA shall be accessible to the public (notwithstanding personally identifiable information).

### **Sec. 620 – Non-confidential Information**

*Makes all non-confidential information available to the public.*

- Specifically, name, chemical identity and structure, function, exposure, health and environmental hazard information, fragrance, flavor and colorants cannot be claimed as confidential business information (CBI) for cosmetic ingredients, contaminants or impurities.
- Concentration of a cosmetic ingredient used in a finished product may be claimed as CBI.
- Secretary shall create a process whereby companies can petition for certain information to be claimed as CBI if the entity can prove economic harm should the information become public except the ingredient name, identify, structure and all health and safety data related to or used to substantiate the

safety of the substance cannot be protected under the petition process.

#### **Sec. 621 – Savings Clause**

*Allows states to set more stringent standards.*

#### **Sec. 622 – Animal Testing Alternatives**

*Minimizes animal testing for cosmetic ingredients when possible.*

- This includes mandating disclosure and use of unpublished data for safety assessments as well as requiring alternative testing methods that do not utilize animals, provided they are of equivalent or superior scientific quality and use fewer animals than conventional animal-based tests.
- HHS will also encourage the formation of industry consortia to avoid duplication of testing and utilize estimation of toxicological properties of a chemical.
- Within a year of enactment and every three years after that, HHS must publish a list of approved alternative testing methods.

#### **Sec. 623 – Interagency Cooperation and Funding**

- *Requires the formation of an interagency council on cosmetic safety – to include FDA, NIEHS, CDC, OSHA and EPA – to share existing data and new information.*

#### **Sec. 624 – Authorization of Appropriations**

*Authorizes funds to be appropriated for implementation of these provisions.*

#### **Sec. 3 – Worker Issues**

*Expands Material Safety Data Sheets (MSDSs) to be developed by distributors of cosmetics intended for salon use to include, for cosmetics or ingredients, health hazards listed by authoritative bodies or found in scientific studies.*

- Translated versions of the MSDS, including at least in Spanish and Vietnamese, are required.
- Operators of salons to have expanded MSDS sheets available in the workplace and provide translated copies upon request.

#### **Sec. 4 – FDA Safety Standard As It Related to Other Administrative Agencies**

*Authorizes the Secretary of HHS to request and utilize ingredient toxicity, use and exposure data from other Federal agencies as appropriate.*

- Permits the FDA to adopt a safety standard developed by another agency if it satisfies relevant provisions for cosmetics.