Introducing Act

FOOD AND DRUGS - REGULATION OF PERSONAL CARE PRODUCTS

Introduced By: Senators Valverde, Goldin, Coyne, Lawson, and Euer

Date Introduced: February 27, 2019

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Declaration of legislative findings and purpose. The general assembly hereby finds and declares that:

(1) There are tens of thousands of chemicals used commercially in the United States, and each year approximately one thousand (1,000) chemicals are added for commercial use. The majority of chemicals in commercial use in the United States, including those used as ingredients in personal care products, have never been fully tested for potential impacts on human health or the environment.

(2) Some chemicals used in personal care products have been identified through scientific studies as being carcinogenic, reproductive or developmental toxicants, or endocrine disruptors. They have also been found through biomonitoring studies to be present in human blood, breast milk, and urine. Some of these chemicals have been listed by respected national and international scientific authoritative bodies as chemicals of concern based on the chemicals’ potential to negatively impact human health and the environment, yet they are present in personal care products that consumers and professional salon workers use every day.

(3) Federal law requires personal care products sold at the retail level and marketed to consumers to list ingredients on the product label. However, information concerning the potential health effects of exposure to these chemical ingredients is not widely available, chemicals used as fragrances or flavoring are exempt from labelling requirements, and personal care products sold for use by hair, nail and beauty professionals are not required to carry any ingredient labeling. At
present, it is extremely challenging for consumers or salon workers to identify a product as containing a chemical of concern.

(4) Furthermore, independent testing and laboratory analyses by other states have identified products that contain substances that could potentially cause harmful health effects but that are not identified as an ingredient on the product’s label. Nevertheless, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), personal care products and their ingredients are not subject to premarket safety testing, review, or approval by the Federal Food and Drug Administration before they are sold to the public.

(5) Therefore, the general assembly hereby finds and declares that the disclosures required under federal law of ingredients contained in personal care products fail to adequately educate and protect consumers and salon workers. In order to empower consumers and salon workers with the information needed to make well-informed decisions regarding products that they or their families are exposed to daily in their homes or workplaces, it shall be the policy of the state to require the personal care product industry to more fully disclose the ingredients they use and, where applicable, identify ingredients that have been published as a chemical of concern on one or more designated list(s). This will benefit consumers and salon workers, encourage manufacturers to remove potentially harmful chemicals from their products, and encourage development of innovative methods, including green chemistry, to replace these ingredients with those that are safer for human health and the environment.

SECTION 2. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

CHAPTER 31.2

REGULATION OF PERSONAL CARE PRODUCTS

21-31.2-1. Short title.

This chapter shall be known and may be cited as the "Regulation of Personal Care Products”.


As used in this chapter, the following words and terms shall have the following meanings unless the context shall clearly indicate another or different meaning or intent:

(1) "Designated list(s)" means any of the following:

(i) Chemicals found on the Rhode Island hazardous substance list (Source: T - ACGIH F
- NFPA49 C - IARC),

(ii) Chemicals classified by the European Union as carcinogens, mutagens, or reproductive toxicants pursuant to Category 1A or 1B in Annex VI to Regulation (EC)
1272/2008.

(iii) Chemicals included in the European Union Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(f) for endocrine disrupting properties.

(iv) Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the federal Environmental Protection Agency's Integrated Risk Information System.

(v) Chemicals that are identified as carcinogenic to humans, likely to be carcinogenic to humans, or as Group A, B1, or B2 carcinogens in the federal Environmental Protection Agency's Integrated Risk Information System.

(vi) Chemicals included in the European Chemicals Agency Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(d), Article 57(e), or Article 57(f) of Regulation (EC) 1907/2006 for persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative properties.

(vii) Chemicals that are identified as persistent, bioaccumulative, and inherently toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List.


(ix) Group 1, 2A, or 2B carcinogens identified by the International Agency for Research on Cancer.

(x) Neurotoxicants that are identified in the Federal Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System.

(xi) Persistent bioaccumulative and toxic priority chemicals that are identified by the federal Environmental Protection Agency National Waste Minimization Program.

(xii) Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects published by the Federal National Toxicology Program, Office of Health Assessment and Translation.

(xiii) Chemicals identified by the Federal Environmental Protection Agency's Toxics Release Inventory as persistent, bioaccumulative and toxic chemicals that are subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. Sec. 11001, et seq.).

(xiv) The Washington Department of Ecology's Persistent, Bioaccumulative, Toxic

(xv) Chemicals that are identified as known to be, or reasonably anticipated to be, human carcinogens by the thirteenth (13th) Report on Carcinogens prepared by the Federal National Toxicology Program.

(xvi) Chemicals for which notification levels, as defined in Section 116455, have been established by the California department of public health or the state water resources control board.

(xvii) Chemicals for which primary maximum contaminant levels have been established and adopted under Section 64431 or 64444 of Title 22 of the California Code of Regulations.

(xviii) Chemicals identified as toxic air contaminants under Section 93000 or 93001 of Title 17 of the California Code of Regulations.

(xix) Chemicals that are identified as priority pollutants in the California water quality control plans pursuant to subdivision (c) of Section 303 of the Federal Clean Water Act and in Section 131.38 of Title 40 of the Code of Federal Regulations, or identified as pollutants by the state or the federal Environmental Protection Agency for one or more water bodies in the state under subdivision (d) of Section 303 of the Federal Clean Water Act and Section 130.7 of Title 40 of the Code of Federal Regulations.

(xx) Chemicals that are identified with noncancerous endpoints and listed with an inhalation or oral reference exposure level by the California office of environmental health hazard assessment pursuant to paragraph (2) of subdivision (b) of section 44360.

(xxi) Chemicals identified as priority chemicals by the California environmental contaminant biomonitoring program pursuant to section 105449.

(xxii) Chemicals that are identified on Part A of the list of Chemicals for Priority Action prepared by the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic.

(xxiii) Chemicals that are identified on the Centers for Disease Control and Prevention’s Fourth National Report on Human Exposure to Environmental Chemicals and Updated Tables Volume 1 and Volume 2.


(xxv) Chemicals designated as asthmagens by the Association of Occupational and Environmental Clinics (AOEC).

(xxvi) European Union candidate list of Substances of Very High Concern in accordance
with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(f) for endocrine disrupting properties.

(xxi) Danish Environmental Protection Agency List of Endocrine Disrupting Compounds.

(xxii) Chemicals known to the State of California to cause cancer or reproductive toxicity (including developmental, female and male toxicity) that are listed pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200 et seq., also known as Proposition 65).


(xxiv) Chemicals identified as high toxicity air contaminants in Part 212 of Title 6 of the New York Codes of Rules and Regulations (6 NYCRR Subpart 212-2.2, as defined in Subpart 212-1.2 (b)(9)).

(2) "Director" means the director of the Rhode Island department of health.

(3) "Ingredient" means all of the following:

(i) An intentionally added ingredient present in any quantity in the personal care product;

(ii) A nonfunctional byproduct or nonfunctional contaminant, present in a personal care product in any quantity not exceeding one half of one percent (0.5%) of the content of the product by weight or other amount as determined by the director;

(iii) A nonfunctional byproduct present in a personal care product in any quantity not exceeding one half of one percent (0.5%) of the content of the product by weight, provided such element or compound has been published as a chemical of concern on one or more designated list(s);

(iv) A nonfunctional contaminant present in a personal care product in a quantity determined by the director and not exceeding one half of one percent (0.5%) of the content of the product by weight, provided such element or compound has been published as a chemical of concern on one or more designated list(s).

(4) "Intentionally added ingredient" means any element or compound that a manufacturer has intentionally added to a personal care product, and which has a functional or technical effect in the finished product, including, but not limited to, the components of intentionally added fragrance, flavoring and colorants, and the intentional breakdown products of an added element or compound that also have a functional or technical effect on the finished product.

(5) "Nonfunctional byproduct," means any element or compound which has no functional or technical effect in the finished product which:
(i) Was intentionally added during the manufacturing process for a personal care product at any point in a product's, a raw material's or ingredient's supply chain; or

(ii) Was created or formed during the manufacturing process as an intentional or unintentional consequence of the manufacturing process at any point in the product's, raw material's, or an ingredient's supply chain. This includes, but is not limited to, an unreacted raw material, a breakdown product of an intentionally added ingredient, or a byproduct of the manufacturing process.

(6) "Nonfunctional contaminant" means any element or compound present in a personal care product as an unintentional consequence of manufacturing which has no functional or technical effect in the finished product. Nonfunctional contaminants include, but are not limited to, elements or compounds present in the environment as contaminants which were introduced into a product, raw material, or a product ingredient as a result of the use of an environmental medium, such as a naturally occurring mineral, air, soil or water, in the manufacturing process at any point in a product's, raw material's, or an ingredient's supply chain.

(7) "Manufacturer" means any person, firm, association, partnership, limited liability company, or corporation that has its brand name affixed to a personal care product. In the case of a personal care product imported into the United States, "manufacturer" means the importer or first domestic distributor of the product if the entity that manufactures the product or whose brand name is affixed to the product does not have a presence in the United States.

(8) "Personal care product" means any article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and any article intended for use as a component of any such article; except that such term shall not include soap.

(9) "Professional Use" means the use of any cosmetic by an employee (within the scope of the employment of such employee) or purchased by a consumer in a hair salon, nail salon, beauty salon, spa, or other establishment that provides cosmetic treatment services for humans.

(10) "Soap" means any article comprised entirely of an alkali salt of fatty acids where the detergent properties of the article are due to the alkali-fatty acid compounds, and the article shall be labeled, sold, and represented only as soap.


(a) Manufacturers of personal care products distributed, sold or offered for sale in this state, whether at retail or wholesale, for personal or professional use, or distributed for promotional purposes, shall furnish to the public records administrator such information regarding such products pursuant to rules and regulations promulgated by the director of the
For each personal care product, such information shall include, but shall not be limited to:

(1) A list naming each ingredient, as defined in § 21-31.2-2 of this chapter, of the product in descending order of predominance by weight in the product, except that ingredients present at a weight below one percent (1%) may be listed following other ingredients without respect to the order of predominance by weight;

(2) The nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and the environment of such product or such ingredients, including which studies were performed by or for them, and any other information in their knowledge or possession; and

(3) Where applicable, a statement disclosing that an ingredient is published as a chemical of concern on one or more designated list(s).

(b) Manufacturers shall furnish such information on or before July 1, 2020 and every two years thereafter. In addition, such manufacturers shall furnish such information:

(1) Prior to the sale of any new personal care product;

(2) Prior to the sale of a currently disclosed product when the formulation of such product is changed;

(3) Prior to the sale of any currently disclosed product when any chemicals of concern included on a designated list(s) pursuant to this chapter is changed to include an ingredient present in a personal care product subject to this chapter; or

(4) At such other times as may be required by the director.

(c) Information shall be made available to the public by the director, in accordance with this section, with the exception of ingredients which the manufacturer is claiming to be a trade secret. The director shall not approve any exceptions under this subsection with respect to any ingredient published as a chemical of concern on one or more designated list(s).

(d) A manufacturer that protects a fragrance or flavor ingredient, or combination of fragrance or flavor ingredients pursuant to the uniform trade secrets act set forth in chapter 41 of title 6 shall maintain justification for protecting confidential business information consistent with the requirements of the act and provide that justification on request for audit by the attorney general.

(e) In lieu of the manufacturer’s providing notice to the authority under subsection (a) of this section, the director may require that the notice described in subsection (a) of this section be submitted to the Interstate Chemicals Clearinghouse. The authority by rule shall specify procedures for the provision of such notice by manufacturers to the Interstate Chemicals
Clearinghouse.

21-31.2-4. Penalties.
A manufacturer in violation of this chapter is subject to a civil penalty not to exceed five thousand dollars ($5,000) dollars for each violation in the case of a first offense. Manufacturers who are repeat violators are subject to a civil penalty not to exceed ten thousand dollars ($10,000) dollars for each repeat offense.

SECTION 3. This act shall take effect on January 1, 2020, provided that, upon passage, effective immediately, the director of health shall be authorized to promulgate any and all rules and regulations necessary to implement the provisions of this act on its effective date.
EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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FOOD AND DRUGS - REGULATION OF PERSONAL CARE PRODUCTS

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This act would require the personal care product industry to more fully disclose the ingredients they use and, where applicable, identify ingredients that have been published as a chemical of concern on one or more designated list included in the act.

This act would take effect on January 1, 2020, provided that, upon passage, effective immediately, the director of health shall be authorized to promulgate any and all rules and regulations necessary to implement the provisions of this act on its effective date.