SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

SENATE
S. No. 1574

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

Government scientists recently identified a group of toxic chemicals known as phthalates in the urine of adults, with highest levels in premenopausal women, resulting from inhalation and skin exposure to volatile parent ingredients used extensively as solvents and plasticizers in personal care and cosmetic (PCC) products. These include perfumes, shampoos, hair sprays, and nail polishes.

These findings raise major concerns in view of documented evidence, dating back to 1985, that these phthalates induce birth defects, low sperm counts, and other reproductive toxicity in experimental animals.[1]

For some time now, it has been observed that a number of cosmetics are made with cancer-causing chemicals. However, the public remains unaware that the substances used could be human carcinogens. Examples of these cosmetics and their carcinogenic components are the following:

- Black and dark brown permanent hair dyes contain numerous ingredients, such as diaminoanisole and FD&C Red 33, recognized as carcinogens in experimental animals. This evidence is supported by studies establishing that regular use of these dyes poses major risks of relatively rare cancers such as non-Hodgkin's lymphoma, Hodgkin's disease, and multiple myeloma.

[1] http://www. safe2use.com/health/cosmetics.htm

- Cosmetic grade talc is carcinogenic in experimental animals. Also, frequent genital dusting with talc, routinely practiced by some 17% of women, increases risks of ovarian cancer.
- A group of widely used preservatives, such as quaterniuml5 and bronopol, widely used in baby products, though not carcinogenic themselves, breaks down to release formaldehyde, a potent irritant and carcinogen.
- Lanolin, widely used on babies' skin and nipples of nursing mothers, is commonly contaminated with DDT and other carcinogenic pesticides.
- Commonly used PCC detergents and foaming agents, such as polysorbates and PEG, are usually contaminated with the volatile carcinogen dioxane, although this could be easily removed by vacuum stripping during manufacture.
- DEA, another widely used chemical detergent, has been known since 1975 to combine with nitrite preservatives or contaminants in PCC products to form a highly carcinogenic nitrosamine. Furthermore, recent government studies showed that DEA itself is also carcinogenic following application to mouse skin.[2]

Hence, this bill seeks to ensure the safety of cosmetic products sold in the Philippines by requiring that such products be free of any ingredients which have been identified as chemicals causing cancer or reproductive toxicity. Because the compliance of resident manufacturers and sellers – in the case of foreign manufacturers – is key, this bill also provides a penalty in case of their non-compliance.[3]

Graduate students of the University of the Philippines Open University have expressed their support of this legislative measure: "We find the Bill very important because it seeks to ensure that cosmetic products should be free of any ingredients which have been identified as chemical-causing cancer or reproductive toxicity, among other things. We are a group of

[2] *Ibid.*
[3] This bill was originally filed during the Fourteenth Congress, First Regular Session.

students who aims at generating awareness campaign to the public on the health and safety benefits of organically-based personal-care products."[4]

MIRIAM DEFENSOR SANTIAGO

[4] "Statement of Support," 29 August 2013, by Domar Alviar, Jocelyn Asignacion, Marilou Allyn Baldemor, Maureen Maquidang, Jose Juancho Perez, May Serrano, and Rechelle Ann Tolinero of Group C2, DevC 208, 1st Semester, 2013-2014, Master of Development Communication, U.P. Open University.

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Senate
Office of the Secretary

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AN ACT
ESTABLISHING THE SAFE COSMETICS ACT

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. *Short Title.* – This Act shall be known as "Safe Cosmetics Act."

SECTION 2. *Declaration of Policy.* – It is the policy of the State to promote the general welfare of the people. Pursuant to this policy, this Act seeks to ensure that cosmetic products are free of any ingredients which have been identified as chemicals causing cancer or reproductive toxicity.

SECTION 3. *Definition of Terms.* – For the purposes of this Act, the term:

(A) "Authoritative body" means any agency, division, body, or formally organized program or group recognized by the Department of Health as being authoritative for the purpose of identifying chemicals that may cause cancer or reproductive toxicity;

(B) "Center" means the Occupational Safety and Health Center of the Department of Labor and Employment;

(C) "Chemical identified as causing cancer or reproductive toxicity" means a chemical identified by an authoritative body as any of the following:

(1) A substance listed as known or reasonably anticipated to be a human carcinogen in a national toxicology report on carcinogens;

(2) A substance given on overall carcinogencity evaluation of Group 1, Group 2A or Group 2B by the International Agency for Research on Cancer;

(3) A substance identified as a Group A, Group B1 or Group B2 carcinogen, or as a known or likely carcinogen by the United States Environmental Protection Agency;

(4) A substance identified as having some clear evidence of adverse developmental, male reproductive or female reproductive toxicity effects in a report by an expert panel of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction of the United States;

(D) "Department" means the Department of Health;

(E) "Ingredient" means anything that forms part of a cosmetic product's formulation;

(F) "Manufacturer" means any person whose name appears on the label of a cosmetic product; and

(G) "Seller" means any person who offers for sale any cosmetic product.

SECTION 4. *Listing of Products.* – (A) Commencing January 1 of the year following the passage of this Act, the manufacturer of any cosmetic product that is subject to regulation by the Food and Drug Administration and is manufactured and/or sold in the Philippines, shall, on a schedule and in electronic or other format, provide the Department of Health with a complete and accurate list of its cosmetic products that contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity, including:

(1) A chemical contained in the product for purposes of fragrance or flavoring; or

(2) A chemical identified by the phrase "and other ingredients" and determined to be a trade secret.

(B) Any ingredient identified pursuant to this Section shall be considered to be a trade secret and shall be treated by the Department in a manner consistent with the Intellectual Property Law.

(C) If the cosmetic product is sold in the Philippines but is manufactured outside the Philippines by a foreign entity, the resident seller thereof shall have the same obligation to provide the Department the product listing described in the preceding paragraph.

(D) Any information submitted pursuant to paragraph (A) of this Section shall identify each chemical both by name and chemical abstract service number and shall specify the product or products in which the chemical is contained.

(E) If any ingredient identified pursuant to this Section subsequently is removed from the product in which it was contained, or is removed from the list of chemicals known to cause cancer or reproductive toxicity, or is no longer a chemical identified as causing cancer or reproductive toxicity by an authoritative body, the manufacturer of the product containing the ingredient shall submit the new information to the Department. Upon receipt of new information, the Department, after verifying the accuracy of that information, shall revise the manufacturer's information on record with the Department to reflect the new information. The manufacturer shall not be under obligation to submit subsequent information on the presence of the ingredient in the product unless subsequent changes require submittal of the information.

SECTION 5. *Investigation.* – (A) In order to determine potential health effects of exposure to ingredients in cosmetics manufactured, sold, and/or distributed in the Philippines, the Department may conduct an investigation of one or more cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity or other ingredients of concern to the Department.

(B) An investigation conducted pursuant to paragraph (A) of this Section may include, but not be limited to, a review of available health effects, data and studies, worksite health hazard evaluations, and epidemiological studies to determine the health effects of exposures to chemicals in various subpopulations, and exposure assessments to determine total exposures to individuals in various settings.

(C) If an investigation is conducted pursuant to paragraph (A) of this Section, the manufacturer of the product subject to the investigation may submit relevant health effects data and studies to the Department.

(D) In order to further the purposes of an investigation, the Department may require manufacturers of products subject to the investigation to submit to the Department relevant health effects data and studies available to the manufacturer and other available information as

requested by the Department, including, but not limited to, the concentration of the chemical in the product, the amount by volume or weight of the product that comprises the average daily application or use, and sales and use data necessary to determine where the product is used in the occupational setting.

(E) The Department shall establish reasonable deadlines for the submission of information required pursuant to paragraph (D) of this Section. Failure by a manufacturer to submit the information in compliance with the requirements of the Department shall constitute a violation punishable under Section 7 of this Act.

SECTION 6. *Referral of Results.* – (A) If the Department determines pursuant to an investigation that an ingredient in a cosmetic product is potentially toxic at the concentration present in the product or under the conditions used, the Department shall immediately refer the results of its investigation to the Occupational Safety and Health Center.

(B) Within one hundred eighty (180) days after it receives the results of an investigation pursuant to paragraph (A) of this Section, the Center shall develop and present one or more proposed occupational health standards to the Department of Labor and Employment, unless the Center affirmatively determines, in a written finding within ninety (90) days, that a standard is not necessary to protect the health of an employee or has regular exposure to the hazard for the period of his or her working life. The written finding shall identify the reasons for determining the standard is not necessary and the factual basis for the finding.

SECTION 7. *Penalty for Non-Compliance.* – Failure by a manufacturer to submit the information in compliance with the requirements of the Department under Section 5 of this Act shall constitute a violation punishable by a penalty of Ten Thousand Pesos (P10,000.00) to not more than One Hundred Thousand Pesos (P100,000.00) at the discretion of the court, taking into consideration the circumstances of the case.

SECTION 8. *Separability Clause.* – If any provision or part thereof is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 9. *Repealing Clause.* – Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule, or regulation contrary to or inconsistent with the provisions of this Act is hereby repealed, modified, or amended accordingly.

SECTION 10. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,