**FOURTEENTH CONGRESS OF THE )**
**REPUBLIC OF THE PHILIPPINES )**
**Second Regular Session )**

9 MAR -2 A

**SENATE**

**S. NO. 3108**

**Introduced by Senator Antonio "Sonny" F. Trillanes IV**

## EXPLANATORY NOTE

Polyvinyl Chloride (PVC) or simply vinyl plastic is most widely and commonly used plastic in medical devices. However, the use of PVC in these devices can prove to be harmful to patients, the environment, and the public in general. PVC upon manufacturing and during incineration or burning can produce Dioxins, a known human carcinogen.

Moreover, manufacturers often use DEHP or diehylhexyl phthalate to soften PVC plastic and to make them more flexible. However, DEHP is linked to reproductive birth defects and other illnesses. DEHP may leach out from PVC devices/ materials and cause harm to the public.

In addition, soft PVC toys have been made for babies for years, and concerns were raised because it is possible that these additives leach out of soft toys into the mouths of the children chewing on them. Other vinyl products, including car interiors, shower curtains, and flooring, initially release chemical gases into the air. Some studies indicate that this outgassing of additives may contribute to health complications, and have resulted in a call for banning the use of DEHP on shower curtains, among other uses. In 2004, a joint Swedish-Danish research team found a statistical association between allergies in children and indoor air levels of DEHP.

Some countries in Asia, Europe and the US have started to require the labeling of PVC products particularly medical devices made with DEHP in a move to adopt PVC- and DEHP-free products.

This bill seeks to address the need to protect the public from the harmful effects of PVC products by requiring all manufacturers to provide proper labeling of all PVC products with the end view of protecting the general public from the harmful effects of dioxin and phthalates to human health and the environment.

In view of the foregoing, immediate passage of this bill is earnestly sought.

ANTONIO "SONNY" F. TRILLANES IV
Senator

FOURTEENTH CONGRESS OF THE )
REPUBLIC OF THE PHILIPPINES )
Second Regular Session )

9 MAR -2 A10 :00

SENATE

S. NO. 3108

Introduced by Senator Antonio "Sonny" F. Trillanes IV

# AN ACT
# PROVIDING FOR A MANDATORY LABELING OF POLYVINYL CHLORIDE (PVC) PRODUCTS AND FOR OTHER PURPOSES

*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 the "PVC Labeling Act of 2009".

**SEC. 2.** ***Declaration of Policy.*** – It shall be the policy of the State to protect the interest of the public and to promote their general welfare. Toward this end, the State shall implement measures to achieve the provision of safety standards for consumer products by requiring that polyvinyl chloride (PVC) made products be consistently marked with or accompanied by clear safety warnings that these products pose a risk to human health and development.

**SEC. 3.** ***Objectives.*** – This Act shall have the following objectives:

(a) To protect public health, patients and environment from the harmful effects of PVC;

(b) To warn the public about the risk of potentially harmful exposures for vulnerable populations from DEHP;

(c) To minimize exposures to DEHP;

(d) To provide alternatives to PVC products including those made with DEHP.

**SEC. 4.** ***Definition of Terms.*** – For purposes of this Act, the following terms are hereby defined as follows:

(a) Di-ethylhexyl-phthalate or DEHP – means a phthalate used to soften PVC plastic that can leach from PVC medical devices which is linked to reproductive birth defects and other illnesses

(b) Label, labeling – means a display of written, printed or graphic matter upon the surface of the product, immediate container or article and a requirement made by or under authority of this Act that any word, statement, or other information appearing

on the label shall not be considered to be complied with unless such word, statement or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(c) Manufacturer – means any natural person or juridical entity, whether domestic or foreign who manufactures, assembles or processes consumer products except that if the goods are manufactured, assembled or processed for another person who attaches his own brand name to the consumer products, the latter shall be deemed the manufacturer. In case of imported products, the manufacturer's representative or, in his absence, the importer, shall be deemed the manufacturer.

(d) Medical device – means an apparatus or contrivances, including their components, parts and accessories intended (1) for use in the diagnosis, cure, mitigation/ alleviation, treatment, monitoring, or prevention of disease, injuries/ handicap in man or animals; or (2) to affect the structure or any function of the body of man or animals.

**SEC. 5.** ***PVC Products Labeling Requirements.*** – All manufacturers are hereby required to consistently label all PVC products including medical devices that may cause patient exposure to DEHP. PVC products that contain DEHP shall include a cautionary statement in a prominent, clearly-worded warning label on the product stating the following:

**WARNING:**
**PVC CONTAINS DEHP**

and/ or

**BABALA:**
**PVY MAY DEHP**

In the case of PVC products that do not contain DEHP, they shall bear or contain the following statements:

**WARNING:**
**PVC NO DEHP**

and/ or

**BABALA:**
**PVC WALANG DEHP**

**SEC. 6.** ***General Labeling Requirements.*** – Any warning label or statement shall be displayed in its entirety on PVC product, on the principal display panel of the PVC product's package and on any descriptive material which accompany the product, if there is any, in English

or Filipino or both, in conspicuous and legible type in contrast by typography, lay-out, or color with other printed matter on such package and descriptive materials and in the manner consistent with the provisions of RA 7394 on labeling.

**SEC. 7.** ***Treatment as Mislabeled or Banned Hazardous Product.*** – Any PVC product that is not in compliance with the requirements of this Act shall be considered a mislabeled or banned hazardous product and shall be withdrawn from the market at the expense of the manufacturer or shall not be allowed to be distributed, sold or offered for sale unless and until the requirements of this Act is complied without prejudice to whatever liability and penalty to be incurred under Section 10.

**SEC. 8.** ***Public Awareness Programs.*** – The Department of Trade and Industry (DTI), with the Assistance of the Department of Health (DOH), shall develop, lead and coordinate a nationwide program to heighten public awareness and involvement in furtherance of the objectives of this Act. The program shall utilize existing resources and efforts of the national government, local government units and concerned non-government organizations.

**SEC. 9.** ***Reduction Strategies for PVC Products and Medical Devices.*** – The Department of Health (DOH) is hereby authorized to issue a directive, under such regulations as may be prescribed in the implementing rules and regulations of this Act, to all heads of government and private hospitals, clinics and health centers to conduct an audit to determine the presence of PVC medical devices including those made with DEHP in their respective medical facilities and to implement a purchasing policy that requires the reduction or elimination of such medical devices.

The Department of Trade and Industry (DTI) shall coordinate with concerned government and private institutions in identifying and evaluating alternative products to PVC and in establishing a mechanism for the procurement of PVC- and DEHP-free products of equivalent quality and performance.

**SEC. 10.** ***Penalties.*** – Any person who shall violate any provision of this Act, shall, upon conviction suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty Thousand Pesos (P50,000.00) but not more than Five Hundred Thousand Pesos (P500,000.00), or both at the discretion of the court.

Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/ or the persons directly responsible therefor shall be penalized.

Should the offense be committed by a foreign national, he shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

**SEC. 11.** ***Regulations.*** – The Department of Trade and Industry, with the assistance of the Department of Health, shall promulgate regulations for the implementation of this Act in accordance with the provisions of RA 7394 on labeling. In addition, the Department of Trade and Industry shall regularly publish the list of all manufacturers who failed to comply with the requirements of this Act.

**SEC. 12.** ***Grace Period.*** – Manufacturers are given three (3) months grace period to comply with these requirements from the effectivity of this Act.

**SEC. 13.** ***Separability Clause.*** – If any provision of this Act is held invalid, the other provisions not affected shall remain in full force and effect.

**SEC. 14.** ***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.

**SEC. 15.** ***Effectivity Clause.*** – This Act shall take effect fifteen (15) days after the completion of its publication in the Official Gazette or in at least two (2) newspapers of general circulation.

Approved,