FIFTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Third Regular Session)

SENATE
S.B. No. ~~3337~~

INTRODUCED BY SEN. MANNY VILLAR

EXPLANATORY NOTE

The 1987 Constitution states that "[t]he State shall protect and promote the right to health of the people and instill health consciousness among them (Article II, Section 15)." Further, our Constitution also provides that "[t]he State shall protect consumers from trade malpractices and from substandard or hazardous products (Article XVI, Section 9)."

Recently, the United States of America enacted their Consumer Product Safety Improvement Act of 2008, which banned products with toxic lead that exceeded federal guidelines. Considering the dangers posed by lead in toys, other countries followed suit in the banning of use of lead in manufacture of toys, these countries include members of the European Union, Canada and Samoa.

Unfortunately, there is currently no strict policy being implemented by the Philippine government as regards the banning or restriction of manufacture or importation of toys laden with either lead or Cadmium or any other toxic materials.

These pieces of legislations are timely to curb the growing number of toys laced with toxic materials. For example in the USA, in the Associated Press (AP) investigation, wherein a lab technician tested 103 children's metal charm bracelets and pendant trinkets from around the country and sold at US Stores i.e. Wal-Mart, Claire's, and dollar stores, it was found that "twelve percent of those tested contained at least 10 percent cadmium, a carcinogenic metal that has been shown to cause developmental problems in small children. Some items tested contained more than 90 percent cadmium by weight, and many shed the toxic metal easily, making it particularly dangerous to children, who often put toys in their mouth."[1]

Locally, in a pre-Christmas screening made by an independent group of toys bought from the metropolis last September 2012 revealed that 74 of the 150 samples (49 percent) were laced with heavy metals above levels of concern, including lead that exceeded the US lead in paint limit of 90 parts per million (ppm) in 54 samples (36 percent).[2]

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[1] http://www.rodale.com/toxic-toys-china
[2] http://www.pchrd.dost.gov.ph/index.php/2012-05-23-07-46-36/2012-05-24-00-03-06/5484-you-d-better-watch-out-for-toxic-toys-for-christmas

Considering the health risks posed to the public especially to children, it is necessary that this legislation be passed to ensure that the toys bought and sold in the market are free from excessively high levels of toxic metals such as, but not limited to, that of cadmium or lead.

This bill is earnestly sought.

Manny Villar

FIFTEENTH CONGRESS OF THE)
Republic of the Philippines)
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SENATE
NO. 3337

Introduced by **SEN. MANNY VILLAR**

AN ACT
TO REGULATE THE IMPORTATION, MANUFACTURE, SALE AND DISTRIBUTION OF CHILDREN'S TOYS, SCHOOL SUPPLIES, CHILDCARE ARTICLES AND OTHER RELATED PRODUCTS, CONTAINING TOXIC CHEMICALS AND FOR OTHER PURPOSES

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

SECTION 1. *Short Tiltle.* - This Act shall be known as the *"Safe and Non-toxic Children's Products Act of 2012"*

SEC. 2. *Declaration of Policy.* – It is hereby declared the policy of the State to protect and promote the rights of the people to health, a balanced and healthful ecology and to information. Towards this end, the State shall regulate the importation, manufacture, sale and distribution of children's toys, school supplies and other childcare articles containing toxic chemicals.

SEC. 3. *Definition of Terms.* – For purposes of this Act, the following terms are hereby defined:

a. *Bioavailability* refers to the availability and possibility of the chemical from a product or children's toys to be released and absorbed into a child's body via the gastro intestinal tract, the lungs, or the skin and mucus membranes;

b. *Chemical substance* refers to any organic or inorganic substance of a particular molecular identity, including:

1) any combination of such substances occurring, in whole or in part, as a result of chemical reaction or occurring in nature; and
2) any element or uncombined chemical

c. *Childcare article* refers to any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children such as nipples, feeding bottles, baby dresses, pacifiers etc.

d. Children refer to persons below eighteen (18) years of age or those over but are unable to fully take care of themselves or protect themselves from abuse, neglect, cruelty, exploitation or

discrimination because of a physical or mental disability or condition;

e. *Distributor* refers to any entity to which the toy product is delivered or sold for purposes of distribution in commerce, or in such case repackages toys under different trade name or trademark with permission from the original legal distributor, except that such term does not include a manufacturer or retailer of such product;

f. *Educational Kit* refers to a collection of materials and associated scientific apparatus that are not likely to be licked or put in the mouth by children and which are typically used to perform experiments or demonstrations in the different fields of science. These materials include, among others, notebooks, pad papers, envelopes, plastic covers, folders, mugs, school uniforms and school bags;

g. *Hazardous Wastes* refer to substances that are without any safe commercial, industrial, agricultural, or economic usage to by-products, side-products, process residues, spent reaction, media, contaminated plant or equipment or other substances from manufacturing operations, and as consumer discards from manufactured products. It can also refer to waste which, because of its quantity, concentration, or physical, chemical, or infectious characteristics, may pose a substantial present or potential hazard to human health or the environment when improperly treated, stored or disposed of, otherwise mismanaged; or cause or contribute to an increase in mortality, or an increase in irreversible or incapacitating illness;

h. *Hazardous Substance/Chemical* refers to :

1. a substance which presents short-term acute hazards, such as acute toxicity by ingestion, inhalation or skin absorption, corrosivity or other skin or eye contact hazard or the risk of fire or explosion;
2. a substance which presents long-term environmental hazards, including chronic toxicity upon repeated exposure, carcinogenicity (which may in some cases result from acute exposure but with a long latent period), resistance to detoxification process such as biodegradation, the potential to pollute underground or surface waters, or aesthetically objectionable properties such as offensive odors;
3. a chemical for which there is statistically significant evidence (based on at least one study conducted according to established scientific principles) that acute or chronic health effects may occur;
4. any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the DOH determines by regulation that it is sufficiently hazardous to require labeling in accordance with this Act in order to protect the public health;
5. any toy or other articles intended for use by children that may, by regulation, be determined to contain an electrical, mechanical or thermal hazard; or

6. any substance which the DOH finds to be under the categories enumerated above.

i. *Importation* refers to the entry of a product or substance into the Philippines (through the seaports or airports of entry) whether already properly cleared through or still remaining under customs control, which is intended for direct consumption, merchandising, warehousing and for further processing;

j. *Label* refers to the display of printed or graphic matter on any consumer product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, ingredients, attributes, directions for use, specifications and such other information as may be necessary to protect health and safety of the consumers;

k. *License to Operate* (LTO) refers to the license issued by the FDA to manufacturers, importers and distributors whose toy products, children articles and school implements, under this Act, conform to the health and safety requirements of the DOH and the relevant Philippine National Standards and their future amendments;

l. *Manufacturer* refers to any establishment that assembles or processes products under this Act, provided that if such products are manufactured, assembled or processed for another establishment that attaches its own brand name to the products, the latter shall be deemed the manufacturer. In case of imported products under this Act, the manufacturer's representative or, in his absence, the importer shall be deemed the manufacturer;

m. *Philippine National Standards (PNS)* refer to the national standards approved by the Technical Committee under the Bureau of Products Standard of the Department of Trade and Industry;

n. *Sale or distribution* refers to an act made by a manufacturer or seller, or the respective representative or agent to make available consumer products, services or credit to the end consumers under a consumer sale transaction. It shall not include sampling or any other distribution not for sale;

o. *School Implement* refers to a tool used for writing, drawing, coloring, marking, gluing, or erasing by children that are likely to be licked or put in the mouth;

p. *School Supplies* refer to items/articles used for educational purposes which are not likely to be licked or put inside the mouth by children. These include, among others, notebooks, crayons, pad papers, envelopes, plastic covers, folders, mugs, school uniforms and school bags;

q. *Testing Laboratory* refers to an accredited facility for measuring, examining, and determining the level of chemical elements in products under this Act;

r. *Toy* refers to an object or a number of objects clearly intended as a *plaything* for children as defined in Section 3 of this Act;

s. *Toxic substance* refers to any substance other than a radioactive substance which can cause injury, illness or death through ingestion, inhalation, or absorption through any body surface.

SEC. 4. *Scope.* – This Act shall apply to the importation, manufacture, sale and distribution of children's toys, school supplies, childcare articles and other related products, whether or not designed or intended for use or play solely by children under the age of eighteen (18), and other childcare articles and related products that are sold or given free of charge in the Philippines.

SEC. 5. *Chemicals and Substances Covered.* - Within three (3) months from the effectivity of this Act, the Food and Drug Administration (FDA) shall prepare a list of chemicals and substances used in children's products which cause or may cause harm, injury, or death to children. The FDA shall specifically identify absolutely banned or prohibited substances and chemicals used in the manufacture, production, and preparation of children's products. Maximum levels and limits and reference values for certain chemicals used for this purpose shall also be specifically and clearly identified.

Chemicals and substances deemed most harmful and toxic to children and commonly used in the manufacture and production of children's products shall include, but shall not be limited, to the following:

a. Toxic Metals:
    1. Antimony
    2. Arsenic
    3. Cadmium
    4. Chromium
    5. Lead
    6. Mercury
b. Phthalates – when applied in the manufacture and production of products covered under this Act, include:
    1. Di (2-Ethlyhexyl) Phthalate (Dehp)
    2. Dibutyl Phthalate (Dbp)
    3. Benzyl Butyl Phthalate (Bbp)
    4. Diisononyl Phthalate (Dinp)
    5. Diisodecyl Phthalate (Didp)
    6. Di-N-Octyl Phthalate (Dnop)
c. Bisphenol-A (Bpa)

SEC. 6. *Compliance with Philippine National Standards (PNS).* – Importers, manufacturers, distributors and sellers of products under this Act shall comply with the standards, rules and processes of the Bureau of Product Standards of the Department of Trade and Industry. The same shall collaborate with other relevant government agencies to harmonize/upgrade existing standards, where applicable.

SEC. 7. *Powers and Functions of the DOH.* – To effectively carry out its mandate of ensuring the quality of products under this Act, the DOH shall have the following powers and functions:

a. Formulate guidelines in the filing of application for the issuance of License to Operate (LTO) to importers, distributors and local manufacturers of products under this Act;

b. Formulate specific guidelines on the issuance of the Certificate of Conformity to manufacturers, distributors, and importers for every shipment, freight, batch/lot of their products covered in this Act;

c. Issue quality control orders (QCOs) to enforce the provisions of this Act and to ensure strict compliance with existing standards and regulations set by government authorities;

d. Issue compliance orders (COs) if it finds non-compliance and/or non-conformity with this Act, its rules and regulations, and guidelines issued to enforce and implement the same;

e. Undertake researches, develop and establish quality and safety standards for products covered by this Act in coordination with other implementing government agencies ;

f. Set the maximum allowable level of toxicity of chemical elements in products covered by this Act;

g. Inspect and analyze products covered by this Act for purposes of determining conformity to established quality and safety standards;

h. Conduct constant and regular inspection, product testing, and on-sight and random product testing and sampling of various children's products in the market;

i. Levy, asses, collect and retain fees as are necessary to cover the cost of inspection, certification, analysis and tests of samples of products under this Act;

j. Investigate the causes of and maintain a record of product-related deaths, illnesses and injuries for use in researches or studies on the prevention of such deaths, illnesses and injuries;

k. Accredit independent, competent non-government bodies, to assist in monitoring the market for the presence of toxic chemicals in products under this Act and to look for appropriate means to expand the monitoring and enforcement outreach of the Department in relation to its manpower, testing and certification resources at a given time;

l. Accredit independent competent testing laboratories; and

m. Perform such other functions as needed and necessary in the enforcement of this Act.

SEC. 8. *Role Delineation of Implementing Agencies.* - The provisions of this Act and its implementing rules and regulations shall be enforced by the following agencies:

a. DOH – The Department of Health shall formulate policies, rules and regulations on food, drugs, cosmetics, devices and substances;

The FDA shall conduct regular testing, evaluation, monitoring and post-market surveillance of covered products to include all school implements as defined in Section 3 of this Act to ensure compliance with the Philippine National Standards on the Safety of Toys;

b. DENR – The Department of Environment and Natural Resources shall regulate, control, restrict or prohibit the importation, manufacture, processing, sale, distribution, handling, use, transport and disposal of chemical substances mixtures under Republic Act No. 6969, "Toxic Substances and Hazardous and Nuclear Waste Control Act of 1990". It shall monitor toxic substances/chemicals used as industrial raw material to produce the covered products under this Act in terms of their compliance to environmental laws. It shall administer the industrial toxic chemicals through a system of review, evaluation and monitoring of these toxic chemicals under the DENR Administrative Order No. 2007-23 and formulate policies and guidelines for the gradual phase-out of lead in paints pursuant to Sec. 20 (1) of DAO 20, Series of 1992 and DAO 05,Series of 2005 (Toxic Chemical Substances for Issuance of Chemical Control Orders);

c. DOF – The Department of Finance, through the Bureau of Customs, shall monitor the entry of imported products covered under this Act at the different ports of entry in the Philippines. It shall review and conduct examination of documentary requirements of imported products pursuant to the guidelines of the Department;

d. DTI – The Department of Trade and Industry shall enforce policies and regulate the importation, manufacture, distribution and sale of educational kits or school supplies as defined in Section 3 of this Act and other consumer products not covered by the mandates of the other implementing agencies. It shall ensure that covered products comply with the Philippine National Standards on the Safety of Toys set by the Bureau of Product Standards and shall monitor and conduct market inspections on covered products.

SEC. 9. *Creation of the Children's Product Safety Council.* There is hereby created a Children's Product Safety Council (CPSC) to be attached to the Department of Health (DOH) and composed of the following:

a. The Secretary of the DOH - Chairperson
b. The Secretary of the DTI - Vice Chairperson
c. The Secretary of the DENR - Member
d. The Secretary of the Department of Interior and Local Government (DILG) - Member
e. The Secretary of the Department of Education (DEPEd) – Member
f. The Secretary of DOF - Member
g. The Director of the FDA -Member
h. The National Consumer Affairs Council (NCAC) - Member
i. One (1) Representative from a Non-Government Organization (NGO) engaged in consumer rights protection - Member
j. One (1) Representative from a Non-Government Organization (NGO) engaged in environmental protection and advocacy - Member

The departments and government agencies shall be represented by their respective heads or their duly designated representatives who shall be of a rank not lower than Director level.

The Chairperson of the CPSC shall recommend the nominees for the NGO Sector Representatives to the President of the Philippines.

The FDA shall serve as the secretariat and operational arm of the CPSC.

Other government agencies and private sector representatives may be invited to participate in the CPSC as the exigencies and circumstances may require.

SEC 10. *Powers and Functions of the CPSC.* The CPSC shall have the following powers and functions:

a. To provide coordination and linkage mechanisms between and among its members, other government agencies concerned, local government units (LGUs), the private sector, and other stakeholders;
b. To engage in studies and researches on harmful and toxic chemicals and substances, and provide the necessary information materials on the same;
c. To conduct and facilitate consultation and dialogues within and among all concerned stakeholders in the industry;
d. To conduct information and education campaigns, especially for children;
e. To propose amendments to laws, rules, and regulations pursuant to its mandate and the objectives of this Act;
f. To provide periodic and regular reports to the Secretary of Health ;
g. To create a Technical Advisory Committee composed of experts from both government and private sectors that would assist the council in providing technical and scientific recommendations necessary to effectively carry out its mandate;
h. To provide coordination and linkage mechanisms between and among its members, other government agencies concerned, the Business Processing and Licensing Office (BPLO) of Local Government Units (LGUs) , the private sector, and other stakeholders; and
i. To perform such other functions as may be directed by the DOH.

SEC. 11. Application to Trade. – The following procedures shall be observed at the first port of entry of imported products:

a. The FDA, or its commissioned/designated agent, in coordination with the Bureau of Customs (BOC), shall conduct product inspection, sample testing and clearance of imported products covered under this Act for compliance with the national standards for the safety of toys prior to their assessment and charging of tariffs and other charges by the BOC;

b. Samples of products covered by this Act being imported into the Philippines shall be obtained for purposes of determining the toxicity level of chemical elements and substances content without charge from the owner or consignee thereof. The owner or consignee of the imported product under examination shall be afforded an opportunity to a hearing with respect to the

importation of such product into the Philippines. If it is proven that such product does not conform to the allowable level of chemical elements and substances content as provided for under the implementing rules and regulation of this Act, said product shall be refused admission;

c. Any product covered by this Act, the sale or use of which has been banned or withdrawn in the country of manufacture, shall not be imported into the country; and

d. All expenses in connection with the storage, destruction and disposition of any product under this Act which was refused admission shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. *Clearance for Customs Release.* – All importers of products under this Act shall secure a Clearance for Customs Release from the DOH prior to importation.

A Clearance for Conditional Release shall be issued by the appropriate Center of the FDA to facilitate the release of goods from the BOC custody pending the issuance of the Certificate of Conformity. The importer, however shall not sell, distribute or transfer in whole or in part, the products to any place other than the address specified in the conditional release. To ensure that no distribution, sale, transfer to or use of products covered by this Act in any place other than the address specified in the conditional release is made, the importers shall allow authorized personnel of the FDA to conduct an inspection/inventory of the import shipment within three days from the date of issuance of the clearance for conditional release at anytime within official working hours.

SEC.13. *Certification.* - The DOH, after the conduct of a thorough examination, shall issue the necessary certificate to show whether or not the imported products are safe for distribution in the market

SEC. 14. *Disposal of Non-compliant Products.* – All products covered by this Act that are recalled by the manufacturer or the Department for whatever reason, shall be disposed of in accordance with the submitted disposal plan subject to FDA approval. The plan shall comply with the existing rules and regulations set by all concerned agencies of the government and other related laws of the country. The concerned manufacturer, importer or distributor shall shoulder the expenses to be incurred in the disposal of the recalled products.

All import-shipments denied the requisite Certificate of Conformity shall not be disposed of in the domestic market in any manner. They must be properly disposed in accordance with the provisions of the Tariff and Customs Code and other pertinent rules and regulations.

SEC.15. *Labeling and Packaging Requirement.* – The packaging and labeling requirement of products under this Act shall comply with the relevant Philippine National Standards.

SEC. 16. *Monitoring and Factory Inspection.* – The FDA shall observe the following procedures in the inspection and monitoring of establishments to determine compliance with safety regulations:

a. Officers or employees duly designated by the FDA, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable hours, any factory, warehouse or establishment in which products under this Act are manufactured or held for introduction into domestic commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such products; and (2) to inspect, in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein,

b. Upon completion of the inspection of a factory, warehouse or other establishment and prior to leaving the premises, the officer or employee who conducted such inspection and has obtained any sample in the course of the inspection, shall give the owner, operator, or agent in charge a receipt describing the samples obtained;

c. Whenever in the course of any such inspection of a factory or other establishment where products covered by this Act are manufactured or held, the officer or employee making the inspection obtains a sample of any such product, and an analysis made of such sample for the purpose of ascertaining whether such product contains, in whole or in part, disallowed level of toxicity of chemical elements and hazardous substances, a copy of the result of such analysis shall be furnished the owner, operator, or officer- in- charge.

SEC. 17. *Market Inspection.* – The DOH shall conduct routine inspection in the market and take samples of suspected products for examination.

SEC. 18. *Injurious, Dangerous and Unsafe Products.* – Whenever the DOH finds, by its own initiative or by petition of a consumer, that a product covered by this Act is injurious, unsafe or dangerous, it shall, after due notice and hearing, make the appropriate order for its recall, prohibition, or seizure from public sale or distribution. It may declare a product to be imminently injurious, unsafe or dangerous, and order its immediate recall, ban or seize from public sale or distribution, in which case, the seller, distributor or producer thereof shall be afforded a hearing within forty-eight (48) hours from such order.

There shall be immediate information dissemination, through the mass media, of products which are found to be injurious, dangerous and unsafe.

SEC. 19. *Product Confiscation.* – Imported products shall be allowed entry into the country as provided under Section 11 of this Act when accompanied by Certificate of Testing or Analysis of its composition. The BOC shall require pertinent clearance or certification from the FDA prior to entry. The entire shipment or batch of the product found to be in violation of the provisions of this Act shall be seized. The confiscated products shall be properly disposed of in accordance with the prescribed procedure to be issued by the DOH in coordination with the DENR.

SEC. 20. Publication and *Information.* – The Department of Health (DOH) is mandated to conduct information campaigns utilizing any form of mass media and other electronic means deemed effective to ensure the proper guidance of consumers, industries, businesses and other concerned sectors.

The DOH shall likewise publish a consumer chemical substance advisory notice which shall include a list of toxic chemicals and substances

used in the manufacture, distribution and sale of covered products for the information of the general public. Such advisory notice shall be made available to government agencies, consumers, industries, businesses and general public.

The advisories to be issued under this Act shall explain in an easily understandable manner, the dangers of hazardous substances exposure. It shall be printed in English and Filipino or in any dialect determined by the DOH to be culturally and linguistically appropriate utilizing any form of mass media and electronic means of communication.

SEC. 21. *Public Access to Records, Reports or Notification.* – The public shall have access to records, reports, test results, or information concerning chemicals, substances and mixtures, including safety data submitted, and methods of production and preparation.

Such documents shall be available for inspection or reproduction during normal business hours: *Provided,* That the DTI may consider a record, report or information or particular portions thereof confidential and which may not be made public when such would divulge trade secrets, production or sales figures or methods, production or processes unique to such manufacturer, processor or distributor, or would otherwise tend to affect adversely the competitive position of such manufacturer, processor or distributor. The DTI, however, may release information subject to claim of confidentiality to a medical research or scientific institution where the information is needed for the purpose of medical diagnosis or treatment of a person exposed to the chemical substance or mixture.

The DOH shall establish a website to be maintained by the CPSC which shall provide the following information: basic data on manufacturer, producer, assembled, importer, distributor and seller of covered products; kinds and amount of chemicals and substances used in the production of products; and the potential risks and dangers to consumers. The website shall also make available reports, records, and inventories submitted by the companies and businesses covered by this Act.

SEC. 22. *Disclosure of Toxicological Information on Labels-* It shall be mandatory for manufacturers, distributors and importers of products covered by this Act to disclose and identify, through accurate and truthful labeling, the substances and chemical contents and bioavailability of said substances /chemicals. Graphic symbols shall also be used in product packaging showing product safety and regulatory compliance.

SEC. 23. *Prohibited Acts.* – The following acts are hereby prohibited:

a. The importation, distribution, manufacture and sale of products under Section 4 hereof containing more than the allowable level of chemical elements and hazardous substances such as, but not limited to, antimony, arsenic, bisphenol, cadmium, chromium, lead, mercury and phthalate;

b. Mislabeling of the level of chemical elements in products under this Act;

c. Material misrepresentation or concealment of significant data or information about the product sought for certification;

d. Importation, manufacture, sale, distribution, labeling, operation without registration;

e. Non-compliance with the standards and requirements of the DOH on the importation, manufacture, distribution, sale of covered products,

f. Refusal to allow required inspections as determined by the Department; and

g. Other prohibited acts stipulated in Republic Act 9711, otherwise known as the "Food and Drug Administration Act of 2009."

SEC. 24. *Administrative Sanctions* – Where there is a finding of a violation against the provisions of this Act and a determination of the persons liable thereto, after notice and hearing, the FDA director-general may impose one or more of the following administrative penalties:

a. Suspension of License to Operate (LTO);
b. Revocation of LTO; and
c. Seizure of the unregistered, non-compliant or falsely represented products covered by this Act.

SEC. 25. *Penalties* – Pursuant to Section 11 of Republic Act 9711, any person who violates any of the provisions of Section 24 hereof and other prohibited acts stipulated in the same 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: *Provided,* That if the offender is a manufacturer, importer or distributor of any product covered under this Act, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five Hundred Thousand Pesos (P500,000.00) but not more than Five Million Pesos (P5,000,000.00) shall be imposed. *Provided, further,* That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One Thousand Pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: *Provided, finally,* That products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the FDA director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such products may cause injury or prejudice to the consuming public.

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 therefore shall be penalized.

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

SEC 26. *Citizens Suit.* - For purposes of enforcing the provisions of this Act or its implementing rules and regulations, any citizen may file an appropriate civil, criminal or administrative action in the proper courts/bodies against:

a. any person who violates or fails to comply with the provisions of this Act and its implementing rules and regulations; or
b. the officials or employees of the DOH and other implementing agencies with respect to orders, rules and regulations issued inconsistent with this Act, and/or
c. any public officer who willfully or grossly neglects the performance of an act specifically enjoined as a duty by this Act or its implementing rules and regulations; or abuses authority in the performance of duty; or, in any manner improperly performs his duties under this Act or its implementing rules and regulations: *Provided, however*, That no suit can be filed until after a thirty-day (30) notice has been given to the public officer and the alleged violator concerned and no appropriate action has been taken thereon.

The court shall exempt such action from the payment of filing fees and shall likewise, upon *prima facie* showing of the non-enforcement or violation complained of, exempt the plaintiff from the filing of an injunction bond for the issuance of preliminary injunction.

In the event that the citizen suit should prosper, the court may award reasonable attorney's fees, moral damages and litigation costs.

SEC 27. *Suits and Strategic Legal Action Against Public Participation (SLAPP) and the Enforcement of this Act.*- Where a suit is brought against a person who filed an action as provided in Section 26 of this Act, or against any person, institution or government agency that implements this Act or any other consumer related laws, rules, and regulations, it shall be the duty of the investigating prosecutor or the court, as the case may be, to immediately make a determination within a period not exceeding thirty (30) days whether said legal action has been filed to harass, vex, exert undue pressure or stifle such legal recourses of the person complaining or enforcing the provisions of this Act. Upon determination of the evidences, the court may dismiss the case and award attorney's fees and damages.

This provision shall also apply and benefit public officers who are sued for acts committed in their official capacity, there being no grave abuse of authority, and done in the course of enforcing this Act, its rules, regulations, and guidelines.

SEC. 28. *Burden of Proof of Product Safety.*- The burden of proof to prove the exercise of due diligence, compliance with this Act and other laws, rules, and regulations relating to consumer products, precaution, and to prove the absence of fault and/or negligence shall lie with the manufacturer, producer, assembler, importer, and/or seller of the children's product involved or concerned.

SEC. 29. *Appropriations* – Such amount as may be necessary to implement the provisions of this Act shall be included in the annual appropriations of the Department of Health under the General Appropriations Act.

SEC. 30. *Congressional Oversight Committee.* - The joint Congressional Oversight Committee created under R.A. No. 9711 or the Food and Drug Administration (FDA) Act of 2009 shall function as the oversight committee to monitor and evaluate the implementation of this Act.

SEC.31. *Suppletory Provision* - Pertinent provisions of Republic Act No. 7394 otherwise known as the "Consumer Act of the Philippines" shall have suppletory effect in the implementation of this Act.

SEC. 32. *Implementing Rules.* – Within sixty (60) days after the effectivity of this Act, the DOH, in coordination with the DTI, DENR and the DOF through the BOC, shall issue the rules and regulations to implement the provisions of this Act.

SEC. 33. *Separability Clause.* – If, for any reason, a provision or part hereof is declared invalid, the other provisions not affected thereby shall remain in full force and effect.

SEC. 34. *Repealing Clause.* – All laws, decrees, executive orders, rules and regulations or parts thereof inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SEC. 35. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its publication in any newspaper of general circulation.

Approved,