

SEVENTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
FIRST REGULAR SESSION)



Senate
Office of the Secretary

'16 AUG 25 A11 :20

SENATE

SENATE BILL NO. 1084

RECEIVED BY: J

INTRODUCED BY SENATOR JOSEPH VICTOR G. EJERCITO

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

EXPLANATORY NOTE

Article 15, Section 3(2) of the 1987 Philippine Constitution ensures the right of children to assistance, including proper care and nutrition, and special protection from all forms of neglect, abuse, cruelty, exploitation, and other conditions prejudicial to their development.

Choosing harmless toys are undeniably crucial for the health and wellness of our children. For the past years there has been a number of alarming news about the manufacture and sale of toxic and unsafe toys that endanger our children's health.

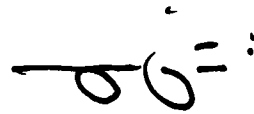
And although there are existing laws that already afford protection to children, similarly PRESIDENTIAL DECREE NO. 603, otherwise known as THE CHILD AND YOUTH WELFARE CODE, nonetheless, we still consider that there is a need for the Congress to pass a specific law that should regulate the importation, manufacture, sale and distribution of children's toys, school supplies, childcare articles and other related products, containing toxic chemicals as it is their legal responsibility.

Selecting safe toys for our children can be simpler if only there are accessible information available to every parent to afford them conscious awareness on the perilous and prohibited chemicals that maybe found in toys which might pose a hazard to children.

The goal of this proposed measure is to provide guidelines that will standardize the contents used on the manufacture of children toys, so as to deplore poison toys, where unknown to children, playing with said toxic toys expose them to jeopardy, especially when they place these things into their mouths as they often do.

Through these guidelines, the risk of a child being poisoned will be addressed; appropriately, preventing possible diseases and or death to innocent children.

Hence, immediate passage of the bill is earnestly sought.

A handwritten signature in black ink, appearing to read 'JOE EJERCITO', with a stylized flourish at the end.

JOSEPH VICTOR G. EJERCITO

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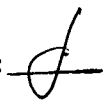


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AN ACT
TO REGULATE THE IMPORTATION, MANUFACTURE, SALE AND
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*Be it enacted by the Senate and the House of Representatives of the Philippines in
Congress assembled:*

1 **SECTION 1. *Short Title.*** - This Act shall be known as the "Safe and
2 **Nontoxic Children's Products Act of 2016".**

3
4 **SEC. 2. *Declaration of Policy.*** - It is hereby declared the policy of the
5 State to protect and promote the rights of the people to health, a balanced and
6 healthful ecology and to information. Toward these ends, the State shall
7 regulate the importation, manufacture, sale and distribution of children's toys,
8 school supplies and other childcare articles containing toxic chemicals.

9
10 **SEC. 3. *Definition of Terms.*** - For purposes of this Act, the following
11 terms are hereby defined:

12
13 (a) *Bioavailability* refers to the availability and possibility of the
14 chemical from a product or children's toys to be released and
15 absorbed into a child's body via the gastro intestinal tract, the
16 lungs or the skin and mucus membranes.

17 (b) *Chemical substance* refers to any organic or inorganic substance of

1 a particular molecular identity, including:
2

3 (1) Any combination of such substances occurring, in whole
4 or in part, as a result of chemical reaction or occurring in
5 nature; and
6

7 (2) Any element or uncombined chemical.

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

12 (d) *Children* refer to persons below eighteen (18) years of age or those
13 over but are unable to fully take care of themselves or protect
14 themselves from abuse, neglect, cruelty, exploitation or
15 discrimination because of a physical or mental disability or
16 condition.

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

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

30 (g) *Hazardous wastes* refer to substances that are without any safe
31 commercial, industrial, agricultural, or economic usage to
32 byproducts, side-products, process residues, spent reaction,
33 media, contaminated plant or equipment or other substances
34 from manufacturing operations, and as consumer discards
35 from manufactured products. It can also refer to waste which,
36 because of its quantity, concentration, or physical, chemical,
37 or infectious characteristics, may pose a substantial present or
38 potential hazard to human health or the environment when
39 improperly treated, stored or disposed of, otherwise
40 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 Department of Health (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

- 1 of the consumers.
- 2 (k) *License to operate (LTO)* refers to the license issued by the Food
3 and Drug Administration (FDA) to manufacturers, importers
4 and distributors whose toy products, children articles and
5 school implements, under this Act, conform to the health and
6 safety requirements of the DOH and the relevant Philippine
7 National Standards (PNS) and their future amendments.
- 8 (l) *Manufacturer* refers to any establishment that assembles or
9 processes products under this Act: *Provided*, That if such
10 products are manufactured, assembled or processed for another
11 establishment that attaches its own brand name to the
12 products, the latter shall be deemed the manufacturer. In
13 case of imported products under this Act, the manufacturer's
14 representative or, in his absence, the importer shall be
15 deemed the manufacturer.
- 16 (m) *Philippine National Standards (PNS)* refer to the national standards
17 approved by the technical committee under the Bureau of
18 Product Standards (BPS) of the Department of Trade and
19 Industry (DTI).
- 20 (n) *Sale or distribution* refers to an act made by a manufacturer or
21 seller, or the respective representative or agent to make
22 available consumer products, services or credit to the end
23 consumers under a consumer sale transaction. It shall not
24 include sampling or any other distribution not for sale.
- 25 (o) *School implement* refers to a tool used for writing, drawing,
26 coloring, marking, gluing or erasing by children that are likely to
27 be licked or put in the mouth.
- 28 (p) *School supplies* refer to items/articles used for educational purposes
29 which are not likely to be licked or put inside the mouth by
30 children. These include, among others, notebooks, crayons, pad
31 papers, envelopes, plastic covers, folders, mugs, school uniforms
32 and school bags.
- 33 (q) *Testing laboratory* refers to an accredited facility for measuring,
34 examining and determining the level of chemical elements in
35 products under this Act.
- 36 (r) *Toy* refers to an object or a number of objects clearly intended as
37 a plaything for children as defined in Section 3 of this Act.
- 38 (s) *Toxic substance* refers to any substance other than a radioactive
39 substance which can cause injury, illness or death through
40 ingestion, inhalation or absorption through any body surface.

1
2 **SEC. 4. Scope.** - This Act shall apply to the importation, manufacture,
3 sale and distribution of children's toys, school supplies, childcare articles and
4 other related products, whether or not designed or intended for use or play
5 solely by children under eighteen (18) years old, and other childcare articles
6 and related products that are sold or given free of charge in the Philippines.
7

8 **SEC. 5. Chemicals and Substances Covered.** - Within three (3) months
9 from the effectivity of this Act, the FDA shall prepare a list of chemicals
10 and substances used in children's products which cause or may cause
11 harm, injury or death to children. The FDA shall specifically identify
12 absolutely banned or prohibited substances and chemicals used in the
13 manufacture, production and preparation of children's products. Maximum
14 levels and limits and reference values for certain chemicals used for this purpose
15 shall also be specifically and clearly identified.
16

17 Chemicals and substances deemed most harmful and toxic to children
18 and commonly used in the manufacture and production of children's products
19 shall include, but shall not be limited to, the following:
20

21 (a) Toxic metals:

- 22 (1) Antimony;
23 (2) Arsenic;
24 (3) Cadmium;
25 (4) Chromium;
26 (5) Lead; and
27 (6) Mercury.

28 (b) Phthalates - when applied in the manufacture and
29 production of products covered under this Act, include:

- 30 (1) Di (2-Ethylhexyl) Phthalate (Dehp);
31 (2) Dibutyl Phthalate (Dbp);
32 (3) Benzyl Butyl Phthalate (Bbp);
33 (4) Diisononyl Phthalate (Dinp);
34 (5) Diisodecyl Phthalate (Didp); and
35 (6) Di-N-Octyl Phthalate (Dnop).

1 (c) Bisphenol-A (Bpa).

2
3 **SEC. 6. *Compliance With Philippine National Standards (PNS).*** -
4 Importers, manufacturers, distributors and sellers of products under this Act
5 shall comply with the standards, rules and processes of the BPS of the DTI.
6 The same shall collaborate with other relevant government agencies to
7 harmonize/upgrade existing standards, where applicable.

8
9 **SEC. 7. *Powers and Functions of the Department of Health (DOH).*** - To
10 effectively carry out its mandate of ensuring the quality of products under this
11 Act, the DOH shall have the following powers and functions:

- 12 (a) Formulate guidelines in the filing of application for the issuance
13 of LTO to importers, distributors and local manufacturers of
14 products under this Act;
- 15 (b) Formulate specific guidelines on the issuance of the Certificate
16 of Conformity (COC) to manufacturers, distributors and
17 importers for every shipment, freight, batch/lot of their products
18 covered in this Act;
- 19 (c) Issue quality control orders (QCOs) to enforce the provisions of
20 this Act and to ensure strict compliance with existing standards
21 and regulations set by government authorities;
- 22 (d) Issue compliance orders (COs) if it finds noncompliance and/or
23 nonconformity with this Act, its rules and regulations, and
24 guidelines issued to enforce and implement the same;
- 25 (e) Undertake researches, develop and establish quality and
26 safety standards for products covered by this Act in
27 coordination with other implementing government agencies;
- 28 (f) Set the maximum allowable level of toxicity of chemical
29 elements in products covered by this Act;
- 30 (g) Inspect and analyze products covered by this Act for purposes
31 of determining conformity to established quality and safety
32 standards;
- 33 (h) Conduct constant and regular inspection, product testing,
34 and on sight and random product testing and sampling of
35 various children's products in the market;
- 36 (i) Levy, assess, collect and retain fees as are necessary to cover the
37 cost of inspection, certification, analysis and tests of samples of
38 products under this Act;
- 39 (j) Investigate the causes of and maintain a record of product-

- 1 related deaths, illnesses and injuries for use in researches or
2 studies on the prevention of such deaths, illnesses and injuries;
3 (k) Accredit independent, competent nongovernment bodies to assist
4 in monitoring the market for the presence of toxic chemicals in
5 products under this Act and to look for appropriate means to
6 expand the monitoring and enforcement outreach of the
7 Department in relation to its manpower, testing and certification
8 resources at a given time;
9 (l) Accredit independent competent testing laboratories; and
10 (m) Perform such other functions as needed and necessary in the
11 enforcement of this Act.

12
13 **SEC. 8. *Role Delineation of Implementing Agencies.*** - The provisions of
14 this Act and its implementing rules and regulations (IRR) shall be enforced by
15 the following agencies:

- 16 (a) DOH. - The Department of Health shall formulate policies, rules
17 and regulations on food, drugs, cosmetics, devices and
18 substances. The FDA shall conduct regular testing, evaluation,
19 monitoring and post-market surveillance of covered products to
20 include all school implements as defined in Section 3 of this Act
21 to ensure compliance with the PNS on the Safety of Toys;
22 (b) DENR. - The Department of Environment and Natural Resources
23 shall regulate, control, restrict or prohibit the importation,
24 manufacture, processing, sale, distribution, handling, use,
25 transport and disposal of chemical substances mixtures under
26 Republic Act No. 6969, "Toxic Substances and Hazardous and
27 Nuclear Wastes Control Act of 1990". It shall monitor toxic
28 substances/chemicals used as industrial raw material to
29 produce the covered products under this Act in terms of their
30 compliance to environmental laws. It shall administer the
31 industrial toxic chemicals through a system of review,
32 evaluation and monitoring of these toxic chemicals
33 under DENR Administrative Order No. 2007-23 and formulate
34 policies and guidelines for the gradual phase-out of lead in
35 paints pursuant to Section 20(1) of DENR Administrative Order
36 No. 20, Series of 1992 and DENR Administrative Order No. 05,
37 Series of 2005 (Toxic Chemical Substances for Issuance of
38 Chemical Control Orders);
39 (c) DOF - The Department of Finance, through the Bureau of

1 Customs (BoC), shall monitor the entry of imported products
2 covered under this Act at the different ports of entry in the
3 Philippines. It shall review and conduct examination of
4 documentary requirements of imported products pursuant to the
5 guidelines of the Department; and

- 6 (d) DTL. - The Department of Trade and Industry shall enforce
7 policies and regulate the importation, manufacture, distribution
8 and sale of educational its or school supplies as defined in
9 Section 3 of this Act and other consumer products not covered
10 by the mandates of the other implementing agencies. It shall
11 ensure that covered products comply with the PNS on the Safety
12 of Toys set by the BPS and shall monitor and conduct market
13 inspections on covered products.

14
15 **SEC. 9. *Creation of the Children's Product Safety Council (CPSC).*** -

16 There is hereby created a Children's Product Safety Council (CPSC) to be
17 attached to the DOH and composed of the following:

- 18 (a) The Secretary of the DOH, Chairperson;
19 (b) The Secretary of the DTL, Vice Chairperson;
20 (c) The Secretary of the DENR, member;
21 (d) The Secretary of the Department of the Interior and
22 Local Government DILG, member;
23 (e) The Secretary of the Department of Education (DepED),
24 member;
25 (f) The Secretary of the DOF, member;
26 (g) The Director of the FDA, member;
27 (h) The National Consumer Affairs Council (NCAC), member;
28 (i) One (1) representative from a nongovernment
29 organization (NGO) engaged in consumer rights
30 protection, member; and
31 (j) One (1) representative from an NGO engaged in
32 environmental protection and advocacy, member.

33
34 The government departments and agencies shall be represented by
35 their respective heads or their duly designated representatives who shall be of
36 a rank not lower than Director level.

1 The Chairperson of the CPSC shall recommend the nominees for the
2 NGO sector representatives to the President of the Philippines. The FDA shall
3 serve as the secretariat and operational arm of the CPSC. Other government
4 agencies and private sector representatives may be invited to participate in
5 the CPSC as the exigencies and circumstances may require.

6
7 **SEC. 10. Powers and Functions of the CPSC.** - The CPSC shall have
8 the following powers and functions:

- 9 (a) To provide coordination and linkage mechanisms between
10 and among its members, other government agencies concerned,
11 local government units (LGUs), the private sector and other
12 stakeholders;
- 13 (b) To engage in studies and researches on harmful and toxic
14 chemicals and substances, and provide the necessary
15 information materials on the same;
- 16 (c) To conduct and facilitate consultation and dialogues within and
17 among all concerned stakeholders in the industry;
- 18 (d) To conduct information and education campaigns, especially for
19 children;
- 20 (e) To propose amendments to laws, rules and regulations pursuant
21 to its mandate and the objectives of this Act;
- 22 (f) To provide periodic and regular reports to the Secretary of
23 Health;
- 24 (g) To create a technical advisory committee composed of experts
25 from both government and private sectors that would assist the
26 council in providing technical and scientific recommendations
27 necessary to effectively carry out its mandate;
- 28 (h) To provide coordination and linkage mechanisms between and
29 among its members, other government agencies concerned, the
30 Business Processing and Licensing Office (BPLO) of LGUs, the
31 private sector and other stakeholders; and
- 32 (i) To perform such other functions as may be directed by the DOH.

33
34 **SEC. 11. Application to Trade.** - The following procedures shall be
35 observed at the first port of entry of imported products:

- 36
37 (a) The FDA or its commissioned/designated agent, in
38 coordination with the BoC, shall conduct product inspection,
39 sample testing and clearance of imported products covered

1 under this Act for compliance with the national standards for
2 the safety of toys prior to their assessment and charging of tariffs
3 and other charges by the BoC;

4 (b) Samples of products covered by this Act being imported into the
5 Philippines shall be obtained for purposes of determining the
6 toxicity level of chemical elements and substances content
7 without charge from the owner or consignee thereof. The owner
8 or consignee of the imported product under examination shall
9 be afforded an opportunity to a hearing with respect to the
10 importation of such product into the Philippines. If it is
11 proven that such product does not conform to the allowable
12 level of chemical elements and substances content as provided
13 for under the IRR of this Act, said product shall be refused
14 admission;

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

18 (d) All expenses in connection with the storage, destruction
19 and disposition of any product under this Act which was refused
20 admission shall be paid by the owner or consignee and, in
21 default of such payment, shall constitute a lien against any
22 future importation made by such owner or consignee.
23
24

25 **SEC. 12. Clearance for Customs Release.** - All importers of products
26 under this Act shall secure a clearance for customs release from the DOH prior
27 to importation.
28

29 A clearance for conditional release shall be issued by the appropriate
30 center of the FDA to facilitate the release of goods from BoC custody pending
31 the issuance of the COC. The importer, however, shall not sell, distribute or
32 transfer, in whole or in part, the products to any place other than the address
33 specified in the conditional release. To ensure that no distribution, sale,
34 transfer to or use of products covered by this Act in any place other than the
35 address specified in the conditional release is made, the importers shall allow
36 authorized personnel of the FDA to conduct an inspection/inventory of
37 the import shipment within three (3) days from the date of issuance of
38 the clearance for conditional release at any time within official working hours.
39

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

4
5 **SEC. 14. Disposal of Noncompliant Products.** - All products covered
6 by this Act that are recalled by the manufacturer or the Department for
7 whatever reason, shall be disposed of in accordance with the submitted
8 disposal plan subject to the FDA approval. The plan shall comply with the
9 existing rules and regulations set by all concerned agencies of the government
10 and other related laws of the country. The concerned manufacturer, importer
11 or distributor shall shoulder the expenses to be incurred in the disposal of the
12 recalled products.

13
14 All import-shipments denied the requisite COC shall not be disposed of
15 in the domestic market in any manner. They must be properly disposed in
16 accordance with the provisions of the Tariff and Customs Code of the
17 Philippines and other pertinent rules and regulations.

18
19 **SEC. 15. Labeling and Packaging Requirement.** - The labeling and
20 packaging requirement of products under this Act shall comply with the
21 relevant PNS.

22
23 **SEC. 16. Monitoring and Factory Inspection.**

24
25 (a) Officers or employees duly designated by the FDA, upon presenting
26 appropriate credentials to the owner, operator or agent in charge, are
27 authorized:

- 28 (1) To enter, at reasonable hours, any factory, warehouse or
29 establishment in which products under this Act are
30 manufactured or held for introduction into domestic
31 commerce or are held after such introduction, or to enter
32 any vehicle being used to transport or hold such products;
33 and
34 (2) To inspect, in a reasonable manner, such factory,
35 warehouse, establishment or vehicle and all pertinent
36 equipment, finished and unfinished materials, containers
37 and labeling therein.

38

1 (b) Upon completion of the inspection of a factory, warehouse or other
2 establishment and prior to leaving the premises, the officer or employee who
3 conducted such inspection and has obtained any sample in the course of the
4 inspection, shall give the owner, operator or agent in charge a receipt
5 describing the samples obtained; and
6

7 (c) Whenever in the course of any such inspection of a factory or other
8 establishment where products covered by this Act are manufactured or held,
9 the officer or employee making the inspection obtains a sample of any such
10 product, and an analysis made of such sample for the purpose of ascertaining
11 whether such product contains, in whole or in part, disallowed level of toxicity
12 of chemical elements and hazardous substances, a copy of the result of such
13 analysis shall be furnished the owner, operator or officer-in-charge.
14

15 **SEC. 17. *Market Inspection.*** - The DOH shall conduct routine
16 inspection in the market and take samples of suspected products for
17 examination.
18

19 **SEC. 18. *Injurious, Dangerous and Unsafe Products.*** - Whenever the
20 DOH finds, by its own initiative or by petition of a consumer, that a product
21 covered by this Act is injurious, dangerous or unsafe, it shall, after due notice
22 and hearing, make the appropriate order for its recall, prohibition or seizure
23 from public sale or distribution. It may declare a product to be imminently
24 injurious, dangerous or unsafe, and order its immediate recall, ban or seize
25 from public sale or distribution, in which case, the seller, distributor or
26 producer thereof shall be afforded a hearing within forty-eight (48) hours from
27 such order.
28

29 There shall be immediate information dissemination, through the mass
30 media, of products that are found to be injurious, dangerous and unsafe.
31

32 **SEC. 19. *Product Confiscation.*** - Imported products shall be allowed
33 entry into the country as provided under Section 11 of this Act when
34 accompanied by certificate of testing or analysis of its composition. The BoC
35 shall require pertinent clearance or certification from the FDA prior to entry.
36 The entire shipment or batch of the product found to be in violation of the
37 provisions of this Act should be seized. The confiscated products shall be
38 properly disposed of in accordance with the prescribed procedure to be
39 issued by the DOH in coordination with the DENR.
40

1 **SEC. 20. *Publication and Information.*** - The DOH is mandated to
2 conduct information campaigns utilizing any form of mass media and other
3 electronic means deemed effective to ensure the proper guidance of consumers,
4 industries, businesses and other concerned sectors.

5 The DOH shall likewise publish a consumer chemical substance
6 advisory notice which shall include a list of toxic chemicals and substances
7 used in the manufacture, distribution and sale of covered products for the
8 information of the general public. Such advisory notice shall be made
9 available to government agencies, consumers, industries, businesses and the
10 general public.

11
12 The advisories to be issued under this Act shall explain in an easily
13 understandable manner, the dangers of hazardous substances exposure. It
14 shall be printed in English and Filipino or in any dialect determined by the
15 DOH to be culturally and linguistically appropriate utilizing any form of
16 mass media and electronic means of communication.

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

21
22 Such documents shall be available for inspection or reproduction
23 during normal business hours: *Provided*, That the DTI may consider a record,
24 report or information or particular portions thereof confidential and which
25 may not be made public when such would divulge trade secrets, production or
26 sales figures or methods, production or processes unique to such
27 manufacturer, processor or distributor, or would otherwise tend to affect
28 adversely the competitive position of such manufacturer, processor or
29 distributor. The DTI, however, may release information subject to claim of
30 confidentiality to a medical research or scientific institution where the
31 information is needed for the purpose of medical diagnosis or treatment of a
32 person exposed to the chemical substance or mixture.

33
34 The DOH shall establish a website to be maintained by the CPSC which
35 shall provide the following information:

- 36
37 (a) Basic data on manufacturer, producer, assembler, importer,
38 distributor and seller of covered products;
39 (b) Kinds and amount of chemicals and substances used in
40 the production of products; and

1 (c) The potential risks and dangers to consumers.

2
3 The website shall also make available reports, records and inventories
4 submitted by the companies and businesses covered by this Act.

5
6 **SEC. 22. *Disclosure of Toxicological Information on Labels.*** - It shall
7 be mandatory for manufacturers, distributors and importers of products
8 covered by this Act to disclose and identify, through accurate and
9 truthful labeling, the substances and chemical contents and bioavailability
10 of said substances/chemicals. Graphic symbols shall also be used in product
11 packaging showing product safety and regulatory compliance.

12
13 **SEC. 23. *Prohibited Acts.*** - The following acts are hereby prohibited:

14
15 (a) The importation, distribution, manufacture and sale of products
16 under Section 4 hereof containing more than the allowable level of chemical
17 elements and hazardous substances such as, but not limited to, antimony,
18 arsenic, bisphenol, cadmium, chromium, lead, mercury and phthalate;

19 (b) Mislabeling of the level of chemical elements in products under this
20 Act;

21 (c) Material misrepresentation or concealment of significant data or
22 information about the product sought for certification;

23 (d) Importation, manufacture, sale, distribution, labeling and
24 operation without registration;

25 (e) Noncompliance with the standards and requirements of the DOH on
26 the importation, manufacture, distribution and sale of covered products;

27 (f) Refusal to allow required inspections as determined by the
28 Department; and

29 (g) Other prohibited acts stipulated in Republic Act No. 9711,
30 otherwise known as the "Food and Drug Administration (FDA) Act of 2009".

31
32 **SEC. 24. *Administrative Sanctions.*** - Where there is a finding of a
33 violation against the provisions of this Act and a determination of the persons
34 liable thereto, after notice and hearing, the FDA director-general may impose
35 one or more of the following administrative penalties:

36 (a) Suspension of License to Operate (LTO);

37 (b) Revocation of LTO; and
38

1 (c) Seizure of the unregistered, noncompliant or falsely represented
2 products covered by this Act.

3
4 **SEC. 25. Penalties.** - Pursuant to Section 11 of Republic Act No. 9711,
5 as amended, any person who violates any of the provisions of Section 24
6 hereof and other prohibited acts stipulated in the same Act shall, upon
7 conviction, suffer the penalty of imprisonment ranging from one (1) year but not
8 more than ten (10) years or a fine of not less than Fifty thousand pesos
9 (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or
10 both, at the discretion of the court: *Provided*, That if the offender is a
11 manufacturer, importer or distributor of any product covered under this Act,
12 the penalty of at least five (5) years imprisonment but not more than ten (10)
13 years and a fine of at least Five hundred thousand pesos (P500,000.00) but not
14 more than Five million pesos (P5,000,000.00) shall be imposed: *Provided*,
15 *further*, That an additional fine of one percent (1%) of the economic value/cost of
16 the violative product or violation, or One thousand pesos (P1,000.00),
17 whichever is higher, shall be imposed for each day of continuing violation:
18 *Provided, finally*, That products found in violation of the provisions of this Act
19 and other relevant laws, rules and regulations may be seized and held in
20 custody pending proceedings, without hearing or court order, when the FDA
21 director-general has reasonable cause to believe from facts found by him/her
22 or an authorized officer or employee of the FDA that such products may
23 cause injury or prejudice to the consuming public.

24
25 Should a juridical person commit a crime, the Chairman of the Board of
26 Directors, the president, general manager, or the partners and/or the persons
27 directly responsible therefor shall be penalized.

28
29 Should the offense be committed by a foreign national, he/she shall, in
30 addition to the penalties prescribed, be deported without further proceedings
31 after service of sentence.

32
33 **SEC. 26. Citizens Suit.** - For purposes of enforcing the provisions of
34 this Act or its IRR, any citizen may file an appropriate civil, criminal or
35 administrative action in the proper courts/bodies against:

36
37 (a) Any person who violates or fails to comply with the provisions
38 of this Act and its IRR; or

39 (b) The officials or employees of the DOH and other

1 implementing agencies with respect to orders, rules and
2 regulations issued inconsistent with this Act; and/or

3 (c) Any public officer who willfully or grossly neglects the
4 performance of an act specifically enjoined as a duty by this Act
5 or its IRR; or abuses authority in the performance of duty; or,
6 in any manner improperly performs his duties under this Act or
7 its IRR: *Provided, however,* That no suit can be filed until after a
8 thirty (30)-day notice has been given to the public officer and the
9 alleged violator concerned and no appropriate action has been
10 taken thereon.

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

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

19
20 **SEC. 27. *Suits and Strategic Legal Action Against Public Participation***
21 ***(SLAPP) and the Enforcement of this Act.*** - Where a suit is brought against a
22 person who filed an action as provided in Section 26 of this Act, or against any
23 person, institution or government agency that implements this Act or any other
24 consumer related laws, rules and regulations, it shall be the duty of the
25 investigating prosecutor or the court, as the case may be, to immediately make
26 a determination within a period not exceeding thirty (30) days whether said
27 legal action has been filed to harass, vex, exert undue pressure or stifle such
28 legal recourses of the person complaining or enforcing the provisions of this
29 Act. Upon determination of the evidences, the court may dismiss the case and
30 award attorney's fees and damages.

31
32 This provision shall also apply and benefit public officers who are sued
33 for acts committed in their official capacity, there being no grave abuse of
34 authority, and done in the course of enforcing this Act, its rules, regulations
35 and guidelines.

36
37 **SEC. 28. *Burden of Proof of Product Safety.*** - The burden of proof to
38 prove the exercise of due diligence, compliance with this Act and other laws,
39 rules and regulations relating to consumer products, precaution and to prove
40 the absence of fault and/or negligence shall lie with the manufacturer,

1 producer, assembler, importer and/or seller of the children's product involved
2 or concerned.

3
4 **SEC. 29. Appropriations.** - Such amount as may be necessary to
5 implement the provisions of this Act shall be included in the annual
6 appropriations of the DOH under the General Appropriations Act.

7
8 **SEC. 30. Congressional Oversight Committee.** - The Joint
9 Congressional Oversight Committee created under Republic Act No. 9711 or
10 the "Food and Drug Administration (FDA) Act of 2009" shall function as the
11 oversight committee to monitor and evaluate the implementation of this Act.

12
13 **SEC. 31. Suppletory Provision.** - Pertinent provisions of Republic Act
14 No. 7394, otherwise known as the "Consumer Act of the Philippines" shall
15 have suppletory effect in the implementation of this Act.

16
17 **SEC. 32. Implementing Rules and Regulations.** - Within sixty (60)
18 days after the effectivity of this Act, the DOH, in coordination with the DTI,
19 the DENR and the DOF through the BoC, shall issue the rules and regulations
20 to implement the provisions of this Act.

21
22 **SEC. 33. Separability Clause.** - If, for any reason, any provision or
23 part hereof is declared invalid, the other provisions not affected thereby shall
24 remain in full force and effect.

25
26 **SEC. 34. Repealing Clause.** - All laws, decrees, executive orders,
27 rules and regulations or parts thereof inconsistent with the provisions of this
28 Act are hereby repealed, amended or modified accordingly.

29
30 **SEC. 35. Effectivity Clause.** - This Act shall take effect fifteen (15) days
31 after its publication in any newspaper of general circulation.

32
33
34 Approved,
35