

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



'14 JUL -7 AIO :08

SENATE

Senate Bill No. 2302

RECEIVED BY: 

INTRODUCED BY SEN. JINGGOY EJERCITO ESTRADA

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


Toys are effective instruments to give joy, entertainment and education to our children. Toys and school supplies such as marbles, spin tops, toy make-up and jewelries, crayola, and water color might seem harmless but not visible to the naked eye is the possible grave threat they pose to our children's health if their chemical composition is left unchecked.

In the recent efforts of some private organizations to check the chemical composition of toys, it was revealed that toxic toys that contain high levels of arsenic, antimony, cadmium, chromium, lead, and mercury, are being sold near the area of at least thirty eight (38) public elementary schools in Metro Manila. These chemicals could cause serious health problems, including neurological and behavioural disorders.

The "**Safe and Non-Toxic Children's Products Act of 2014**" intends to regulate the importation, manufacture, sale and distribution of children's toys, school supplies and other child care articles containing toxic chemicals.

A Children's Product Safety Council (CPSC) is created under this proposed measure which shall be attached to the Department of Health (DOH). It shall, among others, provide coordination and linkage mechanisms between and among government and private stakeholders, and engage in studies and researches on harmful and toxic chemicals and substances, and provide the necessary information materials on the same.

This measure was previously filed by Sen. Manny Villar in the 15th Congress. For the protection and safety of our children, the immediate passage of this bill is earnestly sought.


JINGGOY EJERCITO ESTRADA
Senator

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CHEMICALS AND FOR OTHER PURPOSES

*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 Non-Toxic**
2 **Children’s Products Act of 2014**”.

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

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

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

19
20 (b) *Chemical substance* refers to any organic or inorganic substance of a
21 particular molecular identity, including:

22
23 1. any combination of such substances occurring, in whole or in part,
24 as a result of chemical reaction or occurring in nature; and,

25
26 2. any element or uncombined chemical

27
28 (c) *Childcare article* refers to any product intended to facilitate sleep,
29 relaxation, hygiene, the feeding of children or sucking on the part of
30 children such as nipples, feeding bottles, baby dresses, pacifiers etc.;

31

1 (d) *Children* refer to persons below eighteen (18) years of age or those over
2 but are unable to fully take care of themselves or protect themselves from
3 abuse, neglect, cruelty, exploitation or discrimination because of a
4 physical or mental disability or condition;

5
6 (e) *Distributor* refers to any entity to which the toy product is delivered or sold
7 for purposes of distribution in commerce, or in such case repackages toys
8 under different trade name or trademark with permission from the original
9 legal distributor, except that such term does not include a manufacturer or
10 retailer of such product;

11
12 (f) *Educational Kit* refers to a collection of materials and associated scientific
13 apparatus that are not likely to be licked or put in the mouth by children
14 and which are typically used to perform experiments or demonstrations in
15 the different fields of science. These materials include, among others,
16 notebooks, pad papers, envelopes, plastic covers, folders, mugs, school
17 uniforms and school bags;

18
19 (g) *Hazardous Wastes* refer to substances that are without any safe
20 commercial, industrial, agricultural, or economic usage to by-products,
21 side-products, process residues, spent reaction, media, contaminated
22 plant or equipment or other substances from manufacturing operations,
23 and as consumer discards from manufactured products. It can also refer
24 to waste which, because of its quantity, concentration, or physical,
25 chemical, or infectious characteristics, may pose a substantial present or
26 potential hazard to human health or the environment when improperly
27 treated, stored or disposed of, otherwise mismanaged; or cause or
28 contribute to an increase in mortality, or an increase in irreversible or
29 incapacitating illness;

30
31 (h) Hazardous Substance/Chemical refers to:

- 32
- 33 1. a substance which presents short-term acute hazards, such as
34 acute toxicity by ingestion, inhalation or skin absorption, corrosivity
35 or other skin or eye contact hazard or the risk of fire or explosion;
 - 36
37 2. a substance which presents long-term environmental hazards,
38 including chronic toxicity upon repeated exposure, carcinogenicity
39 (which may in some cases result from acute exposure but with a
40 long latent period), resistance to detoxification process such as
41 biodegradation, the potential to pollute underground or surface
42 waters, or aesthetically objectionable properties such as offensive
43 odors;
 - 44
45 3. a chemical for which there is statistically significant evidence
46 (based on at least one study conducted according to established
47 scientific principles) that acute or chronic health effects may occur;
 - 48
49 4. any radioactive substance, if, with respect to such substance as
50 used in a particular class of article or as packaged, the DOH
51 determines by regulation that it is sufficiently hazardous to require
52 labeling in accordance with this Act in order to protect the public
53 health;
 - 54
55 5. any toy or other intended for use by children that may, by
56 regulation, be determined to contain an electrical, mechanical or
57 thermal hazard; or,

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

3
4 (i) *Importation* refers to the entry of a product or substance into the
5 Philippines (through the seaports or airports of entry) whether already
6 properly cleared through or still remaining under customs control, which is
7 intended for direct consumption, merchandising, warehousing and for
8 further processing;

9
10 (j) *Label* refers to the display of printed or graphic matter on any consumer
11 product, its immediate container, tag, literature or other suitable material
12 affixed thereto for the purpose of giving information as to the identity,
13 components, ingredients, attributes, directions for use, specifications and
14 such other information as may be necessary to protect health and safety
15 of the consumers;

16
17 (k) *License to Operate* (LTO) refers to the license issued by the FDA to
18 manufacturers, importers and distributors whose toy products, children
19 articles and school implements, under this Act, conform to the health and
20 safety requirements of the DOH and the relevant Philippine National
21 Standards and their future amendments;

22
23 (l) *Manufacturer* refers to any establishment that assembles or processes
24 products under this Act, provided that if such products are manufactured,
25 assembled or processed for another establishment that attaches its own
26 brand name to the products, the latter shall be deemed the manufacturer.
27 In case of imported products under this Act, the manufacturer's
28 representative or, in his absence, the importer shall be deemed the
29 manufacturer;

30
31 (m) *Philippine National Standards* (PNS) refer to the national standards
32 approved by the Technical Committee under the Bureau of Products
33 Standard of the Department of Trade and Industry;

34
35 (n) *Sale or distribution* refers to an act made by a manufacturer or seller, or
36 the respective representative or agent to make available consumer
37 products, services or credit to the end consumers under a consumer sale
38 transaction. It shall not include sampling or any other distribution not for
39 sale;

40
41 (o) *School Implement* refers to a tool used for writing, drawing, coloring,
42 marking, gluing, or erasing by children that are likely to be licked or put in
43 the mouth;

44
45 (p) *School Supplies* refer to items/articles used for educational purposes
46 which are not likely to be licked or put inside the mouth by children. These
47 include, among others, notebooks, crayons, pad papers, envelopes,
48 plastic covers, folders, mugs, school uniforms and school bags;

49
50 (q) *Testing Laboratory* refers to an accredited facility for measuring,
51 examining, and determining the level of chemical elements in products
52 under this Act;

53
54 (r) *Toy* refers to an object or a number of objects clearly intended as a
55 plaything for children as defined in Section 3 of this Act;

56

1 (s) Toxic substance refers to any substance other than a radioactive
2 substance which can cause injury, illness or death through ingestion,
3 inhalation, or absorption through any body surface.
4
5

6 **SEC. 4. Scope.** – This Act shall apply to the importation, manufacture, sale and
7 distribution of children's toys, school supplies, childcare articles and other related
8 products, whether or not designed or intended for use or play solely by children
9 under the age of eighteen (18), and other childcare articles and related products
10 that are sold or given free of charge in the Philippines.
11

12
13 **SEC. 5. Chemicals and Substances Covered.** – Within three (3) months from the
14 effectivity of this Act, the Food and Drug Administration (FDA) shall prepare a list
15 of chemicals and substances used in children's products which cause or may
16 cause harm, injury, or death to children. The FDA shall specifically identify
17 absolutely banned or prohibited substances and chemicals used in the
18 manufacture, production, and preparation of children's products. Maximum
19 levels and limits and reference values for certain chemicals used for this purpose
20 shall also be specifically and clearly identified.
21

22 Chemicals and substances deemed most harmful and toxic to children and
23 commonly used in the manufacture and production of children's products shall
24 include, but shall not be limited, to the following:
25

26 (a) Toxic Metals:

- 27
- 28 1. Antimony
- 29 2. Arsenic
- 30 3. Cadmium
- 31 4. Chromium
- 32 5. Lead
- 33 6. Mercury
- 34

35 (b) Phthalates – when applied in the manufacture and production of products
36 covered under this Act, include:
37

- 38 1. Di (2-Ethylhexyl) Phthalate (Dehp)
- 39 2. Dibutyl Phthalate (Dbp)
- 40 3. Benzyl Butyl Phthalate (Sbp)
- 41 4. Diisononyl Phthalate (Dinp)
- 42 5. Diisodecyl Phthalate (Didp)
- 43 6. Di-N-Octyl Phthalate (Dnop)
- 44

45 (c) Bisphenol-A (Spa)
46
47

48 **SEC. 6. Compliance with Philippine National Standards (PNS).** – Importers,
49 manufacturers, distributors and sellers of products under this Act shall comply
50 with the standards, rules and processes of the Bureau of Product Standards of
51 the Department of Trade and Industry. The same shall collaborate with other
52 relevant government agencies to harmonize/upgrade existing standards, where
53 applicable.
54
55

1 **SEC. 7. Powers and Functions of the DOH.** – To effectively carry out its
2 mandate of ensuring the quality of products under this Act, the DOH shall have
3 the following powers and functions:
4

- 5 (a) Formulate guidelines in the filing of application for the issuance of License
6 to Operate (LTO) to importers, distributors and local manufacturers of
7 products under this Act;
8
- 9 (b) Formulate specific guidelines on the issuance of the Certificate of
10 Conformity to manufacturers, distributors, and importers for every
11 shipment, freight, batch/lot of their products covered in this Act;
12
- 13 (c) Issue quality control orders (QCOs) to enforce the provisions of this Act
14 and to ensure strict compliance with existing standards and regulations set
15 by government authorities;
16
- 17 (d) Issue compliance orders (COs) if it finds non-compliance and/or
18 nonconformity with this Act, its rules and regulations, and guidelines
19 issued to enforce and implement the same;
20
- 21 (e) Undertake researches, develop and establish quality and safety standards
22 for products covered by this Act in coordination with other implementing
23 government agencies;
24
- 25 (f) Set the maximum allowable level of toxicity of chemical elements in
26 products covered by this Act;
27
- 28 (g) Inspect and analyze products covered by this Act for purposes of
29 determining conformity to established quality and safety standards;
30
- 31 (h) Conduct constant and regular inspection, product testing, and on-sight
32 and random product testing and sampling of various children's products in
33 the market;
34
- 35 (i) Levy, asses, collect and retain fees as are necessary to cover the cost of
36 inspection, certification, analysis and tests of samples of products under
37 this Act;
38
- 39 (j) Investigate the causes of and maintain a record of product-related deaths,
40 illnesses and injuries for use in researches or studies on the prevention of
41 such deaths, illnesses and injuries;
42
- 43 (k) Accredite independent, competent non-government bodies, to assist in
44 monitoring the market for the presence of toxic chemicals in products
45 under this Act and to look for appropriate means to expand the monitoring
46 and enforcement outreach of the Department in relation to its manpower,
47 testing and certification resources at a given time;
48
- 49 (l) Accredite independent competent testing laboratories; and,
50
- 51 (m) Perform such other functions as needed and necessary in the
52 enforcement of this Act.
53

54
55 **SEC. 8. Role Delineation of Implementing Agencies.** – The provisions of this Act
56 and its implementing rules and regulations shall be enforced by the following
57 agencies:

- 1 (a) DOH – The Department of Health shall formulate policies, rules and
2 regulations on food, drugs, cosmetics, devices and substances. The FDA
3 shall conduct regular testing, evaluation, monitoring and post-market
4 surveillance of covered products to include all school implements as
5 defined in Section 3 of this Act to ensure compliance with the Philippine
6 National Standards on the Safety of Toys;
7
- 8 (b) DENR – The Department of Environment and Natural Resources shall
9 regulate, control, restrict or prohibit the importation, manufacture,
10 processing, sale, distribution, handling, use, transport and disposal of
11 chemical substances mixtures under Republic Act No. 6969, "Toxic
12 Substances and Hazardous and Nuclear Waste Control Act of 1990". It
13 shall monitor toxic substances/chemicals used as industrial raw material to
14 produce the covered products under this Act in terms of their compliance
15 to environmental laws. It shall administer the industrial toxic chemicals
16 through a system of review, evaluation and monitoring of these toxic
17 chemicals under the DENR Administrative Order No. 2007-23 and
18 formulate policies and guidelines for the gradual phase-out of lead in
19 paints pursuant to Sec. 20 (1) of DAO 20, Series of 1992 and DAO 05,
20 Series of 2005 (Toxic Chemical Substances for Issuance of Chemical
21 Control Orders);
22
- 23 (c) DOF – The Department of Finance, through the Bureau of Customs, shall
24 monitor the entry of imported products covered under this Act at the
25 different ports of entry in the Philippines. It shall review and conduct
26 examination of documentary requirements of imported products pursuant
27 to the guidelines of the Department;
28
- 29 (d) DTI – The Department of Trade and Industry shall enforce policies and
30 regulate the importation, manufacture, distribution and sale of educational
31 kits or school supplies as defined in Section 3 of this Act and other
32 consumer products not covered by the mandates of the other
33 implementing agencies. It shall ensure that covered products comply with
34 the Philippine National Standards on the Safety of Toys set by the Bureau
35 of Product Standards and shall monitor and conduct market inspections
36 on covered products.
37
38

39 **SEC. 9.** *Creation of the Children's Product Safety Council (CPSC).* – There is
40 hereby created a Children's Product Safety Council (CPSC) to be attached to the
41 Department of Health (DOH) and composed of the following:
42

- 43 (a) The Secretary of the DOH – Chairperson;
44 (b) The Secretary of the DTI – Vice Chairperson;
45 (c) The Secretary of the DENR – Member;
46 (d) The Secretary of the Department of Interior and Local Government
47 (DILG) – Member;
48 (e) The Secretary of the Department of Education (DepEd) – Member;
49 (f) The Secretary of DOF – Member;
50 (g) The Director of the FDA – Member;
51 (h) The National Consumer Affairs Council (NCAC) – Member;
52 (i) One (1) Representative from a Non-Government Organization (NGO)
53 engaged in consumer rights protection – Member; and,
54 (j) One (1) Representative from a Non-Government Organization (NGO)
55 engaged in environmental protection and advocacy – Member;
56

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

4
5 The Chairperson of the CPSC shall recommend the nominees for the NGO
6 Sector Representatives to the President of the Philippines.

7
8 The FDA shall serve as the secretariat and operational arm of the CPSC.

9
10 Other government agencies and private sector representatives may be invited to
11 participate in the CPSC as the exigencies and circumstances may require.

12
13
14 **SEC. 10. Powers and Functions of the CPSC.** – The CPSC shall have the
15 following powers and functions:

- 16
17 (a) To provide coordination and linkage mechanisms between and among its
18 members, other government agencies concerned, local government units
19 (LGUs), the private sector, and other stakeholders;
20
21 (b) To engage in studies and researches on harmful and toxic chemicals and
22 substances, and provide the necessary information materials on the same;
23
24 (c) To conduct and facilitate consultation and dialogues within and among all
25 concerned stakeholders in the industry;
26
27 (d) To conduct information and education campaigns, especially for children;
28
29 (e) To propose amendments to laws, rules, and regulations pursuant to its
30 mandate and the objectives of this Act;
31
32 (f) To provide periodic and regular reports to the Secretary of Health;
33
34 (g) To create a Technical Advisory Committee composed of experts from both
35 government and private sectors that would assist the council in providing
36 technical and scientific recommendations necessary to effectively carry
37 out its mandate;
38
39 (h) To provide coordination and linkage mechanisms between and among its
40 members, other government agencies concerned, the Business
41 Processing and Licensing Office (BPLO) of Local Government Units
42 (LGUs), the private sector, and other stakeholders; and,
43
44 (i) To perform such other functions as may be directed by the DOH.

45
46
47 **SEC. 11. Application to Trade.** – The following procedures shall be observed at
48 the first port of entry of imported products:

- 49
50 (a) The FDA, or its commissioned/designated agent, in coordination with the
51 Bureau of Customs (BOC), shall conduct product inspection, sample
52 testing and clearance of imported products covered under this Act for
53 compliance with the national standards for the safety of toys prior to their
54 assessment and charging of tariffs and other charges by the BOC;
55
56 (b) Samples of products covered by this Act being imported into the
57 Philippines shall be obtained for purposes of determining the toxicity level

1 of chemical elements and substances content without charge from the
2 owner or consignee thereof. The owner or consignee of the imported
3 product under examination shall be afforded an opportunity to a hearing
4 with respect to the importation of such product into the Philippines. If it is
5 proven that such product does not conform to the allowable level of
6 chemical elements and substances content as provided for under the
7 implementing rules and regulation of this Act, said product shall be
8 refused admission;

9
10 (c) Any product covered by this Act, the sale or use of which has been
11 banned or withdrawn in the country of manufacture, shall not be imported
12 into the country; and,

13
14 (d) All expenses in connection with the storage, destruction and disposition of
15 any product under this Act which was refused admission shall be paid by
16 the owner or consignee and, in default of such payment, shall constitute a
17 lien against any future importation made by such owner or consignee.

18
19
20 **SEC. 12. Clearance for Customs Release.** – All importers of products under this
21 Act shall secure a Clearance for Customs Release from the DOH prior to
22 importation.

23
24 A Clearance for Conditional Release shall be issued by the appropriate Center of
25 the FDA to facilitate the release of goods from the BOC custody pending the
26 issuance of the Certificate of Conformity. The importer, however shall not sell,
27 distribute or transfer in whole or in part, the products to any place other than the
28 address specified in the conditional release. To ensure that no distribution, sale,
29 transfer to or use of products covered by this Act in any place other than the
30 address specified in the conditional release is made, the importers shall allow
31 authorized personnel of the FDA to conduct an inspection/inventory of the import
32 shipment within three days from the date of issuance of the clearance for
33 conditional release at anytime within official working hours.

34
35
36 **SEC. 13. Certification.** – The DOH, after the conduct of a thorough examination,
37 shall issue the necessary certificate to show whether or not the imported
38 products are safe for distribution in the market.

39
40
41 **SEC. 14. Disposal of Non-Compliant Products.** – All products covered by this
42 Act that are recalled by the manufacturer or the Department for whatever reason,
43 shall be disposed of in accordance with the submitted disposal plan subject to
44 FDA approval. The plan shall comply with the existing rules and regulations set
45 by all concerned agencies of the government and other related laws of the
46 country. The concerned manufacturer, importer or distributor shall shoulder the
47 expenses to be incurred in the disposal of the recalled products.

48
49 All import-shipments denied the requisite Certificate of Conformity shall not be
50 disposed of in the domestic market in any manner. They must be properly
51 disposed in accordance with the provisions of the Tariff and Customs Code and
52 other pertinent rules and regulations.

53
54
55 **SEC. 15. Labeling and Packaging Requirement.** – The packaging and labeling
56 requirement of products under this Act shall comply with the relevant Philippine
57 National Standards.

1 **SEC. 16. *Monitoring and Factory Inspection.*** – The FDA shall observe the
2 following procedures in the inspection and monitoring of establishments to
3 determine compliance with safety regulations:
4

5 (a) Officers or employees duly designated by the FDA, upon presenting
6 appropriate credentials to the owner, operator, or agent in charge, are
7 authorized (1) to enter, at reasonable hours, any factory, warehouse or
8 establishment in which products under this Act are manufactured or held
9 for introduction into domestic commerce or are held after such
10 introduction, or to enter any vehicle being used to transport or hold such
11 products; and (2) to inspect, in a reasonable manner, such factory,
12 warehouse, establishment or vehicle and all pertinent equipment, finished
13 and unfinished materials, containers and labeling therein;
14

15 (b) Upon completion of the inspection of a factory, warehouse or other
16 establishment and prior to leaving the premises, the officer or employee
17 who conducted such inspection and has obtained any sample in the
18 course of the inspection, shall give the owner, operator, or agent in charge
19 a receipt describing the samples obtained;
20

21 (c) Whenever in the course of any such inspection of a factory or other
22 establishment where products covered by this Act are manufactured or
23 held, the officer or employee making the inspection obtains a sample of
24 any such product, and an analysis made of such sample for the purpose
25 of ascertaining whether such product contains, in whole or in part,
26 disallowed level of toxicity of chemical elements and hazardous
27 substances, a copy of the result of such analysis shall be furnished the
28 owner, operator, or officer- in- charge.
29
30

31 **SEC. 17. *Market Inspection.*** – The DOH shall conduct routine inspection in the
32 market and take samples of suspected products for examination.
33
34

35 **SEC. 18. *Injurious, Dangerous and Unsafe Products.*** – Whenever the DOH
36 finds, by its own initiative or by petition of a consumer, that a product covered by
37 this Act is injurious, unsafe or dangerous, it shall, after due notice and hearing,
38 make the appropriate order for its recall, prohibition, or seizure from public sale
39 or distribution. It may declare a product to be imminently injurious, unsafe or
40 dangerous, and order its immediate recall, ban or seize from public sale or
41 distribution, in which case, the seller, distributor or producer thereof shall be
42 afforded a hearing within forty-eight (48) hours from such order.
43

44 There shall be immediate information dissemination, through the mass media, of
45 products which are found to be injurious, dangerous and unsafe.
46
47

48 **SEC. 19. *Product Confiscation.*** – Imported products shall be allowed entry into
49 the country as provided under Section 11 of this Act when accompanied by
50 Certificate of Testing or Analysis of its composition. The BOC shall require
51 pertinent clearance or certification from the FDA prior to entry. The entire
52 shipment or batch of the product found to be in violation of the provisions of this
53 Act shall be seized. The confiscated products shall be properly disposed of in
54 accordance with the prescribed procedure to be issued by the DOH in
55 coordination with the DENR.
56
57

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

5
6 The DOH shall likewise publish a consumer chemical substance advisory notice
7 which shall include a list of toxic chemicals and substances used in the
8 manufacture, distribution and sale of covered products for the information of the
9 general public. Such advisory notice shall be made available to government
10 agencies, consumers, industries, businesses and 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 shall
14 be printed in English and Filipino or in any dialect determined by the DOH to be
15 culturally and linguistically appropriate utilizing any form of mass media and
16 electronic means of communication.

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

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

34
35 The DOH shall establish a website to be maintained by the CPSC which shall
36 provide the following information: basic data on manufacturer, producer,
37 assembled, importer, distributor and seller of covered products; kinds and
38 amount of chemicals and substances used in the production of products; and the
39 potential risks and dangers to consumers. The website shall also make available
40 reports, records, and inventories submitted by the companies and businesses
41 covered by this Act.

42
43
44 **SEC. 22. *Disclosure of Toxicological Information on Labels.*** – It shall be
45 mandatory for manufacturers, distributors and importers of products covered by
46 this Act to disclose and identify, through accurate and truthful labeling, the
47 substances and chemical contents and bioavailability of said substances /
48 chemicals. Graphic symbols shall also be used in product packaging showing
49 product safety and regulatory compliance.

50
51
52 **SEC. 23. *Prohibited Acts.*** – The following acts are hereby prohibited:

- 53
54 (a) The importation, distribution, manufacture and sale of products under
55 Section 4 hereof containing more than the allowable level of chemical
56 elements and hazardous substances such as, but not limited to, antimony,
57 arsenic, bisphenol, cadmium, chromium, lead, mercury and phthalate;

- 1 (b) Mislabeling of the level of chemical elements in products under this Act;
2
3 (c) Material misrepresentation or concealment of significant data or
4 information about the product sought for certification;
5
6 (d) Importation, manufacture, sale, distribution, labeling, operation without
7 registration;
8
9 (e) Non-compliance with the standards and requirements of the DOH on the
10 importation, manufacture, distribution, sale of covered products;
11
12 (f) Refusal to allow required inspections as determined by the Department;
13 and,
14
15 (g) Other prohibited acts stipulated in Republic Act 9711, otherwise known as
16 the "Food and Drug Administration Act of 2009".
17
18

19 **SEC. 24. Administrative Sanction.** -- Where there is a finding of a violation
20 against the provisions of this Act and a determination of the persons liable
21 thereto, after notice and hearing, the FDA director-general may impose one or
22 more of the following administrative penalties:
23

- 24 (a) Suspension of License to Operate (LTO);
25
26 (b) Revocation of LTO; and,
27
28 (c) Seizure of the unregistered, non-compliant or falsely represented products
29 covered by this Act.
30
31

32 **SEC. 25. Penalties.** -- Pursuant to Section 11 of Republic Act 9711, any person
33 who violates any of the provisions of Section 24 hereof and other prohibited acts
34 stipulated in the same Act shall, upon conviction, suffer the penalty of
35 imprisonment ranging from one (1) year but not more than ten (10) years or a
36 fine of not less than Fifty Thousand Pesos (P50,000.00) but not more than Five
37 Hundred Thousand Pesos (P500,000.00) or both, at the discretion of the court;
38 *Provided*, That if the offender is a manufacturer, importer or distributor of any
39 product covered under this Act, the penalty of at least five (5) years imprisonment
40 but not more than ten (10) years and a fine of at least Five Hundred Thousand
41 Pesos (P500,000.00) but not more than Five Million Pesos (P5,000,000.00) shall
42 be imposed; *Provided, further*, That an additional fine of one percent (1 %) of the
43 economic value / cost of the violative product or violation, or One Thousand
44 Pesos (P1,000.00), whichever is higher, shall be imposed for each day of
45 continuing violation; *Provided, finally*, That products found in violation of the
46 provisions of this Act and other relevant laws, rules and regulations may be
47 seized and held in custody pending proceedings, without hearing or court order,
48 when the FDA director-general has reasonable cause to believe from facts found
49 by him/her or an authorized officer or employee of the FDA that such products
50 may cause injury or prejudice to the consuming public.
51

52 Should the offense be committed by a juridical person, the Chairman of the
53 Board of Directors, the president, general manager, or the partners and/or the
54 persons directly responsible therefore shall be penalized.
55

1 Should the offense be committed by a foreign national, he/she shall, in addition
2 to the penalties prescribed, be deported without further proceedings after service
3 of sentence.
4
5

6 **SEC. 26. Citizens' Suit.** – For purposes of enforcing the provisions of this Act or
7 its implementing rules and regulations, any citizen may file an appropriate civil,
8 criminal or administrative action in the proper courts/bodies against:
9

- 10 (a) any person who violates or fails to comply with the provisions of this Act
11 and its implementing rules and regulations; or,
12
13 (b) the officials or employees of the DOH and other implementing agencies
14 with respect to orders, rules and regulations issued inconsistent with this
15 Act; and/or,
16
17 (c) any public officer who willfully or grossly neglects the performance of an
18 act specifically enjoined as a duty by this Act or its implementing rules and
19 regulations; or abuses authority in the performance of duty; or, in any
20 manner improperly performs his duties under this Act or its implementing
21 rules and regulations; *Provided, however,* That no suit can be filed until
22 after a thirty-day (30) notice has been given to the public officer and the
23 alleged violator concerned and no appropriate action has been taken
24 thereon.
25

26 The court shall exempt such action from the payment of filing fees and shall
27 likewise, upon *prima facie* showing of the non-enforcement or violation
28 complained of, exempt the plaintiff from the filing of an injunction bond for the
29 issuance of preliminary injunction.
30

31 In the event that the citizen suit should prosper, the court may award reasonable
32 attorney's fees, moral damages and litigation costs.
33
34

35 **SEC. 27. Suits and Strategic Legal Action Against Public Participation (SLAPP)**
36 **and the Enforcement of this Act.** – Where a suit is brought against a person who
37 filed an action as provided in Section 26 of this Act, or against any person,
38 institution or government agency that implements this Act or any other consumer
39 related laws, rules, and regulations, it shall be the duty of the investigating
40 prosecutor or the court, as the case may be, to immediately make a
41 determination within a period not exceeding thirty (30) days whether said legal
42 action has been filed to harass, vex, exert undue pressure or stifle such legal
43 recourses of the person complaining or enforcing the provisions of this Act.
44 Upon determination of the evidences, the court may dismiss the case and award
45 attorney's fees and damages.
46

47 This provision shall also apply and benefit public officers who are sued for acts
48 committed in their official capacity, there being no grave abuse of authority, and
49 done in the course of enforcing this Act, its rules, regulations, and guidelines.
50
51

52 **SEC. 28. Burden of Proof of Product Safety.** – The burden of proof to prove the
53 exercise of due diligence, compliance with this Act and other laws, rules, and
54 regulations relating to consumer products, precaution, and to prove the absence
55 of fault and/or negligence shall lie with the manufacturer, producer, assembler,
56 importer, and/or seller of the children's product involved or concerned.
57

1 **SEC. 29. Appropriations.** – Such amount as may be necessary to implement the
2 provisions of this Act shall be included in the annual appropriations of the
3 Department of Health under the General Appropriations Act.
4

5
6 **SEC. 30. Congressional Oversight Committee.** – The joint Congressional
7 Oversight Committee created under RA No. 9711 or the Food and Drug
8 Administration (FDA) Act of 2009 shall function as the oversight committee to
9 monitor and evaluate the implementation of this Act
10

11
12 **SEC. 31. Suppletory Provision.** – Pertinent provisions of Republic Act No. 7394
13 otherwise known as the "Consumer Act of the Philippines" shall have suppletory
14 effect in the implementation of this Act.
15

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

21
22 **SEC. 33. Separability Clause.** – If, for any reason, a provision or part hereof is
23 declared invalid, the other provisions not affected thereby shall remain in full
24 force and effect.
25

26
27 **SEC. 34. Repealing Clause.** – All laws, decrees, executive orders, rules and
28 regulations or parts thereof inconsistent with the provisions of this Act are hereby
29 repealed, amended or modified accordingly.
30

31
32 **SEC. 35. Effectivity Clause.** – This Act shall take effect after fifteen (15) days
33 after its complete publication in two (2) newspapers of general circulation.
34

35
36
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38
39 *Approved,*