



## HOUSE OF REPRESENTATIVES

H. No. 5087

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BY REPRESENTATIVES DEL ROSARIO (A.G.), CRUZ-GONZALES, YAP (S.), TAN (A), BRAVO (A.), PAEZ, RODRIGUEZ (R.), RODRIGUEZ (M.), LOBRIGAI, KHO, CO. BATOCABLE, PAQUIZ, REVILLA, TURABIN-HATAMAN, SEMA, ABAYON, ABELLANOSA, ACHARON, ACOSIA-ALBA, ALMONTE, ALVAREZ (M.), AMATONG (I.), AMATONG (R.), ARBISON, ASILO, BALINDONG, BAUTISTA, BELMONTE (V.), CABILAO, CAGAS, CAMINERO, CARI, CASTRO, CATAMCO, CERAFICA, CUEVA, DAYANGHIRANG, CERILLIS, FORJUN, GARAY, GARCIA-ALBANO, GORRICIA, GULLAS, HERNANDEZ, IWAY, LLONARDIA, LOPEZ (C.), MACROHON-NUÑO, MANALO, MANGUDADATU, MATUGAS, MELLANA, MERCADO, MIRASOL, NAVA (J.), OAMINAL, RADAZA, ROMARATE, ROQUE, SACDALAN, SANTIAGO, UNABIA, UY (J), VELASCO, YU, SAHALI, TAMBUNTING, ADIONG, GARCIA (G.), VILLARICA AND DE VENECIA, PER COMMITTEE REPORT NO. 453

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AN ACT REGULATING THE IMPORTATION, MANUFACTURE, DISTRIBUTION AND SALE OF CHILDREN'S TOYS, SCHOOL SUPPLIES, CHILDCARE ARTICLES AND OTHER RELATED PRODUCTS CONTAINING HAZARDOUS CHEMICALS AND PROVIDING PENALTIES FOR VIOLATION THEREOF

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

- 1           SECTION 1. *Short Title* – This Act shall be known as the “Safe and  
2 Non-Hazardous Children’s Products Act”

1           SEC. 2. *Declaration of Policy.* - It is hereby declared the policy of the  
2 State to protect and promote the right to health of the people and of access to  
3 information on matters of public concern. Towards this end, the State shall  
4 regulate the importation, manufacture, distribution and sale of children's toys,  
5 school supplies and other childcare articles containing hazardous chemicals.

6           SEC. 3. *Definition of Terms.* - As used in this Act

7           (a) *Bioavailability* refers to the amount or proportion of a chemical  
8 substance actually available to interact with human biological systems through  
9 ingestion by mouth, skin exposure or by inhalation of a product under  
10 consideration, taking into account solubility under conditions present in the  
11 body, biological deactivation mechanisms, accessibility to physiological  
12 activity sites, and other relevant factors;

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

15           (1) Any combination of such substances occurring, in whole or in part,  
16 as a result of chemical reaction or occurring in nature; and

17           (2) Any element or uncombined chemical.

18           (c) *Childcare article* refers to any product intended to facilitate sleep,  
19 relaxation, hygiene, the feeding of children or sucking on the part of children;

20           (d) *Children* refer to persons under fourteen (14) years of age;

21           (e) *Distributor* refers to any entity to which the toy product is delivered  
22 or sold for purposes of distribution in commerce or, in such case, any entity  
23 which repackages toys under a different trade name or trademark with  
24 permission from the original legal distributor: *Provided*, That such term does  
25 not include a manufacturer or retailer of such product;

26           (f) *Educational kit* refers to a collection of materials or associated  
27 scientific apparatus that is intended for children but is not likely to be chewed  
28 or put in the mouth by children and which are typically used to perform

1 experiments or demonstrations in the different fields of science or associated  
2 with educational purposes;

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

13 (h) *Hazardous substance or hazardous chemical* refers to a substance  
14 which has been determined to be in one (1) or more of the following categories  
15 of the United Nations Globally Harmonized System (GHS) for classification  
16 and labeling of chemicals:

17 (1) Flammable liquids and solids: Category 1

18 (2) Explosives: Category 1.1

19 (3) Acute toxicity (oral, dermal, inhalation): Category 1

20 (4) Eye irritation/corrosivity: Category 1

21 (5) Dermal irritation/corrosivity: Category 1

22 (6) Mutagenicity: Category 1A

23 (7) Carcinogenicity: Category 1A

24 (8) Reproductive toxicity: Category 1A

25 (9) Acute/Chronic aquatic toxicity: Category 1A

26 (i) *Importation* refers to the entry of a product or substance into the  
27 Philippines (through seaports or airports of entry), whether already properly

1 cleared through or still remaining under customs control, which is intended for  
2 direct consumption, merchandising, warehousing or for further processing;

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

9 (k) *License to Operate (LTO)* refers to the license issued by the Food  
10 and Drug Administration (FDA) to importers, manufacturers and distributors  
11 whose toy products, childcare articles and school implements, under this Act,  
12 conform to the health and safety requirements of the Department of Health  
13 (DOH) and the relevant Philippine National Standards (PNS) and their future  
14 amendments;

15 (l) *Manufacturer* refers to any establishment that assembles or  
16 processes products under this Act: *Provided*, That if such products are  
17 manufactured, assembled or processed for another establishment that attaches  
18 its own brand name to the products, the latter shall be deemed the  
19 manufacturer. In case of imported products under this Act, the manufacturer,  
20 manufacturer's designated representative or, in the absence of one of these  
21 parties, the importer shall be deemed the manufacturer;

22 (m) *Philippine National Standards (PNS)* refer to the national standards  
23 promulgated by the Bureau of Product Standards of the Department of Trade  
24 and Industry (DTI);

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

1           (o) *School implement* refers to a tool used by children for writing,  
2 drawing, coloring, marking, gluing, or erasing that is likely to be licked or put  
3 in the mouth;

4           (p) *School supplies* refer to items/articles used for educational purposes  
5 which are not likely to be put inside the mouth by children;

6           (q) *Testing laboratory* refers to a facility which is accredited by  
7 the Philippine Accreditation Office with International Organization for  
8 Standardization (ISO) 17025 or by an International Laboratory Accreditation  
9 Committee Mutual Recognition Agreement (ILAC MRA) signatory; and

10          (r) *Toy* refers to any product or material designed and clearly intended  
11 for use in play by children under fourteen (14) years of age.

12          SEC. 4. *Scope.* – This Act shall apply to the importation, manufacture,  
13 distribution and sale of children’s toys, school supplies, and childcare articles  
14 as defined in Section 3 hereof that are manufactured, distributed, or sold in the  
15 Philippines.

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

24          Chemicals and substances deemed most harmful and hazardous to  
25 children and commonly used in the manufacture and production of children’s  
26 products shall include the following:

27           (a) Toxic Metals:

28           (1) Antimony;

- 1 (2) Arsenic;
- 2 (3) Cadmium;
- 3 (4) Chromium,
- 4 (5) Lead; and
- 5 (6) Mercury.

6 (b) Phthalates – When used in the manufacture and production of  
7 products covered under this Act, include:

- 8 (1) Di (2-Ethylhexyl) Phthalate (DEHP);
- 9 (2) Dibutyl Phthalate (DBP);
- 10 (3) Benzyl Butyl Phthalate (BBP);
- 11 (4) Diisononyl Phthalate (DINP);
- 12 (5) Diisodecyl Phthalate (DIDP); and
- 13 (6) Di-N-Octyl Phthalate (DNOP).
- 14 (c) Bisphenol-A (BPA).

15 *SEC. 6. Compliance With Philippine National Standards (PNS).* –  
16 Importers, manufacturers, distributors and sellers of products under this Act  
17 shall comply with the standards, rules and processes of the Bureau of Product  
18 Standards of the DTI who shall collaborate with other relevant government  
19 agencies to harmonize and upgrade existing standards, where applicable.

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

23 (a) Formulate guidelines in the filing of application for the issuance of  
24 a License to Operate (LTO) to importers, distributors and local manufacturers  
25 of products covered by this Act;

26 (b) Formulate specific guidelines on the issuance of the Certificate of  
27 Conformity to manufacturers, distributors, and importers for every shipment,  
28 freight, batch or lot of their products covered in this Act;

- 1           (c) Issue Quality Control Orders (QCOs) to enforce the provisions of  
2 this Act and to ensure strict compliance with existing standards and regulations  
3 set by government authorities;
- 4           (d) Issue Compliance Orders (COs) if it finds noncompliance and/or  
5 nonconformity with this Act, its rules and regulations, and guidelines issued to  
6 enforce and implement the same;
- 7           (e) Undertake researches, develop and establish quality and safety  
8 standards for products covered by this Act in coordination with other  
9 implementing government agencies.
- 10          (f) Set the maximum allowable level of toxicity of chemical elements  
11 in products covered by this Act;
- 12          (g) Inspect and analyze products covered by this Act for purposes of  
13 determining conformity to established quality and safety standards;
- 14          (h) Conduct constant and regular inspection, product testing, and  
15 on-sight and random product testing and sampling of various children's  
16 products in the market;
- 17          (i) Assess and collect fees as necessary to cover the cost of inspection,  
18 certification, analysis and tests of samples of products under this Act;
- 19          (j) Investigate the causes of and maintain a record of product-related  
20 deaths, illnesses and injuries for use in researches or studies on the prevention  
21 of such deaths, illnesses and injuries;
- 22          (k) Accredit independent, competent nongovernment bodies, to assist  
23 in monitoring the market for the presence of hazardous chemicals in products  
24 under this Act and to look for appropriate means to expand the monitoring and  
25 enforcement outreach of the DOH in relation to its manpower, testing and  
26 certification resources at a given time;
- 27          (l) Accredit independent competent testing laboratories; and

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

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

6 (a) The DOH, through the FDA, shall formulate policies, rules and  
7 regulations on food, drugs, cosmetics, devices and substances; the FDA shall  
8 conduct regular testing of toxicity levels of chemical elements and substances  
9 content of products covered by this Act and accreditation of product importers:

10 (b) The Department of Environment and Natural Resources (DENR)  
11 shall regulate, control, restrict or prohibit the importation, manufacture,  
12 processing, distribution, sale, handling, use, transport and disposal of chemical  
13 substances or mixtures listed under Republic Act No. 6969, otherwise known  
14 as the “Toxic Substances and Hazardous and Nuclear Wastes Control Act of  
15 1990”. It shall monitor toxic substances/chemicals used as industrial raw  
16 material to produce the covered products under this Act in terms of their  
17 compliance to environmental laws. It shall administer the industrial toxic  
18 chemicals through a system of review, evaluation and monitoring of these toxic  
19 chemicals under DENR Administrative Order (DAO) No. 2013-24 and  
20 formulate policies and guidelines for the gradual phase-out of lead in paints  
21 pursuant to Section 20(1) of DAO 20, series of 1992 and DAO 05, series of  
22 2005 (Toxic Chemical Substances for Issuance of Chemical Control Orders):

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



1 (d) The DTI shall ensure that the products covered by this Act comply  
2 with the Philippine National Standards on the Safety of Toys set by the Bureau  
3 of Product Standards and shall monitor prices of school supplies and conduct  
4 market inspections on these products.

5 SEC. 9. *Creation of the Children's Product Safety Council.* – There is  
6 hereby created a Children's Product Safety Council (CPSC) which shall be  
7 attached to the DOH. It shall be composed of the following:

- 8 (a) Secretary of the DOH – Chairperson;
- 9 (b) Secretary of the DTI -- Vice Chairperson;
- 10 (c) Secretary of the DENR – member;
- 11 (d) Secretary of the Department of the Interior and Local Government  
12 (DILG) – member;
- 13 (e) Secretary of the Department of Education (DepED) – member;
- 14 (f) Secretary of the DOF – member;
- 15 (g) Director-General of the FDA – member;
- 16 (h) National Consumer Affairs Council (NCAC) – member;
- 17 (i) One (1) representative from a nongovernment organization (NGO)  
18 engaged in consumer safety and environment protection – member; and
- 19 (j) One (1) representative from the health groups – member.

20 The heads of departments may be represented by their duly designated  
21 representatives who shall be of a rank not lower than Director level.

22 The Chairperson of the CPSC shall nominate to the President of the  
23 Philippines the representative of the NGO sector.

24 The FDA shall serve as the Secretariat of the CPSC.

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

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

3           (a) To serve as primary link and coordinator for its member  
4 institutions such as the Business Processing and Licensing Office (BPLO) of  
5 the local government units (LGUs), the private sector and other stakeholders;

6           (b) To engage in studies and researches on hazardous chemicals and  
7 substances, and provide the necessary information materials on the same;

8           (c) To conduct and facilitate consultation and dialogues within and  
9 among all concerned stakeholders in the industry;

10           (d) To conduct information and education campaigns on the adverse  
11 health effects of hazardous chemicals on children;

12           (e) To propose amendments to laws, rules and regulations pursuant to  
13 its mandate and the objectives of this Act;

14           (f) To provide periodic and regular reports to the Secretary of Health  
15 on the compliance of importers and manufacturers on the provisions of this  
16 Act;

17           (g) To create a Technical Advisory Committee composed of experts  
18 from both government and private sectors that would assist the Council in  
19 providing technical and scientific recommendations necessary to effectively  
20 carry out its mandate; and

21           (h) To perform such other functions as may be directed by the DOH.

22           SEC. 11. *Disclosure of Toxicological Information on Labels.* – It shall  
23 be mandatory for importers, manufacturers and distributors of products  
24 covered by this Act to provide documentation showing compliance with  
25 international standards when the products left the port of origin through test  
26 reports from testing laboratories accredited with ISO 17025 or by an ILAC  
27 MRA signatory.

1           SEC. 12. *Application to Trade.* – Importers shall provide the FDA  
2 with test reports from laboratories accredited with ISO 17025 or by an ILAC  
3 MRA signatory, which confirms compliance of a representative sample of the  
4 products which left the port of origin with the following international  
5 standards:

6           (a) For heavy metals identified in PNS/ISO 8124-3, compliance with  
7 ISO 8124-3, EN-71-3, or ASTM F963-standards, and

8           (b) For phthalates listed in Section 5(b), compliance with US CPSIA  
9 (Section 108 of CPSIA 2008) or EU REACH (Entity 52 of Annex XVII to  
10 REACH Regulation 1907/2006).

11           The following procedures shall be observed at the first port of entry in  
12 the inspection of imported products covered by this Act:

13           (1) The FDA, or its commissioned/designated agent, in coordination  
14 with the BOC, shall conduct inspection, testing and clearance of representative  
15 samples of imported products covered under this Act for compliance with the  
16 national standards for the safety of toys prior to their assessment and charging  
17 of tariffs and other charges by the BOC;

18           (2) Samples of products covered by this Act being imported into the  
19 Philippines shall be obtained for purposes of determining the toxicity level of  
20 chemical elements and substances content without charge from the owner or  
21 consignee thereof. The owner or consignee of the imported product under  
22 examination shall be afforded an opportunity to a hearing with respect to the  
23 importation of the product into the Philippines. If it is proven that the product  
24 does not conform with the allowable level of chemical elements and substance  
25 content as provided for under the implementing rules and regulations of this  
26 Act, the product shall be refused admission:

27           (3) Imported products that are supported by test reports from  
28 laboratories accredited with ISO 17025 or by an ILAC MRA signatory which

1 confirms compliance of a representative sample with international standards  
2 when the products left the port of origin, shall be exempt from the  
3 requirements of subparagraphs (1) and (2) of this section:

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

7 (5) All expenses in connection with the storage, destruction and  
8 disposition of any product under this Act which was refused admission shall be  
9 paid by the owner or consignee and, in default of the payment, shall constitute  
10 a lien against any future importation to be made by the owner or consignee

11 SEC. 13. *Clearance for Customs Release* - All importers of products  
12 under this Act shall secure a Clearance for Customs Release from the DOH  
13 prior to importation.

14 A Clearance for Conditional Release shall be issued by the appropriate  
15 office of the FDA to facilitate the release of goods from BOC custody, pending  
16 the issuance of the Certificate of Conformity. The importer, however, shall not  
17 distribute, transfer, or sell in whole or in part, the products to any place other  
18 than the address specified in the conditional release. To ensure that no  
19 distribution, transfer, sale to or use of products covered by this Act in any  
20 place other than the address specified in the conditional release is made, the  
21 importers shall allow authorized personnel of the FDA to conduct an  
22 inspection/inventory of the import shipment within three (3) days from the date  
23 of issuance of the clearance for conditional release at anytime within official  
24 working hours.

25 SEC. 14. *Certification*. - The DOH, after the conduct of a thorough  
26 examination, shall certify whether or not the imported products are safe for  
27 distribution in the market.

1           SEC. 15. *Disposal of Noncompliant Products.* – All products covered  
2 by this Act that are recalled by the manufacturer or the DOH for whatever  
3 reason, shall be disposed of in accordance with the submitted disposal plan of  
4 the manufacturer subject to FDA approval. The plan shall comply with the  
5 existing rules and regulations set by all concerned agencies of the government  
6 and other related laws of the country. The concerned importer, manufacturer,  
7 or distributor shall shoulder the expenses to be incurred in the disposal of the  
8 recalled products.

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

13           SEC. 16. *Labeling and Packaging Requirement.* – The labeling and  
14 packaging requirement of products under this Act shall comply with relevant  
15 PNS and existing laws.

16           SEC 17. *Monitoring and Factory Inspection.* – The FDA shall  
17 observe the following procedures in the inspection and monitoring of  
18 establishments to determine compliance with safety regulations:

19           (a) Officers or employees duly designated by the FDA, upon presenting  
20 appropriate credentials to the owner, operator, or agent in charge, shall be  
21 authorized to enter, at reasonable hours, any factory, warehouse or  
22 establishment in which products under this Act are manufactured or held for  
23 introduction into domestic commerce or are held after such introduction, and  
24 any vehicle being used by such officers or employees to transport or hold the  
25 products shall likewise be allowed entry. They shall inspect, in a reasonable  
26 manner, the factory, warehouse, establishment, or vehicle and all pertinent  
27 equipment, finished and unfinished materials, containers and labeling therein;

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 a sample or samples in the course  
4 of the inspection, shall give the owner, operator, or agent in charge a receipt  
5 describing the samples obtained; and

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

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

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

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

27 SEC. 20. *Product Confiscation.* – Imported products shall be allowed  
28 entry into the country as provided under Section 12 of this Act when

1 accompanied by Certificates of Testing or Analysis of its composition. The  
2 BOC shall require pertinent clearance or certification from the FDA prior to  
3 entry. The entire shipment or batch of the product found to be in violation of  
4 the provisions of this Act shall be seized. The confiscated products shall be  
5 properly disposed of in accordance with the prescribed procedure to be issued  
6 by the DOH in coordination with the DENR.

7       SEC. 21. *Publication and Information* – The DOH is mandated to  
8 conduct information campaigns utilizing any form of mass media and other  
9 electronic means deemed effective to ensure the proper guidance of consumers,  
10 industries, businesses, and other concerned sectors.

11       The DOH shall likewise publish, for the information of consumers, a list  
12 of products that may be in the market that have been determined to be  
13 noncompliant.

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

19       SEC. 22. *Public Access to Records, Reports or Notification*. - The  
20 public shall be allowed easy access to publicly disclosed records, reports, test  
21 results, or information concerning chemicals, substances and mixtures,  
22 including safety data submitted, and methods of production and preparation.

23       The DOH shall establish a website to be maintained by the CPSC which  
24 shall publish all publicly disclosed information.

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

26       (a) The importation, manufacture, distribution and sale of products  
27 under Section 4 hereof containing more than the allowable level of substances  
28 listed in Section 5 of this Act;

1 (b) Intentional misrepresentation or concealment of significant data or  
2 information about the product sought for certification;

3 (c) Importation, manufacture, distribution, sale, labeling, and operation  
4 without registration;

5 (d) Noncompliance with the standards and requirements of the DOH on  
6 the importation, manufacture, distribution, and sale of covered products;

7 (e) Refusal to allow required inspections as determined by the DOH;  
8 and

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

11 SEC. 24. *Administrative Sanctions* - Where there is a finding of a  
12 violation against the provisions of Section 23 of this Act and a determination  
13 of the persons liable thereto, after notice and hearing, the following  
14 administrative penalties shall be imposed.

15 (a) Suspension of LTO;

16 (b) Revocation of LTO; and

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

19 SEC. 25. *Penalties*. Any person who shall commit any of the  
20 prohibited acts under Section 23 hereof shall, upon conviction, suffer the  
21 penalty of imprisonment ranging from one (1) year but not more than ten (10)  
22 years or a fine of not less than fifty thousand pesos (P50,000.00) but not more  
23 than five hundred thousand pesos (P500,000.00), or both, at the discretion of  
24 the court and in accordance with Section 11 of the "Food and Drug  
25 Administration (FDA) Act of 2009": *Provided*, That if the offender is a  
26 manufacturer, importer or distributor of any product covered under this Act,  
27 the penalty of at least five (5) years of imprisonment but not more than ten (10)  
28 years and a fine of at least five hundred thousand pesos (P500,000.00) but not



1 more than five million pesos (P5,000,000.00) shall be imposed. *Provided,*  
2 *further,* That an additional fine of one percent (1%) of the economic value/cost  
3 of the violative product or violation, or one thousand pesos (P1,000.00),  
4 whichever is higher, shall be imposed for each day of continuing violation after  
5 reasonable notice of such violation. *Provided, finally,* That products found in  
6 violation of the provisions of this Act and other relevant laws, rules and  
7 regulations may be seized and held in custody pending proceedings, without  
8 hearing or court order, when the FDA Director-General has reasonable cause  
9 to believe from facts found by an authorized officer or employee of the FDA  
10 that the products may cause injury or prejudice to the consuming public.

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

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

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

21 (a) Any person who violates or fails to comply with the provisions of  
22 this Act and its implementing rules and regulations;

23 (b) Any official or employee of the DOI and other implementing  
24 agencies with respect to orders, rules and regulations issued inconsistent with  
25 this Act; and

26 (c) Any public officer who willfully or grossly neglects the  
27 performance of an act specifically enjoined as a duty by this Act or its  
28 implementing rules and regulations; or abuses authority in the performance of

1 duty; or, in any manner improperly performs the duties under this Act or its  
2 implementing rules and regulations: *Provided, however,* That no suit can be  
3 filed until after a thirty (30)-day notice has been given to the public officer and  
4 the alleged violator concerned, and no appropriate action has been taken  
5 thereon.

6 The court shall exempt such action from the payment of filing fees and  
7 shall likewise, upon *prima facie* showing of the nonenforcement or violation  
8 complained of, exempt the plaintiff from the filing of an injunction bond for  
9 the issuance of preliminary injunction

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

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

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

27 SEC 28. *Burden of Proof of Product Safety.* – The burden of proof to  
28 prove the exercise of due diligence, compliance with this Act and other laws,

1 rules and regulations relating to consumer products, precaution, and to prove  
2 the absence of fault and/or negligence shall lie with the manufacturer,  
3 producer, assembler, importer, and/or seller of the children's product involved  
4 or concerned.

5 SEC. 29. *Appropriations.* – The amount as may be necessary to  
6 implement the provisions of this Act shall be included in the annual  
7 appropriations of the DOH under the General Appropriations Act.

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

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

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

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

25 SEC. 35. *Effectivity* – This Act shall take effect fifteen (15) days after  
26 its publication in the *Official Gazette* or in a newspaper of general circulation.

Approved,