

REPUBLIC OF THE PHILIPPINES
HOUSE OF REPRESENTATIVES
QUEZON CITY

Seventeenth Congress
First Regular Session

House Bill No. 3943



Introduced by AGRI PARTYLIST Representative Orestes T. Salon

EXPLANATORY NOTE

This bill seeks to regulate the importation, manufacture, distribution and sale of children's toys, school supplies, childcare articles and other related products containing hazardous chemicals and providing for violation thereof.

The Constitution provides in Section 15 Article II that "The State shall protect and promote the right to health of the people and instill health consciousness among them". Likewise, in Section 12 Article XIII, it declares that "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate manpower development and research, responsive to the country's health needs and problems".

Playtime is one of the most fundamental parts of childhood development and toys are considered vital tools that help foster mental, physical, emotional and social development of children.

However, the inadequate labeling of these products or materials and the inability of the consumers to tell whether a particular toy or child article contains toxic and hazardous substances poses danger to the consumers, more particularly the children. Such exposure can cause adverse health effects ranging from asthma and allergy symptoms, acute poisoning, neurological disorders, hyperactivity, deficits in fine motor function, lowered intelligence performance, kidney and skin problems and even cancers among others.

It is also the purpose of this bill to make mandatory for toy designers, makers, manufacturers, importers, distributors and suppliers, as part of their social responsibility, to fully disclose the chemical contents of their products for proper information of the buying public. Labeling standards and enforcement are an effective approach to toy safety.

This bill was originally filed as House Bill 220 in the 16th Congress introduced by former Rep. Cinchona Cruz-Gonzales which was considered the same and recommended as House Bill 5087 as an approved substitution of the previous bill. The bill was referred in the Committee on Health.

*Amend
by
Agri
Partylist*



REP. ORESTES T. SALON
AGRI Partylist

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1 **AN ACT REGULATING THE IMPORTATION, MANUFACTURE,**
2 **DISTRIBUTION AND SALE OF CHILDREN’S TOYS, SCHOOL**
3 **SUPPLIES, CHILDCARE ARTICLES AND OTHER RELATED**
4 **PRODUCTS CONTAINING HAZARDOUS CHEMICALS AND**
5 **PROVIDING PENALTIES FOR VIOLATION THEREOF**
6

7 *Be it enacted by the Senate and House of Representatives of the Philippines in*
8 *Congress assembled:*
9

10 **SECTION 1. Short Title.** – This Act shall be known as the “Safe and Non-
11 Hazardous Children’s Products Act”.
12

13 **SEC. 2. Declaration of Policy.** – It is hereby declared the policy of the State
14 to protect and promote the right to health of the people and of access to
15 information on matters of public concern. Towards this end, the State shall regulate
16 the importation, manufacture, distribution and sale of children’s toys, school
17 supplies and other childcare articles containing hazardous chemicals.

18
19 **SEC. 3. Definition of Terms.** – As used in this Act:

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

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

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

30 (2) Any element or uncombined chemical.

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

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

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

39 (f) *Educational kit* refers to a collection of materials or associated scientific
40 apparatus that is intended for children but is not likely to be chewed or put in the
41 mouth by children and which are typically used to perform experiments or
42 demonstrations in the different fields of science or associated with educational
43 purposes;

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

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

- 58 (1) Flammable liquids and solids: Category 1
- 59 (2) Explosives: Category 1.1
- 60 (3) Acute toxicity (oral, dermal, inhalation): Category 1
- 61 (4) Eye irritation/corrosivity: Category 1
- 62 (5) Dermal irritation/corrosivity: Category 1
- 63 (6) Mutagenicity: Category 1A
- 64 (7) Carcinogenicity: Category 1A
- 65 (8) Reproductive toxicity: Category 1A
- 66 (9) Acute/Chronic aquatic toxicity: Category 1A

67
68 (i) *Importation* refers to the entry of a product or substance into the
69 Philippines (through seaports or airports of entry), whether already properly

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Toxic Metals:

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

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

- (1) Di (2-Ethylhexyl) Phthalate (DEHP);
- (2) Dibutyl Phthalate (DBP);
- (3) Benzyl Butyl Phthalate (BBP);
- (4) Diisononyl Phthalate (DINP);
- (5) Diisodecyl Phthalate (DIDP); and
- (6) Di-N-Octyl Phthalate (DNOP).

(c) Bisphenol-A (BPA).

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

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

- 150 (a) Formulate guidelines in the filing of application for the issuance of a
151 License to Operate (LTO) to importers, distributors and local manufacturers of
152 products covered by this Act;
- 153 (b) Formulate specific guidelines on the issuance of the Certificate of
154 Conformity to manufacturers, distributors, and importers for every shipment,
155 freight, batch or lot of their products covered in this Act;
- 156 (c) Issue Quality Control Orders (QCOs) to enforce the provisions of this
157 Act and to ensure strict compliance with existing standards and regulations set by
158 government authorities;
- 159 (d) Issue Compliance Orders (COs) if it finds noncompliance and/or
160 nonconformity with this Act, its rules and regulations, and guidelines issued to
161 enforce and implement the same;
- 162 (e) Undertake researches, develop and establish quality and safety standards
163 for products covered by this Act in coordination with other implementing
164 government agencies;
- 165 (f) Set the maximum allowable level of toxicity of chemical elements in
166 products covered by this Act;
- 167 (g) Inspect and analyze products covered by this Act for purposes of
168 determining conformity to established quality and safety standards;
- 169 (h) Conduct constant and regular inspection, product testing, and on-sight
170 and random product testing and sampling of various children's products in the
171 market;
- 172 (i) Assess and collect fees as necessary to cover the cost of inspection,
173 certification, analysis and tests of samples of products under this Act;
- 174 (j) Investigate the causes of and maintain a record of product-related deaths,
175 illnesses and injuries for use in researches or studies on the prevention of such
176 deaths, illnesses and injuries;

177 (k) Accredite independent, competent nongovernment bodies, to assist in
178 monitoring the market for the presence of hazardous chemicals in products under
179 this Act and to look for appropriate means to expand the monitoring and
180 enforcement outreach of the DOH in relation to its manpower, testing and
181 certification resources at a given time;

182 (l) Accredite independent competent testing laboratories; and

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

185

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

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

193 (b) The Department of Environment and Natural Resources (DENR) shall
194 regulate, control, restrict or prohibit the importation, manufacture, processing,
195 distribution, sale, handling, use, transport and disposal of chemical substances or
196 mixtures listed under Republic Act No. 6969, otherwise known as the “Toxic
197 Substances and Hazardous and Nuclear Wastes Control Act of 1990”. It shall
198 monitor toxic substances/chemicals used as industrial raw material to produce the
199 covered products under this Act in terms of their compliance to environmental
200 laws. It shall administer the industrial toxic chemicals through a system of review,
201 evaluation and monitoring of these toxic chemicals under DENR Administrative
202 Order (DAO) No. 2013-24 and formulate policies and guidelines for the gradual
203 phase-out of lead in paints pursuant to Section 20(1) of DAO 20, series of 1992

204 and DAO 05, series of 2005 (Toxic Chemical Substances for Issuance of Chemical
205 Control Orders);

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

211 d) The DTI shall ensure that the products covered by this Act comply with
212 the Philippine National Standards on the Safety of Toys set by the Bureau of
213 Product Standards and shall monitor prices of school supplies and conduct market
214 inspections on these products.

215

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

219 a) Secretary of the DOH – Chairperson;

220 (b) Secretary of the DTI – Vice Chairperson;

221 (c) Secretary of the DENR – member;

222 (d) Secretary of the Department of the Interior and Local Government
223 (DILG) – member;

224 (e) Secretary of the Department of Education (DepED) – member;

225 (f) Secretary of the DOF – member;

226 (g) Director-General of the FDA – member;

227 (h) National Consumer Affairs Council (NCAC) – member;

228 (i) One (1) representative from a nongovernment organization (NGO)
229 engaged in consumer safety and environment protection – member; and

230 (j) One (1) representative from the health groups – member.

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

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

The FDA shall serve as the Secretariat of the CPSC.

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

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

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

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

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

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

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

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

(g) To create a Technical Advisory Committee composed of experts from both government and private sectors that would assist the Council in providing

258 technical and scientific recommendations necessary to effectively carry out its
259 mandate; and

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

261

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

267

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

272 (a) For heavy metals identified in PNS/ISO 8124-3, compliance with ISO
273 8124-3, EN-71-3, or ASTM F963-standards; and

274 (b) For phthalates listed in Section 5(b), compliance with US CPSIA (Section
275 108 of CPSIA 2008) or EU REACH (Entity 52 of Annex XVII to REACH
276 Regulation 1907/2006).

277

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

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

285 (2) Samples of products covered by this Act being imported into the
286 Philippines shall be obtained for purposes of determining the toxicity level of
287 chemical elements and substances content without charge from the owner or
288 consignee thereof. The owner or consignee of the imported product under
289 examination shall be afforded an opportunity to a hearing with respect to the
290 importation of the product into the Philippines. If it is proven that the product does
291 not conform with the allowable level of chemical elements and substance content
292 as provided for under the implementing rules and regulations of this Act, the
293 product shall be refused admission;

294 3) Imported products that are supported by test reports from laboratories
295 accredited with ISO 17025 or by an ILAC MRA signatory which confirms
296 compliance of a representative sample with international standards when the
297 products left the port of origin, shall be exempt from the requirements of
298 subparagraphs (1) and (2) of this section;

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

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

306
307 **SEC. 13. Clearance for Customs Release.** – All importers of products under
308 this Act shall secure a Clearance for Customs Release from the DOH prior to
309 importation.

310 A Clearance for Conditional Release shall be issued by the appropriate
311 office of the FDA to facilitate the release of goods from BOC custody, pending the

312 issuance of the Certificate of Conformity. The importer, however, shall not
313 distribute, transfer, or sell in whole or in part, the products to any place other than
314 the address specified in the conditional release. To ensure that no distribution,
315 transfer, sale to or use of products covered by this Act in any place other than the
316 address specified in the conditional release is made, the importers shall allow
317 authorized personnel of the FDA to conduct an inspection/inventory of the import
318 shipment within three (3) days from the date of issuance of the clearance for
319 conditional release at anytime within official working hours.

320

321

322 **SEC. 14. *Certification.*** – The DOH, after the conduct of a thorough
323 examination, shall certify whether or not the imported products are safe for
324 distribution in the market.

325

326 **SEC. 15. *Disposal of Noncompliant Products.*** – All products covered by
327 this Act that are recalled by the manufacturer or the DOH for whatever reason,
328 shall be disposed of in accordance with the submitted disposal plan of the
329 manufacturer subject to FDA approval. The plan shall comply with the existing
330 rules and regulations set by all concerned agencies of the government and other
331 related laws of the country. The concerned importer, manufacturer, or distributor
332 shall shoulder the expenses to be incurred in the disposal of the recalled products.

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

337

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

341
342 **SEC. 17. *Monitoring and Factory Inspection.*** – The FDA shall observe the
343 following procedures in the inspection and monitoring of establishments to
344 determine compliance with safety regulations:

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

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

359 (c) Whenever in the course of any inspection of a factory, warehouse, or
360 other establishment where products covered by this Act are manufactured or held,
361 the officer or employee making the inspection obtains a sample of any product, and
362 an analysis made of the sample for the purpose of ascertaining whether the product
363 contains, in whole or in part, disallowed levels of toxicity of chemical elements

364 and hazardous substances, a copy of the result of the analysis shall be furnished the
365 owner, operator, or agent in charge.

366

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

369

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

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

380

381 **SEC. 20. *Product Confiscation.*** – Imported products shall be allowed entry
382 into the country as provided under Section 12 of this Act when accompanied by
383 Certificates of Testing or Analysis of its composition. The BOC shall require
384 pertinent clearance or certification from the FDA prior to entry. The entire
385 shipment or batch of the product found to be in violation of the provisions of this
386 Act shall be seized. The confiscated products shall be properly disposed of in
387 accordance with the prescribed procedure to be issued by the DOH in coordination
388 with the DENR

389

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

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

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

401
402 **SEC. 22. *Public Access to Records, Reports or Notification.*** – The public
403 shall be allowed easy access to publicly disclosed records, reports, test results, or
404 information concerning chemicals, substances and mixtures, including safety data
405 submitted, and methods of production and preparation.

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

408
409 **SEC. 23. *Prohibited Acts.*** – The following acts are hereby prohibited:

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

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

415 (c) Importation, manufacture, distribution, sale, labeling, and operation
416 without registration;

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

419 (e) Refusal to allow required inspections as determined by the DOH;

420 And

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

423

424 **SEC. 24. *Administrative Sanctions.*** – Where there is a finding of a violation
425 against the provisions of Section 23 of this Act and a determination of the persons
426 liable thereto, after notice and hearing, the following administrative penalties shall
427 be imposed:

428 (a) Suspension of LTO;

429 (b) Revocation of LTO; and

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

432

433 **SEC. 25. *Penalties.*** – Any person who shall commit any of the prohibited
434 acts under Section 23 hereof shall, upon conviction, suffer the penalty of
435 imprisonment ranging from one (1) year but not more than ten (10) years or a fine
436 of not less than fifty thousand pesos (P50,000.00) but not more than five hundred
437 thousand pesos (P500,000.00), or both, at the discretion of the court and in
438 accordance with Section 11 of the "Food and Drug Administration (FDA) Act of
439 2009": Provided, That if the offender is a manufacturer, importer or distributor of
440 any product covered under this Act, the penalty of at least five (5) years of
441 imprisonment but not more than ten (10) years and a fine of at least five hundred
442 thousand pesos (P500,000.00) but not more than five million pesos
443 (P5,000,000.00) shall be imposed: Provided, further, That an additional fine of one

444 percent (1%) of the economic value/cost of the violative product or violation, or
445 one thousand pesos (P1,000.00), whichever is higher, shall be imposed for each
446 day of continuing violation after reasonable notice of such violation: Provided,
447 finally, That products found in violation of the provisions of this Act and other
448 relevant laws, rules and regulations may be seized and held in custody pending
449 proceedings, without hearing or court order, when the FDA Director-General has
450 reasonable cause to believe from facts found by an authorized officer or employee
451 of the FDA that the products may cause injury or prejudice to the consuming
452 public.

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

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

459

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

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

465 (b) Any official or employee of the DOH and other implementing agencies
466 with respect to orders, rules and regulations issued inconsistent with this Act; and

467 (c) Any public officer who willfully or grossly neglects the performance of
468 an act specifically enjoined as a duty by this Act or its implementing rules and
469 regulations; or abuses authority in the performance of duty; or, in any manner
470 improperly performs the duties under this Act or its implementing rules and

471 regulations: Provided, however, That no suit can be filed until after a thirty (30)-
472 day notice has been given to the public officer and the alleged violator concerned,
473 and no appropriate action has been taken thereon.

474 The court shall exempt such action from the payment of filing fees and shall
475 likewise, upon prima facie showing of the nonenforcement or violation complained
476 of, exempt the plaintiff from the filing of an injunction bond for the issuance of
477 preliminary injunction.

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

480
481 **SEC. 27. *Suits and Strategic Legal Action Against Public Participation***
482 ***(SLAPP) and the Enforcement of this Act.*** – Where a suit is brought against a
483 person who filed an action as provided in Section 26 of this Act, or against any
484 person, institution or government agency that implements this Act or any other
485 consumer-related laws, rules and regulations, it shall be the duty of the
486 investigating prosecutor or the court, as the case may be, to immediately make a
487 determination within a period not exceeding thirty (30) days whether the legal
488 action has been filed to harass, vex, exert undue pressure or stifle such legal
489 recourses of the person complaining or enforcing the provisions of this Act. Upon
490 determination of the evidence, the court may dismiss the case and award attorney's
491 fees and damages.

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

495
496 **SEC. 28. *Burden of Proof of Product Safety.*** – The burden of proof to prove
497 the exercise of due diligence, compliance with this Act and other laws, rules and

498 regulations relating to consumer products, precaution, and to prove the absence of
499 fault and/or negligence shall lie with the manufacturer, producer, assembler,
500 importer, and/or seller of the children's product involved or concerned.
501

502 **SEC. 29. *Appropriations.*** – The amount as may be necessary to implement
503 the provisions of this Act shall be included in the annual appropriations of the
504 DOH under the General Appropriations Act.
505

506 **SEC. 30. *Congressional Oversight Committee.*** – The joint Congressional
507 Oversight Committee created under Republic Act No. 9711, or the "Food and Drug
508 Administration (FDA) Act of 2009", shall function as the oversight committee to
509 monitor and evaluate the implementation of this Act.
510

511 **SEC. 31. *Supplementary Provision.*** – Pertinent provisions of Republic Act No.
512 7394, otherwise known as the "Consumer Act of the Philippines", shall have
513 supplementary effect in the implementation of this Act.
514

515 **SEC. 32. *Implementing Rules and Regulations.*** – Within sixty (60) days
516 after the effectivity of this Act, the DOH, in coordination with the DTI, the DENR
517 and the DOF, through the BOC, shall issue the rules and regulations to implement
518 the provisions of this Act.
519

520 **SEC. 33. *Separability Clause.*** – If, for any reason, any provision or part
521 hereof is declared invalid, the other provisions not affected thereby shall remain in
522 full force and effect.
523

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

527

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

530

531 **Approved,**