



**Implementing Rules and Regulations (IRR) of
Republic Act (RA) No. 10620, Otherwise Known as
“An Act Providing for Toy and Game Safety Labeling, Appropriating Funds
Therefor”**

Pursuant to Section 12 of Republic Act (RA) No. 10620, the following rules and regulations are hereby promulgated:

**TITLE I
GENERAL PROVISIONS**

**Rule I
Title**

Section 1. Title. These Rules shall be referred to as the Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 10620, otherwise known as the “Toy and Game Safety Labeling Act of 2013”.

**Rule II
Scope and Coverage**

Section 1. Scope and Coverage. These Rules shall apply to all manufacturers, distributors, importers, exporters, wholesalers and retailers of toys or games manufactured locally and/or internationally that are imported, exported, donated, distributed and sold in the Philippines.

**Rule III
Definition of Terms**

Section 1. Definition of Terms. For purposes of this IRR, the following terms shall mean or be understood as follows:

- 1.1. *Act* - refers to RA No. 10620, entitled “An Act Providing for Toy and Game Safety Labeling, Appropriating Funds Therefor,” otherwise known as “Toy and Game Safety Labeling Act of 2013”.
- 1.2. *Age Grading* - refers to the category used for the selection of appropriate toys for children with respect to average abilities, interests of various age groups and safety aspects of the toys themselves.

- 1.3. *BOC* - refers to the Bureau of Customs of the Department of Finance;
- 1.4. *Cautionary Statement* - refers to group of words conveying necessary information or warnings that should be indicated on the label.
- 1.5. *Children* - refers to any person whose age is chronologically and/ or mentally below fourteen (14) years of age.
- 1.6. *DENR* - refers to the Department of Environment and Natural Resources.
- 1.7. *Descriptive Material* - refers to an additional printed material that accompanies the product which is intended to provide additional information including instructional literature.
- 1.8. *Display Panel* - refers to the portion(s) of the surface of the immediate container, and of any outer container or wrapping, which bears the labeling.
- 1.9. *Distributor/ Importer/ Exporter* - refers to any establishment that imports or exports toy products for its own use or for wholesale distribution to other establishment or outlets. If the distributor, importer, exporter sells to the general public, it shall be considered a retailer.
- 1.10. *Distributor/ Wholesaler* - refers to any establishment that procures toy products from a local establishment for local distribution on wholesale basis.
- 1.11. *DOF*- refers to the Department of Finance.
- 1.12. *DOH* - refers to the Department of Health.
- 1.13. *DTI* - refers to the Department of Trade and Industry.
- 1.14. *EMB* - refers to the Environment Management Bureau of the DENR.
- 1.15. *Establishment* - refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of toys or game products, including the facilities and installation needed for its activities.
- 1.16. *FDA* - refers to the Food and Drug Administration of the DOH.
- 1.17. *Household/ Urban Hazardous Substance* - refers to any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard. For this purpose "toys and other articles intended for use by children" shall refer to those toys and articles specified to be for children less than fourteen (14) years of age.
- 1.18. *Instructional Literature* - refers to the information and instructions that are provided for the safe use or assembly, or both, of a toy, whether on the packaging or in a leaflet form that are easy to read.

- 1.19. *Label or Labeling* - refers to the display of written, printed or graphic matter on any toy or game product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations.
- 1.20. *LTO* - refers to License to Operate issued by the FDA.
- 1.21. *Manufacturer* - refers to an establishment engaged in any and all operations involved in the production of toys and game products. A trader shall be categorized as a manufacturer.
- 1.22. *Manufacturer's Marking* - refers to the packaging, label, leaflet/pamphlet or other descriptive material e.g. tags of the toy or game bearing the complete name and address reflected in the LTO of the local company such as manufacturer, distributor responsible for placing the product in the market and a trademark or trade name, if any.
- 1.23. *NRAs* - refers to National Regulatory Agencies, FDA Philippines counterpart government regulatory agencies around the world.
- 1.24. *Package or Packaging* - refers to any container or wrapping in which any consumer product is enclosed for use in the delivery or display of that consumer product to retail purchasers.
- 1.25. *Post-marketing Surveillance* - refers to activities involved in safety, efficacy, and quality monitoring of toy and game products. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of toy and game products in the market.
- 1.26. *Principal Display Panel* - refers to the part of the label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail or sale.
- 1.27. *PNS*- refers to the Philippine National Standards for Safety of Toys and its future amendments. The word standard shall also mean PNS.
- 1.28. *Retailer* - refers to a natural person and juridical entity engaged in the business of selling any toy or game directly to consumers.
- 1.29. *SKU* - refers to Stock Keeping Unit.
- 1.30. *Toy and Game* - refers to an object or a number of objects clearly intended as plaything for children as defined in these Rules, subject to the exclusions as provided herein.
- 1.31. *Trademark* - refers to a group of words, name, title, symbol, emblem, sign, device or any combination thereof used as an advertisement, sign, label poster or otherwise for the purpose of enabling the public to distinguish the product of the person who owns and uses such legally registered trademark or trade name.

Rule IV
Delineation of Responsibilities

Section 1. *Department of Health (DOH).* The DOH through the FDA shall:

- 1.1. Develop rules and regulations, policies, guidelines and standards that cover products, and establishments related to toys and games in coordination with the DTI and other concerned agencies;
- 1.2. Issue appropriate authorizations to establishments and their toy and game products;
- 1.3. Disseminate information and implement this IRR;
- 1.4. Institute and strengthen the post-marketing surveillance system in monitoring toy and game products in the market as defined in the FDA Act of 2009, its IRR, other relevant laws, and the FDA-promulgated issuances;
- 1.5. Conduct inspection, monitoring and surveillance of establishments, and collection of samples, in collaboration with other concerned agencies to determine compliance with this Act and its IRR;
- 1.6. Verify and perform laboratory analysis on collected/ complaint samples;
- 1.7. Require all manufacturers, donors, distributors, importers, exporters, wholesalers, retailers, and encourage consumers of toys and games to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient or any person;
- 1.8. Provide the DTI with the list/information of all manufacturers, distributors, importers, exporters, wholesalers and retailers who failed to comply with the requirements herein;
- 1.9. Regularly publish every six (6) months or as necessary all misbranded or banned hazardous substances intended to be sold, offered for sale or distributed; and
- 1.10. Provide continuous updating of the technical capabilities for both DTI and FDA staffs through the conduct or attendance to trainings, meetings, technical working groups (TWG) with NRAs, toy industry associations/ organizations with regard to the safety and quality of toys and game, in coordination with DTI.

Section 2. *Department of Trade and Industry (DTI).* The DTI shall:

- 2.1. Develop rules and regulations, policies, guidelines and Philippine National Standards that cover products, services, establishments, facilities related to toys and games in coordination with the DOH through FDA and other concerned agencies;

- 2.2. Implement and disseminate the IRR and the PNS through mass media such as but not limited to broadcast, print and internet to guide consumers, manufacturers, distributors, retailers and various sellers;
- 2.3. Institute and strengthen the post-marketing surveillance system in monitoring products as defined in Republic Act No. 7394, otherwise known as the "Consumer Act of the Philippines", its IRR, other relevant laws, and the DTI-promulgated issuances;
- 2.4. Assist the FDA, upon its request, in the conduct of inspection, monitoring and surveillance of establishments;
- 2.5. Provide and refer consumer product reports to the FDA regarding any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient or any person;
- 2.6. Regularly publish the list/information provided by the FDA, every six (6) months or as necessary of all the manufacturers, importers, distributors and retailers who failed to comply with the requirements of this Act; and
- 2.7. Provide continuous updating of the technical capabilities for both DTI and FDA staffs through the conduct or attendance to trainings, meetings, technical working groups (TWG) with NRAs, toy industry associations/ organizations with regard to the safety and quality of toys and game, in coordination with FDA.

Section 3. Other Coordinating Agencies. To effectively carry out the provisions of this Rule, the DOH-FDA and the DTI may coordinate with DOF-BOC, DILG and DENR-EMB.

TITLE II LABELING AND PACKAGING REQUIREMENTS

Rule I General Requirements

Section 1. Labeling Requirements for Toy and Game. Toys and games covered by these Rules shall comply with the existing applicable PNS. Any amendments to or revisions on the said PNS shall be applied accordingly.

The following shall be embossed on, directly printed, appeared on, or affixed to the package, container, wrapper or protective covering of the product/s:

- 1.1. LTO Number issued by FDA
- 1.2. Age Grading - determined by the manufacturer according to international norms, including but not restricted to ISO Technical Report 8124-8 "Age Determination Guidelines" or its equivalent
- 1.3. Cautionary statements/warnings;

- 1.4. Instructional literature;
- 1.5. Manufacturer's marking - The principal component of the toy, the packaging, label, leaflet/ pamphlet or other descriptive materials e.g. tags accompanying the toy shall be marked with the complete name and address reflected in the LTO of the local company (manufacturer/ distributor) responsible for placing the product in the market and trademark or trade name, if any, which clearly identifies the manufacturer/ distributor.

These markings shall be visible, readable and easily understood by the consumer and shall resist normal use conditions. Abbreviations, acronyms and the like are not allowed to be used as the name of the local company (manufacturer/ distributor) responsible for placing the product in the market.
- 1.6. Item, Model, SKU number - All toys and games to be sold within the Philippines shall have item, model, SKU number. In case of imported products without SKU numbers, the local company (distributor) responsible for placing the product in the market shall devise its own system in assigning SKU numbers to their products.

Section 2. *Language.* The label shall be generally written in English, otherwise, a parallel translation in English or Filipino or both shall appear thereon or be made an integral part thereof.

Section 3. *Manner of Labeling.* The label shall be in a visible, easily legible, understandable and indelible form. Component parts of the label such as stickers shall form an integral part thereof without the danger of being erased or detached under ordinary handling of the product, provided that, it shall not hide or cover any important or essential information as required by law.

Section 4. *Availability of Instructional Literature for Perusal by Buyer.* The products must be accompanied by an instructional literature for perusal or examination of the buyer. Small toys, games, leaflets, pamphlets, tags, carton box holding the individual units prior to retail and other descriptive material may contain the instructional literature.

Rule II Additional Requirements

Section 1. *Label Exhaustion.* A company may request for the approval of label exhaustion of not more than six (6) months with the FDA provided that the company submits the following:

- Valid reason for label exhaustion;
- Actual label to be used;
- Initial inventory of remaining labels;
- Reconciliation inventory on the number of labels exhausted and unused for destruction at the end of the label exhaustion period.

**TITLE III
SAFETY LABELING STATEMENTS**

**Rule I
Cautionary Statements**

Section 1. *Locally Manufactured and/or Packed Products.* The safety information shall be in a format that draws the attention of the consumer, and shall be placed on the packaging and also on the toy or game itself so that in the event the packaging thereof is discarded, the safety or cautionary warning remains.


Any cautionary statements shall be displayed in the following manner:

- 1.1. On its entirety on the principal display panel of the product's package which accompanies the product;
- 1.2. In the case of bulk sales of such product when unpacked, the cautionary statement shall be displayed on the bin or container used for the retail display of the product, and any vending machine from which the unpacked product is dispensed and displayed in:
 - 1.2.1. English or Filipino or both;
 - 1.2.2. Conspicuous and legible type in contrast by typography, layout, or color with other printed matter on such package, descriptive materials, bin, container and vending machine; and
 - 1.2.3. In the manner consistent with the provisions of Chapter IV - Labeling and Fair Packaging under Republic Act No. 7394, otherwise known as the "Consumer Act of the Philippines."

Section 2. *Special Rules for Certain Packages.* A cautionary statement required under Title II, Rule I hereof or in lieu of display on the principal panel of the product's package, shall be displayed on another panel of the package if the package has a principal display panel of approximately ninety-six (96) square centimetres (fifteen (15) square inches or less) and the statement is displayed on the principal display panel and is accompanied by an arrow or other indicator pointing towards the place on the package where the statement required appears.

Section 3. *Standard Warnings.* All toys and games shall contain labeling requirements and cautionary statements (warning) with regard to the product's mechanical and physical properties which shall be similar to or convey the same meaning as the following:

Safety Aspects Related to Mechanical and Physical Properties	Labeling Requirements/Cautionary Statements (CS)
Small Toys and Toys Containing Small Parts	CS:

	<p>“Warning! Not suitable for children under 3 years. Contains small parts.”</p> <p>“Babala! Hindi pwedeng ipagamit sa batang may edad na mas mababa sa 3 taon. Naglalaman ng maliliit na parte.”</p> <p>The above warning may be substituted with a graphical symbol below:</p> <div style="text-align: center;">  </div> <p>The details of the design of the graphical symbol shall be as follows:</p> <ul style="list-style-type: none"> • The circle and the stroke shall be red; • The background shall be white; • The age range and the outline of the face shall be black; • The symbol shall have a diameter of at least 10 mm and the proportions between its different elements shall be such as those prescribed in the above figure; and • The age range of which the toy is not suitable shall be expressed in years, e.g. 0-3 years
<p>Balloons</p>	<p>CS:</p> <p>“Warning! Children under 8 years can choke or suffocate on uninflated or broken balloons. Adult supervision required. Keep uninflated balloons from children. Discard broken balloons at once.”</p> <p>“Babala! Ang mga batang may edad na mas mababa sa 8 taon ay maaaring mabulunan o mapigilang huminga sa paggamit ng mga walang hangin o sirang lobo. Patnubay ng nakatatanda ay kailangan. Itapon kaagad ang mga sirang lobo.”</p>
<p>Small Balls and Marbles</p>	<p>CS:</p> <p>“This toy is a small ball/marble which may present a choking hazard. Not for children under 3 years.” or “This product contains a small ball/ marble which may present a choking hazard. Not for children under 3 years.”</p>

	<p>“Ang laruang ito ay maliit na bola/holen na maaaring bumara sa lalamunan ng bata. Bawal sa batang may edad na mas mababa sa 3 taon.”</p>
<p>Aquatic Toys</p>	<p>CS:</p> <p>“Warning! This is not a life-saving device. This shall only be used in shallow water and under supervision.”</p> <p>“Babala! Ang laruang ito ay hindi makasasagip ng buhay. Ito ay ginagamit lamang sa tubig na mababaw at kung may kaukulang pagbabantay ng nakatatanda.”</p>
<p>Crib, Crib Gyms, Playpen Toys, Mobiles and Similar Toys</p>	<p>The toy and its packaging shall carry a statement drawing attention to the possible entanglement or strangulation injury if the toy is not removed when the baby begins to push up on hands and knees.</p> <p>Crib gyms and similar toys intended exclusively to be strung across a crib, playpen or perambulator by string, cord, elastic or straps, as well as their packaging, shall carry a statement drawing attention to the possible entanglement or strangulation injury if attached to the crib, playpen or perambulator and not removed when the baby begins to push up on hands and knees.</p>
<p>Toys in Contact with Food</p>	<p>The packaging, instructions or both, for toys and their components intended to be used in contact with food, shall carry a statement to alert adults to wash the product thoroughly before and after use.</p>
<p>Toys Intended to be Assembled by an Adult</p>	<p>The packaging of toys that are intended to be assembled by an adult shall also be labeled.</p>
<p>Simulated Protective Equipment</p>	<p>Toys that simulate safety/personal protective equipment such as but not limited to, construction helmets, sports helmets and fire-fighter helmets, as well as their packaging, shall carry a statement informing the consumer that they are toys and do not offer protection.</p>
<p>Toys with Functional Sharp Edges and Functional Sharp Points</p>	<p>Toys that are intended for use by children from 37 months up to 96 months (> 3-8 years), which contain accessible sharp edges or accessible sharp points that are necessary part of the function of the toy, shall carry a statement on the packaging that sharp edge or sharp point, or both exists.</p>

Functional Toys	Functional toys shall carry a label stating that the product shall only be used under direct adult supervision.
Toy Roller Skates and Toy Skateboards	Toy roller skates and toy skateboards are products that are intended for children with a maximum mass of 20 kg. Toy roller skates and toy skateboards shall carry a label recommending the user to use personal protective equipment such as helmet, wrist-pads, knee pads and elbow pads and to avoid use of the product on the road.
Projectile Toys	Toys with projectiles shall be accompanied by instructions for use which draw attention to the hazard of aiming at eyes or face and of using projectiles other than those supplied or recommended by the manufacturer.
Toy Kites	<p>CS:</p> <p>“Warning! Do not use near overhead power lines or during thunderstorms.”</p> <p>“Babala! Huwag gamitin malapit sa kawad ng kuryente o sa panahon na may bagyo/unos.”</p>
Toy Bicycles	<p>Toy bicycles shall carry a label recommending the use of a protective helmet when cycling.</p> <p>In addition, the instructions for use shall contain a reminder that this bicycle is not permitted for use on public highways. Moreover, parents or carers shall ensure that children are properly instructed in the use of toy bicycles, particularly in the safe use of the braking systems.</p>
Percussion Caps	<p>CS:</p> <p>“Warning! Do not use indoors or near eyes and ears. Do not carry loose in a pocket.”</p> <p>“Babala! Huwag gamitin sa loob ng kabahayan o malapit sa mga mata at tainga. Huwag basta ilagay sa bulsa.”</p>

Battery-Operated Toys	The battery compartment or the area immediately adjacent shall be permanently marked to show the correct battery polarity and voltage. If it is impractical to mark this information on the toy, the marking may be placed in the instructions.
Toys which Produce High Impulsive Sound Levels	<p>CS:</p> <p>“Warning! Do not use close to the ear! Misuse may damage hearing.”</p> <p>“Babala! Huwag gamitin malapit sa tainga! Ang maling paggamit ay maaaring makasira sa pandinig.”</p>

The above stated labeling requirements shall be without prejudice to any cautionary statements or warnings that may be issued from time to time by the DTI or DOH-FDA, where necessary.

Section 4. Instructional Literature. Instructional literature for toys and games covered under PNS BHDT ISO 8124-1:2008 and its future amendments.

Instructional Literature for the Following Toy and Game	Labeling Requirements
Crib, Playpen Toys and Mobiles	<p>Mobiles intended to be mounted on a crib, playpen, wall or ceiling shall be provided with instructions for proper assembly, installation and use to ensure that the products do not present an entanglement hazard. The instructions shall include at least the following information:</p> <ul style="list-style-type: none"> • A crib mobile is not intended to be grasped by the child; • If attached to the crib or playpen, remove when the baby begins to push up on hands and knees; • If mounted on a wall or ceiling, install the mobile clearly out of a standing baby’s reach; • Always attach all provided fasteners (strings, straps, clamps, etc.) lightly to a crib or playpen according to the instructions. Check frequently; and • Do not add additional strings or straps to attach to a crib or playpen.
Crib Gyms and Similar Toys	Crib gyms and similar toys intended exclusively to be strung across a crib, playpen or perambulator by string, cord, elastic or straps (including, but not limited to, crib exercises, crib gyms and activity toys) shall be provided with instructions for proper assembly, installation and use to ensure that the products do not present an entanglement or strangulation hazard.

	<p>The instructions shall include at least the following information:</p> <ul style="list-style-type: none"> • This toy is not intended to be “mouthed” by the baby and shall be positioned clearly out of reach of the baby’s face and mouth; • On cribs with adjustable mattress levels, the highest position can cause the toy to be too close to the baby; • The drop side of the crib shall never be lowered with the toy in place and the baby left unattended; • Always attach all provided fasteners (stings, straps, clamps, etc.) tightly to a crib or playpen according to the instructions. Check frequently; and • Do not add additional strings or straps to attach to a crib or playpen.
Toy Chest	<p>Instructions for proper assembly and maintenance shall be provided with sufficient detail to describe the correct assembly of components, the resulting hazard if the lid support device is not installed, and a description of how to determine whether the support is working properly.</p>
Liquid-filled Teethers and Liquid-filled Teething Toys	<p>Liquid-filled teethers and liquid-filled teething toys shall be accompanied by instruction that they shall not be placed in the freezer compartment.</p>
Toys Intended to be Assembled by an Adult	<p>Assembly instructions that accompany toys that are intended to be assembled by an adult and that contain potentially hazardous sharp edges or sharp points, or contain small parts of the toy intended for children under 3 years of age, shall carry a statement stating this and also that it is to be assembled by an adult.</p>
Battery-Operated Toys	<p>Battery-operated toys shall contain instructions on safe battery usage, when applicable. These instructions shall contain the following to advise the consumer(s):</p> <ul style="list-style-type: none"> • How to remove and insert batteries; • That non-rechargeable batteries are not to be recharged; • That adult supervision is required when charging rechargeable batteries; • When rechargeable batteries are fully charged, remove batteries from charger and unplug the charger from the electrical outlet; • Do not mix old and new or different types of batteries;

	<ul style="list-style-type: none"> • To remove exhausted batteries from the toy; and • That supply terminals are not to be short circuited.
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Section 5. Warnings. Cautionary statements with regard to the product’s flammability are similar to or convey the same meaning as the following:

Safety Aspects with Regard to Flammability for the Following Toy and Game	Cautionary Statements
Toy Disguise Costumes and Toys Intended to be Worn by a Child in a Play	“Warning! Keep away from fire.” “Babala! Ilayo sa apoy.”
Toys Intended to be Entered by a Child	“Warning! Keep away from fire.” “Babala! Ilayo sa apoy.”

The above stated labeling requirements shall be without prejudice to any cautionary statements or warnings that may be issued from time to time by the DTI or DOH-FDA, where necessary.

Section 6. Additional Labeling Requirements. Labeling Requirements for Swings, Slides and Similar Activity Toys for Indoor and Outdoor Family Domestic Use are as follows:

Safety Aspects with Regard to Swings, Slide and Similar Activity Toys for Indoor and Outdoor Family Domestic Use

Labeling shall be permanently and prominently applied to both the toy and the packaging (if supplied). The following information shall be provided:

- That the toy is for domestic use only;
- Whether the toy is intended for indoor or outdoor use;
- Information as to the mass and/or age of the child for whom the toy is intended;
- If appropriate, the maximum number of children that may safely use the equipment simultaneously; and
- Identity or contact details of the manufacturer or distributor.

Section 7. Assembly and Installation Instructions. Assembly and Installation Instructions for Swings, Slides and Similar Activity Toys for Indoor and Outdoor Family Domestic Use are as follows:

7.1 General Information

The information given on the labeling/ purchase information shall also be given in the installation instructions.

Activity toys that require assembly by the consumer shall be accompanied by appropriate assembly instructions, including drawings, which shall enable an unskilled layman to correctly assemble the activity toy.

The assembly and installation instructions shall also, when appropriate, include:

- A recommendation to place the activity toy on a level surface at least 1.8 meters from any structure or obstruction such as a fence, garage, house, overhanging branches, laundry lines or electrical wires;
- Detailed instructions on how anchors shall be installed to prevent overturning or lifting of the support members during normal use or foreseeable misuse, also taking into account the condition of the soil normally encountered;
- Instructions that anchors shall be placed in level with or under the ground in order to reduce tripping hazards;
- Instructions that activity toys (for example swings, slides, climbing frames) shall be installed over impact absorbing surfaces such as sand, wood-bark chips, rubber and foam and shall not be installed over concrete, asphalt or any hard surface;
- Scale drawings of assembly hardware to facilitate the correct length of fasteners being used; and
- Information to keep assembly and installation instructions for further reference.

7.2 Information on Playground Surfacing Materials

7.2.1 Maximum Fall Heights

The instructions shall include the manufacturer's determination of maximum fall height for the product.

Maximum fall heights for products are determined as follows:

- For swings, the maximum fall height is the height of the suspension connector;
- For elevated platforms with barriers, the maximum fall height is the height of the top surface of the barrier;
- For climbing frames and horizontal ladders, the maximum fall height is the height of the top surface of the component; and
- For rocking toys and seesaws, the maximum fall height is the maximum height of the designated play surface normally occupied by a user.

7.2.2 Impact Attenuating Surface

The instructions shall include the "*Consumer information sheet for playground surfacing materials*" from Annex B of PNS BHDT ISO 8124-4:2012 and its future amendments or specific surfacing guidelines for the product that are consistent with Annex B of PNS BHDT ISO 8124-4:2012 and its future amendments.

Section 8. Maintenance Instructions. Maintenance Instructions for Swings, Slides and Similar Activity Toys for Indoor and Outdoor Family Domestic Use are as follows:

Maintenance Instruction

Activity toys shall be accompanied by maintenance instructions drawing attention to the need for carrying out checks and maintenance of the main parts (crossbeams, suspensions, anchors, etc.) at regular intervals, pointing out that if these checks are not carried out, the toy could overturn or otherwise become a hazard.

Guidelines shall also be provided on how to determine when deterioration has occurred and the requirements for replacing parts when necessary.

The maintenance instructions shall include the wording "*Please keep for future reference*".

The maintenance instructions, shall, when appropriate, also include the following recommendations pointing out that it is of particular importance that they be followed at the beginning of each season as well as at regular intervals during the usage season:

- Check all nuts and bolts for tightness and tighten when required;
- Oil all metallic moving parts;
- Check all covering and bolts for sharp edges and replace when required;
- Check swing seats, chains, ropes and other means of attachment for evidence of deterioration; replace when required in accordance with the manufacturer's instruction; and
- Sand rusted areas and tubular members and repaint using a non-lead based paint when required.

TITLE IV EXCLUSIONS IN CAUTIONARY STATEMENTS

Rule I Exclusions

Section 1. Excluded Products. Toys and games manufactured and packaged outside the Philippines and directly shipped from the manufacturer to the consumer by mail or other delivery services which do not bear the cautionary statement required pursuant to Section 5 of Republic Act No. 10620 and Rule I, Title III (Safety Labeling Statements) of these Rules shall be admitted, provided that, other accompanying material shipped with the product bears such statement.

Notwithstanding the foregoing, the DOH through the FDA, may exclude specific toys and games from the cautionary statement required in the label, provided that, other accompanying material of the product bears such statement. Provided further, that any toy and game so excluded may be reinstated from the requirement when health and safety so requires as determined by the FDA.

**TITLE V
INSPECTION AND MONITORING**

**Rule I
General Guidelines**

Section 1. *General Guidelines.* The DOH-FDA with the assistance of the DTI shall lead the conduct of inspection, monitoring and surveillance of establishments, and collection of samples, in collaboration with other concerned government agencies to determine compliance with this Act and its IRR. In every market monitoring activity/operation, all members of the monitoring team shall, before entering a particular business establishment, be properly authorized in writing and present their written authority/valid order and proper identification papers to any responsible person within the premises.

Section 2. *Powers and Functions.* The inspection team shall have the following powers and functions in their respective assigned regions:

- 2.1. To enter and inspect establishments and facilities engaged in the manufacture, importation, exportation, distribution, sale, offer for sale and transfer, and, where appropriate, use of covered products;
- 2.2. To request or examine relevant documents and other information related to the covered products;
- 2.3. Upon finding in the course of its evaluation, monitoring, inspection and spot checking of any violation in the compliance and other requirements required by this Act and its IRR, submit a report to serve as basis for the *motu proprio* action of the FDA;
- 2.4. To conduct post market monitoring of the covered products; and
- 2.5. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

**TITLE VI
ENFORCEMENT AND ACTIONS FOR VIOLATIONS OF RA 10620 AND
ITS IRR**

**Rule I
Persons Liable**

Section 1. *Persons Liable.* If the offense is committed by a corporation, trust, firm, partnership or association or other entity, the penalty shall be imposed upon the guilty officer or officers of such corporation, trust, firm, partnership or association or entity.

Rule II Administrative Action

Section 1. *Administrative Action.* Administrative action for violations of this Act and its IRR shall be subject to the provisions of RA No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and its IRR particularly Book III, the Uniform Rules of Procedures of the Food and Drug Administration and its future amendments.

Section 2. *Seizure of Covered Products.* Covered products found to be in violation of the provisions of this Act and its IRR shall be seized or confiscated in favor of the government and shall be disposed in accordance with pertinent laws and regulations without prejudice to Section 3 below. Cost for disposal shall be levied on the manufacturer and/or distributor (importer, exporter, wholesaler) responsible for the seized covered products.

Section 3. *Custodia Legis.* During the pendency of the case filed in violation of this Act and its IRR, the seized covered products shall remain in custody of the DOH-FDA. The DOH-FDA shall have the option to have sufficient representative sample retained of the seized covered products for evidentiary purposes. The retained representative sample shall remain in *custodia legis* until the final resolution of proceedings thereon. Disposal of products mentioned herein shall be in accordance with the FDA guidelines.

Section 4. *Development of Regulations on Disposal of Seized Product.* Within ninety (90) days after approval of this IRR, the FDA shall coordinate with the EMB-DENR and BOC on the development of regulations on imported equipment and materials seized during the monitoring and inspection including its final disposition.

Section 5. *Administrative Penalties.* Any violation of this Act and its IRR shall be dealt with in accordance with the provisions of Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", its future amendments, and other applicable laws.

Rule III Criminal Action

Section 1. *Institution of Criminal Proceedings.* In the enforcement of RA 10620, the usual procedure for prosecution provided by the Rules of Court shall be observed and such prosecution shall be conducted by the appropriate provincial/city prosecutor.

Criminal Penalties:

- a. Imprisonment of not less than three (3) months but not more than two (2) years; or
- b. Fine of not less than ten thousand pesos (P10,000.00) but not more than fifty thousand pesos (P50,000.00); or
- c. Both imprisonment and fine at the discretion of the court.

The criminal penalties shall be without prejudice to administrative sanctions which the DOH may impose.

TITLE VII MISCELLANEOUS PROVISIONS

Rule I Misbranded or Banned Toys and Games

Section 1. *Misbranded or Banned Hazardous Substance.* Covered products which are not in compliance with Titles II and III of these Implementing Rules and Regulations (IRR) shall be considered as misbranded or banned hazardous substance.

Section 2. *Actions on Misbranded or Banned Toys and Games.* Misbranded toys and games or banned hazardous substances shall be ordered withdrawn from the market at the expense of the manufacturer or distributor (importer, exporter, wholesaler) and shall not be allowed to be distributed, sold or offered for sale in the Philippines without prejudice to any liability and penalty when action is pursued pursuant to Rule II and/or Rule III of Title VI.

Rule II Reporting

Section 1. *Report to the DOH.* A manufacturer, distributor, retailer or importer of a marble, small ball or latex balloon, or a toy or game that contains a marble, small ball or latex balloon, or other small parts, shall report to the DOH through FDA, any information obtained by such manufacturer, distributor, retailer or importer which reasonably supports the conclusion that an incident occurred in which a child, regardless of age, choked with such marble, small ball, or latex balloon, or other small parts contained in such toy or game, and that, as a result of that incident the child died, suffered serious illness or injury, ceased breathing for any length of time, or was treated by a medical professional.

Other untoward incident(s) during the usage of any toy and/ or game apart from the aforementioned toy or game product category resulting to the death, serious illness or injury, ceased breathing for any length of time, or treatment by a medical professional of a child shall also be reported.

Rule III Other Provisions

Section 1. *Funding.* The DTI and the DOH through the FDA shall include in their respective annual budget the amount necessary for the effective implementation of this Act and its IRR.

Section 2. *Separability Clause.* The provisions of this Order are hereby declared be separable and if any provision or part hereof is held invalid or unconstitutional, the

remainder of this Order or the provisions not otherwise affected shall remain valid and subsisting.

Section 3. Repealing Clause. The provisions of the Department Orders, rules and regulations and other issuances of the implementing agency which are inconsistent with these IRR are hereby repealed, modified or amended accordingly.

Section 4. Effectivity. This IRR shall take effect fifteen (15) days after its publication in the Official Gazette or in at least two (2) newspapers of general circulation, whichever comes first, and copy thereof furnished the Office of the National Administrative Register at the UP Law Center, University of the Philippines, Diliman, Quezon City.

Issued this 20th day of January ^{9 ~~18~~} 2018 in Makati City, Philippines.

Approved by:



FRANCISCO T. DUQUE III, MD, MSc
Secretary
Department of Health



RAMON M. LOPEZ
Secretary
Department of Trade and Industry