



September 28, 2007

ADMINISTRATIVE ORDER

No. 2007- 0032

SUBJECT: Regulations on the Issuance of a License to Operate to Companies that Manufacture, Import or Distribute Toys for the Philippine Market.

I. RATIONALE / BACKGROUND

To ensure the safety of Filipino children using locally manufactured or imported toys or any other plaything intended for children, the Department of Trade and Industry (DTI) established the Philippine National Standard for toys.

To implement this Standard, the Department of Health pursuant to Chapter III Title II "Hazardous Substances" of Article 43 of Republic Act 7394, otherwise known as the Consumer Act of the Philippines, hereby issues these "Regulations on the Issuance of a License to Operate to Companies that Manufacture, Import or Distribute Toys for the Philippine Market", herein referred to as "Regulations".

II. SCOPE / COVERAGE

These Regulations shall apply to all local manufacturers, importers and distributors of toys that are sold or given free of charge in the Philippines.

III. OBJECTIVE

These Regulations are developed to establish guidelines governing the licensing of manufacturers, importers and distributors of toys in the Philippines.

IV. DEFINITION OF TERMS

For purposes of this order, the terms below are defined as follows:

- **ACCREDITATION** – refers to a procedure by which the Department of Health gives formal recognition that a body (government or private) or a person achieves the accreditation standards demonstrated through assessment of that body's / person's level of performance in carrying out specific tasks.

- **ACCREDITED TESTING LABORATORIES** – refers to the laboratories accredited by the Philippine Accreditation Office of the Department of Trade and Industry or its counterpart agencies in the countries covered by the Mutual Recognition Agreement of the World Trade Organization;
- **APPLICANT** – refers to a local or foreign establishment that seeks to secure a License to Operate from the BHDT.
- **BATCH** – refers to a specific quantity of toys which has uniform character and quality within specified limits and is produced according to a single manufacturing order during the same cycle of manufacture.
- **BHDT** – refers to the Bureau of Health Devices and Technology of the Department of Health.
- **CHD** – refers to the Center for Health Development of the Department of Health.
- **CHILDREN** – refers to any person whose age is chronologically and/or mentally below eighteen (18) years old.
- **CONFORMITY ASSESSMENT** - refers to a procedure by which the Department of Health evaluates a batch of toys and all its pertinent data and information to ensure conformance with the set of essential health and safety requirements.
- **CLEARANCE FOR CUSTOMS RELEASE** – refers to a document issued by the BHDT allowing the release by the Bureau of Customs of a batch of toys for which a CONFORMITY ASSESSMENT had been complied and approved by the BHDT
- **DTI** – refers to the Department of Trade and Industry.
- **DOH** – refers to the Department of Health.
- **DISTRIBUTOR** – refers to any entity to which the toy product is delivered or sold for purposes of distribution in commerce, or in such case repackages toys under different trade name or trademark with permission from the original legal distributor, except that such term does not include a manufacturer or retailer of such product.
- **ESTABLISHMENT** - refers to an importer, manufacturer, or distributor of toys.
- **HRDRD** – refers to the Health Related Device Regulation Division of the Bureau of Health Devices and Technology of the Department of Health.

- **LABEL** – refers to the display of printed or graphic matter on any consumer product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, ingredients, attributes, directions for use, specifications and such other information as may be necessary to protect health and safety of the consumers.
- **LICENSE TO OPERATE (LTO)** – refers to the license issued by BHDT to manufacturers, importers and distributors whose toy products conform with the health and safety requirements of the Department of Health and the Philippine National Standard for Toys and their future amendments.
- **MANUFACTURER** – refers to any establishment that assembles or processes toy products, except that if the toys are manufactured, assembled or processed for another establishment that attaches its own brand name to the toy products, the latter shall be deemed the manufacturer. In case of imported toys, the manufacturer’s representative or, in his absence, the importer, shall be deemed the manufacturer.
- **PNS** – refers to the Philippine National Standards for Safety of Toys and its future amendment.
- **TESTING LABORATORY** – refers to a facility for measuring, examining, and determining one or more characteristics or performance of a toy, its material and component parts.
- **TOY** – refers to an object or a number of objects clearly intended as plaything for children below eighteen (18) years old.
- **TRADEMARK** – refers to a group of words, name, title, symbol, emblem, sign, or device or any combination thereof used as an advertisement, sign, label, poster or otherwise for the purpose of enabling the public to distinguish the business of the person who owns and uses said trade name or trademark.

V. POLICIES AND GUIDELINES

A. GENERAL REQUIREMENTS

1. All toys that are imported, distributed and manufactured in the Philippines shall comply with the Philippine National Standards for Safety of Toys and its subsequent amendments. (i.e. PNS 174:1988, PNS 1408-2:1996/ISO 8124-2:1994, PNS 1408-3:1998/IDT:ISO 8124-3:1997(E) and all other appropriate PNS for Safety of Toys)
2. All manufacturers, distributors and importers of toys shall apply for a License to Operate (LTO) at the DOH through the BHDT. Approval of the LTO shall be based on compliance with PNS and on the completeness of documentary

requirements. Should the establishment, after receiving its LTO, manufacture, import, or distribute a new batch of toys, documents pertaining to this new batch shall be submitted to the BHDT. This new batch shall not be marketed or distributed without a Conformity Assessment by the BHDT. Importers/Distributors shall secure this Conformity Assessment prior to the issuance of the Clearance for Customs Release if the toys are imported.

3. Companies that manufacture, import or distribute the following products which are not considered as toys are exempted from the processes of this regulation. However, their products shall comply with the appropriate requirements of the DTI and other government agencies.
 - a. Sports equipment;
 - b. Aquatic equipment intended to be used in deep water;
 - c. Air guns and air pistols;
 - d. Fireworks, including percussion caps;
 - e. Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts;
 - f. Sets of darts with metallic points;
 - g. Products containing heating elements intended for use under the supervision of an adult in a teaching context;
 - h. Bicycles designated for sport or for travel on the public highway.
4.
 - a. If post market surveillance yields toys that are non-complying with the PNS, the immediate recall and disposal of the toys shall be the responsibility of the establishment.
 - b. Toys re-called by the manufacturer or the DOH for whatever reasons shall be disposed of in accordance with the submitted disposal plan subject to BHDT approval. This plan shall comply with existing rules and regulations set by all concerned agencies of the government and other related laws of the country. All disposal expenses shall be shouldered by the establishment.
 - c. Expenses incurred for press releases, warnings, notice of recalls, safety alerts issued in print or broadcasted over radio or TV stations regarding the conduct of prohibited act/s shall be shouldered by the company concerned.
5.
 - a. Manufacturers, distributors, private or public organizations, individuals or any entity intending to distribute brand new, used or second-hand, locally-made or imported donated toys including toy parts and accessories through charities, donations, or promotional activities shall secure a clearance from the DOH. These toys, toy parts and accessories shall conform with the provisions of these regulations. Non-functional, incomplete, worn-out, broken or unsanitary imported donated toys shall be prohibited to enter the Philippines and shall be reshipped to the country of origin.

- b. The issuance of the clearance shall be exclusive only to the batch of the donated toys to be distributed.
6. A change of ownership or management shall result in revocation of the LTO.
7. The License to Operate (LTO) to be issued by the BHDT Director shall be valid for three (3) years from the date of issuance and subject to renewal unless sooner suspended or revoked in accordance with the regulations of the Department of Health.
8. The following shall be grounds for disapproval or revocation of the LTO:
 - a. Material misrepresentation or concealment of significant data or information about the product sought for certification;
 - b. Submission of falsified documents by the applicant;
 - c. Manufacture, importation, labeling, distribution, operation without registration;
 - d. Material misrepresentation and/or falsifications in the submission of registration/renewal requirements;
 - e. Non-compliance with the standards and requirements on the manufacture, importation, labeling, distribution, retailing and operation; and
 - f. Refusal to allow required inspections as determined by the bureau.
11. The following administrative proceedings and sanctions shall be imposed by the Department of Health:
 - a. Upon verified information of the conduct of prohibited act/s, the bureau shall conduct an administrative hearing with proper notices to determine conduct of prohibited actions and the persons liable.
 - b. In cases where there is finding of prohibited actions and determination of the persons liable, the bureau is authorized to impose any or all of the following sanctions:
 - i. suspension of LTO;
 - ii. revocation of LTO;
 - iii. seizure of the unregistered, non-compliant or falsely represented toy products;
 - iv. other sanctions and penalties mentioned in Title II, Chapter III of Republic Act 7394 otherwise known as the Consumer Act of the Philippines.

B. ANALYSIS AND TESTING REQUIREMENTS

1. The accredited testing laboratories shall conduct the appropriate testing and analysis of toys according to the PNS.

2. Only toy test results from accredited laboratories of the DTI, duly recognized testing laboratories of the DOH, and testing laboratories under the Mutual Recognition Arrangement (MRA) shall be accepted under these Regulations.
3. The results of the tests done in other countries shall be written in English and authenticated by the Philippine consulate in the country of origin.

C. DOCUMENTARY REQUIREMENTS

1. The following requirements for an initial LTO application shall be submitted to the HRDRD office for evaluation:
 - a. Properly filled-up application form;
 - b. Copy of DTI Certificate of Registration / SEC Registration Certificate (to present original or certified true copy from SEC);
 - c. Certificate of Tax Clearance;
 - d. Photograph and description of the toy product (an actual toy may be presented) ;
 - e. Results of Laboratory Analysis from accredited laboratories;
 - f. Labels used in the marketing of the toy;
 - g. Vicinity map;
 - h. Disposal plan that conforms with the rules and regulations set by all concerned agencies in the Philippines.
2. For renewal applications, the following documents shall be submitted to the BHDT office:
 - a. Properly filled up application form;
 - b. Certificate of Tax Clearance; and
 - c. Affidavit of Continuous Compliance.

Applicants whose documents have deficiencies shall be notified and be given (30) thirty calendar days abeyance period to correct the deficiencies; otherwise, the application shall be discarded.

3. Fees

All fees are payable to the Department of Health in accordance with the following schedule:

Registration Fee	Capitalization
PhP 1,000.00	< P 500,000
PhP 2,000.00	P 500,000 – P 999,999
PhP 3,000.00	> or equal to P 1,000,000

Fees and charges are subject to change as may be deemed necessary. Filing of renewal for LTO shall be made at least two months before the expiration date. A

penalty of fifty (50%) percent of the registration fee shall be paid by the applicant for late filing of renewal.

4. The LTO number issued by the BHDT shall appear in all toy packages or protective coverings. This number can be embossed, directly printed, or affixed to the package or protective covering.

E. LABELING AND PACKAGING REQUIREMENTS

The packaging and labeling requirements of toys shall comply with the PNS for Safety of Toys and its future amendments.

1. The DOH shall enforce compulsory labeling and fair packaging to enable the user to obtain accurate information as to the nature, quality and quantity of the contents of toy products and to facilitate comparison of the value of such toy products;
2. All toy products to be marketed or found in the market, whether imported or locally manufactured, shall indicate legibly in its label or package, the minimum information which shall form an integral part of the label or package without the possibility of being erased, or detached under normal weather exposure, storage or handling condition:
 - a) correct and registered trade or brand name;
 - b) duly registered trademark;
 - c) model or reference of the toy product;
 - d) duly registered business name and address of the manufacturer and/or distributor of the toy product in the Philippines;
 - e) the place, country and date or year of manufacture;
 - f) the LTO number issued by the BHDT;
 - g) the warning and/or precautionary indications;
 - h) written instructions for toy's usage, functions, features and assembly; and
 - i) information on the specified age requirements.
3. If information is written in a foreign language, the toy package shall contain a translation in Filipino and/or English as verified and authenticated by the Philippine Consulate in the country of origin;
4. All toy products shall be provided with clearly legible warning or precautionary tags and important indications as written on the packaging material.

F. MONITORING AND INSPECTION

1. The BHDT shall cause the inspection, monitoring and surveillance of establishments to determine compliance with these Regulations.

2. The concerned Bureau personnel shall assess and maintain documentation of all records including those of measuring and testing equipment used. The said equipment used for such activity shall ensure valid results which shall therefore:
 - a. be properly checked and calibrated regularly at specified intervals, as when the need arises in case of doubt or exposed to extreme/exceptional conditional condition, prior to use;
 - b. be checked against nationally-adopted measurement standards;
 - c. be adjusted or re-adjusted when necessary in case of deviation, in order to obtain reliable and valid result; and
 - d. be protected from damage and deterioration during handling, maintenance and storage.
4. Linkages with other concerned government agencies and NGOs shall be maintained in the implementation of these Regulations.
5. Power of Entry. The BHDT technical staff shall secure the necessary Bureau Order prior to the conduct of the monitoring and inspection activity. Upon presentation of this Order, the BHDT technical staff member shall have the authority to undertake the following activities pursuant to these rules and regulations:
 - a. enter or access premises of manufacturer or distributor
 - b. request or examine relevant documents and other information related to the toy being applied for;
 - c. conduct sampling of toy products, parts and accessories.
6. The company or his duly authorized representative shall maintain appropriate documents and pertinent information concerning the manufactured toy product and shall make these available for inspection by the BHDT staff member.

VI. ROLES AND FUNCTIONS OF THE CHD

The Centers for Health Development nationwide shall assist the BHDT in the implementation of these Regulations. The CHDs shall:

1. Disseminate information to the stakeholders regarding the implementation of these Regulations.
2. Make available application forms and the list of requirements to the clients in remote areas applying for LTO with the BHDT.
3. Coordinate with the BHDT and the local government units in their area of jurisdiction on the implementation of these Regulations.
4. The CHD may receive applications for LTO in remote areas provided that such shall be forwarded to the BHDT office in Manila for evaluation and issuance.

VII. HANDLING OF APPEALS

1. The BHDT Director shall approve issuance of LTOs. The BHDT Director shall also impose sanctions on establishments violating these Regulations. The establishments affected by these decisions may file a motion for reconsideration with the Office of the Undersecretary for Health Regulations within fifteen (15) days from receipt thereof.
2. The aggrieved party may appeal the decision on its original appeal within fifteen (15) days from receipt thereof to the Office of the Undersecretary for Health Regulations. The decision of the Undersecretary of Health for Health Regulations shall be final and executory.

VIII. PENAL PROVISIONS

Any person or entity that violates any of the provisions of these Regulations shall, upon conviction, be subject to a fine of not less than One Thousand Pesos (PhP 1,000) or an imprisonment of not less than six (6) months but not more than five (5) years or both upon the discretion of the court and other sanctions and penalties stated in Republic Act 7394 otherwise known as the "Consumer Act of the Philippines"

IX. TRANSITORY PROVISIONS

Upon effectivity of this Order, the manufacturers, distributors and importers of toys containing hazardous substances that are already in the market shall be given six (6) months from the date of newspaper publication of this Order to comply with the provisions of these Regulations. A certificate of pending application shall be given upon the request of the company.

X. SEPARABILITY CLAUSE

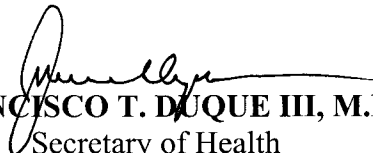
In the event that any rule, section, paragraph, sentence, clause or words of these Regulations is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

XI. REPEALING CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of these regulations are hereby repealed or amended accordingly.

XII. EFFECTIVITY

This order shall take effect fifteen (15) days after its publication in an official gazette or in a newspaper of general circulation.


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Secretary of Health