

January 12, 2009

ADMINISTRATIVE ORDER
No. 2009 - 0005

SUBJECT: Revised Policies and Guidelines on the “Regulations on the Issuances of a License to Operate (LTO), Certificate of Conformity and Clearance for Customs Release Prescribed to Manufacturers, Importers and Distributors of Toys in the Philippines”.

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 issued on September 28, 2007 Administrative Order (AO) No. 2007-0032 entitled, “Regulations on the Issuance of a License to Operate to Companies that Manufacture, Import or Distribute Toys for the Philippine Market”.

However, there is a need to amend and supplement provisions to effectively implement the subject matter, the Department of Health through the Bureau of Health Devices and Technology (BHDT) hereby issues these revised polices and guidelines amending and supplementing Administrative Order No. 2007-0032.

II. SCOPE

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

III. OBJECTIVE

This Administrative Order is developed to establish, innovate, improve the procedures and the health and safety requirements for toys marketed in the Philippines.

IV. DEFINITION OF TERMS

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

ACCREDITED TESTING LABORATORIES – refers to the laboratories accredited by the Philippine Accreditation Office of the Department of Trade and Industry or its counterpart body in other countries that are signatories to the International Laboratory Accreditation Cooperation (ILAC) / Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA).

APPLICANT – refers to a local or foreign establishment that seeks to secure a License to Operate from the BHDT.

BATCH /LOT – 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.

CERTIFICATE OF CONFORMITY – refers to the certificate issued by the BHDT-DOH upon compliance of the product with the requirements of the PNS.

CHILDREN – refers to any person whose age is chronologically and/or mentally below fourteen (14) years old.

CONFORMITY ASSESSMENT - refers to a procedure by which the BHDT-DOH 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.

CLEARANCE FOR CONDITIONAL RELEASE – refers to the document issued to an importer allowing the temporary release of goods from Custom's custody, upon

compliance with the BHDT's requirements, while awaiting process completion of its application for a Certificate of Conformity.

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.

INTENDED USE – use of a product, process or service in accordance with information provided by the supplier.

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.

PACKAGING – refers to the material accompanying the toy when purchased, but having no intended play function.

PAO – refers to the Philippine Accreditation Office of the Department of Trade and Industry.

PNS – refers to the Philippine National Standards for Safety of Toys and its future amendment.

RETAILER – refers to a person engaged in the business of selling consumer products directly to consumers.

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 fourteen (14) 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.

WHOLESALE – refers to any natural person or juridical entity that sells products in bulk or in large scale but not to the end user.

V. **POLICIES AND GUIDELINES**

A. **General Guidelines**

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.
2. All local 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 the Philippine National Standards (PNS) and on the completeness of documentary requirements. The License to Operate (LTO) shall be issued and approved by the BHDT Director, which 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. A change of ownership or management shall result in revocation of the LTO.
3. All local manufacturers, importers and distributors of toys are required to secure a Certificate of Conformity for every shipment / freight, batch / lot (whichever is applicable) of toys manufactured, imported or distributed in the Philippines. Upon application, a sample(s) of the toy in its final packaging for each kind of toy shall be submitted to the BHDT. These toys shall be kept for a specified period of time. After the specified retention period, the manufacturers, distributors and importers shall retrieve the toys from the BHDT; otherwise, the BHDT shall dispose of the toys accordingly. Toys not complying with the requirements of the specific PNS and/or other rules and regulations of the BHDT shall not be issued a Certificate of Conformity.
4. All importers of toys shall secure a Clearance for Customs Release from the BHDT prior to importation.

5. A Clearance for Conditional Release shall be issued by BHDT-DOH to facilitate the release of goods from the Customs custody pending the issuance of the Certificate of Conformity. The importer however shall not sell, distribute or transfer in whole or in part, the toy products to any place other than the address specified in the conditional release. To ensure that no distribution, sale, use and /or transfer of the toy products to any place other than the address specified in the conditional release occurs, the importer shall allow authorized personnel of the BHDT-DOH to conduct inspection/inventory of the import shipment anytime within the official working hours.
6. 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 Certificate of Conformity 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.
7. Retailers / wholesalers selling toys in the Philippine market are required to:
 - a. buy toys only from manufacturers, importers and distributors with a valid LTO from the BHDT;
 - b. sell or offer for sale only toy products that were issued with a Certificate of Conformity; and
 - c. post in a conspicuous place the list of their toy suppliers / distributors.
8. 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.
9. All toys recalled by the manufacturer or the DOH for whatever reasons shall be disposed of in accordance with the submitted disposal plan subject to BHDT approval. The plan shall comply with existing rules and regulations set by all concerned agencies of the government and other related laws of the country. The concerned manufacturer, importer or distributor shall shoulder all expenses regarding the disposal of the re-called toys.
10. All 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.
11. All import shipments denied the requisite Certificate of Conformity shall not be disposed of in the domestic market in any manner. They must be properly disposed of in accordance with the provisions of the Tariff and Custom's Code and other pertinent rules and regulations.
12. Toys that are not covered within the scope of the PNS are exempted from the scope of these regulations. A Certificate of Exemption maybe issued by the BHDT for toy products not covered by these regulations upon request.
13. The existing relevant international standards shall prevail in case there are safety concerns on toy products that are not covered in the Philippine National Standard.

14. Linkages with other concerned government agencies and NGOs shall be maintained in the implementation of these Regulations.

B. Requirements for Laboratory Testing of Toys

The laboratory testing of toys shall be in accordance with the requirements in the Philippine National Standards for the safety of toys.

C. Toy Samples Evaluation

1. Locally Manufactured toys

- a. The BHDT technical staff shall evaluate the documents and toy samples submitted by the applicant.
- b. The applicant shall be given the list of accredited laboratories and the endorsement form for laboratory testing.
- c. The accredited laboratory chosen by the applicant shall fill up the endorsement form and submit the same to the BHDT together with the test reports.

2. Imported Toys

- a. The BHDT shall recognize test results done by an accredited laboratory in another country subject to verification regarding its authenticity and the applicability and validity of the tests conducted.
- b. The counterpart laboratory in the Philippines that is accredited by PAO-DTI may issue the certificate of authenticity for test reports made by their accredited testing laboratory in another country.

VI. DOCUMENTARY REQUIREMENTS

1. License to Operate (initial application)

- a. Duly accomplished application form;
- b. Copy of DTI Certificate of Registration / SEC Articles of Incorporation;
- c. List of toys and their SKUs or model numbers;
- d. List of distributors / retailers;
- e. Vicinity map;
- f. Sworn undertaking;
- g. Disposal plan / recall plan that conforms with the rules and regulations set by all concerned agencies in the Philippines.

2. License to Operate (renewal application)

- a. Duly accomplished application form;
- b. Affidavit of Continuous Compliance.

3. Certificate of Conformity
 - a. Duly accomplished application form;
 - b. Packaging of the toys;
 - c. One sample of toy for each kind / model of toys in its final packaging;
 - d. Laboratory test report written in English for each kind of toy.
4. Clearance for Customs Release
 - a. Duly accomplished application form;
 - b. Certificate of Conformity;
 - c. Bill of lading / airway bill;
 - d. Invoice / Packing list.
5. Clearance for Conditional release
 - a. Duly accomplished application form;
 - b. Bill of lading/ airway bill;
 - c. Invoice / Packing List.

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.

6. Schedule of Fees (please see attached Annex A)

VII. LABELING AND PACKAGING REQUIREMENTS

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. The LTO number issued by the BHDT shall appear in all toy containers or covering wrappers. This number can be embossed, directly printed, or affixed to the package or protective covering.
3. The packaging and labeling requirements of toys shall comply with the PNS for Safety of Toys and its future amendments.
4. The cautionary statements (warnings) for toys shall be written in English and / or Filipino in a visible, easily legible, understandable and indelible form. It shall be placed on the packaging of the product so the consumer can easily see it.
5. The toys shall be labeled to indicate the minimum age for intended use. The age label shall be placed on the packaging for easy reference.
6. Toys with magnets should come with a cautionary statement (warning) written in English and/or Filipino on the packaging of the toy.

VIII. MONITORING AND INSPECTION

1. The BHDT shall cause the inspection, monitoring and surveillance of establishments to determine compliance with these Regulations.
2. Power of Entry. The BHDT technical staff shall secure the necessary Department Personnel 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.

IX. 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 an LTO in remote areas provided that such shall be forwarded to the BHDT office in Manila for evaluation and issuance.

X. HANDLING OF APPEALS

The BHDT Director shall approve the 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.

The aggrieved party may appeal the decision 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.

XI. PENAL PROVISIONS

1. Prohibited Acts

The following are the Acts prohibited under these regulations:

- 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

2. Administrative Sanctions / Penalties

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;

3. 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 R. A. 7349 otherwise known as the Consumer Act of the Philippines

XII. SEPARABILITY CLAUSE

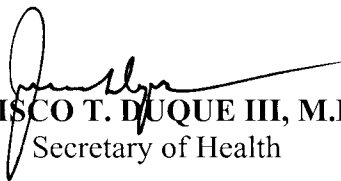
In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared invalid for any reason, the other provisions thereof shall not be affected.

XIII. REPEALING CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this guideline including Administrative Order No. 2007-0032 are hereby repealed or amended accordingly.

XIV. EFFECTIVITY

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


FRANCISCO T. DUQUE III, M.D. MSc.
Secretary of Health

Annex A

Fees

a. License to Operate (LTO)

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

b. Certificate of Conformity

50.00 per Certificate issued

c. Certificate of Conditional Release

200.00

d. Clearance for Custom's Release

200.00

e. Certificate of Exemption (toy product)

200.00

f. Certificate of Exemption from securing an LTO

Exemption 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.

The toys applied for a Certificate of Conformity shall be evaluated based on the minimum requirements set by the Bureau of Health Devices and Technology (BHDT).