

SECOND DRAFT

May 13, 2008

ADMINISTRATIVE ORDER

No. 2008 - _____

SUBJECT: Supplemental Guidelines to Administrative Order No. 2007-0032 entitled “ Regulations on the Issuance of a License to Operate (LTO) to Companies that Manufacture, Import or Distribute Toys for the Philippine Market”.

I. RATIONALE / BACKGROUND

The Department of Health issued Administrative Order (AO) No. 2007-0032 herein referred to as “Regulations” in order to implement the Philippine National Standards for the safety of toys.

To effectively implement these Regulations, the Department of Health through the Bureau of Health Devices and Technology (BHDT) hereby issues these supplemental guidelines on the safety of toys.

II. SCOPE

These guidelines shall apply to all manufacturers, retailers, importers and distributors of toys applying for a License to Operate (LTO) from the BHDT.

III. OBJECTIVE

This Administrative Order is developed to establish the 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 ILAC/APLAC Mutual Recognition Arrangement (MRA) of the World Trade Organization.

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.

Certificate of conformity – refers to the certificate issued by the BHDT-DOH upon compliance of the product with the requirements of the PNS.

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

Packaging - 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.

Retailer – means a person engaged in the business of selling consumer products directly to consumers.

V. POLICIES AND GUIDELINES

A. General Guidelines

1. All local manufacturers, importers and distributors of toys are required to secure a Certificate of Conformity for every batch / lot of toys manufactured, imported or distributed in the Philippines.
2. Retailers / vendors intending to sell toys in the Philippine market shall secure a License to Operate from the BHDT. The retailers / vendors are required to buy toys that have complied with these regulations subject to monitoring by the BHDT.
3. Companies that intend to import toys from other countries for the Philippine market shall secure a Clearance for Customs Release from the BHDT prior to importation.
4. The issuance of the Certificate of Conformity shall be based on the following:
 - Compliance to the documentary requirements of the BHDT;

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 on the packaging of the toy.
7. The cautionary statements (warnings) for toys shall be written in English and Pilipino 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.
8. The manufacturers, importers and distributors applying for LTO shall submit a sample(s) of the toy in its final packaging for each kind of toys. The toys shall be kept by the BHDT for a minimum period of two months to a maximum period of six months. After these specified retention period, the manufacturers, distributors and importers shall retrieve the toys from the BHDT; otherwise, the BHDT shall dispose the toys accordingly.
9. Toys that are not covered within the scope of the PNS (ISO 8124-1:2000(E) (Safety aspects related to mechanical and physical properties), ISO 8124-2:2007(E) – (Flammability) and ISO 8124-3:1997(E)- Migration of elements) 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 of the applicant.

B. Requirements for laboratory testing of toys

Please refer to 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 duly recognized laboratories of the DOH, 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.
- d. The BHDT shall evaluate all the test reports submitted by the client and verify its authenticity.

2. Imported Toys

- a. For toys tested by an accredited laboratory in other countries, the BHDT shall verify the authenticity and the applicability of the tests conducted.

- b. For test reports issued by accredited laboratory in other country with the same facility in the Philippines, the certificate of authenticity maybe issued by their counterpart laboratory in the Philippines.
- c. For accredited laboratories in other countries without the same facility in the Philippines, the test reports shall be verified by the BHDT.

VI. DOCUMENTARY REQUIREMENTS

1. Certificate of Conformity
 - a. Duly accomplished application form;
 - b. Packaging of the toys;
 - c. One sample of toy for each batch / lot of toys applied;
 - d. Laboratory test report for each kind of toys written in English;
2. Clearance for Customs Release
 - a. Certificate of Conformity;
3. License to Operate for retailers / vendors
 - a. Duly accomplished application form;
 - b. SEC Certificate of Registration / DTI Certificate of Registration;
 - c. List of suppliers with approved LTO;

IX. 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 thereby.

X. REPEALING CLAUSE

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

XI. 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