

batch of toys or at least one toy when the batch is not sampled. All product names should be registered in the name column of the inspection application form in the automated system of the BSMI, accompanied by relevant electronic files. Paper applications may be processed with attached forms. Failure to comply with the aforementioned requirements will result in refusal of acceptance. The Obligatory Inspection Applicant is requested to reapply after making the necessary corrections.

b. For toys applied for inspection by the same Obligatory Inspection Applicant, if ten consecutive batches are examined under the batch-by-batch examination and meet the requirements, the inspection method will be changed to random-selected batch inspection with a probability of 50% for each batch. After another ten consecutive batches pass inspection, the inspection method will be further adjusted to random-selected batch inspection with a probability of 20% for each batch.

c. If a randomly selected batch is found to be non-compliant, the inspection method for subsequent goods applied for inspection by the same Obligatory Inspection Applicant will be changed to batch-by-batch examination for ten consecutive batches of inspections. When all of the ten batches of goods for inspection meet the requirements, Item b. of Subparagraph (4) of Paragraph 5 will apply to the subsequent batches.

d. The sampling rate of the randomly selected batch is as follows: for batch with less than 100 items, one item shall be randomly sampled for every five items, with a minimum of one item and a maximum of five items; for batch exceeding 100 items, one additional item should be randomly sampled for every additional twenty items. Two samples (sets) should be taken for each item. However, the sampling rate and quantity may be adjusted as needed based on actual circumstances.

e. For batch-by-batch examination and random-selected batch inspection, only key inspection items within the selected batch are inspected. Other inspection items outside the key inspection scope will be inspected by the BSMI's surveillance plan.

f. When there is a type test report which demonstrates that all items listed in the inspection application of the selected batch under batch-by-batch examination and random-selected batch inspection are compliant, sampling and inspection can be exempted. Only items like packaging, exterior appearance and labelling shall be on-site verified. The type test report shall be issued by the BSMI-designated testing laboratory for toys (hereinafter referred to as the "designated testing laboratory") and such report shall be for the same type of toys inspected and issued within 12 months prior to the application for inspection. However, if there are safety concerns, samples can be taken for inspection.

g. For the batches not selected under the random-selected batch inspection, it is necessary to check the computer database to confirm whether the inspected goods is applicable to the inspect method "release after document examination." A verification checklist will be generated by the automated system and the verification shall be conducted in the following manner:

(a) Labelling is verified at the possibility of 50%. Items of verification include exterior appearance, commodity inspection mark and Chinese label. Sampling for inspection may be exercised if necessary.

(b) For batches not verified, the procedure "release after document examination" shall apply. Items for document examination are specified in item a. of subparagraph (4) of Paragraph 5.

h. For cases where the inspection result is non-compliant, and a re-inspection is required, the following procedures shall be followed in addition to the Regulations Governing Disposition of Commodities Failing Inspection:

(a) If the improvement plan for non-compliant products is to replace spare parts (accessories), a valid certificate proving that the replacement spare parts (accessories) meet the requirements shall be provided.

(b) For cases of re-inspection of non-compliant products, the sampling rate and inspection items shall be handled according to subparagraph item d. and item e. of subparagraph (4) of Paragraph 5. However, items that have failed to pass the inspection and are re-submitted for inspection after improvement shall be sampled and the sampling rate shall double.

(c) For cases of re-inspection, when the non-compliant parts of the products are approved by the BSMI to be destroyed, the item can be exempted from sampling.

i. If the inspection result of sampling or monitoring program shows that a toy is found non-compliant with the inspection standards or the required conformity assessment procedures for the toy are not completed, the inspection method for subsequent goods applied for inspection by the same Obligatory Inspection Applicant will be changed to batch-by-batch examination for ten consecutive batches of inspections. When all of the ten batches of goods for inspection meet the requirements, item b. of subparagraph (4) of Paragraph 5 will apply to the subsequent batches.

6. The inspection method of the Registration of Product Certification:

(1) Application procedures for type test reports, test principles, determination principles for type

and

series type:

a. Application procedures for type test report: The Obligatory Inspection Applicant shall fill in the Commodity Type Classification Form for Registration of Product Certification (Appendix 3) and submit samples to apply for type testing at the designated testing laboratory.

b. Test principle:

(a) Sample quantity: At least 3 samples of each product of the main type and series type shall be submitted.

(b) Type test items: key inspection items.

(c) Fee for type test: In accordance with the fee regulations of the designated testing laboratory.

c. Determination principles for Type and series type:

(a) If the main processes of toys are the same, and the primary materials, raw materials, or components are identical, and the basic design is also the same, the toys are considered as the same type. The most complex one can be determined as the main type, and the others are considered as series types.

(b) If the main processes of toys are the same and the same group of materials is used, and the toys have a similar appearance, they are considered as the same type and there is no series type. If there are differences in appearance, the toys are considered as series types.

(2) When applying for the Registration of Product Certification, the applicant is required to submit basic documents and conformity assessment documents in accordance with Application Procedures for Registration of Product Certification. Additionally, the applicant should provide the following technical documents when submitting the application to the inspection authority:

a. Commodity Type Classification Form for Registration of Product Certification (Appendix 3) signed by a designated testing laboratory.

b. Declaration of Conformity to Type (Appendix 4).

c. Declaration for the Validation of Toys (Appendix 5):

(3) Review Timeframe: 14 workdays (excluding the time of waiting for the supplementary data). An additional 7 workdays will be required for cases involving sample testing.

(4) Validity period of the certificate of the registration of product certification: 3 years. The certificate holder may apply for extension for another 3 year for once only.

(5) Commodity inspection mark: character "R" and designated codes (assigned by the BSMI when issuing the certificate). The commodity inspection mark shall be printed by the Obligatory Inspection Applicant and be affixed on the body of the commodity or minimum packaging of the product. The character "R" and the designated codes shall be placed in close proximity to the right or below the basic diagram.

An example:

or R00000

R00000

(6) Any change to the commodities registered on the certificate of the registration of product certification shall be handled in accordance with the following:

a. For addition of series type (without changing the original main type), the Commodity Type Classification Form for Registration of Product Certification and type test report signed by a designated testing laboratory shall be submitted to the inspection authority for the application of the re-issuance of the certificate.

b. For changing the main type or series type, the Commodity Type Classification Form for Registration of Product Certification and type test report signed by a designated testing laboratory shall be submitted to the inspection authority for approval.

7. The inspection method of Declaration of Conformity:

(1) The low risk of hazard toys listed in Appendix 1 are classified by the material of commodities as below:

a. Paper.

b. Plastic.

c. Other composite materials: Commodities contain more than 2 materials.

(2) The procedures to apply for type test report and test principles:

a. The procedures to apply for type test report: the Obligatory Inspection Applicant shall fill in the Commodity Type Classification Form for Declaration of Conformity (Appendix 6) and apply for type test report at the designated testing laboratory.

b. Test principles:

(a) Selection of test items: The designated testing laboratory selects the most complex or high-risk items for each type of commodities from the List of Declaration of Conformity Type Classification. If the total number of items in the List of Declaration of Conformity Type Classification is less than or equal to 100, one test item is selected from every 20 items for testing; If the total number of items

is more than one hundred, one test item is selected from every 50 items for testing.

(b) The testing items for the type test: key inspection items

(c) Numbers of samples: The Obligatory Inspection Applicant shall submit at least 3 samples for each item.

(d) Fee for type test: in accordance with the fee regulations of the designated testing laboratory.

(3) The Obligatory Inspection Applicant shall keep the following documents in accordance with Article 46 of the Commodity Inspection Act:

a. Declaration of conformity.

b. Technical documents:

(a) Type test report issued by designated testing laboratory.

(b) Commodity Type Classification Form for Declaration of Conformity signed by designated testing laboratory.

(c) Declaration for the Validation of Toys.

(4) For a product that its applicant has signed a declaration of conformity and retained relevant technical documents, if there are any of the following conditions in Appendix 6 and the type test report, the applicant shall submit the original Commodity Type Classification Form for Declaration of Conformity, the updated Appendix 6, the original type test report, or samples, etc., to the designated testing laboratory and apply for changes. The testing principles for such changes are as follows:

a. If the total number of items in the List of Declaration of Conformity Type Classification is over or equal to that specified in Sub-item (a) of Item b. of Subparagraph (2) of Paragraph 7, the testing shall be conducted in accordance with Item b. of Subparagraph (2) of Paragraph 7.

b. If the total number of items in the List of Declaration of Conformity Type Classification is less than that specified in a. of Sub-item (a) of Item b. of Subparagraph (2) of Paragraph 7, only Appendix 6 shall be updated.

(5) Commodity Inspection Mark: character “D” and designated codes. The Obligatory Inspection Applicant shall apply to the inspection authority for the designated code of Declaration of Conformity. The Obligatory Inspection Applicant shall self-print the Commodity Inspection Mark in accordance with regulations, place it to the right or below the basic diagram, and affix it to the product body or the smallest external packaging.

or D00000

D00000

Attachments : Appendix 1 Table of Identification of Risks of Hazard for toy commodities.pdf
Appendix 2 The testing items for the type classification/Sample selection and test methods.pdf
Appendix 3 Commodity Type Classification Form for Registration of Product Certification[Applicable to toy commodities].pdf
Appendix 4 Declaration of Conformity to Type.pdf
Appendix 5 Declaration for the Validation of Toys.pdf
Appendix 6 Commodity Type Classification Form for Declaration of Conformity[Applicable to toys].pdf
The content of Article 5.pdf
The content of Article 6.pdf
The content of Article 7.pdf

Data Source : Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System