

केन्द्रीय मुहर विभाग -2

संदर्भ -: के मू वी-2/16 : 14625

06/04/2023

विषय: **IS 14625 : 2015** के **Amendment Nos. 3 and 4** के अनुपालन के दिशा निर्देश

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशा निर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशा निर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

(शौविक चंदा)

वैज्ञानिक-डी

प्रमुख (के मू वी 2)

सभी क्षेत्रीय/शाखा कार्यालय/प्रयोगशालाओं/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16 : 14625

06/04/2023

Subject : Guidelines for implementation of Amendment Nos. 3 and 4 to IS 14625:2015

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

(Shouvik Chanda)
Scientist D

Head (CMD-2)

All ROs/BOs/Labs/PCD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:14625

Date: 06-04-2023

Subject: Guidelines for implementation of Amendment Nos. 3 and 4 to IS 14625:2015 for Plastics Feeding Bottles— Specification

1. Amendment Nos. 3 and 4 to IS 14625:2015 has been published. The concurrent running period for IS 14625:2015 with and without the amendment nos. 3 and 4 is till **14 September 2023**.
2. The significant changes in the standard through these amendments, as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the amendment.

Clause nos.	Changes
Page 2, clause 3.3.1	Words 'or drinking accessory' has been deleted from the definition of feeding bottles
Page 2, clause 3.4	Words 'or drinking accessory' has been deleted from the definition of Locking Rings
Page 5, Table 1	'Plastics Feeding Bottles' has been replaced with 'feeding bottle and its components excluding hood'
Page 5, clause 5.2.2	Printing inks shall be conforming to IS 15495 for Printing Ink for Food Packaging- Code of Practice
Clause 5.2.1.8 and Table 1, Sl. No. (i)	Requirement of testing of Antimony has been deleted
Clause 5.3.9	New requirement has been introduced for Determination of Specific Migration. It includes specific migration limit of toxic substances like Barium, Cobalt, Copper, Iron, Lithium, Manganese, Zinc, Antimony and Phthalic acid, bis(2-ethylhexyl) ester(DEHP).
Page 2, clause 4.3 and 4.4	Plastics Feeding Bottles shall not be containing Bisphenol A(BPA) and the same shall be tested as per ISO 18857-2 or EN 13130-13
Page 2, clause 4.5	Teats shall conform to IS 3565

3. The existing product manual has been revised to incorporate the above changes and it is being circulated separately through BIS website, as Product manual Doc: PM/IS 14625/2, March 2023
4. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above amendment within a week of issuance of these guidelines.
5. The guidelines for implementation of the revised IS 14625:2015 is given below:

a) LICENSEES:

(i) All Licensees shall implement the Amendment nos. 3 and 4 by **14 September 2023**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest but in any case, at least 30 days before the last date of implementation. BOs shall ensure that no Licences are under operation, without

implementation of Amendment nos. 3 and 4 of IS 14625:2015 after **14 September 2023**. The status of implementation of Amendment nos. 3 and 4 of IS 14625:2015 shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.

(ii) Licensees are required to submit evidence of conformity for the test requirement of 'Determination of Specific Migration' as per Cl. 5.3.9 of IS 14625:2015 and for Bisphenol A (BPA) as per Cl. 4.3 and 4.4 of IS 14625:2015 through submission of Independent /in-house test reports.

(iii) Licensees are also required to submit test certificates for the raw materials being used, in compliance to Cl. 4.1 and 4.2 of IS 14625:2015. Licensees are also required to submit consent letter from the BIS licensed manufacturer or test report/ test certificate conforming to IS 3565, for the tests in compliance to Cl. 4.5 of IS 14625:2015. In case the licensee uses Printing Inks, declaration/undertaking from the supplier in compliance to Cl. 5.2.2 of IS 14625:2015 to be submitted.

(iv) Verification of implementation of Amendment nos. 3 and 4, shall be done by the BO preferably within 30 days of implementation of the revised IS by the licensee.

(v) If the Licensee fails to complete all actions by **14 September 2023**, it shall be dealt as per the prevailing guidelines.

b) APPLICATIONS FOR GRANT OF LICENCE:

i) Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed without consideration of the amendments. However, if the Applicant is desirous of considering Amendment nos. 3 and 4, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall also be obtained from such Applicants that if the sample fails while considering the provisions of Amendment nos. 3 and 4, Licence will not be granted by BIS, without consideration of the amendments.

ii) Applications which are recorded henceforth may be processed with or without consideration of the Amendment nos. 3 and 4 to IS 14625:2015. Processing of Applications without consideration of the Amendment nos. 3 and 4 shall be permitted only up to **14 September 2023** and for such cases Applicant shall give a declaration that they will implement Amendment nos. 3 and 4 by **14 September 2023**.

(iii) Beyond **14 September 2023**, no Licence shall be granted without consideration of Amendment nos. 3 and 4.

c) CHANGE IN SCOPE OF LICENCE:

(i) For change in scope of licence, the relevant provisions as given above for Applicants shall apply.

6. The above guidelines shall come into force with immediate effect.

(Shouvik Chanda)
Scientist D(CMD-2)

Head (CMD-2)

DDG (Certification)

Circulated to:

- i) All RO/BOs
- ii) All other concerned - through BIS intranet