# केन्द्रीय मुहर विभाग -2

संदर्भ -: के मू वी-2/16 : 1656 17/11/2022

विषय: संशोधित IS 1656: 2022 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/FAD/LRMD

## **CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/16: 1656 17/11/2022

Subject: Guidelines for implementation of revised IS 1656: 2022

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/FAD/LRMD

## **CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/16:1656 17-11-2022

Subject: Guidelines for implementation of revised IS 1656:2022 to IS 1656:2007 and Amendment No. 1 to IS 1656:2022 for Infant Food - Milk Cereal Based Complementary Foods - Specifications

- 1. IS 1656:2007 and IS 1656:2022 for Infant Food Milk Cereal Based Complementary Foods Specification are under concurrent running till 18 January 2023 and the last date for implementation of IS 1656:2022 is 18<sup>th</sup> January 2023, after which the old standard (IS 1656:2007) shall stand withdrawn. Furthermore, Amendment no.01 to IS 1656:2022 has also been published and the last date for implementation of Amendment No.01 to IS 1656:2022 is 27<sup>th</sup> March 2023.
- 2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above revision and the amendment, within a week of issuance of these guidelines. Further, BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard IS 1656:2022 including amendment no.01 to IS 1656:2022, as applicable.
- 3. The significant changes in the standard through this revision as listed in the Table are given below for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Indian Standard.

Clause No. of IS 1656:2022	Changes
Cl. 1	Scope of the Indian Standard has been modified from "complementary foods intended for feeding infants at the weaning stage" to "complementary foods intended to complement the diet of infants after six months up to twenty-four months of age".
Cl. 4.1, 4.2, 4.3, 4.4	Product description has been updated
Cl. 4.5 and Table 1	<ul> <li>a) List of permitted optional ingredients has been updated and test methods have been specified for each of the ingredients</li> <li>b) Test method for following Vitamins have been incorporated: Vitamin K to be tested as per IS 21446 to be tested in HPLC</li> </ul>
Cl. 4.6	List of permitted food additives as well as their levels have been updated
Cl. 4.7	The list for source compounds for minerals, vitamins and other nutrients have been updated

Cl. 4.9	In cases of products, claiming to have higher quality protein, test method and minimum requirement for protein efficiency ratio (PER) has been incorporated
Cl. 4.8, Table 2	Chemical requirements have been updated: a) Requirement of Protein (Total protein including milk protein and Milk protein) has been incorporated
	<ul><li>b) Requirement of Dietary Folate equivalent has been incorporated</li><li>c) Requirement of Folic acid has been deleted</li></ul>
	d) Test method for Iron has been modified. The earlier method (IS 2860) was spectrophotometric/AAS and the modified (ISO 14377) method pertains to AAS/ICP-OES/ICP-AES
	e) Test method for following Vitamins have been incorporated: i) Vitamin A to be tested as per IS 16639 in HPLC method ii) Vitamin D to be tested as per IS 17177 in LCMS
Cl. 4.8, Table 3	Microbiological requirements have been updated: b) Requirements for Listeria monocytogenes, Bacillus cereus, Sulphite reducing clostridia has been incorporated c) Requirement of Shigella has been deleted
Cl. 4.10	Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 have been referred regarding the use of pesticide residues, antibiotic and veterinary drug residues, naturally occurring toxins and other contaminants,
Cl. 4.11, Table 4	a) Requirement of Melamine has been incorporated b) Test method for Tin has been modified. The earlier method (IS 2860) was gravimetric and the modified (ISO 14377) method pertains to AAS
Cl. 5.1.1	Packing - the following sentence has been introduced:  "The packaging material used for product shall be free from Bisphenol A (BPA)."
Cl. 5.2	Marking clause has been modified
Annex D	Sampling Plan for Microbiological Requirements has been incorporated

4. The significant changes due to the Amendment no.01 to IS 1656:2022 are as listed below for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per Amendment no.01.

Clause No. of IS 1656:2022	Changes
Cl. 3.1 (Terminology for Milk-Cereal Based Complementary Food)	Milk-Cereal Based Complementary Food may also contain 'Edible vegetable oil and edible vegetable oil seeds after processing', in addition to the items already permitted

Cl. 4.6.2 (Food	The second sentence has been corrected to state that 'the food
Additives)	additives listed under Cl. 4.6.1 maybe used and the food additives
	listed under Cl. 4.6.2 maybe used as nutrient carriers'
Cl. 5.1.1	It was previously stated that the packaging material shall be
(Packing)	Bisphenol A(BPA) free.
	Now, with this amendment, a test method as per ISO 18857-2:2009
	or EN 13130-13 for Bisphenol A(BPA), has been specified

- 5. The existing Product manual has been revised to incorporate the changes due to the revised IS and it is being circulated separately, through BIS website, as Product Manual Doc: PM/ IS 1656/ 2, October 2022.
- 6. The guidelines for implementation of the revised IS is given below:

### A. <u>LICENSEES</u>:

- (i) All Licensees shall implement the revised Indian Standard by **18 January 2023 and the amendment no. 01 to IS 1656:2022 by 27<sup>th</sup> March 2023**. Any difficulty in implementation shall be brought to the notice of CMD-2 at the earliest, but in case at least 30 days before the last date of implementation. BOs shall ensure that no Licences are under operation as per IS 1656:2007(old standard) after 18 January 2023 and without implementation of amendment no. 01 after **27<sup>th</sup> March 2023**. The status of implementation of the revised Indian Standard and the amendment, shall be confirmed by Head (BO) to CMD-II within two weeks of the last date of implementation of concurrent running.
- (ii) Licensees shall submit evidence of conformity to the modified/additional requirements through In-house/Independent Test Reports. Verification of implementation of the revised IS, shall be done during next visit, within 30 days of confirmation of implementation of the revised standard by licensee.
- (iii) If the Licensee fails to complete all actions by **18th January 2023 and 27th March 2023**, as applicable, it shall be dealt with 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 as per the old standard or the revised standard without the amendment. However, if the Applicant is desirous of considering the Application, as per the revised IS and as per the revised Standard with the amendment, 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 the

- revised IS or the revised IS with the amendment, Licence will not be granted by BIS as per the old version or the standard without the amendment.
- (ii) Applications which are recorded henceforth may be processed as per the old standard / the revised Standard or the standard with or without the amendment. Processing of Applications as per the old Standard, shall be permitted only upto 18th January 2023 and the standard without the amendment up to 27th March 2023. For such cases Applicant shall give a declaration that they will implement the revised Standard by 18th January 2023 and the amendment by 27th March 2023.
- (iii) Beyond **18th January 2023** no Licence shall be granted as per IS 1656:2007 and beyond **27th March 2023** no Licence shall be granted as per IS 1656:2022 without amendment no.01.
- 7. The above guidelines come into force with immediate effect.

(Shouvik Chanda) Scientist D

Head (CMD-2)
DDG(Certification)

#### Circulated to:

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