केन्द्रीय मुहर विभाग –2

संदर्भ -: के मू वी-2/16 : 15757 17/11/2022

विषय: संशोधित **IS 15757 : 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 : 15757 17/11/2022

Subject : Guidelines for implementation of revised IS 15757 : 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: 15757 17.11.2022

Subject: Guidelines for implementation of Revised IS 15757:2022 and implementation of Amendment No.01 to IS 15757:2022 (Infant Food-Follow-Up Formula— Specification)

1. IS 15757:2007 has been revised as IS 15757:2022 and has been published. The last date for implementation of the revised Standard is **18th January 2023** after which the old Standard shall stand withdrawn. Furthermore, Amendment no.01 to IS 15757:2022 has also been published and the last date for implementation of Amendment No.01 to IS 15757:2022 is **27th March 2023**.

2. The significant changes in the revision of **IS 15757:2007 as IS 15757:2022** are listed below:-

Clause No. of IS 15757:2022	**Changes**
	Title of the Indian Standard has been Changed from: Follow-Up Formula -Complementary Foods to Infant Food-Follow-Up Formula
Cl. 3.1	Terminology – Definition of Follow-Up Formula has been modified
Cl. 4	a) Description- It has been modified b) Test method and requirement has been specified for scorched particles
Cl. 4.3.2	Additional test method(ISO 16958) has been added for Linoleic Acid
Cl. 4.5	List of permitted optional ingredients has been updated including test methods for testing of the ingredients has been updated
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. 4.8, Table 1	Chemical requirements have been updated : a) test method for Total protein has been changed to IS 11917 b) Additional test method(AOAC) has been added for Chloride c) Test method(IS 17668) has been added for Choline d) Requirement of Dietary Folate equivalent as per AOAC method has been incorporated

	e) Requirement of Folic acid has been deleted f) Test methods have been changed for testing of Vitamin B_{12}(is 16640/AOAC) g) Requirement of Inositol as per IS 16649 has been incorporated h) Requirement of Taurine as per AOAC method has been incorporated i) Requirement of Essential Amino Acid has been incorporated j) Additional test method(IS 17176 as per HPLC method) for Vitamin C has been incorporated k) Additional Test method (ISO 15151as per ICP-AES and/or ISO 21424 as per ICP-MS) for Sodium, Potassium, Calcium, Phosphorus, Magnesium, Zinc, Copper, Manganese, Selenium and Iron has been prescribed. Parts of IS 3025 for testing of Selenium and Manganese have been deleted l) Fatty Acid profile has been specified, to be tested as per ISO 16958 and IS 10633 m) Test method for following Vitamins have been incorporated: n) Vitamin A to be tested as per IS 16639 in HPLC method o) Vitamin D to be tested as per IS 17177 in LCMS
Cl. 4.8, Table 2	Microbiological requirements have been updated : a) Requirements for *Listeria monocytogenes, Bacillus cereus, Sulphite reducing clostridia* has been incorporated b) 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 3	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 B	Sampling Plan for Microbiological Requirements has been

	incorporated

3. The significant changes as per amendment no.01 to IS 15757:2022 are listed below: -

Clause No. of IS 15757:2022	Changes
Cl. 4.6.2 (Food Additives)	The second sentence has been corrected to state that 'the food additives listed under Cl. 4.6.1 maybe used and the food additives as listed under this Cl. 4.6.2 maybe used as nutrient carriers'
Cl. 4.8, Table 1 (Requirements for Follow-up Formula)	a) Vitamin D (expressed as chole-calciferol) has been modified as Vitamin D b) Alternative test method for Chloride has been changed from AOAC 2016.02 to AOAC 2016.03 c) The value of maximum limit as given in the specified requirements per 100 g for Vitamin B_{12} have been changed from 4.20 to 4.50 d) The specified requirements per 100 kcal for inositol have been changed from 8.00 to 8.50
Cl. 5.1.1 (Packing)	It was previously stated that the packaging material shall be 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

4. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the above revision and amendment. Further, BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard IS 15757:2022 and as per amendment no.01 to IS 15757:2022.

5. Consequent upon the issuance of the revised Standard and the amendment, the existing product manual has been revised. The same is being circulated separately.

6. The guidelines for implementation of the revised Standard and implementation of amendment no.01 to the revised standard are given below:

A. **LICENSEES**

(i) All Licensees shall implement the revised Standard IS 15757:2022 by **18th January 2023 and the amendment no.01 to IS 15757:2022 by 27th March 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 as per old Standard after **18th January 2023** and without implementation of amendment **after 27th March 2023**. The status of implementation of the revised Standard and

the amendment shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.

(ii) Licensees shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports or Test Certificates, as applicable. **Verification of implementation of the revision of standard and the amendment, may be done through a surveillance visit carried out preferably within 30 days of switchover of the licence**.

(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 and standard without the amendment. However, if the Applicant is desirous of considering the Application as per the revised Standard and the 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 in new test requirements, Licence will not be granted by BIS as per the old version or standard without the amendment.

(ii) Applications which are recorded henceforth may be processed as per the old Standard/the revised Standard or the revised standard with/without the amendment. Processing of Applications as per the old Standard shall be permitted only up to **17th January 2023** and the standard IS 15757:2022 without the Amendment No. 1 up to **26th 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 15757:2007 and beyond **27th March 2023** no Licence shall be granted as per IS 15757:2022 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