केंद्रीय मुहर विभाग -2

संदर्भ : कें.मु.वि-2/16: 14433 & 17945 दिनांक 22/10/2022

विषय: संशोवित आई एस 14433 : 2022 और आई एस 17945:2022 के अनुपालन के दिशा निर्देश:

1) यह उपरोक्त के संदर्भ मे है।
2) सक्षम अविकारी द्वारा अनुमोवदत वदशा वनदेश अनुपालन हेतु संलग्न है।
3) सब शाखा कायाभलयों से अनुरोध है कि वेह अपने अविकार क्षेत्र: में आने वाले आबेदको और लाइसेंसिाररयों को संशोवित मानक के कायाभन्वयन के बा रे में सूवित करें।

(शौविक चंदा)
वैज्ञानिक -डी

प्रमुख , (कें.मु.वि.-2)
सभी क्षत्रीय/शाखा कायाालयों /प्रयोगशालाओं/ FAD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:14433 & 17945 22-10-2022

Subject: Guidelines for Implementation of revised IS 14433:2022 (Infant Milk Substitutes) and implementation of Amendment No.01 to IS 14433:2022; AND IS 17945: 2022 (Food for Special Medical Purpose Intended for Infants — Specification)

1. This has reference to the subject mentioned above.
2. The Competent Authority has approved the enclosed Guidelines for implementation.
3. All BOs are requested to inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard.

(Shouvik Chanda)
Scientist-D

Head(CMD-2)
All ROs/BOs/ FAD/LRMD

CENTRAL MARKS DEPARTMENT – 2

Our Ref: CMD-2/16:14433 & 17945 **21-10-2022**

Subject: Guidelines for Implementation of revised IS 14433:2022 (Infant Milk Substitutes) and implementation of Amendment No.01 to IS 14433:2022; AND IS 17945: 2022 (Food for Special Medical Purpose Intended for Infants — Specification)

1. IS 14433:2007 has been revised and split into the following two standards:

   i) IS 14433:2022 – This standard prescribes the types, requirements, methods of test and sampling for infant milk substitutes. In the revised version i.e. IS 14433:2022 only the following types have been retained:

      a) Type I-Infant Milk food, and
      b) Type II - Infant Formula

   ii) IS 17945:2022 - has been formulated to cover the requirements for food for special medical purpose intended for infants, which is substitute for human milk or formula that is specially manufactured to meet the special requirements of infants from birth to twenty-four months with specific disorders, diseases or medical conditions. It includes the following varieties:

      a) Preterm infant milk substitute,
      b) Lactose free infant milk substitutes and
      c) Hypoallergenic infant milk substitutes

   These varieties were earlier included as a part of Type II variety of Infant Milk Substitutes in IS 14433:2007. Now, in the revised version of IS 14433:2022, these varieties have been removed and a separate Indian standard (IS 17945:2022) has been formulated.

2. IS 14433:2007 and IS 14433:2022; and IS 17945:2022 are under concurrent running till **19 January 2023** and the last date for implementation of IS 14433:2022 and IS 17945:2022 is **19 January 2023**, after which the old standard (IS 14433:2007) shall stand withdrawn. Furthermore, Amendment no.01 to IS 14433:2022 has also been published and the last date for implementation of Amendment No.01 to IS 14433:2022 is **27th March 2023**.

3. All BOs shall inform the Applicants and Licensees under their jurisdiction about the revision of IS 14433:2007 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 14433:2022 including amendment no.01 to IS 14433:2022 or IS 17945:2022, as applicable.

4. The significant changes in the revised standards IS 14433:2022 and IS 17945:2022 are listed in enclosed Annexure-I and Annexure-II, respectively.

5. Consequent upon issuance of IS 17945: 2022, product manuals for IS 14433:2022 (incorporating Amd. No.1) and IS 17945: 2022 has been prepared and are being circulated separately through BIS website.

6. The guidelines for implementation of IS 17945: 2022 and IS 14433:2022 are given below:

A. <u>LICENSEES:</u>

a) With respect to existing licensees, there may be following three situations:

i. Licence scope covers varieties **excluding** those varieties now covered under IS 17495:2022 (i.e. Preterm infant milk substitute, Lactose free infant milk substitutes and Hypoallergenic infant milk substitutes) – In this case licensee has to switch over the licence to IS 14433:2022

ii. Licence scope covers varieties **including** those varieties now covered under IS 17495:2022 (i.e. Preterm infant milk substitute, Lactose free infant milk substitutes and Hypoallergenic infant milk substitutes) – In this case licence has to be split, one licence shall be switched over to IS 14433:2022 and the other to IS 17495:2022

iii. Licence scope covers **only** those varieties now covered under IS 17495:2022 (i.e. Preterm infant milk substitute, Lactose free infant milk substitutes and Hypoallergenic infant milk substitutes) – In this case the licensee has to switch over to IS 17495:2022

b) Regarding situation at Sl No. a(i) above, licesees shall submit evidence of conformity to IS 14433:2022, through In- house/Independent Test Reports. Verification of implementation of IS 14433:2022, shall be done during next visit, within 30 days of confirmation of implementation of the IS 14433:2022 by licensee.

c) Regarding situation at Sl No. a(ii) above, licesees shall submit evidence of conformity through In- house/Independent Test Reports for the varieties, Type I-Infant Milk food and/or Type II- Infant formula. Verification of implementation of IS 14433:2022, shall be done during next visit, within 30 days of confirmation of implementation of the IS 14433:2022 by licensee.

For the remaining varieties (i.e. Preterm infant milk substitute, Lactose free infant milk substitutes and Hypoallergenic infant milk substitutes) now covered under IS 17495:2022, licencee has to apply for a new licence alongwith evidence of conformity through In- house and/or Independent Test Reports as per IS 17945:2022. Since these varieties were already a part of his existing licence, verification of implementation of IS 17495:2022, shall be done during next visit, within 30 days of confirmation of implementation of the IS 17495:2022 by licensee.

d) Regarding situation at Sl No. a(iii) above, licesees shall submit evidence of conformity through In-house and/or Independent Test Reports to IS 17945:2022. Verification of implementation of IS 17945:2022, shall be done during next visit, within 30 days of confirmation of implementation of the IS 17945:2022by licensee.

e) All Licensees of IS 14433:2007 shall switchover to IS 14433:2022 and/or IS 17945:2022 by **19 January 2023**. BOs shall ensure that no Licences are under operation as per the old standard after **19 January 2023**. The status of implementation shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.

f) If the licensees fail to complete all actions by 19 January 2023, it shall be dealt with as per the prevailing guidelines.

g) Acceptance of SIT of IS 14433:2022/IS 17945:2022 shall be submitted by the licensee. In case any licensee fails to give acceptance to revised SIT within the stipulated time norm,

action shall be taken 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 i.e. IS 14433:2007. However, if the Applicant is desirous of considering the Application as per IS 17945:2022 or IS 14433:2022, a declaration may be obtained from the Applicant to the effect and the Application may be processed accordingly. An undertaking from such Applicants shall also be obtained that if the sample fails in new test requirements, Licence will not be granted by BIS as per the old version.

ii) Applications which are recorded henceforth may be processed as per the old standard i.e. IS 14433:2007 or as per IS 14433:2022/IS 17945:2022. Processing of Applications as per the old Standards shall be permitted only upto **19 January 2023** and for such cases Applicants shall give a declaration that they will implement IS 14433:2022 and/or IS 17945:2022 by **19 January 2023**.

iii) Beyond **19 January 2023,** no Licence shall be granted as per the old standard.

C. CHANGE IN SCOPE OF LICENCE:

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

ii) However, processing of such applications for change in scope of licence as per the old Standard shall be permitted only upto the date of implementation of the revised Standard or upto **19 January 2023** whichever is earlier.

iii) The above guidelines come into force with immediate effect.

(Shouvik Chanda)
Scientist D

Head (CMD-2)
DDG (Certification)

Annexure-I

1. The changes in the revised standard IS 14433:2022 are listed in the Table below and has been given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised standard i.e. IS 14433:2022:

Clause No. of IS 14433:2022	Changes
Cl. 3.1, 3.2	Terminology – Definition of Infant Milk Food and Infant Formula has been modified
Cl. 4	Types – It has been modified to remove the earlier types of Infant Formula like, Pre-mature/Low birth weight infant milk substitute, Lactose free infant milk substitute, lactose and sucrose free infant milk substitute and sucrose free infant milk substitute and Hypoallergenic infant milk substitute.
Cl. 5.7 and Table 1	a) List of permitted optional ingredients has been updated including test methods for testing of the ingredients has been updated b) Requirement of Inositol as per IS 16649 has been incorporated
Cl. 5.8	List of permitted food additives as well as their levels have been updated
Cl. 5.9	The list for source compounds for minerals, vitamins and other nutrients have been updated
Cl. 5.7 and Cl. 5.10, Table 2	Chemical requirements have been updated : a) test method for Total protein has been changed to IS 11917 b) Additional test method(ISO 16958) has been added for Linoleic Acid c) Additional test method(AOAC) has been added for Cholride d) Test method(IS 17668) has been added for Choline e) Requirement of Dietary Folate equivalent as per AOAC method has been incorporated f) Requirement of Folic acid has been deleted g) Additional Test method (ISO 15151-as 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 h) Fatty Acid profile has been specified , to be tested as per ISO 16958 and IS 10633 j) Additional test method(IS 17176 as per HPLC method) for Vitamin C has been incorporated k) 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. 5.10, Table 3	Microbiological requirements have been updated: a) Requirements for *Listeria monocytogenes, Enterobacteriaceae, Enterobacteriaceae sakazakii, Bacillus cereus, Sulphite reducing clostridia* has been incorporated b) Requirement of Shigella has been deleted
Cl. 5.11	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. 5.12, 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. 6.1.1	Packing - the following sentence has been introduced : “The packaging material used for product shall be free from Bisphenol A (BPA).”

Cl. 6.2	Marking clause has been modified
Annex E	Sampling Plan for Microbiological Requirements has been incorporated

2. The significant changes due to the amendment no.01 to IS 14433:2022 are listed below:-

Clause No. of IS 14433:2022	**Changes**
Cl. 3.2 (Infant Formula)	The definition of Infant Formula has been modified to state that 'the product maybe modified by partial removal/substitution of different milk solids and addition of carbohydrates and salts such as phosphates and citrates, vitamins and minerals'.
Cl. 5.8.2, Table (Food Additives)	The maximum level of Antioxidants(Mixed tocopherols concentrate and L-Ascorbyl palmitate) was 1 mg, now the maximum level of Mixed tocopherols concentrate has been specified as 1 mg and L-Ascorbyl palmitate has been specified as 1 mg
Cl. 5.8.3 (Food Additives)	The second sentence has been corrected to state that 'the food additives listed under Cl. 5.8.2 maybe used and the food additives as listed under this Cl. 5.8.3 maybe used as nutrient carriers'
Cl. 5.7 and 5.10, Table 2 (	The name of the parameter has been modified from Total protein (N × 6.25) to Total protein (N × 6.25^4)
Footnote under Table 2	It has been mentioned that in case of Milk Protein, a factor of 6.38 to be used in place of 6.25
Cl. 6.1.1 (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

Annexure-II

1. The changes in the revised standard IS 17945:2022 are listed in the Table below and has been given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the new Indian Standard i.e. IS 17945:2022:

Clause No. of IS 17945:2022	Changes
	Title of the Indian Standard has been changed
Cl. 5.7 (Food Additives)	A list of permitted food additives has been added
Cl. 5.8.2 (Ingredients)	The list for source compounds for minerals, vitamins and other nutrients have been updated and the following mineral salts, vitamin compounds and nutrients have been added in the list: a) Minerals: 1) Calcium (Ca) – calcium gluconate, calcium glycerophosphate, calcium L-Lactate, calcium hydroxide, calcium sulphate 2) Phosphorus(P) – Magnesium Phosphate Tribasic, Potassium Phosphate monobasic, Sodium phosphate dibasic, Phosphoric Acid 3) Chloride (Cl) – Potassium chloride, Hydrochloric acid (food grade) 4) Iron (Fe) – Ferrous carbonate(stabilized with saccharose), Ferrous fumarate, Ferrous gluconate, Ferrous succinate, Ferric ammonium citrate, Ferric citrate, Ferrous bisglycinate, Sodium ferric pyrophosphate Ferric diphosphate, Ferric orthophosphate, Hydrogen reduced iron, Electrolytic iron, Carbonyl iron, Ferric saccharate, Sodium ferric diphosphate 5) Magnesium (Mg) – Magnesium hydroxide carbonate, Magnesium phosphate tribasic (Trimagnesium phosphate), Magnesium carbonate, Magnesium sulphate, Magnesium hydroxide, Magnesium salts of citric acid, Magnesium gluconate, Magnesium lactate, Magnesium glycerol-phosphate, Magnesium acetate 6) Sodium (Na) – Sodium carbonate, Sodium gluconate, Sodium L-lactate, Sodium phosphate dibasic (disodium hydrogen phosphate), Sodium phosphate tribasic (Trisodium phosphate), Sodium sulphate, Sodium hydroxide 7) Potassium (K) – Potassium bicarbonate, Potassium carbonate, Potassium chloride, Potassium citrate (Tripotassium citrate), Potassium glycerol phosphate, Potassium gluconate, Potassium phosphate monobasic (potassium dihydrogen phosphate), Potassium hydroxide, Potassium phosphate tribasic, Potassium L-Lactate 8) Copper (Cu) – Copper gluconate (Cupric gluconate), Cupric carbonate, 9) Iodine (I) – Potassium iodate, Sodium iodate; 10) Zinc (Zn) – Zinc acetate, Zinc chloride, Zinc oxide, Zinc gluconate, Zinc lactate, Zinc carbonate, Zinc citrate (Zinc citrate dihydrate or Zinc citrate trihydrate); 11) Manganese (Mn) – Manganese(II) carbonate, Manganese(II) citrate, Manganese (II) gluconate, Manganese (II) glycerol-phosphate; 12) Selenium (Se) – Sodium selenate, Sodium hydrogen selenite;

	13) Chromium (Cr) – Chromium(III) sulphate, Chromium(III) chloride; 14) Molybdenum (MoVI) – Sodium molybdate, Ammonium molybdate b) <u>Vitamins:</u> 1) Vitamin E - DL-α-Tocopheryl polyethylene glycol succinate 2)Vitamin K_1 — Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinine/Phylloquinone/ phytonadione); 3) Vitamin K_2 – Menaquinone 4) Pantothenic acid — Sodium-D-pantothenate, 5) Vitamin B_6 — Pyridoxal-5-phosphate 6) Vitamin C — L-Ascorbic acid, Sodium-L-ascorbate, Calcium-L-ascorbate, Potassium-L-ascorbate, 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate) c) Amino acids d) Carnitine e) Taurine f) Choline g) Inositols h) Nucleotides
Cl.5.9 (Lactose Free Infant Milk Substitutes)	It has been mentioned that Lactose Free Infant Milk Substitutes shall meet the following additional requirements: a) Lactose content shall not exceed 0.05 percent by mass; b) The fat content derived from vegetable oils shall not be less than 18 percent by mass.
Cl. 5.11 and Table 1 (Preterm Infant Milk Substitutes)	i) Requirements for Preterm Infant Milk Substitutes have been specified. ii) For pre-term infant milk substitutes, ISO 16958 has been specified for DHA, ARA and EPA iii) Requirement of Linoleic acid and α-linoleic acid, Phosphate, Chromium, Molybdenum, Cobalamin, Inositol has been incorporated iv) Carbohydrate limit has been specified v) Specified requirements/Limits have been changed for the chemical parameters. In the earlier version of IS 14433:2007, Limits were specified as max/min, whereas in IS 17945:2022, range has been specified for these parameters. vi) Additional test methods as per ISO 15151/ISO 21424 has been specified for Sodium, Potassium, Zinc, Copper vii) Test method for Calcium and Magnesium has been changed to IS 12760/ ISO15151/ISO 21424 viii) Additional test method as per AOAC 2016.03 has been specified for Chloride ix) Test method for Iron has been changed to AOAC 985.35/ ISO15151/ISO 21424 x) IS 3025(P-56) has been deleted as a test method for Selenium and additional test methods as per ISO 15151/ISO 20649 has been specified xi) Test method for Manganese has been changed to

	ISO15151/ISO 21424 xii) Test method for Iodine has been changed from Annex-H of IS 7224 to IS 17379 xiii) Test method for Thiamin has been changed from IS 5398 to IS 17669 xiii) Test method for Riboflavin has been changed from IS 5399 to IS 17669 xiv) Test method for Niacin has been changed from IS 5400 to IS 17669 xv) Test method for Pantothenic Acid has been changed from IS 9840 to IS 16642 xvi) Test method for Pyridoxine has been changed from IS 7530 to IS 17669 xvii) Test method for Folic Acid has been changed from IS 7234 to AOAC 2013.13 xviii) Additional test method as per IS 17176 has been specified for L-Ascorbic acid (Vitamin C) xix) Test method for Biotin has been changed from IS 9820 to IS 17670 xx) Test method for Vitamin A has been changed from IS 5886 to IS 16639 xxi) Test method for Vitamin D has been changed from IS 5835 to IS 17177 xxii) Test method for Vitamin E has been changed from IS 7235 to IS 16639 xxiii) Test method for Vitamin K has been changed from IS 5838 to IS 21446 xxiv) Test method for Choline has been changed from IS 5949 to IS 17668
Cl. 5.12, Table 2	<u>Microbiological requirements</u> a) Following new parameters have been added: *Listeria monocytogenes, Bacillus cereus,* Sulphite reducing *Clostridia,* Enterobacteriaceae, *Enterobacter sakazakii* (*Cronobacter sp.*) b) Following parameters have been deleted: Coliform count*, Escherichia coli, Shigella* c) Limits for *Staphylococcus aureus*, Yeast and Mould have been changed
---	Requirement of testing the product for presence of Aflatoxins has been deleted from IS 17945
Cl. 6.1.1 (Packing)	a) It has been specified that the packaging material shall be free from Bisphenol A (BPA), when tested as per ISO 18857-2: 2009 or EN 13130-13. b) Requirement of the product to be packed in nitrogen or a mixture of nitrogen and carbon dioxide has been deleted
Cl. 6.2 (Marking)	Following additional information is required to be marked on the containers: i) An advisory warning “RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY” in capital and bold letters; ii) A warning that Infant milk substitute is not the sole source of nourishment of an infant; iii) A statement indicating instruction for appropriate and hygienic

	preparation including cleaning of utensils, bottles and teats and warning against health hazards of inappropriate preparations; iv) A statement “FOR THE PRETERM BABY (BORN BEFORE 37 WEEKS)” for pre-term infant milk substitutes; v) In case the product is for lactose intolerant infants, the words “LACTOSE-FREE” shall be conspicuously labelled on the container in capital and bold letters; vi) In case the product contains neither milk nor any milk derivatives, the words “CONTAINS NO MILK OR MILK PRODUCTS” shall be conspicuously labelled on the container in capital and bold letters; vii) In case the product is for infants with allergy to milk protein of cow/buffalo/other milch animal (as specified under Cl. 4 of IS 13688), the words “HYPOALLERGENIC FORMULA” shall be conspicuously labelled on the container in capital and bold letters; viii) Feed chart and directions for use; ix) Instructions for discarding leftover feed; x) Instructions for use of measuring scoop (level or heaped) and the quantity per scoop (scoop to be given with pack)
Annex B	Sampling Plan for Microbiological Requirements has been incorporated