

**File No. 7(2)/2016/Ministry/Enf./RCD/FSSAI(PF)**  
**Food Safety and Standards Authority of India**  
**(A Statutory body under Ministry of Health and Family Welfare)**  
**(Regulatory Compliance Division)**

FDA Bhavan, Kotla Road,  
New Delhi-110 002  
Dated, the 17<sup>th</sup> September, 2020

To

The Commissioner of Food Safety of all States/UTs  
The Central Licensing Authorities

**Subject: Licensing of Infant Foods other than those specified under sub-regulations 2.1.19 of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011**

Sir/Madam,

The standards for 'Foods for Infant Nutrition' have been specified under sub-regulation 2.1.19 of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

2. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution Act, 1992) stipulates that any such infant food products which do not have standards under FSS Act, 2006 are required to seek prior approval of the Central Government. The provision has been further elaborated under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, which specifies that 'An article of infant milk substitutes /infant foods, whose standards are not prescribed under Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011 shall be manufactured for sale, exhibited for sale or stored for sale only after obtaining the approval of such articles of food and its label from the Authority.'

3. Further, the FSS (Prohibition and Restriction on Sales) Regulations, 2011 also specify that 'No person shall manufacture, sell, store or exhibit for sale, an infant milk food, infant formula and milk cereal based weaning food, processed cereal based weaning food and follow up formula except under Bureau of Indian Standards Certification Mark.'

4. In view of the above, the licensing authorities are directed to ensure strict compliance of the aforesaid provisions for infant foods enshrined under IMS Act, 1992 and FSS Act, 2006. The infant foods which do not comply with the standards under FSS (Food Products Standards and Food Additives) Regulations, 2011 shall be required to seek approval under FSS (Approval for Non-Specified Foods and Food Ingredients) Regulations, 2017 prior to seeking an FSSAI license.

  
(Dr. Shobhit Jain)

Executive Director  
Regulatory Compliance Division

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