

INDIA

Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, as Amended in 2003

In exercise of the powers conferred by section 26 of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (41 of 1992), the Central Government hereby makes the following rules further to amend the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, namely:-

1. Short title and commencement
 - (1) These rules may be called the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules 1993, as amended in 2003.
 - (2) They shall come into force on the 1st Day of January, 2004.
2. Definitions
 - (1) In these rules, unless the context otherwise requires
 - (a) "Act" means the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 1992, as amended in 2003;
 - (b) "authorised officer" means an officer not below the rank of a Class I (Group A or whatever name called) officer of the Government duly authorised by the State Government under section 12;
 - (c) "Food inspector" means a person appointed by the Government as such under sector 9 of the Prevention of Food Adulteration Act, 1954 (37 of 1954);
 - (d) "Section" means a section of the Act.
 - (2) Words and expressions used in these rules and not defined but defined in the Act shall have the respective meanings assigned to them in the Act.
3. Local limits of jurisdiction of food inspectors. The local limits of jurisdiction of food inspectors shall be the same as are assigned to them under the Prevention of Food Adulteration Act, 1954 (37 of 1954).
4. Authorised officers
 - (1) No officer of the Government shall be authorised by the State Government under section 12 unless he is:
 - (a) a medical officer in charge of health administration of a local area; or
 - (b) a graduate in medicine and has received at least one month's training in food inspection under the Prevention of Food Adulteration Act, 1954 (37 of 1954) by the Central Government or a State Government.
 - (2) The State Government may, by notification in the Official Gazette, define the local limits of jurisdiction of authorised officers.

5. Conditions and restrictions for donations and distribution of infant milk substitutes or infant foods or feeding bottles or equipment and materials relating to them through health care system. No institution, organisation or health worker in private practice, pharmacy, drug store or any association of health workers, engaged in health care for mothers, infants or pregnant woman, shall donate or distribute any educational or other informational or communication aids relating to infant milk substitutes or infant food or feeding bottles without complying with the following conditions and restrictions, namely:
- (a) the donee should be informed in writing on:
 - (i) the need for promoting breastfeeding;
 - (ii) the nutritional superiority of mother's milk;
 - (iii) the benefits of breastmilk, that is to say that breastmilk is:
 - (A) the best natural food for infants;
 - (B) always clean;
 - (C) protects the infant from infection and diseases;
 - (D) available always;
 - (E) requires no special preparation;
 - (iv) that breastfeeding helps parents to space their children.
 - (v) the danger of microbial contaminations involved in bottle feeding.
 - (b) informational or educational equipment or material relating to infant milk substitutes or feeding bottles should be donated or distributed only in case it is found necessary for healthy growth of the infant by a medical practitioner.
6. Language of the notice and other particulars of declaration.
- (1) No person shall produce, supply or distribute any infant milk substitute or infant food unless the container thereof or any label affixed thereto indicates in a clear, conspicuous and in an easily readable and understandable manner the words "IMPORTANT NOTICE", in capital letters in English and its equivalent in Hindi in Devnagri script.
Provided that nothing herein contained shall prevent the use of any local language in addition to the language required to be used under this sub-rule.
 - (2) The particulars of declaration to be specified on the label under the Prevention of Food Adulteration Act, 1954 (37 of 1954) and the rules made thereunder shall be in English or in Hindi in Devnagri script.
Provided that nothing herein contained shall prevent the use of any language in addition to the language required to be used under this sub-rule.
7. Particulars of labelling of infant milk substitutes and infant foods. In addition to the requirements specified by or under the Prevention of Food Adulteration Act, 1954 and under section 6 of the Act, the label or the container of every infant milk substitute or infant food shall conform to the following, namely:

- (a) the types of letters used shall not be less than 5 millimetres in size.
- (b) the colour of the text printed or used shall be different from that of the background of the label, container, as the case may be.
- (c) the text of the particulars shall be prominent and conspicuous in the central panel of the label, container.
- (d) it shall indicate:
 - (i) that an infant milk substitute or an infant food should be prepared appropriately and hygienically besides taking adequate care in cleaning of utensils, bottles and teats.
 - (ii) a warning against health hazards of inappropriate preparation as under:

"Infant milk substitutes / Infant foods"

"Warning / caution Careful and hygienic preparation of infant food is most essential for health. Do not use fewer scoops than directed, since diluted feeding will not provide adequate nutrients needed by your infant. Do not use more scoops than directed since concentrated feed will not provide the water needed by your infant."
 - (iii) the approximate composition of nutrients per 100 grams of product including its energy value in calories.
 - (iv) the storage conditions specifically stating "Store in cool and dry place in an air-tight container" or the like.
 - (v) the feeding chart and direction for use and instruction for discarding left over feed, the batch number and date of manufacture.
 - (vi) instructions for use of measuring scoop (level or heaped) and the quantity per scoop.
 - (vii) the prescribed period by which the infant milk substitutes or the infant foods, as the case may be is to be consumed.
 - (viii) the Protein Efficiency Ratio (PER) which shall be minimum of 2.5 if the product other than the infant milk substitutes and infant foods is claimed to have high quality protein.

8. Particulars which a label or container should not contain. Without prejudice to the requirements under the Prevention of Food Adulteration Act, 1954 (37 of 1954) and the rules made thereunder, the following restrictions on use of words in any language on the label or container, as the case may be, shall be applicable:

- (a) the label or container shall not contain any reference to the Act or these rules or any comment on, or reference to, or explanation of any particulars or declaration required by the Act or any of these rules to be included in the label which directly or by implication, contradicts, qualifies or modifies such particulars or declaration.

- (b) no words implying "recommended by the medical profession" or any words which imply or suggest that the food is recommended, prescribed or approved by medical practitioners shall be used in a label or container.
 - (c) the label or container shall not contain the terms "Humanised" or "Maternalised" or any other similar expressions in any language.
 - (d) no label or container of infant food shall exhibit the words "Full Protein Food", "Energy Food", "Complete Food" or "Health Food" or any other similar expressions in any language.
9. Details of information intended to reach pregnant women or mothers of infants through education or other material.
- (1) Every educational or other material, whether audio or visual, dealing with pre-natal or post-natal care or with the feeding of an infant and intended to reach pregnant women and mothers of infants shall, besides the information specified in clauses (a) to (f) of sub-section (1) of section 7 shall include:
- (a) the following details of advantages, as also nutritional superiority of breastfeeding:
 - (i) Immediately after delivery, breastmilk is yellowish and sticky. This milk is called colostrum, which is secreted during the first week of delivery. Colostrum is more nutritious than mature milk because it contains more protein, more anti-infective properties which are of great importance for the infant's defence against dangerous neonatal infections. It also contains higher levels of Vitamin 'A'.
 - (ii) breastmilk:
 - (A) is a complete and balanced food and provides all the nutrients needed by the infant in the first six months of life;
 - (B) has anti-infective properties that protect the infants from infection in the early months;
 - (C) is always available;
 - (D) needs no utensils or water (which might carry germs) or fuel for its preparation;
 - (iii) breastfeeding is much cheaper than feeding infant milk substitutes as the cost of the extra food needed by the mother is negligible compared to the cost of feeding infant milk substitutes;
 - (iv) mothers who breastfeed usually have longer periods of infertility after child birth than non-lactators.
 - (b) details of management of breastfeeding as under:
 - (i) breastfeeding:
 - (A) immediately after delivery enables the contraction of the womb and helps the mother to regain her figure quickly;

- (B) is successful when the infant suckles frequently and the mother wanting to breastfeed is confident in her ability to do so.
- (ii) in order to promote and support breastfeeding the mother's natural desire to breastfeed should always be encouraged by giving, where needed, practical advice and making sure that she has the support of her relatives.
 - (iii) adequate care for the breast and nipples should be taken during pregnancy.
 - (iv) it is also necessary to put the infant to the breast as soon as possible after delivery.
 - (v) let the mother and the infant stay together after the delivery, the mother and her infant should be allowed to stay together (in hospital, this is called "rooming-in").
 - (vi) give the infant colostrum as it is rich in many nutrients and anti-ineffective factors protecting the infants from infections during the few days of its birth.
 - (vii) the practice of discarding colostrum and giving sugar water, honey water, butter or other concoctions instead of colostrum should be very strongly discouraged.
 - (viii) let the infants suckle on demand.
 - (ix) every effort should be made to breastfeed the infants whenever they cry.
 - (x) mother should keep her body and clothes and that of the infant always neat and clean.