

## Chapter - 6

# THE INFANT MILK SUBSTITUTES, FEEDING BOTTLES AND INFANT FOODS (REGULATION OF PRODUCTION, SUPPLY AND DISTRIBUTION) ACT, 1992

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (hereinafter referred as the “Act”) aims at advancing the cause of breast feeding in preference to the growing trends of bottle feeding. It, therefore, prohibits advertisement of infant milk substitutes and feeding bottles. Measures have been prescribed to ensure that in the marketing of infant milk substitutes, no impression should be given that feeding of these products is equivalent to or better than breast-feeding. The Act contains provisions relating to prohibition of incentives for use or sale of infant milk substitutes, feeding bottles and infant foods. It further provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to protect the interests of the consumers and to ensure proper use of infant foods. The provisions of the present Act are supplementary and not in derogation of the Prevention of Food Adulteration Act, 1954.<sup>1</sup>

The Act provides that no person should produce, supply or distribute any infant milk substitute or infant food unless every container thereof or any label affixed thereto indicates in a clear, conspicuous and in an easily readable and understandable manner, the word “important notice” in the capital letters in such language as may be prescribed and indicate thereunder that mother’s milk is best for baby. There are many more guidelines that are helpful for consumers, but unfortunately the Act is not being implemented in an effective manner. Agencies responsible for consumer education and the concerned departments (child welfare, public health department etc.) which are supposed to support the breast feeding movement need to be better activated to perform their duties. Women should be sensitised to prepare them to reject artificial way of feeding their babies.

The Act gives a wide import to the term “advertisement” which has been defined to include any notice, circular, label, wrapper and other documents and also includes any visible representation or announcement

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1. *Id.*, sec. 25.

made by means of any light, sound, smoke or gas.<sup>2</sup> “Label” means a display of written, marked, stamped, printed or graphic matter affixed to, or appearing upon, any container.<sup>3</sup> Similarly, the term “container” includes any box, bottle, casket, tin, can, barrel, case, tube receptacle, sack, wrapper or other thing in which any infant milk substitute feeding bottle or infant food is placed or packed for sale or distribution.<sup>4</sup> Some other relevant terms have also been defined under the Act to give certainty to their meanings. The “feeding bottle” means any bottle or receptacle used for the purpose of feeding infant milk substitutes and includes a teat and a valve attached or capable of being attached to such bottle or receptacle.<sup>5</sup> The “health care system” means an institution or organisation engaged, either directly or indirectly, in health care for mothers, infants or pregnant women and includes a health worker in private practice, but does not include a pharmacy or drug store.<sup>6</sup> Any person engaged in health care for mothers, infants or pregnant women is called a “health worker”.<sup>7</sup> Any food (by whatever name called) being marketed or otherwise represented as a complement to mother’s milk to meet the growing nutritional needs of the infant after the age of four months is termed as ‘infant food’<sup>8</sup>, and any food being marked or otherwise represented as a partial or total replacement for mother’s milk, whether or not it is suitable for such replacement, is called “infant milk substitute”.<sup>9</sup>

## I Prohibition of Advertisements

Section 3 of the Act prohibits advertisements and taking part in the publication of any advertisement for the distribution, sale or supply of infant milk substitutes or feeding bottles. Clause (b) of section 3 prohibits in express and clear terms giving an impression or creation of a belief that feeding of infant milk substitutes and infant foods are equivalent to or better than mother’s milk. Taking part in the promotion of infant milk substitutes, feeding bottles or infant food is also prohibited.<sup>10</sup>

The Act prohibits the measures taken for promoting use or sale of infant milk substitutes or feeding bottles including supply or distribution of samples of infant milk substitutes or feeding bottles and infant foods or gifts of utensils or other articles. It also restricts contacting any pregnant woman

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2. The Infant Milk Substitutes, Feeding Bottles and Infant Food (Regulation of Production, Supply and Distribution) Act, 1992, sec. 2(a).

3. *Id.*, sec. 2(h).

4. *Id.*, sec. 2(b).

5. *Id.*, sec. 2(c).

6. *Id.*, sec. 2(d).

7. *Id.*, sec. 2(e).

8. *Id.*, sec. 2(f).

9. *Id.*, sec. 2(g).

10. *Id.*, sec. 3(c).

or the mother of an infant in connection with any such promotion. There should not be offering of any other kind of inducement for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles and infant foods.<sup>11</sup> Accordingly, no person can donate or distribute infant milk substitutes or feeding bottles and infant foods to any person except to an orphanage.<sup>12</sup> Giving any informational or educational equipment or material relating infant milk substitutes or feeding bottles and infant foods is also restricted.<sup>13</sup> Donation or distribution of such equipments and materials through the health care system under prescribed conditions and restrictions is allowed.<sup>14</sup>

## II Regulatory Mechanism

### ***Information to be given on containers and labels***

The Act requires the producers, suppliers and the distributors of any infant milk substitute or infant food to indicate on every container or its label in a clear, conspicuous and an easily readable and understandable manner, the words "important notice" in capital letters. It should be in such a language as may be prescribed in this behalf. Under this indication, the following particulars should be given:<sup>15</sup>

- (a) mother's milk is best for your baby' (in capital letters);
- (b) infant milk substitutes or infant food should be used only on the advice of a health worker as to the need for its use and the proper method of its use;
- (c) infant milk substitutes or infant food is not the sole source of nourishment of an infant;
- (d) the instructions for its appropriate preparation and a warning against the health hazards of its inappropriate preparation.
- (e) the composition or analysis;
- (f) the storage conditions required; and
- (g) the batch number, date of its manufacture and the date before which it is to be consumed, taking into account the climatic and storage conditions of the place.

Such other particulars as may be prescribed from time to time would also have to be so indicated.

A container or its label, containing infant milk substitute, should not have pictures of an infant or a woman or both. It should not also have

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11. *Id.*, sec. 4.

12. *Id.*, sec. 5(a).

13. *Id.*, sec. 5(b).

14. *Id.*, proviso to sec. 5.

15. *Id.*, sec. 6(1).

pictures or other graphic material or phrases designed to increase the saleability of infant milk substitute. Use on it of the words "humanized" or "materialized" or any other similar word has been prohibited or such other particulars as may be prescribed has been prohibited.<sup>16</sup>

### ***Nature of educational and other materials for consumers***

Section 7 of the Act provides that every educational or other material, including advertisements or materials relating to promotion of infant milk substitutes, feeding bottles and infant foods, 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 or mothers of infants should include clear information relating to the benefits and superiority of breast-feeding. It should also mention the harmful effects of breast-feeding due to the partial adoption of bottle-feeding and the difficulties in reverting to breast-feeding of infants after a period of feeding by infant milk substitutes and feeding bottles. The financial and social implications in making use of infant milk substitutes and feeding bottles should also be mentioned. The health hazards of improper use of infant milk substitutes and feeding bottles and such other matters as may be prescribed should also be mentioned. The materials should particularly bear the date of printing and publication of such materials alongwith the name of the printer and publisher.

### ***Restriction on misuse of health care system***

Section 8 of the Act prohibits use of any health care system or the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods. However, as mentioned above, the donation or distribution of informational or educational equipment or material and the dissemination of information to a health worker about the scientific and factual matters relating to the use of infant milk substitutes or feeding bottles or infant foods alongwith the information specified in section 7 is allowed.

Any person who produces, supplies, distributes or sells infant milk substitutes or feeding bottles or infant foods cannot make any payment to any person who works in the health care system for the purpose of promoting the use or sale of such substitutes or bottles or foods.<sup>17</sup> This restriction is important because only a health worker is permitted to demonstrate feeding with infant milk substitutes to the mother of an infant or to any member of her family, after clearly explaining to such mother or such other member of her family, the hazards of improper use of infant milk

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16. *Id.*, sec. 6(2).

17. *Id.*, sec. 8(2).

substitutes or feeding bottles or infant foods.<sup>18</sup>

Distribution of infant milk substitutes or feeding bottles to any mother, who cannot resort to breast-feeding and who cannot afford to purchase infant milk substitutes or feeding bottles, can be made by an institution or organisation, engaged in health care for mothers, infants or pregnant women.<sup>19</sup> An orphanage is allowed to purchase infant milk substitutes or feeding bottles at a price lower than their sale price for the purpose of utilizing them in the said orphanage.<sup>20</sup> Such purchases cannot be treated as an inducement for promoting the use or sale of infant milk substitutes or feeding bottles.

Thus, no person can use health care system or the display of placards or posters for the distribution of materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods. Persons, who produce, supply, distribute or sell infant milk substitutes or feeding bottles or infant foods, cannot make any payments to any person working in the health care system for the purpose of promoting the use or sale of such substitutes or bottles or food.

Persons who produce supply, distribute or sell infant milk substitutes or feeding bottles or infant foods are restricted from offering or giving, directly or indirectly, any financial inducements or gifts to any health worker or to any member of his family for the purpose of promoting the use of such substitutes or bottles or foods.<sup>21</sup> No producer of these commodities can offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of any seminar, meeting, conference, educational course, contest, fellowship, research work or sponsorship.<sup>22</sup>

### ***Restriction on fixing salary as per sale and giving commission***

Since in the present day market, sales are promoted by giving commission to employees on the basis of the volume of sale, the Act prohibits producers, suppliers, distributors and sellers of infant milk substitutes, feeding bottles and infant foods from fixing remuneration of any of his employees or give any commission to them on the basis of the volume of sale of their products made by such employees.<sup>23</sup> Such employees are restricted from the performance of any function which relates to educating a pregnant woman or mother of an infant on pre-natal care of the infant.<sup>24</sup>

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18. *Id.*, sec. 8(3).

19. *Id.*, sec. 8(4).

20. *Id.*, sec. 8(5).

21. *Id.*, sec. 9(1).

22. *Id.*, sec. 9(2).

23. *Id.*, sec. 10(1).

24. *Id.*, sec. 10(2).

### III Standard of Infant Milk Substitutes

In order to maintain the standards of infant milk substitutes, the Act prohibits their sale and distribution if they do not conform to the standards, specified thereto under the Prevention of Food Adulteration Act, 1954. The container thereof should carry the relevant standard mark specified by the Bureau of Indian Standards to indicate that the infant milk substitute or infant food conforms to such standards.<sup>25</sup> In the absence of specification of such standards any infant milk substitute or infant food substitute or food can be sold or distributed only after obtaining the approval of the central government and fixation of a label regarding that to the container.<sup>26</sup> Thus, any infant milk substitute or a feeding bottle can be sold or otherwise distributed only after conforming to the standard mark specified by the Bureau of Indian Standards for feeding bottles and such mark having been affixed on its container.<sup>27</sup>

### IV Powers of Entry, Search and Seizure

#### *Entry and search*

Section 12 of the Act empowers any food inspector appointed under section 9 of the Prevention of Food Adulteration Act, 1954 or any officer authorised in this behalf by the state government to enter and search any factory, building, business premises or any other place where any trade or commerce in infant milk substitutes or feeding bottles or infant foods is carried on or such substitutes or foods are produced, supplied or distributed in contravention to its provisions. Before taking any such action, the officer concerned should have reason to believe that such contravention is taking place. Entry or search can be carried out at any reasonable time.<sup>28</sup> The provisions of the Cr PC relating to searches and seizures, so far as may be, apply to every search or seizure made under this Act.<sup>29</sup>

#### *Seizure and confiscation*

The inspector or authorised officer may seize such milk substitutes or bottles or food or containers on a reasonable belief that the provisions of the Act are being contravened.<sup>30</sup> These can, however, not be retained by any food inspector or authorised officer for a period exceeding ninety days from the date of their seizure. The period can be extended with the approval

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25. *Id.*, sec. 11(1).

26. *Id.*, proviso to sec. 11(1).

27. *Id.*, sec. 11(2).

28. *Id.*, sec. 12(1).

29. *Id.*, sec. 12(2).

30. *Id.*, sec. 13(1).

of the district judge concerned.<sup>31</sup> The infant milk substitutes or feeding bottles or infant food or containers are also liable to confiscation for the contravention of the provisions of the Act. However, where it is established to the satisfaction of the adjudging court that the person in whose possession, power or control these articles were found is not responsible for the contravention, the court may, instead of confiscation, make some other appropriate order depending on the nature of the case.<sup>32</sup>

Accordingly, the court may, on specified conditions, give to the owner an option to pay in lieu of confiscation a proper cost to be determined by the court itself. Such cost should not exceed the value of the articles which are subject to confiscation proceeding.<sup>33</sup> On the payment of the cost, the seized items have to be returned to the person concerned on the condition that before making any distribution, sale or supply of such things, he should follow the requirements of the Act.<sup>34</sup> Confiscation or the payment of cost in the said manner does not exonerate the accused from any punishment to which he is liable under this Act or under any other law.<sup>35</sup>

### **Adjudication regarding confiscation**

As regard adjudication, under section 17 any confiscation may be adjudged by the principal civil court of original jurisdiction within the local limits of whose jurisdiction such confiscation has been made. Jurisdiction about making orders of cost of the properties under confiscation also lies with the same court. In the Act, no limit has been fixed for the payment of costs.<sup>36</sup> It would be subject to such limits as the central government may specify in this behalf. The adjudging court can be only a civil court having pecuniary jurisdiction exceeding five thousand rupees.<sup>37</sup>

The confiscation or payment of costs should be ordered only after the owner of the related infant milk substitutes or feeding bottles or infant foods or containers has been given a notice in writing informing him of the grounds of their confiscation. He should be given reasonable opportunity of making a representation in writing against the confiscation and of being heard in the matter. Time period allowed for making representation should be reasonable and specifically mentioned in the notice.<sup>38</sup> Where no such notice is given within a period of ninety days from the date of the seizure, the confiscated articles should be returned to the person from whose

31. *Id.*, sec. 13(2).

32. *Id.*, sec. 14.

33. *Id.*, sec. 15(1).

34. *Id.*, sec. 15(2).

35. *Id.*, sec. 16.

36. *Id.*, sec. 17(a).

37. *Id.*, sec. 17(b).

38. *Id.*, sec. 18(1).

possessions they were seized.<sup>39</sup> The provisions of the CPC apply to every such proceeding.<sup>40</sup> Thus, no order adjudicating confiscation or directing payment of costs can be made unless the owner of the infant milk substitutes or feeding bottle or infant food or container thereof has been given a notice in writing informing him of the grounds of the proposed confiscation, and given reasonable opportunity to make a representation against the confiscation.

### **Appeals regarding confiscation**

Appeal can be preferred against any decision of the court adjudicating a confiscation or ordering the payment of costs in the court to which an appeal lies from the decision of such court. The appellate court may, after giving the appellant an opportunity of being heard, confirm, modify or revise such decision or order or may send back the case with specific directions for a fresh decision or adjudication after taking additional evidence if necessary.<sup>41</sup> However, on appeal any fine in lieu of confiscation or for confiscating goods of greater value cannot be enhanced without giving the appellant an opportunity of making a representation or of being heard in his defence.<sup>42</sup> The orders passed on such appeal are not further appealable.<sup>43</sup>

## **V. Penalties and Cognizance of Offences**

The offences regarding prohibition on advertisements under the Act are punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees, or with both.<sup>44</sup> The contraventions regarding regulation of permissible advertisements are punishable with imprisonment for a term from six months to three years and with fine of not less than two thousand rupees.<sup>45</sup> However, the court can, for any adequate and special reasons to be mentioned in the judgment, impose a lesser sentence of imprisonment for a term of less than three months to two years and with fine of not less than one thousand rupees.<sup>46</sup>

Cognizance of offences punishable under the Act can be taken only on a written complaint made by the authorized person or a representative of any voluntary organization engaged in the field of child welfare and development and child nutrition.<sup>47</sup> If in any case a complaint has been

39. *Id.*, proviso to sec. 18(1).

40. *Id.*, sec. 18(2).

41. *Id.*, secs. 19(1) and (2).

42. *Id.*, proviso to sec. 19(2).

43. *Id.*, sec. 19(3).

44. *Id.*, sec. 20(1).

45. *Id.*, sec. 20(2).

46. *Id.*, proviso to sec. 20(2).

47. *Id.*, sec. 21(b).



made by a representative of the voluntary organization and the court has issued a summons under section 204 (1) Cr PC, dealing with issuance of summons and warrants, the assistant public prosecutor for that court has to take the charge of the case and conduct the prosecution.<sup>48</sup>

As regards offences by companies, the person in charge and responsible to a company for the conduct of the business of the company at the time of commission of the offence would be deemed guilty and liable to be proceeded against. However, if any such person proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence, he would not be liable.<sup>49</sup> If it is proved that the offence had been committed with the consent or connivance of, or any neglect on the part of any director, manager, secretary or other officer of the company, such a person responsible would be liable to be proceeded against and punished accordingly.<sup>50</sup>

The offences punishable under the Act are bailable and cognizable.<sup>51</sup> Anything done or intended to be done by any authority under the Act in goodfaith cannot be subject to prosecution or any other legal proceedings.<sup>52</sup>

## VI. Implementation Measures

The powers of search under the Act can be vested by the government in the medical officer, in charge of health administration, of a local area or a graduate in medicine who has received at least one month's training in food inspection and sampling work, approved for the purpose by the central or the state government.<sup>53</sup>

Any institution, organization or health worker in private practice, engaged in health care for mothers, infants or pregnant women, can donate or distribute any educational or other informational or communication aids relating to infant milk substitutes or feeding bottles only after informing the donor about:<sup>54</sup>

- (a) the need for promoting breast feeding;
- (b) the nutritional superiority of mother's milk;
- (c) the benefits of breast milk, that is to say, that breast milk is –

48. *Id.*, sec. 21(2).

49. *Id.*, sec. 21(1).

50. *Id.*, sec. 22(2). For these purposes, "company" means any body corporate and includes a firm or other association of individuals; and "director", in relation to a firm, means a partner in the firm.

51. *Id.*, sec. 23.

52. *Id.*, rule 24.

53. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993, rule 4.

54. *Id.*, rule 5.

- (i) the best natural food for infants,
  - (ii) always clean,
  - (iii) protects the infant from infection and diseases,
  - (iv) always available, and
  - (v) requires no special preparation
- (d) that breast feeding helps parents to space their children; and
- (e) the danger of microbial contamination involved in bottle feeding.

Before any informational or educational equipment or material relating to infant milk substitutes or feeding bottles is donated or distributed, it should be confirmed through a medical practitioner that such an equipment or material is necessary for the healthy growth of the infant.<sup>55</sup>

So far as indications to be given on the label are concerned, the container of any infant milk substitute or infant food or any label affixed to that should indicate, besides the words "IMPORTANT NOTICE", its equivalent in Hindi in *Devnagri* script.<sup>56</sup> Any local language may also be used in addition to the above language.<sup>57</sup> The type of letters used for labeling should not be less than 5 millimeters in size for IMPORTANT NOTICE and the statement MOTHER'S MILK IS BEST FOR YOUR BABY. The colour of the text printed or used should be different from that of the background of the label, container or the advertisement, as the case may be. It should also carry a warning against health hazards of inappropriate preparation as under:<sup>58</sup>

### **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 dilute 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 needs of your infant".

The other indications include:<sup>59</sup>

- (a) the approximate composition of nutrients per 100 grams of product including its energy value in calories.
- (b) The storage conditions specifically stating "Store in cool and dry place in an air-tight container" or the like.

55. *Id.*, rule 5(b).

56. See *supra*, "Regulatory Mechanism" in this chapter".

57. *Id.*, rule 6.

58. *Id.*, rule 7.

59. *Ibid.*

- (c) The feeding chart and directions for use and instructions for discarding left over feed, the batch number and date of manufacture.
- (d) Instructions for use of measuring scoop (level or heaped) and the quantity per scoop.
- (e) The prescribed period by which the infant milk substitutes or the infant food, as the case may be, is to be consumed.
- (f) The Protein Efficiency Ratio (PER) which shall be minimum of 2.5 if the product other than the infant milk substitutes and infant foods in claimed to have high quality protein.

Indications not to be given on the label include:<sup>60</sup>

- (1) any reference to the Act or rules thereunder 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;
- (2) 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;
- (3) the terms like "Humanized" or "Materialized"; "Full of Protein Food," "Energy Food", "Complete Food" or "Health Food" or any other similar expressions in any language.

### **Indications for pregnant women**

Rule 9 of the Infant Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Rules, 1993 makes it obligatory in the interest of consumers that any 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 should give the details about advantages and the nutritional superiority of breast feedings.<sup>61</sup> Thus, they should be educated about all important matters related to the safety of the child. They should be told that immediately after delivery, breast milk is yellowish and sticky. This milk is called colostrum, which is secreted during the first week of delivery. Colostrum is more nutritious than that of mature milk because it contains more protein, more anti-infective properties which are of great importance for the infant's defence against dangerous neo-natal infections. It also contains higher levels of Vitamin 'A'. It should explained to the pregnant women that the breast milk is a complete and balanced food containing all

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60. *Id.*, rule 8.

61. They are in addition to the information specified in sec. 7(1), clauses (a) to (f).

the nutrients needed by the infant in the first few months of its birth and has anti-infective properties that protect the infant from infection in the early months. It is always available and needs no utensils or water (which might carry germs) or fuel for its preparation. Breast feeding 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. The prospective mothers should know that a mother who breast feeds usually has longer periods of infertility after child birth than non-lactators. It enables immediate contraction of the womb and helps the mother to regain her figure quickly. It is successful when the infant suckles frequently and the mother wanting to breast-feed is confident in her ability to do so. In order to promote and support breast feeding, the mother's natural desire to breast feed should always be encouraged by giving, where needed, practical advice and making sure that she has the support of her relatives. Adequate care for the breast and nipples should be taken during pregnancy and the infant should be put to the breast as soon as possible after delivery. The mother and the infant should stay together after the delivery, (in hospital, this is called "rooming-in").

The infant should be give colostrum as mentioned above and the practice of discarding colostrum and giving sugar water, honey water, butter or other concoctions instead of colostrum should be very strongly discouraged. The infants should be suckled on demand and every effort should be made to breast feed the infants whenever they cry. A mother should keep her body and clothes and that of the infant always neat and clean.