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Government of the People's Republic of Bangladesh

Ministry of Health and Family Welfare

Health Service Division

NOTIFICATION

Dated 6 August 2017 A.D./ 22 Srabon 1424 BS

S.R.O. No. 261-Law/2017.- In exercise of the powers conferred under section 21 of the Breast-milk Substitutes, Infant Foods, Commercially Manufactured Complementary Foods and the Accessories thereof (Regulation of Marketing) Act, 2013 (Act No. 35 of 2013), the Government has made the following rules, namely-

1. **Title-** These rules shall be called, the Breast-milk Substitutes, Infant Foods, Commercially Manufactured Complementary Foods

and the Accessories Thereof (Regulation of Marketing) Rules, 2017.

2. **Definitions.-** (1) Unless there is anything repugnant to the subject or context, under Rules,-

(a)“Act” means the Breast-milk Substitutes, Infant Foods, Commercially Manufactured Complementary Foods and the Accessories Thereof (Regulation of Marketing) Act, 2013 (Act No. 35 of 2013);

(b)“National Advisory Committee” or “Committee” means the National Advisory Committee constituted in these Rules 7;

(c)“**Registration Certificate**” means any Registration Certificate issued under rule 10;

(d)“**Form**” means any form attached with these rules.

(2) The words or expressions used in these rules and not defined, shall have the meanings as assigned in the Act.

3. **Certain Prohibitions about Breastmilk Substitute, Infant Food, etc.-**

The following activities shall not be carried out or administered, for the purpose of clause 4 of the Act, namely:-

- (a) offering any sample of Breast-milk Substitutes, Infant Foods, Commercially Manufactured Complementary Foods and the Accessories Thereof (for example, bottle, nipple, pacifier, cup, etc.) to any infant, mother of an infant or their caregivers or any health service providers or health workers;
- (b) delivery of any speech or giving any statement including demonstration of any picture on excellence of bottle feeding;
- (c) administering out any such activities in conflict of interest with the purpose of the Act and contrary to the prohibitions imposed under sub-clause (i) of clause (b) of sub-section (2) of section 4 of the Act;
- (d) circulating or sending any misleading or tempting information or message on child health affairs, enhancement of physical and mental development of the child, improved nutritional value of Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary foods or its risk-freeness to any pregnant woman, lactating mother, infant's mother, infant's caregiver or guardian through organising any activities or programs with the assistance or funding of any importer, locally producer, distributor, marketing agency or seller;

- (e) observing any special week or day by any importer, locally producer, distributor, marketing agency or seller of Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Foods and the Accessories for the purpose of its promotion and advertisement;
- (f) giving commission, providing financial benefit or any gift to any seller or worker of any health service center on the sale of Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Foods and the Accessories;
- (g) assisting or participating in any informative and educational programs or circulating or disseminating any information on the health of mother and child, food and nutrition by any importer, locally producer, distributor, marketer or seller of Breastmilk Substitute, Infant Foods, Commercially Manufactured Complementary Foods and any Accessories thereof .

4. Rules to be followed while issuing Prescription of Breastmilk Substitute.- To carry out the purpose of the Act, if it is considered extremely indispensable in order to save child life and reduce health hazards or risks, any registered medical practitioner under the Bangladesh Medical and Dental Council Act, 2010 (Act No. 61 of 2010) may, on the basis of appropriate evidences or proofs, provide necessary advice including prescription on any Breastmilk Substitute only.

5. Relevant information relating to breastmilk substitutes, infant foods, etc. on the receptacle and label. (1) To carry out the purpose of section 6 of the Act, under the heading of “Important Information” on the receptacle and label attached thereto of any Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food or any Accessories thereof-

(a) a statement shall be printed as “to reduce health hazards or risks of the child, Breastmilk Substitute Powdered Infant Formula should be prepared appropriately as it may contain “PATHOGENIC MICROORGANISM”;

(b) the following information shall be printed or depicted, namely:-

(i) instructions to be followed in case of feeding any Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food printed or mentioned on the label of the container or packet.

(ii) warning about deterioration of child health due to not following instructions specified in sub-rule (i).

(2) To carry out the purpose of clause (d) of sub-section (2) of section 6 of the Act, the following statement shall not be affixed with receptacle or label attached to receptacle of Breastmilk Substitute, Infant

Food, Commercially Manufactured Complementary Food and the Accessories thereof in Bangla or any other languages, namely:-

(a) “this product is approved, advised or instructed by physician” or any other expression or statement of similar nature;

(b) this product is “complete protein food” or “energy yielding food” or “complete food” or “healthy food” or any other expression or statement of similar nature.

(3) The size of the logo or mark of the concerned companies of Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food and the Accessories thereof affixed with label attached to receptacle shall not be more than half of the name of that product.

6. Other Information to be Included in the Educational or Informative Materials.- To carry out the purpose of clause (h) of section 7 of the Act, the following information shall be included in the educational or informative materials, namely:-

(a) information to child’s mother or caregiver about the techniques of breastfeeding;

(b) initiation of breastfeeding within 1 hour reduces the risk of neonatal death;

- (c) breastmilk is a complete and balanced food for child;
- (d) breastmilk is empowered with prevention of diseases;
- (e) breastmilk is inexpensive;
- (f) the possibility of pregnancy of exclusively breastfeeding mother is reduced, if the infant is breastfed upto 6(six) months of age after birth.

7. Formation of National Advisory Committee.- National Advisory Committee shall be formed consisting the following members under section 8 of the Act, namely:-

- (a) Secretary, Ministry of Health and Family Welfare, who shall also be its Chairperson;
- (b) an officer, not below the rank of Joint-Secretary, nominated by the Ministry of Commerce;
- (c) an officer, not below the rank of Joint-Secretary, nominated by the Ministry of Women and Children Affairs;
- (d) an officer, not below the rank of Joint-Secretary, nominated by the Legislative and Parliamentary Affairs Division;
- (e) Additional Director General (Administration), Directorate of Health Services;

- (f) Director (Administration), Directorate of Family Planning;
- (g) 1 (one) child specialist or nutritionist nominated by the Government;
- (h) 1 (one) representative nominated by the government from any non-government organisation working in the areas of breastfeeding and infant food;
- (i) Director, Public Health Nutrition Institute, who shall also be its Member Secretary.

8. Functions of the National Advisory Committee.- To carry out the purpose of clause (c) of section 9 of the Act, the National Advisory Committee shall carry out the following functions, namely:-

- (a) to advise the government to take appropriate action with a view to increase public awareness for implementation of the Act and this rule;
- (b) Identification of possible harmful effects due to not breastfeeding and advise the government to do the needful to resolve that.

9. Meetings of the National Advisory Committee, etc.- (1) The meetings of the National Advisory Committee shall be held on such date, time and place as determined by the Chairman:

provided that, there shall be at least one meeting of the Committee in every 3 (three) months.

(2) The chairman shall preside over all meetings of the Committee.

(3) To constitute a quorum at a meeting of the Committee, the presence of at least 5 (five) members of the Committee shall be required.

(4) Decision of a meeting of the Committee shall be taken with the majority votes of present members and in the event of tie of vote the chairman shall have a second or deciding vote.

(5) No action or proceedings of the meeting shall be invalid or no question shall be raised against it, due to the vacancy of the post of any member or any irregularity in the formation of the Committee.

(6) The Chairman, if necessary, may invite any national or international child specialist or nutritionist in the meeting.

10. Registration Certificate and Registration of Breastmilk Substitute, Infant Food, etc.- (1) An application shall be submitted to the Director in Form -'A' to register for the purpose to import, local production, marketing, sale or distribution of any Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food and the Accessories thereof.

(2) The following documents shall be attached along with the application under sub-rule (1) , namely:-

- (a) a Safety Certificate issued by appropriate authority from its country of origin that the Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food or the Accessories thereof is free from radioactivity;
- (b) a Certificate issued by the Bangladesh Atomic Energy Commission that the Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food or the Accessories thereof is free from radioactivity;
- (c) a copy of the Certificate issued by the Bangladesh Standards and Testing Institute (BSTI);
- (d) a copy of the Certificate issued by the Codex Alimentarius Commission;
- (e) the original copy of Treasury Chalan as a proof of submission of applicaiton fee of 10,000/-TK in the code of 1-2711-0090-2023;
- (f) Attested copy, if any, of Trade License,
- (g) Attested copy, if any, of Tax Identification Number;

- (h) The copy of Memorandum of Association, Article of Association and Certificate of Incorporation, if it is a company;
- (g) Any other document or information asked by the Director.

(3) After receiving the application within 30 (thirty) days submitted under sub-rule (1), the Director shall approve it, being satisfied after examining the submitted application and documents attached along with it and shall issue an order towards the applicant for depositing the 1,00,000/-TK registration fee through treasury chalan in the code mentioned in the clause (e) of sub-rule (2) within following 15 (fifteen) days.

(4) The Director shall reject the application, if he is not satisfied or required document or information under sub-rule (5) is not submitted, and shall inform the applicant about the matter along with the reasons of rejection within the following 7 (seven) days.

(5) If the Director thinks that, any important document or information is required to be examined for considering the application, he may issue an order towards the concerned applicant, within specified time limit, for submitting such document or information and the applicant shall be bound to submit such document or information accordingly.

(6) After receiving the registration fee from the applicant within the time limit specified under sub-rule (3), the Director shall register it within 15 (fifteen) days and shall record it in the registered book according to the Form-'B' and shall issue a registration certificate according to the Form 'C' to the applicant.

11. Renewal of Registration Certificate.- (1) To carry out the purpose of sub-section (5) of section 10 of the Act, before 6 (six) months of expiring the period of registration certificate, an application for renewal of registration certificate shall have to be submitted to the Director according to the Form 'D' along with renewal fee of 50,000/-TK through treasury Chalan in the code of 1-2711-0090-2023.

(2) If any application for renewal of registration certificate cannot be submitted within time specified in sub-rule (1), for any justified reason, an application for renewal of registration certificate can be submitted depositing the late fee as may be prescribed by the Director within 1 (one) month after its expiration period.

(3) After receiving the application under sub-rule (1), any provision of the Act or rules or any condition specified in the registration certificate regarding the registration period, -

- (a) has not been violated by the applicant, being satisfied, the director shall renew the registration certificate for the following 3 (three) years; or

(b) has been violated by the applicant, being confirmed, the director may reject such application and inform the applicant about it immediately.

(4) Until the application for renewal of registration certificate are not accepted or rejected under sub-rule (3), the registration certificate shall remain valid and all other activities can be, on the basis of that certificate, carried out except importation.

12. Mode of Paying the Compensation to the family of the victimized child.- (1) If any penalty is imposed against the accused person by the court under sub-section (2) of section 12 of the Act, the Court may issue an order to deposit such penalty as compensation in the bank account of father, mother or legal guardian of that victimized child under such sub-section.

Explanation.- For the purpose of this sub-rule, “Legal Guardian” means a legal guardian appointed or declared for the welfare of a children by the court under section 7 of the Guardian and Wards Act, 1890 (Act No. VIII of 1890).

(2) The Court may summon the account of properties including bank statement of such person for the purpose of depositing the full amount of compensation according to the direction and specified time limit given in that order by the Court.

(3) If the convicted person fails to carry out the Court order appropriately while paying the compensation, the victimized party shall inform the Court about such matter.

13. Repeal and Savings.-(1) On the commencement of this rule, the Breast-milk Substitute (Regulation of Marketing) Rules, 1993, hereinafter referred as the said rules, shall stand repealed/Stopped.

(2) Notwithstanding such repeal, under these repealed rules-

- (a) all acts done, actions taken or proceeding continued shall be treated as done, taken or continued under the said rules;
- (b) the issued registration certificate shall remain valid in such manner as if it issued under the said rules and an application for renewal shall have to be submitted within 30 (thirty) days before the expiry of such certificate under the said rules.

Form -'A'
[under rule 10(1)]
Application for Registration



To,
 The Director
 Public Health Nutrition Institute, Mohakhali, Dhaka.

Sir,

I/We
 (Name of the Company/Organization).....
 Address.....

am submitting an application for the registration for the purpose to import, local production, marketing, sell or distribution of the Breastmilk Substitute/Infant Food/ Commercially Manufactured Complementary Food/the Accessories thereof mentioned below attaching all documents specified under sub-rule (2) of rule 10 herewith, namely:-

Serial No.	address and mobile number/telephone/e-mail/fax number	of the product, description, sample and name of the country of origin	pount and Description of the product	Sample of the receptacle/label attached thereto
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(1)	(2)	(3)	(4)	(5)

Affidavit: all the information mentioned in and documents attached with this application are true and accurate as to my knowledge and belief.

Date:

(Name and

signature of the applicant)

Attachments:

1. An attested copy of the Certificate issued by the Bangladesh Atomic Energy Commission.
2. An attested copy of the Certificate issued by the Bangladesh Standard and Testing Institute (BSTI).
3. An attested copy of the Certificate issued by the Codex Alimentarius Commission.
4. The original copy of Treasury Chalan.
5. An attested copy of the National Identification card.
6. An attested copy, if any, of the Trade License.
7. An attested copy, if any, of the Tax Identification Number.
8. The copy of Memorandum of Association, Article of Association and Certificate of Incorporation, if it a company.

Form -'B'

[under rule 10(6)]

Registration Book

Serial	Name,	Name of the	Sample of	Amount and	Number of	Lists of	Signature
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Form -'C'

[under rule 10(6)]

Registration Certificate

Registration No:	
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Date of Issuance of

Certificate:

Expiry Date :

Mr/Ms,

Due to the application of the..... (Name of the Person/Organization), Dated:.....

the registration of the following Breastmilk Substitute/Infant Food/ Commercially Manufactured Complementary Food/the Accessories thereof are issued subject to the following conditions, namely:-

Serial No.	Name, address and mobile number/telephon e/e-mail/fax	Name of the product, description, sample and	Amount and Description of the production of	Sample of the receptacle/ label
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	number	name of the country of origin	the product	attached thereto
(1)	(2)	(3)	(4)	(5)

Conditions:-

1. The provisions of the Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food and the Accessories thereof (Regulation of Marketing) Act, 2013 (Act No. XXXV of 2013) and Breastmilk Substitute, Infant Food, Commercially Manufactured Complementary Food and the Accessories thereof (Regulation of Marketing) Rules, 2017 shall be carried out/complied with;
2. There shall be a detailed instruction on receptacle/label attached thereto and no information of the receptacle/label attached thereto shall be amended without approval;
3. The radiation amount and elements of the ingredients of the product are verifiable on demand.

Signature of the Director
(Seal)

[under Rule 11(1)]

Application of Renewal of Registration Certificate

To,

The Director

Public Health Nutrition Institute, Mohakhali, Dhaka.

Sir,

I/We

(Name of the Company/Organization).....

Address.....

The registration period of the Breastmilk Substitute/Infant Food/Commercially Manufactured Infant Additional Food/Use of its Equipments mentioned below shall be expired on date.....Therefore, I am applying for renewal of registration certificate of those products along with necessary information, papers and fee of renewal registration certificate, namely:-

Serial No.	Name, address and mobile number/telephone/e-mail/fax number	Name of the product, description, sample and name of the country of origin	Amount and Description of the production of the product	Sample of the packet/label of container	Registration No	Expiry Date of Registration Period

(1)	(2)	(3)	(4)	(5)	(6)	(7)

Affidavit: all the information mentioned in and documents attached with this application are true and accurate as to my knowledge and belief.

(Name and

signature of the applicant)

Attachments:

1. Copy of Registration Certificate.
2. The original copy of Treasury Chalan.
3. Updated copy of the Trade License, if any.
4. Copy of the last Income Tax Certificate, if any.

By Order of the President

Maksuda Yasmin
Senior Assistant Secretary.

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