

Government of the People's Republic of Bangladesh

Ministry of Health and Family Welfare

Health Service Division

NOTIFICATION

Dated 6 August 2017

S.R.O. No. 261-Law/2017.- In exercise of the powers conferred by/under section 21 of the Breastmilk Substitute, Infant Food, Commercially Manufactured Infact Additional Food and Use of Equipments (Regulation of Marketing) Act, 2013 (Act No. XXXV of 2013) the Government is pleased to make the following rules, namely:-

1. Title.- These rules may be called the Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments (Regulation of Marketing) Rules, 2017.

2. Definitions.- (1) In these rules, unless there is anything repugnant in the subject or context,-

(a) “**Act**” means the the Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments (Regulation of Marketing) Act, 2013 (Act No. XXXV of 2013);

(b) “**National Advisory Committee**” means the Committee constituted under rule 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, but defined in the Act, shall have the meanings respectively assigned to them 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 section 4 of the Act, namely:-

- (a) giving or delivery of any sample of Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments (for example, bottle, nipple, pacifier, cup, etc.) to any infant, mother of an infant or their carers or any health service providers or health workers;
- (b) delivery of any speech or giving any statement including demonstration of any picture on excellence/emminence of bottle feeding;
- (c) administering/carrying out any such activities in conflict of interest with the purpose of the Act and contrary to the prohibitions imposed under sub-clasue (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, physical and mental development of child, nutritional value of Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food or its risk-freeness to any pregnant woman, breastfeeder, infant's mother, infant's carer or guardian through organising any activities or programs with the assistance or funding of any importer, locally producer, distributor, marketing people or saller;

- (e) observing any special week or day by any importer, locally producer, distributor, marketing people or saller of Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments for the purpose of its circulation or dissemination;
- (f) giving commission, providing financial benefit or gifting anything to any seller or worker of any health service certer on the sale of Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments;
- (g) assisting or participating in any informative and educational programs or circulating or ordisseminating any information on the health of mother and child, food and nutrition by any importer, locally producer, distributor, marketer or saller of Breastmilk Substitute, Infact Food, Commercially mmanufactured Infact Additional Food and Use of Equipments.

4. Rules to be followed while issuing Prescription of Breastmilk Substitute.- For the purpose of the Act, if it is considered extremely indispensable in order to save child life and reduce health harzards 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 an appropriate Breastmilk Substitute only.

5. Relevant Information attached with the container or packet/label of any Breastmilk Substitute, Infant food, etc. (1) For the purpose of section 6 of the Act, under the heading of “Important

Information” in any container and its packet/label attached therewith of any Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments-

- (a) a description/statement shall be printed with the heading of “Breastmilk Substitute Powdered Infant Formula need to be prepared appropriately as it may contain PATHOGENIC MICROORGANISM”;
- (b) the following information shall be printed or affixed, namely:-
 - (i) instructions to be followed while feeding any Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food;
 - (ii) warning about child health impariment, if the instructions specified in sub-rule (i) are not followed.

(2) For the purpose of clause (d) of sub-section (2) of section 6 of the Act, the following statement shall not be affixed with any container or its packet/label of Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments in Bangla or any other languages, namely:-

- (a) “this product is approved, advised or instructed by any doctor/medical practitioner” or any other expression or statement of similar nature;
- (b) this product is “complete protein food” or “energetic/stimulating food” or “complete food” or “healthy food” or or any other expression or statement of similar nature.

(3) The size of the logo or mark of the concerned companies of Breastmilk Substitute, Infact Food, Commercially Prepared Infact

Additional Food and Use of Equipments affixed with any packet/label of any container shall not be more than half of the name of such product.

6. Other Information to be Included in the Educational or Informative Materials.- For 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 for infant's mother or carer about the strategies/methods of breastfeeding;
- (b) life-risk of new born is reduced, if he is breastfed within 1 (one) hour of his birth;
- (c) breastmilk is complete and dietary food for infant;
- (d) breastmilk is disease preventive;
- (e) breastmilk is financially viable/cost effective;
- (f) the possibility of re-pregnancy of only breastfed mother is reduced, if the infant is breastfed exclusively upto 6(six) months since his birth.

7. Constitution of the National Advisory Committee.- The National Advisory Committee shall be constituted along with 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), Department of Health;
- (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.- For the purpose of clause (c) of section 9 of the Act, the National Advisory Committee shall carry out the following functions, namely:-

- (a) to provide advise to the government with a view to increase public awareness for the purpose of proper enforcement of the Act and this rule;
- (b) to provide recomendation to the government in order to identify the possible risks or harms of not breastfeeding and necessary actions that need to becarried out in order to resolve it.

9. Meetings of the National Advisory Committee.- (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 meeting 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 equality of votes the person presiding over the meeting shall have a second or casting 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/constitution of the Committee.

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

10. Issuance of Registration Certificate and Registration of Breastmilk Substitute, Infant Food, etc.- (1) An application shall be submitted before the Director in Form -'A' for the purpose of registration of importation, local production, marketing, sale or distribution of any Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments.

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

- (a) a Safety Certificate issued by appropriate authority from its origin country that the Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of

Equipments to be registered are free from radioactivity;

- (b) a Certificate issued by the Bangladesh Atomic Energy Commission that the Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments to be registered are free from radioactivity;
- (c) a copy of the Certificate issued by the Bangladesh Standard 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 a company;
- (g) Any other document or information sought 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 the following 15 (fifteen) days.

(4) The Director shall reject the application, if he 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 deems fit 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 registered 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’ in favour of the applicant.

11. Renewal of Registration Certificate.- (1) For the purpose of sub-section (5) of section 10 of the Act, Before expiring the period of registration certificate within 6 (six) months, an application for renewal of registration certificate shall have to be submitted before the Director according to the Form ‘D’ along 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 2 (three) years; or
- (b) has been violated by the applicant, being satisfied, the director may reject such application and inform it the applicant 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 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.

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

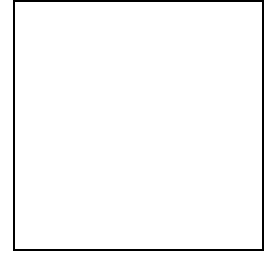
- (a) all acts done, actions taken or proceeding continued shall be treated as done, taken or continued under the said rules;
- (b) the issued registration certificate shall remain valid in such manner as if it issued under the said rules and an application for renewal shall have to be submitted within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

Form –‘A’

[under rule 10(1)]

Attested
Photo of
the
Applicant

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 of importation, local production, marketing, sale or distribution of the Breastmilk Substitute/Infact Food/ Commercially Manufactured Infact Additional Food/Use of it's Equipments mentioned below attaching all documents specified under sub-rule (2) of rule 10 herewith, 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
(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 Number.
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.

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Form –‘C’

[under rule 10(6)]

Registration Certificate

Registration No:	
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Issuance Date of Certificate:

Expiration Date :

Mr/Ms,

Due to the application of the..... (Name of the Person/Organization), Dated:..... the registration of the following Breastmilk Substitute/Infact Food/ Commercially Manufactured Infact Additional Food/Use of it's Equipments are issued subject to the following conditions, 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
(1)	(2)	(3)	(4)	(5)

Conditions:-

1. The provisions of the Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments (Regulation of Marketing) Act, 2013 (Act No. XXXV of 2013) and Breastmilk Substitute, Infact Food, Commercially Manufactured Infact Additional Food and Use of Equipments (Regulation of Marketing) Rules, 2017 shall be carried out/complied with;
2. There shall be a detailed instruction in Packet/label of the container and no information of the packet/label of the container shall be amended without approval;
3. The radiation amount and elements of the ingredients/materials of the product are verifiable on demand.

Signature of the Director
(Seal)

Form- 'D'
[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/Infact Food/Commercially Manufactured Infact Additional Food/Use of it's 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 Iyasmin
Senior Assistant Secretary.