Food Act No 26 of 1980

REGULATIONS made by the Minister of Health in consultation of the Food Advisory Committee under section 32 of the Food Act No 26 of 1980.

Colombo, ...........2012 Minister of Health

REGULATIONS

1. These regulations may be cited as the Food (Registration of Food Products) Regulations-2012 and shall come into operation with effect from..........

2. No person shall import, manufacture, pack, repack, store, sell, offer for sale, keep for sale, transport or advertise any food product specified in Schedule I of these regulations, unless such product has been duly registered by the Chief Food Authority (hereinafter referred to as "the Authority"). Prior to the issue of the Certificate of Registration, the particular food product specified in Schedule I for which registration is sought shall be duly registered by the Authority in terms of the provisions of these regulation.

3. For the purpose of these regulations, products to be registered shall be prescribed in Schedule I of these Regulations subject to change by way of addition, deletion or amendment, by the Chief Food Authority in concurrence with the Food Advisory Committee by publishing such change in the Government Gazette, giving minimum of twelve months for the adoption of such changes.

4. Any person intending to register any food product specified in Schedule I of these regulations with the Authority shall submit to the Authority an application substantially in the form specified in Schedule II to these regulations.

5. Applications for obtaining the Certificate of Registration in respect of any particular food product as is specified in Schedule I to these regulations shall be:

   a) made only by citizens of Sri Lanka, or by a body corporate registered by the Registrar-General of Companies under the Companies Act No 7 of 2007;

   b) made separately, in respect of each product;

   c) accompanied by-

      (i) the fee as specified in Schedule IV to these regulations;

      (ii) a letter of recognition from the manufacturer appointing him as the importer, distributor or the local agent, as the case may be, in the case of imported food products;

      (iii) all such particulars as may be required to be stated in the aforesaid form A set out in Schedule II and any other information that may be called by the Authority for the purpose of making a decision in respect of the application;
and

(iv) an analytical report of the composition of the food product and the proposed label and a reasonably sufficient number of samples, if requested by the Authority, of the food product or products in respect of which the application is made.

6.(1) An application for a Certificate of Registration of any food product specified in Schedule I to these regulations shall be received by the Director in charge of Food Control Administration on behalf of the Authority. All applications shall upon receipt thereof, be forwarded along with the samples, if any, to the Food Control Administration Unit in order to ensure that the requirements specified in regulation 5 have been submitted satisfactorily.

(2) Any application which is incomplete shall be rejected and the applicant shall be informed the reasons for such rejection.

Provided that the rejection of any application for a Certificate of Registration of any food product shall not debar an applicant from submitting a fresh application if new data which meets the requirements for registration is subsequently available.

(3) the Director in charge of Food Control Administration shall forward such application for evaluation and recommendations to the Food Evaluation Sub Committee, (hereinafter referred to as the “FESC”) appointed by the Food Advisory Committee

(4) The FESC shall comprise of the following-

a) Director/Deputy Director in charge of Food Control Administration, who shall be the Chairman;
b) an Assistant Director of the Food Control Administration Unit;
c) a Food Scientist;
d) a Food Technologist;
e) a Nutritionist;
f) a Food Analyst;
g) where necessary, a Food Microbiologist and/or a specialist in Clinical Medicine or Paediatrics; and
h) any expert nominated by the Food Advisory Committee.

(5) The quorum for the meetings of FESC shall be four members.

(6) The FESC shall make its recommendation either to grant or reject registration giving justification in writing to the Chief Food Authority within two calendar months of receiving such application.

However this time period shall not apply if the FESC requires additional information.

(7) The Chief Food Authority shall issue the Certificate of Registration set out in the Schedule III hereto or communicate the reasons for rejection of the application based on the recommendation of the FESC.

7. The Authority shall maintain a Register of all persons to whom a Certificate of Registrations has been granted in terms of these regulations and shall enter or cause to be entered therein the following
particulars relating to each registered food product:

(a) the trade or brand name of the product;
(b) the common name of the product;
(c) the name and address of the holder of the Certificate of Registration;
(d) the names & addresses of the importer, distributor, re-packer and/or manufacturer;
(e) the address of the premises in respect of which the Certificate of Registration has been issued;
(f) the number and date of the Certificate of Registration; and
(g) the date of expiry of the Certificate of Registration.

8 (1). An application for a renewal of a Certificate of Registration shall be -

a) made at least three (3) months prior to the expiration of the validity of the current Certificate of Registration;
b) made substantially in the form set out in Schedule II hereto;
c) accompanied by such fee as specified in Schedule IV hereto;
d) made with an analytical report of the composition of the food product and the proposed label and a reasonably sufficient number of samples, if requested by the Authority, of the food product or products in respect of which the application is made; and
e) accompanied by a copy of the current Certificate of Registration.

(2) Every applicant shall furnish all such particulars as may be required to be stated in the foresaid form and any other information that may be called by the Authority.

9. (1). The following conditions may be attached to a Certificate of Registration-

a) the registration is specific to the nature of the product, source of origin, brand/trade name under which it is marketed and limited to the purpose of use declared in the application;
b) this registration shall be valid up to a maximum period of three (03) years, unless otherwise revoked earlier; and
c) the validity of the registration shall be automatically nullified if the importer, manufacturer, processing plant, packaging plant, or the product for which the registration is granted is changed without prior approval of the Authority.

(2) The holder of the Certificate of Registration shall ensure that-

(a) the product shall meet all the standards stipulated under the Food Act No.26 of 1980 or standards adopted from time to time under the Act or any other standard acceptable to the Authority;
(b) the product shall comply with all requirements related to packaging of food under regulations on packaging or standards adopted under the Food Act published in Gazette Extraordinary No. 1660/30 of 29 June 2010 and any subsequent amendments or replacements;
(c) the product shall comply with all requirements under regulations on hygiene under the Food Act published in Gazette Extraordinary No.1742/26 of 26 January 2012 and any subsequent amendments or replacements;
(d) the label of the product shall conform to the provisions of the Food (Labelling and

(e) no claims or advertisements shall appear in the label, print and/or electronic media or any other means of advertising without the prior approval of the Authority and the media and the advertising industry shall comply with these requirements;

(f) proper storage facility shall be maintained where good practices are implemented as certified by an agency recognized by the Food Advisory Committee;

(g) any officer authorized in that behalf by the Authority, shall be allowed to enter, with or without notice, any premises where the registered product is stored, processed or packed for the purpose of inspection, sampling or analysis;

(h) any officers authorized in that behalf by the Authority, shall be furnished such samples as may consider adequate, from any batch or consignment of the registered product imported, manufactured or repacked for inspection, sampling or analysis, and if required, furnish full particulars of the quality control tests carried out by the manufacturer of that particular batch of a product;

(i) on being informed by the Authority that any part of any batch of the registered product imported, manufactured, packed or distributed has been found to be not in conformity with the labeling and advertising requirements or standards specified by the Authority, such batch of registered product shall be withdrawn from sale;

(j) all such particulars and information as may be required by the Authority in respect of any premises, any brand of product currently manufactured or imported by him with particular reference to the development of any unwanted or adverse effect or any other information, as the case may be, shall be furnished to the Authority; and

(k) any decision to withdraw the food product from the register and the reasons therefor and any decision to terminate his activities as an importer, distributor, re-packer or manufacturer of the said food product shall be informed to the Authority.

10. If the holder of the Certificate of Registration of a food product fails to comply with the provisions of these regulations, the Authority may, after giving such holder of the Certificate of Registration of such product an opportunity to show cause why such an order should not be made, to suspend the registration for a specific period of time or cancel the registration of such food product and state the reasons there for.

11: The Authority shall on the advice of the Food Advisory Committee, remove the name of a food product from the register forthwith and inform the holder of the Certificate of Registration in respect of such food product, the reasons for such removal and also revoke the Certificate of Registration.

**SCHEDULE I**

**Regulation 2, 4, 5, 6(1)**

**Registered Food Products**

i. Full Cream Milk Powder;

ii. Partly Skimmed or Low Fat Milk Powder;

iii. Skimmed Milk Powder or Non Fat Milk Powder;

iv. Infant formulae and Follow on formulae; and

v. Any other fortified or formulated milk powder.
### Application for Certificate of Registration/Renewal of Certificate of Registration

<table>
<thead>
<tr>
<th>Description of the food item</th>
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<tbody>
<tr>
<td>a) Name under which registration is applied for</td>
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<tr>
<td>b) Common name</td>
<td></td>
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<tr>
<td>c) Brand / Trade name</td>
<td></td>
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<tr>
<td>d) Country of origin</td>
<td></td>
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<tr>
<td>e) Name &amp; address of manufacturer</td>
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<td>f) Name &amp; address of importer</td>
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<td>g) Name &amp; address of distributor</td>
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<tr>
<td>h) Name &amp; address of packer</td>
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<tr>
<td>i) Intended use</td>
<td></td>
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<tr>
<td>j) No. &amp; date of previous registration, if any</td>
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<th>Details of Applicant</th>
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<tbody>
<tr>
<td>a) Name &amp; address</td>
<td></td>
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<tr>
<td>b) Sri Lankan citizenship</td>
<td>Yes / No</td>
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<tr>
<td>c) Importer (Provide letter of appointment by manufacture as authorized agent)</td>
<td>Yes / No</td>
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<td>d) Local manufacturer</td>
<td>Yes / No</td>
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<td>e) Person authorized to apply (if yes provide letter of authority)</td>
<td>Yes / No</td>
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<td>f) Name &amp; address of the importing / manufacturing firm / company giving authorization with details of registration with the Registrar of Companies.</td>
<td>Yes / No</td>
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<td>g) Type of quality control system available to the manufacturing firm (e.g. GMP, HACCP)</td>
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| Details of the product: |  |
| a) Composition: The ingredients should be listed in descending order of |  |
proportion;

b) A health certificate from the national food safety authority or similar authority of the country in which it is produced, confirming that the product is in use there and the period of use. If not, reason for not marketing in the country of origin;

c) Certificate of analysis;

d) Samples of the label(s) used on the container.

If you are a local manufacturer, please answer the following:

a) Name and address of the manufacturing facility;

b) Type of quality control system available (e.g. GMP, HACCP);

c) Name and address of the agency certifying quality control system.
(Attach copy of certificate)

If you are a packer, please answer the following:

a) Name and address of the packaging facility;

b) Type of quality control system available;

c) Name and address of the agency certifying the quality control system.
(Attach copy of certificate)

Storage facility

a) Name and address of the storage facility;

b) Name and address of the certifying agency in regard to the suitability and the good storage practices adopted.
(Attach copy of certificate)

I/we .............................................................................................................................. of
.......................................................................................................................... hereby apply for registration of the product
namely .................................................................................................................. details of which are enclosed herewith.

Signature of the applicant:
..............................................................................................................................

Name: ......................................................................................................................

Designation of the applicant....................................................................................

Date:......................................................................................................................
SCHEDULE III  

REGULATION 6(7)

CERTIFICATE OF REGISTRATION OF FOOD PRODUCTS
Subject to the provisions of the Food Act No.26 of 1980 as amended by the Food (Amendment) Act No. 20 of 1991 and Food (Amendment) Act No:29 of 2011, the under mentioned food product is hereby registered in terms of the provisions stipulated in the Food (Registration of Food Products) Regulation -2012 published in the Government Gazette Extraordinary No. of 2012.

1. Name and address of Applicant:

2. Details of Food product registered:
   a) Common name
   b) Brand name (if applicable)
   c) Name & address of manufacturer
   d) Name & address of importer
   e) Country of origin
   f) Intended use
   g) Name & address of distributor or packer

3. Date of Registration:

4. Validity of Registration (maximum of three years from the date of registration unless otherwise specified herein):

5. Conditions attached to Registration :-
   (a) the registration is specific to the nature of the product (state common name), the brand / trade name (if applicable) under which it is marketed and the intended use;
   (b) the validity of registration is subject to conditions stipulated under regulation 9 of the Food (Registration of Food Products) Regulations - 2012, and shall become null and void if any of these conditions are not met with or violated; and
   (c) application for renewal of registration should be submitted to the Director in charge of Food Control Administration three months prior to the expiry of validity of the current registration.

__________________________  __________________________
Date & official seal  Director
Environment and Occupational Health

SCHEDULE IV  

REGULATIONS 5(c) (i) and 8(1)(c)

FEES

1. Application processing fee – The fee for the processing of an application is rupees ten thousand (Rs.10, 000.00).

2. Certificate of Registration - The fee for the Certificate of Registration shall be as follows:-
   (i) Rupees twenty thousand (Rs:20, 000.00) for registration of a food product
   (ii) Rupees twenty thousand (Rs:20, 000.00) for the renewal of registration of a food product.
3. A fee of Rupees two thousand (Rs.2,000.00) be paid for a duplicate copy of the Certificate if the original is damaged or lost and such copy of the certificate shall bear the words "duplicate copy".