ANNEXTURE - 01

FINAL DRAFT

The Gazette of the Democratic Socialist Republic of Sri Lanka

Extraordinary

Part I: Section (I) – General

Government Notifications.

L.D. B 11/80(ii)

FOOD ACT, No. 26 OF 1980

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

Maithreepala Sirisena,

Minister of Health.

Colombo,

(DATE).

Regulations.

1. These regulations may be cited as the Food (Irradiation) Regulations, -(2012) and shall come into operation on (six months from the date of publication)

PART I

GENERAL PROVISIONS.

2. The provisions of these regulations shall be applicable to:

a) every Food Irradiation Facility set up in Sri Lanka;

b) all irradiated food and packaging materials used in conjunction with food.
3. The main objective of these regulations is to ensure that the requirement of food irradiation is achieved without undue risks to human health, safety and the environment. In the implementation of this objective these regulations seek to:

a. control pathogenic micro-organisms and parasites in food and packaging materials used in conjunction with food;

b. reduce post-harvest losses of food products caused by insects, micro-organisms and physiological processes;

c. meet the quarantine requirements relating to trade;

d. extend the marketability of food and packaging materials used in conjunction with food; and

e. ensure the safe operation of food irradiation facilities.

4. a) No facility shall irradiate food and packaging materials without the approval of Chief Food Authority.

b) Chief Food Authority shall not grant approval to a facility which is not approved and licensed by Atomic Energy Authority of Sri Lanka.

c) Facility shall apply to Chief Food Authority for permission. Chief Food Authority will work in concurrence with Atomic Energy Authority of Sri Lanka under MOU for purpose of evaluation and recommendation of this facility for food irradiation.

d) The treatment of any food and packaging materials used in conjunction with food by ionizing radiation shall be carried out in accordance with the provisions of Part II of these regulations and in conformity with the Irradiation License issued by the ATOMIC ENERGY AUTHORITY OF SRI LANKA in relation to such type of food as specified by the CHIEF FOOD AUTHORITY.

5. No food and packaging materials used in conjunction with food shall be treated with ionizing radiation unless the food and packaging materials used in conjunction with food produced conform to the general requirements of quality and hygiene as prescribed by the Food Regulations 1988 published in Gazette Extraordinary No. 560/13 of June 2, 1989 or any other regulation relating to food hygiene published under Food Act No: 26 of 1980 from time to time.
6. The ionizing radiation used on any food and packaging materials used in conjunction with food shall be of the minimum level required to achieve irradiation of the food so produced and shall not be more than the maximum level in order to prevent impairment of the quality of the food.

7. The packaging materials which are of food grade used for the packaging of irradiated foods shall be suitable for irradiation and be adequate to prevent re-infection and re-contamination. Such packaging materials shall be capable of maintaining their integrity during storage, transportation and distribution of the food products being offered for sale. The maximum tolerable doses for selected primary packaging material are as given in Schedule I.

8. No person shall sell, store for sale or transport, or offer for sale any food and packaging materials used in conjunction with food or any part of any such food and packaging materials used in conjunction with food that have been subjected to ionizing radiation, unless:
   a. such food and packaging materials used in conjunction with food are treated with ionizing radiation in Sri Lanka in accordance with the requirements of the Irradiation License issued in relation to that food and packaging materials used in conjunction with food; or
   b. such food and packaging materials used in conjunction with food are labeled in accordance with the provisions of Part V of these regulations; or
   c. such food and packaging materials used in conjunction with food are imported in compliance with the provisions of Part VII of these regulations.

PART II

TREATMENT OF FOOD BY IONIZING RADIATION

9. The conditions that are to be complied with by a Food Irradiation Facility and Dosimetry, shall be as follows.
a. Food irradiation facilities where ionizing radiation is used, must be designed and operated in such a way that the safety of workers, the public and the environment, is assured at all times.

b. The irradiation facilities authorized to treat food by irradiation shall conform to the laws and regulations of the country.

c. Irradiation facilities shall be inspected **jointly or individually** by the Chief Food Authority and Atomic Energy Authority of Sri Lanka to ensure that Good Irradiation Practices established both nationally and internationally are followed. These practices include keeping proper records of the processes and taking necessary precautions including occupational safety and health aspects.

d. Dosimetry shall be part of a quality assurance system and be consistent with recognized national and international practices.

e. Irradiation facilities shall be operated and controlled by trained and competent personnel who have successfully completed a course of study recognized by the Atomic Energy Authority of Sri Lanka.

f. The food irradiation facility shall comply with the Radiation Protection Regulations of the Atomic Energy Authority of Sri Lanka as issued from time to time.

g. Operators or quality control personnel of any food irradiation facility shall carryout dosimetry in the manner described below:
   
   i. regularly measure the absorbed dose and dose distribution, in treated food and packaging materials used in conjunction with food in the manner approved by the Atomic Energy Authority of Sri Lanka;
   
   ii. maintain and ensure ready access to accurate reference dosimeters to calibrate the response of routine measuring or monitoring devices used in the facility;
   
   iii. comply with the prescribed dosimeter selection criteria in order to provide precise, relevant and efficient dosimetry for monitoring;
   
   iv. maintain and keep accurate dosimetry records using check lists at all stages of the dosimetry procedure.
PART III

CONTROL OF IRRADIATION OF FOODS

10. a) The Food Irradiation Facilities established in Sri Lanka shall have a documented Quality Control System to assist independent external audits to be carried out;

b) Food and packaging materials used in conjunction with food to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and adequate for the purpose of irradiation;

c) All food and packaging materials used in conjunction with food which are subjected to ionizing radiation shall be handled before, during and after irradiation according to the accepted Good Manufacturing Practices taking into account the particular requirements of such treatment;

d) The incoming food and packaging materials used in conjunction with food shall be physically separated from the outgoing irradiated food products. Where appropriate, a visual colour changing radiation indicator shall be affixed on each outer pack to enable ready identification of irradiated and non-irradiated food products;

e) Irradiation shall be carried out in conformity with the Good Irradiation Practices recommended by (a) Codex General Standard for Irradiated Food Codex Stan 106-1983 revised from time
to time (b) Codex Recommended International Code of Practices for Radiation Processing of Food CAC/RCP 19-1979 revised from time to time and (c) IPPC Guidelines for Use of Irradiation as a Phytosanitary Measure, including a proper dosimetry procedure. The dosimetry shall be traceable to accepted national and international standard.

f) The irradiation facilities shall maintain a record of each batch of food and packaging materials used in conjunction with food which are subjected to irradiation. Such record shall contain:

i) the batch number;

ii) Document on quality and hygienic status of the food and packaging materials used in conjunction with food to be irradiated as per the guideline developed by ATOMIC ENERGY AUTHORITY OF SRI LANKA with the concurrence of Chief Food Authority;

iii) the date on which the irradiation procedure was carried out;

iv) the type and the quantity of the batch of irradiated food and packaging materials used in conjunction with food;

v) where appropriate, the type of packaging material used during the irradiation treatment;

vi) all controls and measurements performed during the treatment, particularly the doses absorbed;

vii) any incidents or deviations observed during the irradiation treatment.

g) The records maintained under Regulation 10.f shall be kept by the irradiation facility for at least five years and submitted to the Atomic Energy Authority in the event of closure of that irradiation facility and available for inspection by Chief Food Authority;

h) Every irradiation facility shall submit annually a written report to the Atomic Energy Authority of Sri Lanka containing the following information:

i) the name of the food irradiation facility;

ii) the period to which the report relates;
iii) description of each food and packaging materials used in conjunction with food subjected to treatment by ionizing radiation during such period;

iv) the quantity, by volume or weight, of each food and packaging materials used in conjunction with food subjected to ionizing radiation during such period.

i) The Chief Food Authority and Atomic Energy Authority of Sri Lanka shall enforce the provisions of these regulations and shall carry out regular inspection of the irradiation facility at least once a year.

j) The Chief Food Authority and Atomic Energy Authority of Sri Lanka concerned in the implementation of these regulations shall have the right of access to any place, which is used for the irradiation of food and packaging materials used in conjunction with food or for the storage of food and packaging materials used in conjunction with food which has been, or is to be, treated by ionizing radiation.

k) All relevant documents and records shall be made available for inspection by the relevant Authorities.

l) The Chief Food Authority ( &) and Atomic Energy Authority of Sri Lanka shall have the right to obtain samples for prescribed purposes.

PART IV

AUTHORIZATION FOR FOOD IRRADIATION AND GOOD IRRADIATION PRACTICES.

11. a) The classes of food and packaging materials of food grade used in conjunction with food that are authorized to be treated by ionizing radiation shall be those that are specified in Schedule I and II respectively to these regulations.
b) The classes of food and packaging materials of food grade used in conjunction with food to be irradiated shall be determined as and when required by the Chief Food Authority in consultation with the Food Advisory Committee on the recommendation made by the Atomic Energy Authority of Sri Lanka.

c) Notwithstanding to the provisions 11 (a) and (b), the Chief Food Authority shall grant permission to the type of food to be irradiated on a case by case basis.

d) Facility shall apply for the type of food under the relevant class specified in schedule I to the Chief Food Authority with the recommendation of the Atomic Energy Authority of Sri Lanka. The Chief Food Authority, shall make a decision in consultation with the subcommittee appointed by the Food Advisory Committee in this regard and convey the decision to the facility through the Atomic Energy Authority of Sri Lanka.

e) Fees applicable to the processing of the application referred in 11 (d) shall be determined by the Chief Food Authority in consultation with the Food Advisory Committee.

f) The technical need for food and packaging materials used in conjunction with food to be irradiated within a dose range varies from food to food and from purpose to purpose. The minimum and maximum dose limits of food and packaging materials used in conjunction with food that are authorized to be irradiated are as set out in Schedule II to these regulations. The dose absorbed shall be the minimum required to achieve the intended purpose based on technological need, particularly when it serves hygiene or quarantine purposes of food and packaging materials used in conjunction with food.

PART V

LABELLING

12. An irradiated food and packaging materials used in conjunction with food shall be labeled in accordance with the provisions of the Food (Labeling and Advertising) Regulations 2005, published in Gazette Extraordinary No. 1376/9
of 19th January 2005.

13. a) In the case of import or export of irradiated food and packaging materials used in conjunction with food, whether pre-packaged or not, the relevant shipping documents shall set out accurate information to identify the registered irradiation facility which has irradiated the food and packaging materials used in conjunction with food, the date or dates of treatment and Batch Identification Number (BIN).

b) In the case of import or export of prepackaged food and packaging materials used in conjunction with food:

   i) the label attached to a package containing food and packaging materials used in conjunction with food which have been treated with ionizing radiation shall carry a written statement indicating such treatment in close proximity to the common name of the food together with the international food irradiation symbol, as shown in the figure under Regulation 13. e.;

   ii) when an irradiated product is used as an ingredient in another food and packaging materials used in conjunction with food, such product shall be declared in the list of ingredients;

   iii) When a single ingredient product is prepared from a raw material, which has been irradiated, the label of such product shall contain a statement indicating such treatment.

c) In the case of import or export of food and packaging materials used in conjunction with food in bulk containers, the relevant shipping documents shall contain a declaration that the contents have been subject to irradiation.

d) In the case of unpackaged food and packaging materials used in conjunction with food intended for direct consumption, the information that the food and packaging materials used in conjunction with food was irradiated shall be displayed near the food and packaging materials used in conjunction with food.
e) All packages of irradiated food and packaging materials used in conjunction with food shall bear the following declaration and logo

![Processed by Radiation Logo](image)

**NAME OF THE PRODUCT**

**DATE OF RADIATION PROCESSING**

**LICENCE No.**

**BATCH IDENTIFICATION NO. (BIN)**
(as provided by facility)

**PURPOSE OF RADIATION PROCESSING**

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**PART VI**

**RE – IRRADIATION**

14. a) Food and packaging materials used in conjunction with food once irradiated shall not be re-irradiated unless specifically permitted by the Chief Food Authority on a recommendation made by Atomic Energy Authority.

b) For the purpose of this regulation, food and packaging materials used in conjunction with food are not considered as having been re-irradiated when:
i) the food and packaging materials used in conjunction with food prepared from materials which have been irradiated at low dose level, i.e. – at about 1 kGy, is irradiated for another technological purpose;

ii) the food and packaging materials used in conjunction with food, containing less than 5% of irradiated ingredient, is irradiated; or

iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food and packaging materials used in conjunction with food on more than one occasion as part of processing for a specific technological purpose.

PART VII

IMPORTATION AND EXPORTATION OF IRRADIATED FOOD AND PACKAGING MATERIALS

15. The importation and exportation of irradiated food or packaging materials used in conjunction with food shall be done in compliance with the requirements of these regulations and the shipping documents shall be accompanied by:

a) proper labeling documentation;

b) documentation that the Food Irradiation Facility concerned is duly licensed; and

c) a certificate by the competent authorities of the country of origin, to the effect that the food has been inspected by them.

PART VIII

INTERPRETATION

16. In these regulations unless the context otherwise requires:–

“Act” means the Food Act, No. 26 of 1980;
“Food” shall have the same meaning as has been given to it in the Act;

“Ionizing radiation” means any gamma rays, X rays or corpuscular radiation capable of producing ions directly or indirectly as given below.

a) gamma rays from the radionuclide 60Co or 137Cs;

b) X-rays generated from machine sources operated at or below an energy level of 5 MeV;

c) electrons generated from machine source operated at or below an energy level 10 MeV;

“Irradiated Food” means any food which has been subjected to treatment by ionizing radiation to achieve the objectives referred to in Part I of these regulations, but does not include such products subjected to radiation for the purpose of measurement and inspection.

“Dosimetry” means the method used to measure the absorbed dose of radiation by the food and allied products subjected to ionizing irradiation;

“Irradiation License” means a license authorizing the holder to subject food of a particular class to treatment by ionizing radiation.

“IPPC” means International Plant Protection Convention

SCHEDULE I
ADVISORY TECHNOLOGICAL MINIMUM & MAXIMUM DOSES FOR VARIOUS FOOD CLASSES

| CLASSES OF FOOD | PURPOSE OF TREATMENT | TECHNOLOGICAL DOSE RANGE (kGy) |
| Class 1 : Bulbs, roots and tubers | Inhibit sprouting during storage | 0.1 | 0.2 |
| Class 2 : Fresh fruits and vegetables (other than Class 1) | a) delay ripening | 0.3 | 1.0 |
| | b) insect disinfections | 0.3 | 1.0 |
| | c) shelf-life extension | 1.0 | 2.5 |
| | d) quarantine control* | 0.15 | 1.0 |
| Class 3 : Cereals and their milled products, nuts, oil seeds, pulses, dried fruit | a) insect disinfections | 0.3 | 1.0 |
| | b) reduction of microbial load | 1.5 | 5.0 |
| | c) inhibit sprouting (chestnut) | 0.1 | 0.25 |
| Class 4 : Fish, seafood and their products, frog legs, freshwater and terrestrial invertebrates (fresh or frozen) | a) reduction of certain pathogenic microorganisms** | 1.0 | 7.0 |
| | b) shelf-life extension | 1.0 | 3.0 |
| | c) control of infection by parasites** | 0.1 | 2.0 |
| Class 5 : Raw poultry and meat and their products (fresh & frozen) | a) reduction of pathogenic microorganisms** | 1.0 | 7.0 |
| | b) shelf-life extension | 1.0 | 3.0 |
| | c) control of infection by parasites** | 0.5 | 2.0 |
| Class 6 : Dried fruits and vegetables, spices, condiments, animal feed, herbs and herbal teas | a) reduction certain pathogenic microorganisms** | 2.0 | 10.0 |
| | b) insect disinfections | 0.3 | 1.0 |
| Class 7: Dried food of animal origin | a) insect disinfections | 0.3 | 1.0 |
| | b) Control of mould | 1.0 | 3.0 |
| | c) reduction of certain pathogenic microorganisms | 2.0 | 7.0 |
| Class 8 : Ethnic foods and miscellaneous foods, including but not limited to : health foods, ethnic | a) reduction of microorganisms | ** | ** |
| | b) sterilization | ** | ** |
| | c) quarantine control | ** | ** |
preparations of hospital foods, gum arabic and other thickeners, military rations, honey, space foods, special spices, liquid egg

* Minimum dose may be specified for particular pests.

** Minimum dose may be specified keeping in mind the objective of the treatment to ensure hygienic quality of food and packaging materials used in conjunction with food

NOTE: Special approval should be obtained for each food item under Class 8 from the Chief Food Authority.

SCHEDULE II

THE MAXIMUM TOLERABLE DOSES FOR PRIMARY PACKAGING MATERIAL

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Packaging material</th>
<th>Maximum tolerable dose (kGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kraft paper (flour packaging only)</td>
<td>0.5</td>
</tr>
<tr>
<td>2</td>
<td>Biaxially oriented polypropylene (BOPP)</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Cardboard cartons with polyethylene liners</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Cardboard kegs</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Glassine paper</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>Hessain sacks</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>Multiply paper sacks</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Multiply paper sacks with polyethylene liners</td>
<td>10</td>
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<td>Description</td>
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<tr>
<td>9</td>
<td>Nitrocellulose coated cellophane</td>
<td>10</td>
</tr>
<tr>
<td>10</td>
<td>Nylon-II</td>
<td>10</td>
</tr>
<tr>
<td>11</td>
<td>Polyethylene terephthalate film containing coatings comprising a vinlylidine chloride co-polymer with one or more of the following co-monomers: acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate</td>
<td>10</td>
</tr>
<tr>
<td>12</td>
<td>Polyethylene terephthalate film containing coatings of polyethylene</td>
<td>10</td>
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<tr>
<td>13</td>
<td>Polyolefin film (e.g. Polyethylene, BOPP)</td>
<td>10</td>
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<tr>
<td>14</td>
<td>Polyolefin film containing coatings comprising a vinlylidine chloride co-polymer with one or more of the following co-monomers: acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate</td>
<td>10</td>
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<tr>
<td>15</td>
<td>Polystyrene film</td>
<td>10</td>
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<tr>
<td>16</td>
<td>Rubber hydrochloride film</td>
<td>10</td>
</tr>
<tr>
<td>17</td>
<td>Vinlylidene chloride copolymer-coated cellophane</td>
<td>10</td>
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<tr>
<td>18</td>
<td>Vinlylidene chloride-vinyl chloride co-polymer</td>
<td>10</td>
</tr>
<tr>
<td>19</td>
<td>Wax-coated paperboard</td>
<td>10</td>
</tr>
<tr>
<td>20</td>
<td>Woven polypropylene sacks</td>
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<td>21</td>
<td>Ethylene vinyl acetate co-polymer film</td>
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<tr>
<td>22</td>
<td>Polyethylene polyester laminates</td>
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<tr>
<td>23</td>
<td>Nylon-6 film</td>
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<tr>
<td>24</td>
<td>Polyethylene film</td>
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<tr>
<td>25</td>
<td>Polyethylene terephthalate film</td>
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<tr>
<td>26</td>
<td>Vegetable parchment</td>
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</tr>
<tr>
<td>27</td>
<td>Vinyl chloride-vinyl acetate co-polymer</td>
<td>60</td>
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