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PART I : SECTION (I) — GENERAL

Government Notifications

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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.

Nimal Siripala De Silva
Minister of Healthcare, Nutrition and
Uva Wellassa Development

Colombo
15th November, 2005

Regulations

1. These Regulations may be cited as the Food (Irradiation) Regulations – 2005 and shall come into operation on 01st May, 2006

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 foods produced locally, whether for domestic consumption or for export; and
 - (c) to all food which is imported.

3. The main objective of these regulations is to ensure that the requirement of food irradiation is achieved without undue risks to health, safety and the environment. In the implementation of this objective these regulations seek –
- (a) to control pathogenic microorganisms and parasites in food;
 - (b) to reduce post-harvest losses of food caused by insects, microorganisms and physiological processes;
 - (c) to meet quarantine requirements in trades;
 - (d) to extend marketability of food; and
 - (e) to ensure safe operation of food irradiation facilities.
4. (1) No food shall be treated with irradiation except at a Food Irradiation Facility approved and licensed or authorized by the Competent National Authority for Food Irradiation, using a recognized manufacturing process whereby it is apparent that such food could benefit from irradiation.
- (2) The treatment of any 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 in relation to such type of food.
5. No food shall be treated with ionizing radiation unless the food produced conforms 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.
6. The ionizing radiation used on any 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 used for the packaging of irradiated food 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, distribution of the food products being offered for sale.
8. No person shall sell, store for sale or transport, or offer for sale any food or any part of any such food that has been subjected to ionizing radiation, unless-
- (a) such food was treated with ionizing radiation in Sri Lanka in accordance with the requirements of the Irradiation License issued in relation to that food, or
 - (b) such food was imported in compliance with the provisions of Part VII of these regulations; or
 - (c) such food was labelled in accordance with the provisions of Part V 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 away 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 by the Competent National Authority to ensure Good Irradiation Practices established both nationally and internationally are followed, including the keeping of proper records of the processes and the taking of necessary precautions;
- (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 Competent National Authority for Food Irradiation;
- (f) The food irradiation facility shall comply with the Radiation Protection Regulations of the Atomic Energy Authority as are 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 in the manner approved by the Competent National Authority;
 - (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) By complying with the prescribed dosimeter selection criteria in order to provide precise, relevant and efficient dosimetry or monitoring;
 - (iv) Maintaining, keeping accurate dosimetry records and using check lists at all stages of the dosimetry procedures.

PART III

CONTROL OF IRRADIATION OF FOODS

10. (1) The Food Irradiation Facilities established in Sri Lanka shall have a documented Quality Control System to assist independent external audits to be carried out.
- (2) Food to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and adequate for this purpose;
- (3) All food products which are subjected to ionizing radiations shall be handled before, during and after irradiation according to the accepted Good Manufacturing Practices taking into account the particular requirements of such treatment;
- (4) The incoming food products 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;
- (5) Irradiation shall be carried out in conformity with the Good Irradiation Practices recommended by the International Consultative Group on Food Irradiation (ICGFI) of the World Health Organization, including a proper dosimetry procedure. The dosimetry shall be traceable to accepted national and international standards.

(6) The irradiation facilities shall maintain a record of each batch of foods which is subjected to irradiation. Such record shall contain-

- (a) the serial number of the batch;
- (b) the date on which the irradiation procedure was carried out ;
- (c) the type and the quantity of the batch of irradiated foods ;
- (d) where appropriate, the type of packaging material used during the irradiation treatment;
- (e) all controls and measurements performed during the treatment, particularly those related to the minimum and maximum doses absorbed;
- (f) any incidents or deviations observed during the irradiation treatment.

(7) The records maintained under Paragraph (6) shall be kept by an irradiation facility for at least five years and submitted to the licensing authority in the event of closure of that irradiation facility;

(8) Every irradiation facility shall submit annually a written report to the Competent National Authority, containing the following matters:-

- (a) The name of the food irradiation facility;
- (b) The period to which the report relates;
- (c) Description of each food subjected to treatment by ionizing radiation during such period;
- (d) The quantity, by volume or weight, of each food subjected to ionizing radiation during such period;

(9) The Competent National Authority shall enforce the provisions of these regulations and shall carry out regular inspections at least once a year.

(10) Each authority concerned in the implementation of these regulations shall have the right of access to any place, which is used for the irradiation of food or for the storage of food which has been, or is to be, treated, by ionizing radiation.

(11) All relevant documents and records shall be made available for inspection;

(12) The Competent National Authority shall have the right to obtain samples for prescribed purposes.

PART IV

AUTHORIZATION FOR FOOD IRRADIATION AND GOOD IRRADIATION PRACTICES

11. (1) The Foods to be irradiated shall be determined from time to time by the Minister in charge to the subject of Health in consultation with the National Competent Authority. The foods that are

authorized to be treated by ionizing radiation shall be those that are specified in Schedule I to these regulations.

(2) The overall average dose of irradiation shall not be more than 10 MeV.

(3) The technical need for foods to be irradiated within a dose range varies from food to food and from purpose to purpose. The minimum and maximum dose limits of foods that are authorized to be irradiated are as set out in Schedule I to these regulations. The dose absorbed shall be at least the minimum required to achieve the intended purpose based on technological need, particularly when it serves food hygiene or quarantine purposes. The dose absorbed shall also be below a maximum that will ensure that the product retains its natural quality.

PART V

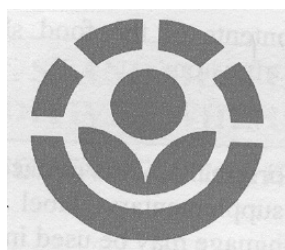
LABELLING

12. An irradiated food shall be labelled in accordance with the provisions of the Food (Labelling and Advertising) Regulations 2005; published in *Gazette Extraordinary* No. 1316/9 of 19th January, 2005.

13. (1) In the case of import or export of irradiated foods, 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, the date or dates of treatment and lot identification numbers.

(2) (a) Irradiated food shall be offered for sale only in pre-packaged containers.

(b) The label attached to a package containing food which has 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 below:



(c) All packages of irradiated food shall bear the following declaration and logo : -

Processed by Irradiation Method : (name):
Date of Irradiation:
License No.:
Purpose of Irradiation:.....

- (d) When an irradiated product is used as an ingredient in another food, such product shall be declared in the list of ingredients-
 - (e) 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.
- (3) In the case of import or export of foods in bulk containers, the relevant shipping documents shall contain a declaration that the contents have been subject to irradiation.
- (4) In the case of unpackaged food intended for direct consumption, the information that the food was irradiated shall be displayed near the food.

PART VI

RE-IRRADIATION

14. (1) Foods once irradiated shall not be re-irradiated unless specifically permitted by the Minister- in -Charge of the subject of Health in consultation with the Competent National Authority.
- (2) For the purpose of this regulation, food is not considered as having been re-irradiated when: -
- (a) the food prepared from materials which have been irradiated at low dose level, *i.e.* - at about 1 kGy, is irradiated for another technological purpose ;
 - (b) the food, containing less than 5% of irradiated ingredient, is irradiated; or
 - (c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food on more - than one occasion as part of processing for a specific technological purpose.
- (3) The cumulative overall average dose absorbed by the food subjected to irradiation shall not exceed the limit recommended by the Codex General Standard for Irradiated Foods.

PART VII

IMPORTATION AND EXPORTATION OF IRRADIATED FOOD

15. The importation and exportation of irradiated foods shall be done in compliance with the requirements of these regulations and the shipping documents shall be accompanied by –
- (a) proper labelling 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.
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 radio nuclides ^{60}Co or ^{137}CS ;

(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 of 10 MeV ;

"Food Irradiation Facility" means a facility approved and licensed or authorized by the Competent National Authority of food irradiation;

"Competent National Authority for Food Irradiation" means the Atomic Energy Authority of Sri Lanka Established under the Atomic Energy Authority Act., No. 19 of 1969;

"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 foods 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 subjected to ionizing irradiation;

"Advisory Dose Limits" are maximum or minimum doses which, under normal GMP, are required to ensure that the treatment of ionizing irradiation achieves its intended purposes and retains the natural quality of the food which is subjected to such treatment (under exceptional circumstances, other dose limits may be used, provided that adequate information and assurance is given that the intended purpose and level of GMP will be achieved);

"Irradiated food" means any food which has been subjected to treatment by ionizing radiation, either by itself or as a part of any batch of each item of food within the same class of food;

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

SCHEDULE I
MINIMUM AND MAXIMUM DOSES OF IRRADIATION

[Regulation 11(3)]

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>		
<i>Serial No.</i>	<i>Name of Foods</i>	<i>Doses of Irradiation (kGy)</i>		
		<i>Minimum</i>	<i>Maximum</i>	<i>Overall average</i>
1	Onions, (Big)	0.03	0.09	0.06
2	Spices	2.0	10.0	6.0
3	Potatoes	0.06	0.15	0.10
4	Rice	0.25	1.0	0.62
5	Semolina (ruling), Atta flour and wheat flour	0.25	1.0	0.62
6	Mango	0.25	0.75	0.50
7	Raisin, Figs and Dried Dates	0.25	0.75	0.50
8	Ginger and Red Onions	0.03	0.15	0.09
9	Meat and Meat Products including Chicken	2.5	4.0	3.25