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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATION

Islamabad, the 30th December, 2023

S. R. O. 1921(I)23.—In exercise of powers conferred by Section 16(2)(a) read with Section 56 of the Pakistan Nuclear Regulatory Authority Ordinance, 2001, the Pakistan Nuclear Regulatory Authority is pleased to make and promulgate the following regulations:

1. **Short Title, Extent, Applicability and Commencement.**—(1) These regulations may be called the “Regulations on Treatment of Food by Ionizing Radiation - (PAK/931)”.

- (2) These regulations extend to the whole of Pakistan.
- (3) These regulations shall be applicable to food irradiation facilities.
- (4) These regulations shall come into force at once.

(1—9)

Price: Rs. 20.00

2. **Definitions.**—In these regulations, unless there is anything repugnant in this subject or context,

- (a) “*absorbed dose*” means the fundamental dosimetric quantity D , defined as:

$$D = \frac{d\bar{E}}{dm}$$

where $d\bar{E}$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The SI unit of absorbed dose is joule per kilogram (J/kg), termed as gray (Gy);

- (b) “*Authority*” means the Pakistan Nuclear Regulatory Authority established under Section 3 of PNRA Ordinance;
- (c) “*calibration*” means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by measurement standards;
- (d) “*customer*” means an organization or person who requests the irradiation treatment of food to the licensee;
- (e) “*dose level*” means 0.1–1 kGy is the *low dose*, 1–10 kGy is the medium dose and 10–100 kGy is the high dose in food irradiation;
- (f) “*dosimeter*” means a device with a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system;
- (g) “*dosimetry*” means a measurement of absorbed dose by the use of dosimeters;
- (h) “*dosimetry system*” means a system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system’s use;
- (i) “*food*” means anything used as food or drink for human consumption other than drugs and may include:

- (i) any substance which is intended for use in the preparation of food;
 - (ii) any flavouring agent or condiment;
 - (iii) any colouring matter intended for use in food;
 - (iv) chewing gum, confectionery and other products of like nature; and
 - (v) water in any form, including ice, intended for human consumption or use in the composition or preparation of food etc.
- (j) "*food safety*" means the concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use;
- (k) "*irradiation*" means the process of exposing the material to ionizing radiation;
- (l) "*irradiation facility*" means the establishment where the irradiation process is performed. There are different types of irradiation facilities depending on the irradiator type, the radiation source, the conveyor system, and the operating mode. An irradiation facility consists of an irradiator, shipping and receiving docks, storage zones for irradiated and non-irradiated products, conveyor system, safety systems and the infrastructure for personnel and facility services, including record control;
- (m) "*irradiation treatment*" means the process of exposing food to ionizing radiation to improve food safety, food security and maintain food quality;
- (n) "*licensee*" means the holder of a valid license issued by the Authority; and
- (o) "*Radura symbol*" means the international symbol indicating the food product has been irradiated.

3. **Scope.**—These regulations shall apply to food treated with ionizing radiation and food irradiation facilities. These regulations shall not apply to food exposed to doses imparted by measuring instruments used for inspection purposes.

4. **Interpretation.**—The decision of the Chairman PNRA regarding the interpretation of any word or phrase of these regulations or applicability of these regulations shall be final and binding.

5. **Notification and Licensing.**—Any person intending to establish an irradiation facility for treatment of food by ionizing radiation shall notify the Authority of such an intention and apply for licensing as per “Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - (PAK/908)”.

6. **Responsibilities of the Licensee.**—(1) The licensee shall ensure that:

- (a) irradiation facility used for the irradiation treatment of food is designed to meet the requirements of safety, efficacy and good hygienic practices of food processing;
- (b) irradiation facility is staffed by adequate, qualified and trained personnel;
- (c) food to be treated or handled before and after the irradiation treatment according to good manufacturing practices taking into account the particular requirement of the technology of the process;
- (d) accidental mixing is restricted to eliminate confusion between irradiated and non-irradiated food;
- (e) areas of the facility for the treated and untreated food be segregated;
- (f) food to be treated with ionizing radiation receives upto the maximum absorbed dose sufficient to achieve the purpose as mentioned in Schedule I of these regulations; and
- (g) the food is accepted for irradiation only if it meets quality and food safety standards and is fit for its intended purpose.

7. **Radiation Sources for Irradiation Treatment of Food.**—(1) The licensee shall use the following types of ionizing radiation:

- (a) Gamma rays from sealed sources of the radionuclides Cobalt-60 or Cesium-137;
- (b) X-rays generated from radiation apparatus operated at or below an energy level of 5 MeV except as permitted by Regulation 7(c) of these regulations;
- (c) X-rays generated from radiation apparatus using tantalum or gold as the target material operated at or below an energy level of 7.5 MeV; and

- (d) Electrons generated from radiation apparatus operated at or below an energy level of 10 MeV.

8. Doses for Irradiation Treatment of Food.—(1) The licensee shall treat food that falls within one of eight permitted classes as specified in Schedule I.

(2) The maximum absorbed dose shall not exceed 10 KGy. However, the doses, under special circumstances to achieve a legitimate technological purpose, may be exceeded if justified but do not compromise consumer safety, wholesomeness or adversely affect structural integrity, functional properties, or sensory attributes of treated food.

9. Packaging.—The licensee shall verify, prior to the treatment, that the packaging is of suitable quality for irradiation..

10. Re-Irradiation.—(1) The foods once irradiated shall not be re-irradiated. However, food with low moisture contents (cereals, pulses, dehydrated food and other such commodities) may be re-irradiated to control insect re-infestation. The maximum dose applied during the treatment of food shall not exceed the maximum radiation doses as specified in Schedule I.

(2) For the purpose of these regulations, food shall not be considered as having been re-irradiated when:

- (a) the food prepared from materials already irradiated at low dose levels for the purpose other than food safety such as quarantine control and preservation of the sprouting of roots and tubers;
- (b) the total food already containing less than 5% of irradiated ingredient is irradiated; or
- (c) the total dose of ionizing radiation required to achieve the desired effect applied to the food in more than one increment as part of the processing for a specific technological purpose.

(3) The cumulative maximum absorbed dose delivered to food shall not exceed 10 kGy as a result of re-irradiation except when it is necessary to achieve a legitimate technological purpose and shall not compromise consumer safety or wholesomeness of the food.

11. Labelling.—(1) The licensee shall ensure that the labelling of pre-packaged irradiated foods shall indicate the irradiation treatment and, in all aspects, shall be in accordance with the relevant provisions of the national and international labeling standards of prepacked foods;

(2) In case the food is irradiated in bulk, the international Radura symbol as prescribed in Schedule II of these regulations and the label "Treated with Ionizing Radiation" or "Treated by Irradiation" or "Irradiated" shall appear together with the name of the product on the container in which the food is placed.

12. **Dosimetry System.**—The licensee shall establish an appropriate dosimetry system at the facility and the dose measurements shall be traceable to national or international standards. The dosimetry system's documentation shall state the dosimetry methods and the calibration frequency of dosimeters.

13. **Records.**—(1) The licensee shall maintain the following records:

- (a) Name, nature, and quantity of food in the batch;
- (b) Unique reference number given to the batch;
- (c) Name and address of each customer of food within the batch;
- (d) Date on which the batch was irradiated;
- (e) Type of packaging in contact with the food in the batch during irradiation treatment;
- (f) Type, energy and dose of ionizing radiation applied to the batch;
- (g) Data used for control of the irradiation treatment including:
 - i. the positioning of dosimeters within the batch and the doses of ionizing radiation recorded by them;
 - ii. previous tests used to validate that positioning; and
 - iii. the method including instrumentation and frequency used for measuring the doses of ionizing radiation applied during the irradiation treatment.
- (h) Any incident or deviation observed during the irradiation treatment;
- (i) Customer's undertaking or certificate about the status of the food, whether non-irradiated or already irradiated;
- (j) Any action taken in case of non-compliance with regulatory requirements;
- (k) Source calibration or beam output measurement certificates, where applicable; and

(1) Any other relevant information as required by the Authority.

(2) The records shall be kept by the licensee for a period of three (03) years and shall be made available to the Authority, when required.

14. Issuance of Certificate for Irradiated Food.—(1) The licensee shall issue a certificate of irradiated food to the customer containing the following information:

- (a) Name of the customer;
- (b) Name and address of the irradiation facility;
- (c) Name and quantity of the food;
- (d) Date of irradiation;
- (e) Type, energy and dose of ionizing radiation;
- (f) The dose uniformity within the irradiated food; and
- (g) Reference number of the batch.

15. Reporting of the Event.—(1) In the event of a breach of any requirement of these regulations having an un-expected impact on food quality, the licensee shall:

- (a) investigate the breach and its causes, circumstances, and consequences;
- (b) take appropriate remedial action to prevent the recurrence;
- (c) report the event to the Authority within twenty-four (24) hours; and
- (d) submit a detailed report of the event to the Authority within sixty (60) days.

16. Enforcement in case of Non-compliance.—If a person contravenes any of the provisions of the Ordinance, the regulations made thereunder, any of the terms and conditions of an authorization, or any of the directives of the Authority, the Authority may take appropriate enforcement actions against such person, as prescribed in the Pakistan Nuclear Regulatory Authority Enforcement Regulations - (PAK/950).

17. Repeal.—The “Pakistan Nuclear Safety and Radiation Protection (Treatment of Food by Ionizing Radiation) Regulations, 1996” notified vide S.R.O.166 (I)/96 dated 5th March 1996 are hereby repealed.

Schedule I

Doses for Irradiation Treatment of Food

Classes of Food	Purpose	¹ Maximum Dose (kGy)
Class 1: Bulbs, roots and tubers	To inhibit sprouting during storage	0.2
Class 2: Fresh fruits and vegetables (other than Class 1)	– To delay ripening	1.0
	– Insect disinfestations	1.0
	– Shelf-life extension	2.5
	– Quarantine control	1.0
Class 3: Cereals and their milled products, nuts, oilseeds, pulses, dried fruits	– Insect disinfestations	1.0
	– Reduction of microbial load	5.0
Class 4: Fish, seafood and their products (fresh or frozen)	– Reduction of certain pathogenic micro-organisms	5.0
	– Shelf-life extension	3.0
	– Control of infection by parasites	2.0
Class 5: Raw poultry and meat products (fresh and frozen)	– Reduction of pathogenic and their micro-organisms	7.0
	– Shelf-life extension	3.0
	– Control of infection by parasites	2.0
Class 6: Dry vegetables, spices, condiments, animal feed, dry herbs and herbal teas	– Reduction of certain pathogenic micro-organisms	10.0
	– Insect disinfestations	1.0
Class 7: Dried food of animal origin	– Disinfestations	1.0
	– Control of moulds	3.0
Class 8: Miscellaneous foods, including, but not limited to honey, space foods, hospital foods, military rations, spices, liquid egg, thickener	– Reduction of micro-organisms	10-70
	– Sterilization	
	– Quarantine control	

¹The maximum dose is set for good irradiation practice. The irradiation treatment is not to be used as a substitute for good manufacturing practice.

Schedule II

Symbol for Food Treated by Ionizing Radiation

Following international Radura Symbol (green colour) along with given labelling shall be displayed on irradiated food container:



“Treated with Ionizing Radiation” or “Treated by Irradiation” or “Irradiated”

NAVEED MAQBUL,
Member (Corporate).