



**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL (NAFDAC)**

FOOD IRRADIATION REGULATIONS 2018

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS
(ending 29th August, 2018).**

PLEASE SEND ALL INPUT TO REGULATORYAFFAIRS@NAFDAC.GOV.NG

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Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap NI Laws of the Federation of Nigeria (LFN) 2004 and all powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

1. Scope

These Regulations shall apply to foods processed by ionizing radiation that is used in conjunction with applicable hygienic codes, food standards and transportation codes, manufactured, imported, exported, distributed, advertised, sold or used in Nigeria.

2. General requirements

- (1) Treatment of foods with ionizing radiation for human and animal consumption are prohibited except special authorization is given by the Agency.
- (2) The irradiation of food is justified only when it fulfills a technological need or where it serves food hygiene purposes and should not be used as a substitute for Good Manufacturing Practices (GMP).
- (3) Only foods intended for human and animal consumption or inputs to foods listed in Schedule 1 to these regulations can be licensed for irradiation, subject to the conditions specified thereof or as may be specified in the license.
- (4) Any person or facility that treats food with ionizing radiation shall comply with the Codes of Good Irradiation Practices (GIP), Good Manufacturing Practices (GMP) and the application of Hazard Analysis Critical Control Points (HACCP) Principles applicable to the particular food product treated.
- (5) Food Irradiation shall be aimed at:
 - (a) Contributing to public health by controlling pathogenic microorganisms, parasites and preservation of nutrients in food;
 - (b) Reducing post-harvest losses of food caused by insects, microorganisms and physiological processes and to increase shelf life;
 - (c) Overcoming quarantine barriers to trade and enhancing marketability of food.
 - (d) Slowing down ripening and ageing
 - (e) Preventing germination and sprouting
 - (f) Ensuring safe operation of food irradiation facilities.While ensuring that;
 - (i) there is reasonable technological need
 - (ii) it poses no health hazard
 - (iii) it benefits consumers
 - (iv) it does not replace hygiene, health or Good Manufacturing Practices (GMP) or Good Agricultural Practices (GAP).

3. Radiation sources

Any of the following types of ionizing radiation shall be used in food irradiation in accordance with the Codex General Standards for Irradiated Foods and licensed by the Nigeria Nuclear Regulatory Authority (NNRA) –

- (1) Gamma rays from the radionuclides of ^{60}Co and ^{137}Cs ;
- (2) X-rays generated from machine sources operated at or below energy Level of 5MeV; and
- (3) Electrons generated from machine sources operated at or below an energy Level of 10 MeV.

4. Absorbed dose

- (1) The overall average absorbed dose by a food subjected to radiation processing shall be less than 10 KGY.
- (2) The critical minimum dose as specified in Schedule 1 to these Regulations must be delivered to all parts of the food to achieve the desired effect of the Irradiation treatment.
- (3) The maximum dose permissible should not exceed 150% of the minimum dose to achieve the desired effect as specified in the Schedule to these regulations or in the license in order to avoid overdose.

5. Facilities and control of the process

- (1) Facilities and control of the process shall be as prescribed by the Agency and in strict compliance with the conditions stated in the license of operation and use of the facilities issued by the NNRA.
- (2) Facilities for Food Irradiation shall be licensed and registered with the NNRA.
- (3) Irradiation facilities shall be designed to meet the requirement of safety, efficacy and Good Hygienic Practices (GHP) of food processing and operated in such a way that the safety of the workers and the public is assured.
- (4) The facilities shall be staffed by adequate, well trained and competent Personnel who are licensed by NNRA.
- (5) Control of the process within the irradiation facility shall include the keeping of adequate records including quantitative dosimetry.
- (6) Premises and records shall be open to inspection by Personnel of the Agency.
- (7) The licensee of the irradiation facility shall have the ability to –
 - (a) measure absorbed dose in a given material of interest in an accurate and precise manner;
 - (b) determine and render useful information about the dose distribution in the materials;
 - (c) maintain or have ready access to accurate reference dose meters to calibrate the response of routine measuring or monitoring devices used in the facility;
 - (d) abide by prescribed dose meter selection criteria in order to provide precise, relevant and efficient dosimetry monitoring;
 - (e) keep accurate dosimetry records and use check lists at all stages of the dosimetry procedures.

6. Wholesomeness of irradiated foods

- (1) The wholesomeness of the irradiated foods shall be preserved by ensuring the minimum and maximum dose are complied with and the overall average dose of up to 10 KGY is

not exceeded, so that there is sufficient margin to guarantee radiological, toxicological and microbiological safety and nutritional adequacy.

- (2) The food shall comply with the provision of the General Principles of Food Hygiene and where appropriate, with the code of Good Hygienic Practices and HACCP Principles relative to a particular food.
 - (a) The food shall be prepared, processed, and transported hygienically in accordance with the provisions of the Codex Alimentarius Commission *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3-1997) including the HACCP Principles where applicable for food safety purposes.
- (3) comply with the enabling Act of the Agency and Regulations made under it and any other relevant National Public Health requirements affecting microbiological safety and nutritional adequacy applicable in Nigeria in which the food is sold, imported, exported, manufactured, stored, advertised, distributed and used shall be observed.

7. Packaging

- (1) Food to be irradiated and their packaging materials shall be of suited quality, acceptable hygienic condition and appropriate for this purpose, and shall be handled before and after irradiation, according to Good Manufacturing Practices (GMP) and HACCP Principles taking into account the particular requirements of the technology of the process.
- (2) The food packaging materials shall be suitable for irradiation and be adequate to prevent re-infestation 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.

8. Quality assurance

- (1) Quality control of irradiated Foods shall be carried out, records shall be kept in order to check compliance with the permitted dose range and the details dosimetry methods used shall be well spelt out and properly documented.
- (2) All products shall be handled before, during and after irradiation according to accepted GIP, GHP, GMP, GAP and HACCP principles taking into account the particular requirements of the process.
- (3) The incoming products shall be physically separated from the outgoing irradiated food products and 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.
- (4) Food irradiation shall be carried out in conformity with the Codes of Good Irradiation Practice (GIP) recommended by the International Consultative Group on Food Irradiation (ICGFI), including a proper dosimetry procedure and the dosimetry shall be in accordance with the Codex Alimentarius Commission standards.

9. Documentation

- (1) The licensee shall maintain a record of each batch of food subjected to radiation treatment.
- (2) The records specified in Regulation 12 (i) shall contain -
 - (a) the serial number of the batch;
 - (b) the date of irradiation;

- (c) the type and quality of the batch of irradiated food;
- (d) where appropriate, the type of packaging used during the irradiation treatment;
- (e) all controls and measurements performed during the irradiation treatment, particularly those related to the minimum and maximum dose absorbed; and
- (f) any incident or deviation observed during the radiation treatment.

The records maintained under Regulation 12(i) 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;

- (3) Every irradiation facility shall submit annually a written report to the Agency, 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;

10. Inspection

- (1) Every food irradiation facility may be inspected by the Agency at least once in a year,
- (2) The inspectors from the Agency shall in the course of their duty, have right of entry (if need be by force) to any place/premise which is used for the irradiation of food or for the storage of food which has been or is to be treated by irradiation.
- (3) The inspectors from the Agency shall have power to seize and detain, for such times as will be necessary for the purpose of these regulations, any articles by means of or in relation to which it reasonably believes is used for irradiation.
- (4) All relevant documents and records shall be made available for inspection by the licensee or his agent and shall cooperate with the inspectors.
- (5) The inspectors of the Agency shall have the right to procure samples or specimen for a specified purpose or examination.

11. Re-irradiation

- (1) Except for foods with low moisture content (cereal, pulse, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect re-infestation, food shall not be re-irradiated.
- (2) For the purpose of these regulations, food is not considered as having been re-irradiated when:
 - (a) the food is prepared from materials which have been irradiated at low dose levels, e.g., about 1KGY, for another technological purpose;
 - (b) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of one process for a specific technological purpose; and
 - (c) the total overall average absorbed dose shall not exceed 10kGY as a result of re-irradiation.

12. Labelling

- (1) All irradiated foods, foods containing irradiated components or processed foods prepared from irradiated materials to be imported, exported, advertised, distributed, stored, manufactured, sold and used shall have on the package label the Food Irradiation logo with inscription boldly written in words “preserved by irradiation” and “not to be re-irradiated” as in Schedule II of these Regulations.
- (2) The declaration of the fact of irradiation shall be made clear on the relevant shipping document and the labelling of such bulk containers shall comply with the provisions of the Codex Alimentarius Commission Standards.
- (3) For irradiated foods, whether pre-packaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the dose, the date of treatment, and the batch number.
- (4) Unpacked irradiated food intended for direct consumption shall have food irradiation logo and a bold inscription of “Food preserved by Irradiation” displayed in close proximity of the food item.

13. Trade in irradiated foods

Only foods listed in Schedule 1 to these Regulations may be preserved by irradiation for the purpose of sale as specified in the license of food irradiation to be granted by the Agency.

14. Importation

For the importation of irradiated foods, documents from the competent authority in the exporting country have to be submitted that demonstrate to the satisfaction of the Agency that the food was treated in accordance with the requirements as described in these Regulations. The shipping documents shall be accompanied by –

- (1) proper labelling documentation;
- (2) documentation that the food irradiation facility concerned is duly licensed; and
- (3) a Certificate by the competent authorities of the country of origin, to the effect that the food has been inspected by them.

15. Exportation

For the exportation of irradiated foods, the food shall be treated in accordance with the requirements of the country where the foods are being shipped to and all the requirements specified in these regulations that the host country does not object to.

16. Penalty.

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :
 - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding 50,000 or to both such imprisonment and fine; and
 - (b) a body corporate, to a fine not exceeding N100, 000.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-
 - (a) director, manager, secretary or other similar officer of the body corporate; or

- (b) partner or officer of the firm or
- (c) trustee of the body concerned ;or
- (d) person concerned in the management of the affairs of the association ;or
- (e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

17. Forfeiture after conviction

- (1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-
 - (a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;
 - (b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.
- (2) In this section, "**proceeds**" means any property derived or obtained, directly or indirectly, through the commission of the offence.

18. Interpretation

For the purpose of these regulations, unless the context otherwise requires:-

"Absorbed dose" means the amount of energy in joules absorbed by 1kg of product subjected to irradiation processing;

"Agency" means the National Agency for Food and Drug Administration and Control;

"Domestic consumption" means to be consumed in the country where they are produced

"Dosimetry" is the measurement of radiation energy absorbed;

"Food" means any article manufactured, sold or advertised for use as food or drink and includes drinking water, chewing gum, and such other ingredients as may be mixed with food for any purpose whatsoever, including supplements processed for addition to animal and poultry feeds;

"Food Irradiation" means Processing of food by ionizing radiation, specifically gamma rays, X-rays or electron beams as stated in the Codex General Standard for Irradiated Food.

"Food Irradiation Facility" means a suitable facility, licensed, authorized and registered by the NNRA to irradiate food;

"GAP" means Good Agricultural Practices

“GHP” means Good Hygienic Practices

“GIP” means Good Irradiation Practices

“GMP” means Good Manufacturing Practices

“Gray” means deposition of energy of energy of one Joule in a material of one kilogram.

“HACCP” means Hazard Analysis and Critical Control Points

“Ionizing radiation” means radiant energy that has the ability to break chemical bonds

“Irradiated food” is any food which has been subjected to treatment by ionizing radiation;

“kGY” means Kilogray

Kilogray (1KGY = 1,000Gy)

“Licensing of Facility” means approval of an irradiation facility by NNRA under regulations governing the safe use of ionizing radiation (including the handling, transport and eventual disposal of radioactive sources).

“Licensee” means the license holder/certificate holder.

“Lot or batch” means a quantity of food irradiated under the same condition and at the same time;

“Main Ingredient” means any ingredient, which constitutes more than 5% of the total mass or volume of the final product;

“MeV” means megaelectronvolt (**MeV**).

“NNRA” means the Nigerian Nuclear Regulatory Authority;

“Radiation” means energy that is emitted from a source.

19. Repeal of 2005 regulations

1. Food Irradiation Regulations 2005 is hereby repealed.
2. The repeal of the Regulations specified in Regulation 22(1) of this regulation shall not affect anything done or purported to be done under the repealed Regulations.

20. Citation

These regulations may be cited as the Food Irradiation Regulations 2018.

DRAFT

SCHEDULE 1
CATEGORIES AND NAMES OF FOODS AND PRODUCTS THAT MAY BE
IRRADIATED

CLASSES OF FOOD PURPOSE REQUIRED DOSE

CLASSES OF FOOD	PURPOSE	REQUIRED DOSE (kGY)
Class I: bulbs, roots, and tubers. (Onions, Yams and Potatoes)	To inhibit sprouting during storage	0.2
Class 2: Fresh fruits and vegetables (other than Class I) Plantains and Mangoes	(a) To delay ripening;	1.0
	(b) Insect disinfestations;	1.0
	(c) Shelf-life extension;	1.5
	(d) Quarantine control	1.5
Class 3: Cereals and their milled Products, nuts, oil seeds, pulses and dried fruits, Beans, Maize, Millet, Sorghum, Cocoa and Kola nuts.	(a) Insect disinfestation	1.0
	(b) Reduction of microbial load.	5.0
Class 4: Fish, seafood and their product (fresh and frozen).	(a) Reduction of Pathogenic microorganisms;	5.0
	(b) Shelf-life extension;	3.0
	(c) Control of infections by parasites	2.0
Class 5: Raw poultry and meat, and their products (fresh and frozen), Chicken, Turkey, Beef etc	(a) Reduction of pathogenic Microorganisms;	7.0
	(b) Shelf-life extension;	3.0
	(c) Control of infections by parasites	2.0
Class 6: Dry vegetables, spices and condiments, animal feeds, Dry herbs and Herbal teas, Pepper	(a) Reduction of certain pathogenic microorganisms;	10.0
	(b) Insect disinfestations.	1.0
Class 7: Dried food of animal origin, Smoked	(a) Insect disinfestations;	1.0

fish, Dried Meat, Stockfish	(b) Control of mould.	3.0
Class 8: Miscellaneous food including but not limited to honey, space foods, hospital foods, military rations, spices, liquid eggs and thickeners.	(a) Reduction of Microorganisms;	less than 10
	(b) Sterilization;	less than 10
	(c) Quarantine control.	less than 10

SCHEDULE II

A thick green-edge circle with discontinuous curve of an upper hemisphere dividing 4 equal sections, 5 equal spaces between outer edge of each section, continuous thick curve of a lower hemisphere, a small full yellow circle within an upper hemi-circle and 2 separately hollow ellipses joining one end of each together by green circumferences within a lower hemi-circle.



Treated by/with Irradiation

SCHEDULE III

LICENSE FOR RADIATION PROCESSING OF FOODS IN NIGERIA

This shall be as described by the Agency.

MADE at Abuja this day of 2018

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**Inuwa Abdulkadir Esq
Chairman Governing Council**

National Agency for Food and Drug Administration and Control (NAFDAC)