[DOH ADMINISTRATIVE ORDER NO. 152, S. 2004, March 01, 2004]

PRESCRIBING REGULATIONS FOR IRRADIATED FOOD

I. RATIONALE/BACKGROUND

Pursuant to Republic Act 3720 Section 26 (a), otherwise known as the Food, Drugs and Devices and Cosmetics Act (as amended), this Administrative Order on Regulation for Irradiated Food is issued to ensure safe supply of irradiated food and prevent undue risk to safety and public health in the application of ionizing radiation to reduce wastage caused by insects, micro-organism, physiological processes, and to control pests of quarantine significance in foods.

II. SCOPE

These regulations shall cover all food irradiation facilities and all irradiated foods, whether produced for domestic consumption, imported or for export.

III. DEFINITION OF TERMS

1. Absorbed Dose, or sometimes simply referred to as Dose - the quantity of ionizing radiation energy imparted per unit mass of the irradiated food.

Such does is expressed as:

1.1 Gray (Gy) - SI unit of absorbed dose, equivalent to the absorption of 1 joule per kilogram food (1Gy = 1j/kg)

2. BFAD - Bureau of Food and Drugs, Department of Health

3. BFAR - Bureau of Fisheries and Aquatic Resources, Department of Agriculture

4. BHDT - Bureau of Health Devices and Technology, Department of Health

5. BPI - Bureau of Plant Industry, Department of Agriculture

6. Dosimetry - measurement of absorbed dose

7. Fish and Fishery Products - raw, frozen and processed fish, fishery products and other aquatic products, e.g., shrimps

8. Food - any substance, whether processed, semi-processed or raw, which is intended for human consumption and includes beverage, chewing gum and any other substance which has been used in the manufacture, preparation of treatment of "food"

9. Food Establishment - food manufacturer, processor and distributor.

10. Food Irradiation - the processing of food by ionizing radiation for a technological objective or to serve a food hygiene purpose.

11. Food Irradiation Facility - a suitable facility licensed to irradiate food

12. Ionizing Radiation - any gamma rays, x-rays or corpuscular radiation capable of producing ions directly or indirectly, as specified in IV. C - Reporting/Recording hereof.

13. Irradiated Food - any food product, which has been subjected to treatment by ionizing radiation with an appropriate absorbed dose. This does not apply to foods exposed to radiation imparted by measuring instruments for inspection purposes.

14. Meat and Meat Products - raw, frozen and processed meat and poultry/livestock products

15. NMIS - National Meat Inspection Service, Department of Agriculture

16. PNRI - Philippine Nuclear Research Institute, Department of Science and Technology

17. Plant Products - products derived from plants, either in their natural state or in manufactured or processed form (fresh and vegetables; rootcrops; cereal, legumes and grains; processed and unprocessed spices, seeds and nuts)

IV. POLICIES AND GUIDELINES

A. Licensing Requirements

a. General Licensing Requirements

1. Radiation treatment of food shall be carried out in a food irradiation facility licensed and registered as required in this AO.

2. The food irradiation facility shall be designed and operated to meet requirements of safety, efficacy and good hygienic practices of food processing.

3. The food irradiation facility shall be staffed and operated by adequate, trained and competent personnel.

4. * Food irradiation facility shall operate within PNRI or BHDT standards and requirements in the utilization and disposal or ionizing radiation for food and food products.

b. Specific Licensing Requirements

b.1 Food Establishment with Food Irradiation Facility

1. Food establishment with food irradiation facility shall be licensed and controlled by BFAD.

2. A License to Operate shall be issued by BFAD if food establishment complies with the following:

a. Current Codex General Standard for Irradiated Foods (Annex A**)
b. Current Codex Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods (Annex B**)
c. Good Manufacturing Practice (GMP) (Annex C**)

3. For food establishment with existing LTO, the LTO shall indicate that it has food irradiation facility.

4. No food establishment shall operate a food irradiation facility without a Radioactive Material License (Large Irradiator) from PNRI in the case of gamma radiation facilities or a license from BHDT in the case of electron beam and x-ray facilities.

b.2 Food Establishment with Irradiated Product/s

1. Food Establishment that intend to irradiate food product/s shall secure a certification from BFAD.

2. A certification shall be issued to food establishments only upon demonstration of compliance with Good Manufacturing Practices.

3. For quarantine control, the food establishment shall be accredited and controlled by:

a. BPI for fresh fruits and vegetables
b. BFAR for fresh and frozen fish
c. NMIS for fresh and frozen meat/poultry/livestock
d. BFAD for processed food and food products

B. Standard Requirements for Food Irradiation

1. Radiation Sources

The following sources of ionizing radiation may be used for irradiation of food:

a. Gamma rays from radionuclides ^{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 sources operated at or below an energy level of 10 MeV

2. Irradiation of food is justified when it fulfils a technological objective or when it serves a food hygiene purpose and should not be used as a substitute for good manufacturing practice.

3. Food intended for irradiation treatment must meet the general requirements of quality and hygiene as recommended by the Codex General Principles of Food Hygiene and other relevant Codex standards and codes of practice.

4. The food packaging materials used shall be suitable for irradiation and be adequate to prevent re-infestation and re-contamination. Such packaging

materials should maintain their integrity during storage, transport and distribution.

5. The recommended dose ranges for the irradiation of various classes of foods for specified treatment objectives is shown in Appendix I. Doses outside this range may be applied provided satisfactory information and assurance is given that the doses applied will commensurate with technological and public health purposes to be achieved and is in accordance with good radiation processing. Food treated by ionizing radiation shall receive at least the minimum dose required to achieve the desired technological effect and the maximum dose received shall not affect the quality of the product.

6. The irradiated food shall comply with the current Codex General Standard for Irradiated Food

7. Control of the irradiation process shall be carried out in accordance with the current Codex Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods

The quality assurance system of the facility shall be documented and shall include:

7.1 Dosimetry complying with duly recognized international practices. As such the operators shall be able to demonstrate the ability to carry out dosimetry as provided hereunder:

7.2 Procedures to physically segregate irradiated from non-irradiated food products.

a. Measure absorbed dose in an accurate and precise manner
b. Determine the dose distribution in the product
c. Calibrate dosimetry systems, traceable to national or international standards
d. Keep dosimetry records

7.2 Procedures to physically segregate irradiated from non-irradiated food products

When applicable, a visual color change radiation indicator can be affixed to the outer package to readily distinguish irradiated from non-irradiated products.

C. Reporting/Recording

1. The facility shall submit an annual written report to BFAD, containing the following information

a. The name of the facility
b. The reporting period (January 1 - December 31)
c. Description of food treated by ionizing radiation
d. The quantity food treated by ionizing radiation, including lot numbers and date of irradiation.

2. Documentation process to maintain a record of each batch of food subjected to the irradiation treatment. Such records shall be kept for a period of three