

**(unofficial translation)**

Notification of the Ministry of Public Health

Re : Irradiated Food

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It deems appropriate to revise the Notification of the Ministry of Public Health Re: Irradiated Food

By virtue of the provision of Section 5, 6(7), and (10) of the Food Act (B.E. 2522 (1979), which restricts personal rights and liberties in conjunction with sections 29, 33, 41, 43 and 45 of the Constitution of the Kingdom of Thailand, the Minister of Public Health, issues the notification as follows:

Clause 1 Notification of the Ministry of Public Health No. 297 B.E. 2549 (2006) entitled: Irradiated Food, dated 7 August 2549 (2006) shall be repealed.

Clause 2 In this Notification:

“Irradiated food” means foods processed by ionizing radiation in order to achieve the purpose of irradiation.

“Food irradiation” means processing of food by ionizing radiation to achieve the purpose of the irradiation.

“Food radiation processor” means one who has been granted an approval for processing of food irradiation.

“Absorbed Dose” means the amount of energy absorbed per unit mass of irradiated food product having unit in Grey.

Clause 3 Irradiated food is the prescribed food on methods and equipments for irradiation as well as the storage and labeling of irradiated foods

Clause 4 Food products intended for radiation process shall be:

(1) Prepared and operated under Good Manufacturing Practices in compliance with the Notification of the Ministry of Public Health on “Production Processes, Production Equipments, and Food Storages” or “Minimum Requirement on Food Hygiene” or “General Principles of Food Hygiene” depending on case in order to achieve the goal of safety of food control.

(2) In complied with the related the Notifications of the Ministry of Public Health regarding on Food.

Cluase 5 Packages used for containing irradiated food either of pre-irradiation or post-irradiation shall be appropriate and hygienic according to the technological

purpose of irradiation as well as to the Notification of the Ministry of Public Health regulations on Food Packaging

Clause 6 Irradiation of food shall not be used as a substitute as specified in clause 4(1)

Clause 7 Food irradiation processors are required to practice the following requirements not lower than the criteria as prescribed in Annex 1 of the proposed draft regulation.

Inspection of methods, and equipments for irradiation including the storage of irradiated food shall follow the criteria and conditions as prescribed by the Secretary General of the Food and Drug Administration under an approval of the Food Committee

Clause 8 The sources of ionizing radiation shall be as follows ;

(a) Gamma rays from radionuclides Cobalt-60 ( $^{60}\text{Co}$ ) or Cesium-137 ( $^{137}\text{Cs}$ ); or

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

(c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

Clause 9 Absorbed dose of food irradiation shall meet:

(1) The minimum absorbed dose which is sufficient to achieve the technological purpose of irradiation and,

(2) The maximum absorbed dose shall meet in accordance with the technological purpose of irradiation, but not exceeding the absorbed dose indicated in Annex 2 of the proposed draft regulation which can still retain the nutrition value; not affect its structural integrity, functional properties and sensory attributes.

For the non-compliant food irradiation as indicated in Annex 2 of the proposed draft regulation, a supportive technical evidence or a reason is required to be shown for the permission by the Secretary General of the Food and Drug Administration under an approval of the Food Committee.

Clause 10 Irradiated foods shall not be re-irradiated except for foods with low moisture content intended to control the insect reinfestation, such as cereals, pulses, dehydrated foods and other such commodities.

Clause 11 Food is not considered as having been re-irradiated when:

(1) Food was prepared from materials which had been irradiated at low dose levels e.g. quarantine pest control, prevention of sprouting of roots and tubers; and is re-irradiated for the other purposes;

(2) Food, containing less than 5% of irradiated ingredient, is irradiated;

(3) Food, that cannot be irradiated in the full dose of ionizing once radiation to achieve the purpose of irradiation.

Clause 12 Irradiated foods in clause 10 and clause 11 shall have cumulative maximum absorbed dose delivered to a food not exceed 10 kGy except when it is necessary to achieve a legitimate technological purpose, and shall not compromise consumer safety or wholesomeness of the food; in this regard, if cumulative maximum absorbed dose exceeds 10 kGy must have a permission from the Secretary General of the Food and Drug Administration under an approval of the Food Committee.

Clause 13 Labeling of irradiated foods shall display the following additional details, other than follows the Notification of Ministry of Public Health, Re: Label and Notification of the Ministry of Public Health for each particular food:

(1) Name and location of head office of food manufacturers and food radiation processor;

(2) The statement of “ผ่านการฉายรังสีแล้ว” (“irradiated”) or other statements that convey the same meaning;

(3) The purpose of irradiation with the following clause “เพื่อ.....” (“For.....”) (specify the purpose of irradiation in the blank)

(4) The food irradiation symbol as appeared in Annex 3 of this Notification in close proximity to the name of the food.

(5) Date, month and year of irradiation.

Clause 14 In case an irradiated food is used as an ingredient in another food or a single ingredient product is prepared from a raw material which has been irradiated. it shall be expressed as clause13(2) accompanied with the name of ingredient.

Clause 15 The transitional period for irradiation of food which the permission approved prior to the effectiveness of this notification, shall follow as stipulated in Clause 7 within one year as from the date of this notification is effective.

Clause 16 Importers of irradiated food are required to provide with the certificate of the establishment for irradiation processing of the imported irradiated food into Thailand not lower than the related criteria as prescribed in Annex 1 or the equivalent standard from the government competent authority or others agencies accepted by the government competent authority of the origin countries

In case where the reason or necessity to protect the consumers is needed; the Food and Drug Administration may prescribe the establishments as indicated above to achieve the assessment conducted by either the Food and Drug Administration or organizations or authorities announced by the Secretary General of the Food and Drugs Administration under an approval of the Food Committee

Clause 17 Licensees of Import of irradiated food which the permission license approved prior to the effectiveness of this notification, shall follow as stipulated in clause 16 within one year as from the date of this notification is effective.

Clause 18 Irradiated food manufacturers or importers, whose permissions were granted by the Food and Drug Administration before the effectiveness of this Notification, and the labels did not comply with the clause 13, they shall improve the labeling to conform to this Notification. The transitional period for the remaining label is allowed to be used not exceeding to one year as from the date of this notification is effective.

Clause 19 This Notification is effective on the day following day of its announcement in the Government Gazette.

Notified on 14<sup>th</sup> September B.E. 2553 (2010)

Jurin Laksanawisit

(Mr. Jurin Laksanawisit)

Minister of Public Health

(Copy from the Government Gazette, General edition no. 127, Special section 121 Ngor., 18<sup>th</sup> October B.E. 2553 (2010))

**Note:** This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

Annex 1**Attachment to the Notification of the Ministry of Public Health Re: Irradiated Food**

Method and Equipments for Irradiation and Storage of Irradiated Food shall be set for irradiation of food as the followings :

No	Item	Description
1.	Location, building and its design	<p>1.1 Location, building and surrounding area shall be located in an area which is appropriate for preventing from contamination on irradiated food</p> <p>1.2 Design of irradiation building:</p> <p>1.2.1 shall be approved by the responsible government agency on the safety aspects.</p> <p>1.2.2 shall be suitable and have adequate size and space partition.</p> <p>1.2.3 shall be easy for maintenance, cleaning, and convenience to work.</p> <p>1.2.4 shall have sufficient light for operation.</p> <p>1.2.5 shall have appropriate ventilation for operation.</p> <p>1.2.6 shall have preventive measures to prevent animals and insects.</p> <p>1.3 Inside of irradiation building, at least should have rooms or areas as the followings :</p> <p>1.3.1 Rooms or areas for storage of non-irradiated foods under appropriate temperature condition.</p> <p>1.3.2 Rooms or areas for storage of irradiated foods under appropriate temperature condition.</p> <p>1.3.3 Rooms or areas for locating of irradiator and irradiation facilities</p> <p>1.3.4 Irradiation room.</p> <p>1.3.5 These rooms or areas are proportionately separated for each line of irradiation operation.</p> <p>1.3.6 These rooms or areas are separated from office restrooms and accommodation for staff in order to prevent cross contamination.</p> <p>1.3.7 No non-use or irrelevant materials for production in production areas.</p>

No	Item	Description
2.	Radiation source and facilities	<p>2.1 The following sources of ionizing radiation may be used in food irradiation:</p> <p>2.1.1 Gamma rays from radionuclide Cobalt-60 (<math>^{60}\text{Co}</math>) or Cesium-137 (<math>^{137}\text{Cs}</math>).</p> <p>2.1.2 X-rays generated from machine sources operated at or below an energy level of 5MeV.</p> <p>2.1.3 Electrons generated from machine sources operated at or below an energy level of 10MeV.</p> <p>2.2 Radiation facilities shall be designed to provide an absorbed dose in the food product within minimum and maximum limits in accordance with process specifications and regulatory requirements.</p>
3.	Food irradiation and operation control	<p>3.1 Foods intended for irradiation process shall be prepared under Good Manufacturing Practices in compliance with the MOPH notifications entitled “Production Processes, Production Equipments, and Food Storages” or “Minimum requirement on food hygiene” or “General Principles of Food Hygiene”</p> <p>3.2 Transportation and storage of the food product prior to irradiation shall have preventive measures to prevent contamination.</p> <p>3.3 The size and shape of packaging used for irradiation shall be designed appropriately for characteristics of food and characteristics of irradiation facilities.</p> <p>3.4 Irradiation of food shall be carried out as the followings :</p> <p>3.4.1 Establish a clear statement for the purpose of irradiation for the irradiation process.</p> <p>3.4.2 Estimate the dose range to achieve the purpose of irradiation which appropriated with the food product intended for irradiation.</p> <p>3.4.3 Test a plant commissioning for the first operation and whenever there is a change in radiation source.</p> <p>3.4.4 Test a dose mapping for a particular food product or a group of food products for the first irradiation and whenever there is a change in loading configuration, weight, density, packaging of foods and radiation source.</p>

No	Item	Description
		<p>3.4.5 Control and record all parameters that influence on absorbed dose, such as: position of radiation source , time, strength, absorbed dose, order of loading configuration, food product density to ensure that the intended purpose of irradiation is achieved throughout the production lot.</p> <p>3.5 Product Identification :</p> <p>3.5.1 Giving a code number to identify the packages at each step in its path through the irradiation process.</p> <p>3.5.2 Recording all relevant parameters such as date, time, strength of radiation source, minimum and maximum absorbed dose, temperature, etc. regarding to the code number of product.</p> <p>3.6 Post-Irradiation Handling :</p> <p>3.6.1 Having appropriate system to separate irradiated foods from non-irradiated foods.</p> <p>3.6.2 Having appropriate inspection and storage of irradiated foods as well as the packaging of irradiated food must be complete appearance.</p> <p>3.6.3 Having adequate control of product and inventory control system to ensure that specific consignments of food products be traced back both to the irradiation facility and the food manufactory prior to irradiation.</p> <p>3.6.4 Having appropriate transportation procedures to prevent contamination of irradiated food.</p>
4.	Dosimetry and control	<p>4.1 Selection an appropriate dosimetry system, which consists of dosimeters, measurement instruments and their associated reference standards. There shall be having appropriate procedures that suitable for the system's use.</p> <p>4.2 Carrying out measurement of a dose distribution.</p> <p>4.3 Carrying out measurement of the absorbed dose of food product in the production lot.</p> <p>4.4 Planning and calibration of dosimetry system for radiation processing shall be traceable to national or international standards at least once a year.</p>



No	Item	Description
5.	Record and report	<p>Food radiation processors shall have adequate records of irradiation and maintain that records in the irradiation establishment for at least 3 years with good record keeping system.</p> <p>5.1 Records of product details as follows:</p> <p>5.1.1 Weight, food density, and quantity of products that intended for the irradiation process at each production lot.</p> <p>5.1.2 Type of packaging materials used for irradiation.</p> <p>5.1.3 Name and address of food manufacturers in each irradiation lot.</p> <p>5.1.4 Product code number or lot number of each production lot.</p> <p>5.2 Records of data and control of parameters affected on irradiation process. :</p> <p>5.2.1 Strength of radiation source</p> <p>5.2.2 Type of irradiation source, dose range intended to use, and the arrangement of products in the package.</p> <p>5.2.3 Date of irradiation and purpose of irradiation</p> <p>5.2.4 Minimum and maximum absorbed dose including type of dosimeters</p> <p>5.2.5 Details of dosimetry system calibration</p> <p>5.2.6 The position of dosimeters, radiation dose, and dosimetry results.</p> <p>5.2.7 Results of test samples to confirm the position of dosimeters on food products.</p> <p>5.2.8 Method (including instruments and frequency of measurement) for dosimetry process and validation tests.</p> <p>5.3 Reports of dosimetry result.</p> <p>5.4 Records of machine and equipment maintenance system.</p> <p>5.5 Records or reports of staffs' trainings</p> <p>5.6 Records of transportation and their conditions</p> <p>5.7 Records of all relevant documents verification.</p>

No	Item	Description
6.	Sanitation	<p>6.1 Water used for general cleaning in irradiation establishment shall be clean and quality adjusted, if necessary.</p> <p>6.2 Providing appropriate and effective drainage to prevent cross contamination into irradiation process.</p> <p>6.3 Providing appropriate garbage bin with lids and having appropriate elimination system.</p> <p>6.4 Providing for staff adequate and sanitary toilets, hand wash basin with fully facilities to wash hand.</p> <p>6.5 Having appropriate measures for animals and insects elimination in irradiation area.</p>
7.	Cleaning and maintenance	<p>7.1 Irradiation building shall be clean and regularly maintain in good condition clean at all time.</p> <p>7.2 Tools, equipments and irradiation facilities used for irradiation process, surface area of tools and equipments contact with packaging shall be cleaned, maintained, and kept in clean condition.</p> <p>7.3 Tools, equipments, irradiation facilities used for irradiation process shall have maintenance program and shall operate and inspected to maintain in good condition for efficient uses.</p> <p>7.4 Chemical for washing or sanitizing, chemicals for maintenance shall be used under specified conditions and kept separately for safety.</p>
8.	Personnel and personal hygiene	<p>8.1 Staffs in irradiation building shall not be infected from contagious disease or repugnant disease as prescribed in the Ministerial Laws.</p> <p>8.2 During irradiation process, all staffs which have direct contact to food, ingredients, or any surface which may have contact to food must be as the followings:</p> <p>8.2.1 Wear clean and suitable clothes for operation, wherever use of outer garment shall be clean.</p> <p>8.2.2 Having measures of a personal hygiene as necessary.</p>

No	Item	Description
		<p>8.3 The operational staffs of irradiation process shall be trained as the followings:</p> <p>8.3.1 Personal hygiene for general staffs</p> <p>8.3.2 The operation of irradiator and irradiation facilities for responsible staffs.</p> <p>8.3.3 Irradiation process control and dosimetry measurement for responsible staffs.</p> <p>8.4 Personnel not relevant to irradiation process shall follow to 8.1 - 8.2 when being in irradiation area.</p>

**Annex 2**

Attachment to the Notification of the Ministry of Public Health

Re: Irradiated Food

Table : the maximum absorbed dose for the purpose of irradiation

No.	Purpose of Irradiation	Maximum Absorbed Dose (Kilogray)
1	To prevent germination of roots and tubers during storage	1
2	To slow down ripeness	2
3	To control insect disinfestation	2
4	To decrease the amount of parasite	4
5	To prolong shelf life	7
6	To decrease the amount of microorganisms and pathogens	10

**Annex 3**

Attachment to the Notification of the Ministry of Public Health

Re: Irradiated Food

The food irradiation symbol



The symbol is a green bold edged circle. The edge of the upper half circle is divided equally into four fragments by five equal spaces. There is one small green bold circle located in the upper half of inner circle. Whereas in the lower half of inner

circle contains two separate green ellipses and each has one end connecting to the other.