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MS 1265-1 (2007) (English): CODE OF GOOD IRRADIATION PRACTICE – PART 1: GENERAL (FIRST REVISION)

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# MALAYSIAN STANDARD

MS 1265: PART 1:2007

# CODE OF GOOD IRRADIATION PRACTICE – PART 1: GENERAL (FIRST REVISION)

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MALAYSIA

Tel: 60 3 8318 0002
Fax: 60 3 8319 3131
http://www.standardsmalaysia.gov.my

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OR

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MALAYSIA

Tel: 60 3 5544 6000
Fax: 60 3 5510 8095
http://www.sirim.my

E-mail: msonline@sirim.my

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## Committee representation

The Food and Food Products Industry Standard Committee (ISC U) under whose authority this Malaysian Standard was developed comprises representatives from the following organisations:

Department of Agriculture

Department of Chemistry

Department of Standards Malaysia

Federal Agricultural Marketing Authority

Federation of Malaysian Manufacturers

Malaysian Agricultural Research and Development Institute

Malaysian Association of Standards Users

Malaysian Institute of Food Technology

Malaysian Palm Oil Association

Malaysian Palm Oil Board

Ministry of Agriculture and Agro-Based Industry

Ministry of Health Malaysia

Ministry of International, Trade and Industry

National Biotechnology Division, MOSTI

Universiti Kebangsaan Malaysia

Universiti Putra Malaysia

The Working Group on Food Irradiation which developed this Malaysian Standard consists of representatives from the following organisations:

Department of Fisheries Malaysia

Department of Veterinary Services Malaysia

Federation of Malaysian Consumers Associations

Malaysian Agricultural Research and Development Institute

Malaysian Nuclear Agency

Ministry of Health Malaysia

SIRIM Berhad (Secretariat)

Universiti Putra Malaysia

## FOREWORD

This Malaysian Standard was developed by the Working Group on Food Irradiation under the authority of the Food and Food Products Industry Standards Committee.

MS 1265 consists of the following parts, under the general title *Code of good irradiation practice:*

- *Part 1: General*

- *Part 2: Bulb and tuber crops for sprout inhibition*

- *Part 3: Fresh fruits and vegetables for insect disinfestations and quarantine treatment*

- *Part 4: Cereal grains for insect disinfestations*

- *Part 5: Dried fish and dried salted fish for insect disinfestations*

- *Part 6: Bananas, mangoes and papayas for shelf-life extension*

- *Part 7: Fish, shrimps and frog legs for the control microflora*

- *Part 8: Prepackaged meat and poultry for the control of pathogens and/or to extend shelf-life*

- *Part 9: Spices, herbs and vegetable seasonings for the control of pathogen and microflora*

- *Part 10: Dried meat and dried salted meat of animal origin for insect disinfestations, control of moulds and reduction of pathogenic microorganisms*

This Malaysian Standard is the first revision of MS 1265: Part 1:1992, *Guidelines for irradiation of foods: Part 1: General.*

Major modifications in this revision are as follows:

a) the requirements and guidance for the overall average absorbed dose (OAAD) have been amended;

b) new radiation source has been added;

c) the requirements and guidance for re-irradiation process have been revised; and

d) the labelling requirements have been revised.

This revised Malaysian Standard cancels and replaces MS 1265: *Code of good irradiation practice*. Part 1:1992: *General*

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

# CODE OF GOOD IRRADIATION PRACTICE – PART 1: GENERAL (FIRST REVISION)

## 1. Scope

**1.1** This Malaysian Standard describes the code of good practice of food processed by ionising radiation. This standard does not apply to foods exposed to radiation imparted by measuring instruments used for inspection purposes.

**1.2** The foods processed by irradiation, like any other foods, shall in all other aspects comply with the requirements of the legislation currently enforced in the country and good manufacturing practices, where applicable.

## 2. Normative references

The following normative references are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the normative reference (including any amendments) applies.

MS 1265: Part 2, *Code of good irradiation practice - Part 2: Bulb and tuber crops for sprout inhibition*

MS 1265: Part 3, *Code of good irradiation practice - Part 3 : Fresh fruits and vegetables for insect disinfestations and quarantine treatment*

MS 1265: Part 4, *Code of good irradiation practice - Part 4: Cereal grains for insect disinfestations*

MS 1265: Part 5, *Code of good irradiation practice - Part 5: Dried fish and dried salted fish for insect disinfestations*

MS 1265: Part 6, *Code of good irradiation practice - Part 6: Bananas, mangoes and papayas for shelf-life extension*

MS 1265: Part 7, *Code of good irradiation practice - Part 7: Fish, shrimps and frog legs for the control of microflora*

MS 1265: Part 8, *Code of good irradiation practice - Part 8: Prepackaged meat and poultry for the control of pathogens and/or extend shelf-life*

MS 1265: Part 9, *Code of good irradiation practice - Part 9: Spices, herbs and vegetable seasonings for the control of pathogens and microflora*

MS 1265: Part 10, *Code of good irradiation practice - Part 10: Dried meat and dried salted meat of animal origin for insect disinfestations, control of moulds and reduction of pathogenic microorganisms*

MS 1514, *General principles of food hygiene*

MS 1480, *Food safety according to hazard analysis and critical control point (HACCP) system*

## 3. Definitions

For the purposes of this standard, the following terms and definitions apply.

### 3.1 Food irradiation

Exposing of food to ionising radiation for the purposes of radiation preservation, insect disinfestation, parasite or microbial pathogen disinfection and quality improvement.

### 3.2 Irradiated foods

Food products processed by ionising radiation in accordance with this standard. Such food is subject to all relevant Malaysian Standards and current legislation applicable to the non-irradiated counterpart.

### 3.3 Radiation preservation

Prolonging shelf/storage life through sprout inhibition, maturation delay, sterilisation or pasteurisation (radurisation).

### 3.4 Ionising radiation

Radiation capable of directly or indirectly causing ionisation in their passage through product.

### 3.5 Dose

#### 3.5.1 Absorbed dose

The amount of ionising energy absorbed by the irradiated food expressed in the Standard International (SI) unit called the Gray (Gy), which is defined as 1 J of energy absorbed per kg of the product.

#### 3.5.2 Overall average absorbed dose (OAAD)

OAAD is defined as $(D^{max+}D^{min})/2$ where $D^{max}$ is the maximum dose absorbed by the product, and $D^{min}$ is the minimum dose absorbed by the product.

## 4. General requirements for the process

### 4.1 Radiation sources

For food irradiation, the following types of ionising radiation may be used.

a) Gamma rays from the radionuclides Cobalt-60 or Caesium-137.

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

c) Electrons generated from machine sources operated at or below 10 MeV.

### 4.2 Overall average absorbed dose (OAAD)

**4.2.1** $D^{max}$ of the OAAD should not exceed 10 kGy for whole food.

**4.2.2** The OAAD should not exceed 10 kGy, except in the cases of spices and vegetable seasonings which may receive up to 30 kGy.

**4.3** A suitable dosimetry system is required for measuring the amount of energy absorbed by the product (i.e. for validating)

### 4.4 Facilities and control of the process

**4.3.1** Food irradiation should be carried out only in the facilities licensed for this purpose by the appropriate regulatory agency(ies).

**4.3.2** The facilities should be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.

**4.3.3** The facilities should be operated by trained personnel certified by the appropriate regulatory agency(ies).

**4.3.4** Control of the process within the facility should include the keeping of records on the application of dose, and its measurement. Initial dose distribution measurements should be carried out to characterise the process for each product, and thereafter dosimeters should be used routinely to monitor correct execution of the process in accordance with the requirements of the appropriate regulatory agency(ies). The dosimetry should be traceable to the national and international standards and thus provide an independent control of the process.

**4.3.5** Premises and records should be open for inspection by the appropriate regulatory agency(ies).

**4.3.6** Operation of the facility and process control should be carried out in accordance with the recommended code of practice for the operation of irradiation facilities used for the treatment of foods described in Annex A, MS 1265 Parts 2, 3, 4, 5, 6, 7, 8, 9 and 10, and the requirements of the legislation currently enforced in the country.

## 5. Hygiene of irradiated food

**5.1** The food intended for irradiation should comply with the good manufacturing practices outlined in MS 1265 Parts 2, 3, 4, 5, 6, 7, 8, 9 and 10, and the requirements of the legislation currently enforced in the country.

**5.2** The irradiated foods is recommended to be prepared, processed and handled in accordance with the appropriate sections of MS 1514 and application of MS 1480.

## 6. Technological requirements

### 6.1 Conditions for irradiation

The irradiation of food should only be done when it fulfils a technological need or where it serves a food hygiene purpose, and should not be used as a substitute for good manufacturing practices.

### 6.2 Food quality and packaging requirements

The doses applied shall commensurate with the technological and public health purposes to be achieved and shall be in accordance with good irradiation practices. Foods to be irradiated and their packaging materials should be of suitable food grade quality, acceptable hygienic condition and appropriate for this purpose and should be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the product and the process.

## 7. Re-irradiation

**7.1** Food irradiated in accordance to Clause 4 and Clause 6 should not be re-irradiated except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation.

**7.2** The cumulative maximum absorbed dose delivered to a food should not exceed 10 kGy as a result of re-irradiation except when it fulfils a technological purpose.

**7.3** For the purpose of this standard, food is not considered as having been re-irradiated when:

a) the irradiated food is prepared from materials that have been irradiated at low dose levels (not exceeding 1 kGy) for the purposes other than food safety, e.g. quarantine control, prevention of sprouting of roots and tubers;

b) the food, containing less than 5 % of irradiated ingredient, is irradiated; and

c) the full dose of ionising radiation required to achieve the desired effect is applied to the food in more than one increment as part of processing for a specific technological purpose.

## 8. Labelling

### 8.1 Inventory control

Irradiated foods which are prepackaged or in bulk containers should be accompanied with the relevant documents containing the following information:

a) identification of the food irradiation premises;

b) the date(s) of irradiation;

c) the dosimetry data; and

d) lot identification of the batch.

### 8.2 Containers description

The food which has been processed by ionising radiation should be labelled with the description of the purpose for which irradiation has been given and according to the current legislation requirements.

### 8.3 Prepackaged foods intended for direct consumption

The following provision should be observed with prepackaged foods containing ingredient treated with ionising radiation.

a) A food containing more than 5 % of any one ingredient which has been treated with ionising radiation should indicate this by means of phrase; 'containing x which has been rendered pathogen free with/by irradiation' or other corresponding phrase as prescribed by the current legislation requirements.

b) When a single ingredient product is prepared by means of a mechanical size-reduction process such as segmenting or milling from a raw material which has been treated with ionising radiation, this should be indicated by the phrase 'prepared from x freed of insects with/by irradiation' or other corresponding phrase as prescribed by the current legislation requirements.

c) No such designation should be needed when a non-mechanical process has been applied such as cooking, frying, baking, drying, concentrating, freezing, smoking, curing, marinating etc.

**8.4** Each package containing food treated by ionising radiation may bear on it the international food irradiation symbol (See Annex B).

# Annex A
(normative)

# Recommended code of practice for the operation of irradiation facilities used for the treatment of foods

## A1. Introduction

**A1.1** This code refers to the operation of irradiation facilities based on the use of either a radionuclide source ($^{60}Co$ or $^{137}Cs$) or x-rays and electrons generated from machine sources. The irradiation facility may be of two designs, either 'continuous' or 'batch' type. Control of the food irradiation process in all types of facility involves the use of accepted methods of measuring the absorbed radiation dose and of the monitoring of the physical parameters of the process.

## A2. Irradiation plants

### A2.1 Parameters

For all types of facility the doses absorbed by the product depend on the radiation parameter, the dwell time or the transportation speed of the product, and the bulk density of the material to be irradiated. Source-product geometry, especially distance of, the product from the source and measures to increase the efficiency of radiation utilisation, will influence the absorbed dose and the homogeneity of dose distribution.

#### A2.1.1 Radionuclide sources

Radionuclides used for food irradiation emit photons of characteristic energies. The statement of the source material completely determines the penetration of the emitted radiation. The source activity is measured in Becquerel (Bq) and should be stated by the supplying organisation. The actual activity of the source (as well as any return or replenishment of radionuclide material) shall be recorded. The recorded activity should take into account the natural decay rate of the source and should be accompanied by a record of the date of measurement or recalculation. Radionuclide irradiators will usually have a well separated and shielded depository for the source elements and a treatment area which can be entered when the source is in the safe position. There should be a positive indication of the correct operational and of the correct safe position of the source which should be interlocked with the product movement system.

#### A2.1.2 Machine sources

A beam of electrons generated by a suitable accelerator, or after being converted to x-rays, can be used. The penetration of the radiation is governed by the energy of the electrons. Average beam power shall be adequately recorded. There should be a positive indication of the correct setting of all machine parameters which should be interlocked with the product movement system. Usually a beam scanner or a scattering device (e.g. the converting target) is incorporated in a machine source to obtain an even distribution of the radiation over the surface of the product. The product movement, the width and speed of the scan and the beam pulse frequency (if applicable) should be adjusted to ensure a uniform surface dose.

### A2.2 Dosimetry and process control

**A2.2.1** Prior to the irradiation of any foodstuff certain dosimetry measurements (see A5) should be made, which demonstrate that the process will satisfy the regulatory requirements. Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner (see Note).

NOTE. It is recommended that manuals on dosimetry procedures to be consulted. Refer to bibliography for list of references.

**A2.2.2** Dosimetry commissioning measurements should be made for each new food, irradiation process and whenever modifications are made to source strength or type and to source product geometry.

**A2.2.3** Routine dosimetry should be made during operation and records kept of such measurement. In addition, regular measurements of facility parameters governing the process, such as transportation speed, dwell time, source exposure time, machine beam parameters, can be made during the facility operation. The records of these measurements can be used as supporting evidence that the process satisfies the regulatory requirements.

## A3. Good radiation processing practice

**A3.1** Facility design should attempt to optimalise the dose uniformity ratio, to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g. for the treatment of frozen food) and also control of the atmosphere. It is also often necessary to minimise mechanical damage to the product during transportation, irradiation and storage and desirable to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility shall permit compliance with these standards.

## A4. Product and inventory control

**A4.1** The incoming product should be physically separated from the outgoing irradiated products.

**A4.2** Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.

**A4.3** Records should be kept in the facility record book which shows the nature and kind of the product being treated, its identifying marks if packed or, if not, the shipping details, its bulk density, the type of source or electron machine, the dosimetry, the dosimeters used and details of their calibration and the date of treatment.

**A4.4** All product shall be handled, before and after irradiation, according to accepted good manufacturing practices taking into account the particular requirements of the technology of the process (see A6). Suitable facilities for refrigerated storage may be required.

## A5. Dosimetry

### A5.1 The overall average absorbed dose

**A5.1.1** It can be assumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose.

**A5.1.2** The overall average dose, $\overline{D}$, is defined by the following integral over the total volume of the goods

$$\overline{D} + \frac{1}{M} \int \rho(x, y, z) \cdot d(x, y, z) \cdot dV$$

where,

M is the total mass of the treated sample;

$\rho$ is the local density at the point (x, y, z);

d is the local absorbed dose at the point (x, y, z); and

dV is the dx dy dz the infinitesimal volume element which in real cases is represented by the volume fractions.

**A5.1.3** The overall average absorbed dose can be determined directly for homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose.

**A5.1.4** If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum ($\overline{D}$ min) and maximum ($\overline{D}$ max) dose will be a good estimate of the overall average dose i.e., in these cases

$$\text{Overall average dose } \underline{\Omega} \quad \frac{\overline{D}\ \text{max} + \overline{D}\ \text{min}}{2}$$

### A5.2 Effective and limiting dose value

**A5.2.1** Some effective treatment e.g. the elimination of harmful microorganisms, or a particular shelf-life extension, or a disinfestation requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

**A5.2.2** The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of A3 on Good radiation processing practice to allow a ratio of maximum to minimum dose of greater than 3.

**A5.2.3** With regards to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose a mass fraction of product of at least 97.5 % should receive an absorbed dose of less than 15 kGy when the overall average absorbed dose is 10 kGy.

### A5.3 Routine dosimetry

**A5.3.1** Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose shall be known. These measurements should be used to ensure the correct operation of the process. A recognised and calibrated system of dosimetry should be used.

**A5.3.2** A complete record of all dosimetry measurements including calibration shall be kept.

### A5.4 Process control

**A5.4.1** In the case of continuous radionuclide facility it will be possible to make automatically a record of transportation speed or dwell time together with indications of source and product positioning. These measurements can be used to provide a continuous control of the process in support of routine dosimetry measurements.

**A5.4.2** In a batch operated radionuclide facility automatic recording of source exposure time can be made and a record of product movement and placement can be kept to provide a control of the process in support of routine dosimetry measurements.

**A5.4.3** In a machine facility a continuous record of beam parameters, e.g. voltage, current, scan speed, scan width; pulse repetition and a record of transportation speed through the beam can be used to provide a continuous control of the process in support of routine dosimetry measurements.

## A6. Examples of technological conditions for the irradiation of some individual food items specifically examined by the joint FAO/IAEA/WHO expert committee

The information in Table A1 illustrates the utility of the irradiation process and describes the technological conditions for achieving the purpose of the irradiation process safely and economically.

**Table A1. Examples of technological conditions for the irradiation of some individual food items**

| Type of food | Purpose of treatment | Average dose, kGy/ Specific requirements |
|---|---|---|
| Chicken (*Gallus domesticus*) | i) To prolong storage life; and/or | Max. 7 |
| | ii) To reduce the number of certain pathogenic microorganisms, such as *Salmonella* from eviscerated chicken. | Max. 7 |
| Cocoa beans (*Theobroma cacao*) | i) To control insect infestation in storage; and | Max. 1 |
| | ii) To reduce microbial load of fermented beans with or without heat treatment. | Max 5 |
| | | Prevention of reinfestation: Cocoa beans whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as this will prevent reinfestation and microbial recontamination and spoilage. |
| Dates (*Phoenix dactylifera*) | To control insect infestation during storage. | Max. 1 |
| | | Prevention of reinfestation: Prepackaged dried dates should be stored under such conditions as this will prevent reinfestation. |
| Mangoes (*Mangifera indica*) | i) To control insect infestation; | Max. 1 |
| | ii) To improve keeping quality by delaying ripening; and | Max. 1 |
| | iii) To reduce microbial load by combining irradiation and heat treatment. | Max. 1 |
| Onions (*Allium cepa*) | To inhibit sprouting during storage. | Max. 0.15 |
| Papaya (Carica papaya L.) | To control insect infestation and to improve its keeping quality by delaying ripening. | Max. 1 |
| | | Source of radiation: The source of radiation should be such as this will provide adequate penetration. |
| Potatoes (*Solanum tuberosum* L.) | To inhibit sprouting during storage. | Max. 0.15 |

**Table A1. Examples of technological conditions for the irradiation of some individual food items** (*continued*)

| Type of food | Purpose of treatment | Average dose, kGy/ Specific requirements |
|---|---|---|
| Pulses | To control insect infestation in storage. | Max. 1 |
| Rice (*Oryza* species) | To control insect infestation in storage. | Max. 1<br><br>Prevention of reinfestation: Rice, whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as this will prevent reinfestation. |
| Spices and condiments, dehydrated onions, onion powder | i) To control insect infestation;<br><br>ii) To reduce microbial load; and<br><br>iii) To reduce the number of pathogenic microorganisms. | Max. 1<br><br>Max. 10<br><br>Max. 10 |
| Strawberry (*Fregaria* species) | To prolong the storage life by partial elimination of spoilage organisms. | Max. 3 |
| Teleost fish and fish products | i) To control insect infestation of dried fish during storage and marketing;<br><br>ii) To reduce microbial load of the packaged or unpackaged fish and fishery products; and<br><br>iii) To reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fishery products. | Max. 1<br><br>Max. 2.2<br><br>Max. 2.2<br><br>Temperature requirement. During irradiation and storage the fish and fishery products referred to in (ii) and (iii) should be kept at the temperature of melting ice. |
| Wheat and ground wheat products (*Triticum* species) | To control insect infestation in the stored product. | Max. 1<br><br>Prevention of reinfestation: These products, whether prepackaged or handled in bulk, should be stored as far as possible under such conditions as this will prevent reinfestation. |
| NOTE. Examples referred to Reports of the Joint FAO/IAEA/WHO expert committees on Food Irradiation (WHO Technical Report Series, 604, 1977 and 659, 1981) | | |

## Annex B
(normative)

## Logo to accompany description of irradiated food

Description of the logo; The 'plant' with two leaves and a flow budd in the centre symbolises a food product of natural agricultural origin. The 'circle' symbolises the prepackaged product through which the gamma rays penetrate (open passage). The 'green colour' is preferred because it symbolises safety and agriculture.

## Bibliography

MS ISO ASTM 51204:2005, *Practice for dosimetry in gamma irradiation facilities for food processing*

MS ISO ASTM 51261:2005, *Guide for selection and calibration of dosimetry systems for radiation processing*

MS ISO ASTM 51431:2005, *Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing*

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**Members of WG on Food Irradiation**

| | |
|---|---|
| Dr Muhamad Lebai Juri (Chairman) | Malaysian Nuclear Agency |
| Dr Ahmad Zainuri Mohd Dzomir (Vice Chairman) | Malaysian Nuclear Agency |
| Ms Irma Munirah (Secretary) | SIRIM Berhad |
| Mr Ahmad Hazizi Aziz | Department of Fisheries Malaysia |
| Dr Maznah Ahmad | Department of Veterinary Services Malaysia |
| Dr Zaliha Abdullah | Department of Veterinary Services Malaysia |
| Dr Noraini Mohd Khalid | Malaysian Agricultural Research and Development Institute |
| Ms Shamsinar Abdul Talib | Ministry of Health Malaysia |
| Assoc Prof Dr Russly Abdul Rahman | Universiti Putra Malaysia |
| Dr Noranizan Mohd Adzahan | Universiti Putra Malaysia |