

SUBSIDIARY LEGISLATION 231.45

IRRADIATION OF FOODS REGULATIONS

16th April, 2001

LEGAL NOTICE 61 of 2001.

- 1.1** The title of these regulations is the Irradiation of Foods Regulations. Title.
- 2.1** These regulations shall apply to the manufacture, marketing and importation of foods and food ingredients, hereinafter called “foodstuffs”, treated with ionising radiation. Scope.
- 2.2** These regulations shall not apply to:
- (a) foodstuffs exposed to ionising radiation generated by measuring or inspection devices, provided that the dose absorbed is not greater than 0.01 Gy for inspection devices which utilise neutrons and 0.5 Gy in other cases, at a maximum radiation energy level of 10 MeV in the case of X-rays, 14 MeV in the case of neutrons and 5 MeV in other cases;
 - (b) the irradiation of foodstuffs which are prepared for patients requiring sterile diets under medical supervision.
- 3.1** Irradiated foodstuffs can be placed on the market only if they comply with the provisions of these regulations. Prohibition of marketing.
- 4.1** The conditions to be fulfilled for authorisation of the treatment of foodstuffs with ionising radiation are set out in the First Schedule. At the time of treatment such foodstuffs must be in a suitably wholesome state. Conditions to be fulfilled.
- 4.2** Irradiation may be carried out only by means of the sources listed in the Second Schedule and in accordance with the requirements of the Code of Practice referred to in regulation 7.2. The overall average absorbed dose shall be calculated in accordance with the Third Schedule.
- 4.3** The maximum radiation dose for foodstuffs may be given in partial doses; however, the maximum radiation dose must not be exceeded.
- 4.4** Irradiation treatment may not be used in combination with any chemical treatment having the same purpose as that treatment.
- 5.1** The foodstuffs that may be treated with ionising radiation and the maximum overall average dose that may be imparted are listed in the Fourth Schedule. Only the foodstuffs listed therein may be treated with ionising radiation. Foodstuffs which may be irradiated.
- 6.1** The labelling of foodstuffs treated with ionising radiation shall be governed by the following provisions: Labelling of irradiated food.
- 6.1.1** in the case of products intended for the ultimate consumer and mass caterers:

S.L.231.27

- (a) if the products are sold as items, the words “irradiated” or “treated with ionising radiation” shall appear on the label as provided for in the Labelling, Presentation and Advertising of Foodstuffs Regulations. In the case of products sold in bulk, these words shall appear together with the name of the product on a display or notice above or beside the container in which the products are placed;
- (b) if an irradiated product is used as an ingredient, the same words shall accompany its designation in the list of ingredients. In the case of products sold in bulk, these words shall appear together with the name of the product on a display or notice above or beside the container in which the products are placed;
- (c) by way of derogation from the Labelling and Presentation of Foodstuffs Regulations, the same words shall be required in order to indicate the irradiated ingredients used in compound ingredients in foodstuffs, even if these constitute less than 25% of the finished product;

6.1.2 in the case of products not intended for the ultimate consumer and mass caterers:

- (a) the words provided for in regulation 6.1.1 shall be used to indicate treatment of both the foods and the ingredients contained in a non-irradiated foodstuff;
- (b) either the identity and address of the facility which carried out the irradiation or its reference number as provided for in these regulations shall be indicated;

6.1.3 the indication of treatment shall in all cases be given on the documents which accompany or refer to irradiated foodstuffs.

Approval of
irradiation
facilities.

7.1 The Superintendent of Public Health shall be responsible for:

- prior approval of all irradiation facilities in Malta,
- the allocation of an official reference number for approved irradiation facilities,
- official control and inspection,
- withdrawal or modification of approval.

7.2 Approval shall be granted only if the facility:

- meets the requirements of the Joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (reference FAO/WHO/CAC, vol. XV edition 1), and any supplementary requirements which may be adopted with the procedure laid down in accordance with the

procedure laid down in Article 12 of Directive 1999/2/EC of the European Parliament and of the Council,

- designates a person responsible for compliance with all the conditions necessary for application of the process.

7.3 The Superintendent of Public Health shall keep a detailed record for each approved irradiation facility, containing:

- the name, address and reference number of the facility, a copy of the text of the approval document and of any decision suspending or withdrawing approval;
- the results of checks carried out at the product marketing stage. The methods used to detect treatment with ionising radiation shall comply with paragraphs 1 and 2 of the Annex to Directive 85/591/EEC* and are to be standardised or validated by 1 January, 2003 at the latest.

7.4 Approved irradiation facilities must, for each source of ionising radiation used, keep a record showing for each batch of foodstuffs treated:

- (a) the nature and quantity of foodstuffs irradiated;
- (b) the batch number;
- (c) the person ordering the irradiation treatment;
- (d) the recipient of the treated foodstuffs;
- (e) the date of irradiation;
- (f) the packaging materials used during treatment;
- (g) the data for control of the irradiation process as provided for in the Third Schedule, the dosimetric checks carried out and the results obtained, with details in particular of the limits, lower and upper, of the dose absorbed and the type of ionising radiation;
- (h) reference to the initial dose validation measurements.

7.5 The records referred to in regulation 7.3 must be kept for a period of five years.

8.1 A foodstuff treated with ionising radiation may not be imported from a country outside the European Community unless it:

Importation of irradiated food.

- complies with the conditions which apply to those foodstuffs,
- is accompanied by documents showing the name and address of the facility which carried out the irradiation and providing the information referred to in regulation 7.3,
- was treated in an irradiation facility approved by the European Community and appearing on the list

*OJ L372, 31.12.1985, p.50

published in the Official Journal of the European Communities pursuant to Article 9 of Directive 1999/2/EC.

Packaging materials.

9.1 Materials used for packaging foodstuffs to be irradiated must be suitable for the purpose.

FIRST SCHEDULE

Conditions for authorising Food Irradiation

1. Food irradiation may be authorised only if:
 - there is a reasonable technological need,
 - it presents no health hazard and is carried out under the conditions proposed,
 - it is of benefit to the consumer,
 - it is not used as a substitute for hygiene and health practices or for good manufacturing or agricultural practice.
 2. Food irradiation may be used only for the following purposes:
 - to reduce the incidence of food-borne disease by destroying pathogenic organisms,
 - to reduce spoilage of foodstuffs by retarding or arresting decay processes and destroying spoilage organisms,
 - to reduce loss of foodstuffs by premature ripening, germination or sprouting,
 - to rid foodstuffs of organisms harmful to plant or plant products.
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SECOND SCHEDULE

Sources of Ionising Radiation

1. Foodstuffs may be treated only by the following sources of ionising radiation:
 - (a) gamma rays from radionuclides ^{60}Co or ^{137}Cs ;
 - (b) X-rays generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 5 MeV;
 - (c) electrons generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 10 MeV.
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THIRD SCHEDULE

1. Dosimetry

Overall average absorbed dose

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

The overall average dose, \bar{D} , is defined by the following integral over the total volume of the goods:

$$\bar{D} = \frac{1}{M} \int p(x,y,z)d(x,y,z)dV$$

where, M = the total mass of the treated sample

p = the local density at the point (x,y,z)

d = the local absorbed dose at the point (x,y,z)

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

The overall average absorbed dose can be determined directly for homogenous products or for bulk goods of homogenous apparent density by distributing an adequate number of dosimeters 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.

If the shape of the dose distribution curve through the product is well determined, the positions of the 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 given an estimate of the overall average dose.

In some cases, the mean value of the average values of the minimum dose (\bar{D}_{\min}) and maximum dose (\bar{D}_{\max}) will be a good estimate of the overall dose: that is, in these cases,

$$\text{overall average dose} = \frac{\bar{D}_{\max} + \bar{D}_{\min}}{2}$$

The ratio of $\frac{\bar{D}_{\max}}{\bar{D}_{\min}}$ should not exceed 3.

2. Procedures

2.1 Before routine irradiation of a given category of foodstuff begins at a radiation facility, the locations of the minimum and maximum doses are determined by making dose measurements throughout the product volume. These validation measurements must be carried out a suitable number of times (e.g. 3-5) in order to make allowance for variations in product density or geometry.

2.2 Measurements must be repeated whenever the product, its

geometry or the irradiation conditions are changed.

2.3 During the process, routine dose measurements are carried out in order to ensure that the dose limits are not exceeded. Measurements should be carried out by placing dosimeters at the positions of the maximum or minimum dose, or at a reference position. The dose at the reference position must be quantitatively linked to the maximum and minimum dose. The reference position should be located at a convenient point in or on the product, where dose variations are low.

2.4 Routine dose measurements must be carried out on each batch and at regular intervals during production.

2.5 In cases where flowing, non-packaged goods are irradiated, the locations of the minimum and maximum doses cannot be determined. In such cases it is preferable to use random dosimeter sampling to ascertain the values of these dose extremes.

2.6 Dose measurements should be carried out by using recognised dosimetry systems, and the measurements should be traceable to primary standards.

2.7 During irradiation, certain facility parameters must be controlled and continuously recorded. For radionuclide facilities the parameters include product transport speed and energy level, electron current and scanner width of the facility.

FOURTH SCHEDULE

Foodstuffs authorised for Irradiation Treatment and Maximum Radiation Doses

<i>Category of foodstuff</i>	<i>Maximum overall average absorbed radiation dose (kGy)</i>
Dried aromatic herbs, spices and vegetable seasonings	10
