Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation

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of 22 February 1999

on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation

Article 1

1 This Directive shall apply to the manufacture, marketing and importation of foods and food ingredients, hereinafter called 'foodstuffs', treated with ionising radiation.

2 This Directive 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.

Article 2

Member States shall take all measures necessary to ensure that irradiated foodstuffs can be placed on the market only if they comply with the provisions of this Directive.

Article 3

1 The conditions which must be fulfilled for authorisation of the treatment of foodstuffs with ionising radiation are set out in Annex I. At the time of treatment such foodstuffs must be in a suitably wholesome state.

2 Irradiation may be carried out only by means of the sources listed in Annex II and in accordance with the requirements of the Code of Practice referred to in Article 7(2). The overall average absorbed dose shall be calculated in accordance with Annex III.

Article 4

1 The Community list of foodstuffs which may be treated with ionising radiation to the exclusion of all others and the maximum radiation doses authorised shall be defined in the implementing Directive, which shall be adopted in accordance with the procedure laid down in Article 100a of the Treaty taking account of the authorisation conditions set out in Annex I.

2 This list shall be established in stages.

3 The Commission shall examine the national authorisations in force and, after consulting the Scientific Committee for Food, submit in accordance with the procedure laid down in Article 100a of the Treaty proposals aiming at establishing the list.

At the latest 31 December 2000, the Commission shall, in accordance with Article 100a of the Treaty, submit a proposal intended to complete the positive list provided for in paragraph 1.

4 Until entry into force of the Directive adopted on the basis of the proposal referred to in the second subparagraph of paragraph 3, Member States may maintain existing authorisations concerning the treatment of foodstuffs with ionising radiation provided that:

a the treatment of the foodstuff concerned has been subject to a favourable opinion of the Scientific Committee for Food;

b the overall average absorbed radiation dose does not exceed the limit values recommended by the Scientific Committee for Food;

c ionising radiation and placing on the market are effected in accordance with this Directive.

5 Until entry into force of the Directive adopted on the basis of the proposal referred to in the second subparagraph of paragraph 3, any Member State may also authorise the treatment of foodstuffs for which authorisations have been maintained by another Member State in accordance with paragraph 4, where the conditions referred to in paragraph 4 are fulfilled.

6 Member States shall forthwith notify the Commission and the other Member States of authorisations maintained under paragraph 4 or granted under paragraph 5 and of conditions attaching to them. The Commission shall publish these notifications in the *Official Journal of the European Communities*.

7 Until the entry into force of the Directive adopted on the basis of the proposal referred to in the second subparagraph of paragraph 3, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on ionising radiation of foodstuffs and on trade in irradiated foodstuffs which are not included in the initial positive list established by the implementing Directive.

Article 5

1 The maximum radiation dose for foodstuffs may be given in partial doses; however, the maximum radiation dose fixed in accordance with Article 4 must not be exceeded. Irradiation treatment may not be used in combination with any chemical treatment having the same purpose as that treatment.

[[F1]2 Exceptions to paragraph 1 may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(4).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 6

The labelling of foodstuffs treated with ionising radiation shall be governed by the following provisions:

1. in the case of products intended for the ultimate consumer and mass caterers:

(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 Article 5(3) of Directive 79/112/EEC.

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 Article 6(7) of Directive 79/112/EEC, 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;

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

(a) the words provided for in the previous paragraph 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 Article 7 shall be indicated;

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

Article 7

1 Member States shall inform the Commission of the competent authority or authorities responsible for:

— prior approval of irradiation facilities,

— the allocation of an official reference number for approved irradiation facilities,

— official control and inspection,

— withdrawal or modification of approval.

[[F1]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 requirement which may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(4),

— designates a person responsible for compliance with all the conditions necessary for the application of the process.**]**

3 Each Member State shall forward to the Commission:

— the names, addresses and reference numbers of the irradiation facilities which it has approved, the text of the approval document, and any decision suspending or withdrawing approval.

Furthermore the Member States shall forward to the Commission every year:

— the results of checks carried out in the ionising irradiation facilities, in particular regarding the categories and quantities of products treated and the doses administered,

— the results of checks carried out at the product marketing stage. Member States shall ensure that the methods used to detect treatment with ionising radiation comply with paragraphs 1 and 2 of the Annex to Directive 85/591/EEC[(1)] and are standardised or validated either already or as soon as possible, up to 1 January 2003 at the latest. Member States shall inform the Commission of the methods used and the Commission shall assess the use and development of these methods having regard to an opinion of the Scientific Committee for Food.

4 On the basis of the data supplied in accordance with paragraph 3, the Commission shall publish in the *Official Journal of the European Communities*:

— the details of the facilities as well as any changes in their status,

— a report based on the information provided every year by the national supervisory authorities.

Textual Amendments

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Article 8

1 Irradiation facilities approved in accordance with Article 7 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 Annex III, 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.

2 The records referred to in paragraph 1 must be kept for a period of five years.

3 Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in **[**[F1]Article 12(2)**]**.

Textual Amendments

F1 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of

the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 9

1 A foodstuff treated with ionising radiation may not be imported from a third country unless it:

— 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 treatment and providing the information referred to in Article 8,

— was treated in an irradiation facility approved by the Community and appearing on the list referred to in paragraph 2 of this Article.

2

a In accordance with the procedure laid down in **[**F1Article 12(2)**]**, the Commission shall draw up the list of approved facilities for which official supervision guarantees that the requirements of Article 7 are complied with.

For the purpose of drawing up this list, the Commission may instruct experts to carry out, under its authority, evaluations and inspections of irradiation facilities in third countries in accordance with Article 5 of Directive 93/99/EEC.

The Commission shall publish that list and any amendments thereto in the *Official Journal of the European Communities*.

b The Commission may conclude technical arrangements with the competent organisations in third countries on the procedures whereby the evaluations and inspections referred to in (a) are to be carried out.

Textual Amendments

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Article 10

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

Article 11

Amendments to the Annexes to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 100a of the Treaty.

[F1Article 12

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 of the European Parliament and of the Council[(2)].

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits provided for in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

5 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 13

The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Directive likely to have an effect on public health.

Article 14

1 Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has clear proof that the irradiation of certain foodstuffs endangers human health although it complies with the provisions of this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving grounds for its decision.

2 The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee on Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in **[**F1Article 12(2)**]**. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.

[F1 3 Adaptations of this Directive or of its implementing directive may be made by the Commission only to the extent necessary to ensure the protection of public health and shall in any event be limited to prohibitions or restrictions as compared to the previous legal situation. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 12(5).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of

the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part One.

Article 15

Member States shall bring into force their laws, regulations and administrative provisions to comply with this Directive in such a way as to:

— permit the marketing and use of irradiated foodstuffs by 20 September 2000,

— prohibit the marketing and use of irradiated foodstuffs not complying with this Directive by 20 March 2001.

They shall inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 16

This Directive shall enter into force on the seventh day following its publication in the *Official Journal of the European Communities*.

Article 17

This Directive is addressed to the Member States.

ANNEX I

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.

ANNEX II

SOURCES OF IONISING RADIATION

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.

ANNEX III

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 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 dose ($D^{-}\,\mathrm{min}$) and maximum dose ($D^{-}\,\mathrm{max}$) will be a good estimate of the overall dose: i.e., in these cases:

$$\text{overall average dose} \approx \frac{D^{-}\,\mathrm{max} + D^{-}\,\mathrm{min}}{2}$$

The ratio of

$$\frac{D^{-}\,\mathrm{max}}{D^{-}\,\mathrm{min}}$$

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 a case 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 or time spent in the radiation zone and positive indication for correct position of the source. For accelerator facilities, the parameters include product transport speed and energy level, electron current and scanner width of the facility.

(**1**) OJ L 372, 31.12.1985, p. 50.

(**2**) **[**[F1]OJ L 31, 1.2.2002, p. 1.**]**

Textual Amendments

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