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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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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

The EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3), in the light of the joint text approved by the Conciliation Committee on 9 December 1998,

(1) Whereas differences between national laws relating to the treatment of foodstuffs by ionising radiation and its conditions of use hinder the free movement of foodstuffs and may create conditions of unequal competition, thereby directly affecting the operation of the internal market;

(2) Whereas it is necessary to adopt measures aimed at the smooth operation of the internal market; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured; whereas this is not the case at present because of the differences in treatment in the Member States, irradiation of foodstuffs being allowed in some and banned in others;

(3) Whereas this framework Directive will be completed by Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation (4), hereinafter referred to as 'the implementing Directive`;

(4) Whereas in several Member States foodstuff irradiation constitutes a sensitive issue in public debate, and whereas consumers may have cause for concern about the consequences of the use of food irradiation;

(5) Whereas, until the entry into force of the Community positive list of foodstuffs which may be treated with ionising radiation, it is appropriate that 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;

(6) Whereas rules relating to the use of ionising radiation for the treatment of foodstuffs should take account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technical needs;

(7) Whereas Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (5) is applicable;

(8) Whereas approved irradiation units should be subject to an official control, through an inspection system to be created for the needs of this Directive;

(9) Whereas approved units should keep records to ensure that the rules of this Directive have been respected;

(10) Whereas Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (6) has already laid down rules concerning the labelling of irradiated foodstuffs for sale to the ultimate consumer;

(11) Whereas appropriate rules must also be laid down for the labelling of foodstuffs treated with ionising radiation not intended for the ultimate consumer;

(12) Whereas, without prejudice to the decision-making procedures laid down in the Treaty establishing the European Community or in this Directive, the Scientific Committee for Food set up by Decision 74/234/EEC (7) should be consulted on any question relating to this Directive which may have an effect on public health;

(13) Whereas foodstuffs may only be treated by the action of ionising radiation if there is a food hygiene need, or a demonstrable technological or other advantage, or benefit to the consumer and if they are wholesome and in a proper condition, since ionising radiation should not be used as a substitute for hygiene or health practices or good manufacturing or agricultural practice;

(14) Whereas the process should not be used as a substitute for good manufacturing practice, and whereas this condition is fulfilled for foodstuffs listed in the Annex to the implementing Directive;

(15) Whereas, in all cases where the Council empowers the Commission to implement rules relating to food irradiation, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs, and, where necessary, the Standing Veterinary Committee or the Standing Committee on Plant Health;

(16) Whereas should the use of the process or of a foodstuff treated with ionising radiation authorised on the basis of this Directive appear to constitute a health risk, Member States should be authorised to suspend or limit such use, or to reduce the limits, pending a decision at Community level;

(17) Whereas Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (8) leaves the choice of means and methods to the national enforcement authorities; whereas Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (9) lays down quality standards for laboratories and requires the use of validated methods of analysis where available; whereas Article 5 of the latter Directive is applicable to the monitoring of the implementation of this Directive;

(18) Whereas a modus vivendi between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty (10) was concluded on 20 December 1994,

HAVE ADOPTED THIS DIRECTIVE:

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.

2. Exceptions to paragraph 1 may be decided on in accordance with the procedure laid down in Article 12.

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.

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 in accordance with the procedure laid down in Article 12 of this Directive,

- designates a person responsible for compliance with all the conditions necessary for 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 (11) 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.

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 Article 12.

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 Article 12, 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.

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.

Article 12

1. Where the procedure defined in this Article is to be followed, the Commission shall be assisted by the Standing Committee on Foodstuffs, hereinafter referred to as 'the Committee`.

The Chairman shall, without delay, refer the matter to the Committee, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

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 Article 12. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.

3. Amendments to this Directive or to the implementing Directive may be made in accordance with the procedure laid down in Article 12 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.

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.

Done at Brussels, 22 February 1999.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

K.-H. FUNKE

(1) OJ C 336, 30. 12. 1988, p. 7 and OJ C 303, 2. 12. 1989, p. 15.

(2) OJ C 194, 31. 7. 1989, p. 14.

(3) Opinion of the European Parliament of 11 October 1989 (OJ C 291, 20. 11. 1989, p. 58), Council Common Position of 27 October 1997 (OJ C 389, 22. 12. 1997, p. 36) and Decision of the European Parliament of 18 February 1998 (OJ C 80, 16. 3. 1998, p. 130). Council Decision of 25 January 1999. Decision of the European Parliament of 28 January 1999.

(4) See page 24 of this Official Journal.

(5) OJ L 159, 29. 6. 1996, p. 1.

(6) OJ L 33, 8. 2. 1979, p. 1. Directive as last amended by Directive 97/4/EC (OJ L 43, 14. 2. 1997, p. 21).

(7) OJ L 136, 20. 5. 1974, p. 1.

(8) OJ L 186, 30. 6. 1989, p. 23.

(9) OJ L 290, 24. 11. 1993, p. 14.

(10) OJ C 102, 4. 4. 1996, p. 1.

(11) OJ L 372, 31. 12. 1985, p. 50.

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 60Co or 137Cs;

(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, >START OF GRAPHIC>

FD>END OF GRAPHIC>

, is defined by the following integral over the total volume of the goods:

>START OF GRAPHIC>

FD>END OF GRAPHIC>

= >NUM>1

>DEN>M

∫ p (x,y,z) d (x,y,z) dV

where >TABLE>

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 (>START OF GRAPHIC>

FD>END OF GRAPHIC>

min) and maximum dose (>START OF GRAPHIC>

FD>END OF GRAPHIC>

max) will be a good estimate of the overall dose: i.e., in these cases:

overall average dose ≈ >NUM"START OF GRAPHIC>

FD>END OF GRAPHIC>

max + >START OF GRAPHIC>

FD>END OF GRAPHIC>

min

>DEN>2

The ratio of >NUM"START OF GRAPHIC>

FD>END OF GRAPHIC>

max

>DEN"START OF GRAPHIC>

FD>END OF GRAPHIC>

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.

STATEMENT BY THE COMMISSION

Recital 17

The Commission stresses that, once the new decision on the reform of the committee procedure has been adopted, it will propose to the legislator that the provisions governing committees in all previous acts should be adjusted to bring them into line with the new 'committee procedure` decision. The Commission undertakes to apply in full any interinstitutional agreement deriving from this new decision.

STATEMENT BY THE COUNCIL AND THE COMMISSION

Article 7(3) third indent

With the objective of ensuring that such methods exist for all products, the Commission and the Member States will encourage the further development of standardised or validated methods of analysis, which aim to verify whether foodstuffs have been treated by ionising radiation. The Commission confirms that the annual report referred to in Article 7(4) will include information on such developments. It will include in its annual report for the year 2001 a review of the application of these provisions to determine whether any problems have arisen with the use of validated or standardised methods. The Commission will, where appropriate and in accordance with the decision-making procedures defined in the Treaties or in this Directive, take steps to deal with these problems and those that are likely to arise. This information shall also be made available to the European Parliament.