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EUROPEAN COMMISSION

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COM(2010)184 final

2010/0098 (CNS)

Proposal for a

**COUNCIL REGULATION (EURATOM)**

**laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency**

**(Recast)**

## EXPLANATORY MEMORANDUM

1. On 1 April 1987 the Commission decided<sup>1</sup> to instruct its staff that all acts should be codified after no more than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that their provisions are clear and readily understandable.
2. The codification<sup>2</sup> of Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency, Commission Regulation (Euratom) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency and Commission Regulation (Euratom) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency was initiated by the Commission, and a relevant proposal was submitted to the legislative authority<sup>3</sup>. The new Regulation was to have superseded the various acts incorporated in it<sup>4</sup>.
3. In the course of the legislative procedure, it was acknowledged that a provision appearing in the proposal for a codified text provided for a reservation of implementing powers by the Council which was not justified in the recitals of Regulation (Euratom) No 3954/87. In the light of the judgment of the Court of Justice of 6 May 2008 in Case C-133/06, it was considered necessary to insert a new recital in the new act replacing and repealing that Regulation in order to justify that reservation of implementing powers. Since the insertion of such a recital would imply a substantive change, and would therefore go beyond straightforward codification, it was considered necessary that point 8<sup>5</sup> of the Interinstitutional Agreement of 20 December 1994 - Accelerated working method for official codification of legislative texts - be applied, in the light of the Joint Declaration on that point<sup>6</sup>.
4. Pursuant to Regulation (Euratom) No 3954/87, the Commission, after being informed of a nuclear accident or of any other case of radiological emergency which is likely to lead or has led to a significant radioactive contamination of foodstuffs and feedingstuffs, is to immediately adopt, if the circumstances so require, a Regulation

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<sup>1</sup> COM(87) 868 PV.

<sup>2</sup> Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis Communautaire, COM(2001) 645 final.

<sup>3</sup> COM(2007) 302 final.

<sup>4</sup> See Annex IV to this proposal.

<sup>5</sup> *"Should it prove necessary during the legislative process to go beyond straightforward codification and make substantive changes, it will be the Commission's responsibility to submit any proposal(s), where appropriate"*.

<sup>6</sup> *"The European Parliament, the Council and the Commission note that if it should appear necessary to go beyond straightforward codification and make substantive changes, the Commission will be able to choose, case by case, whether to recast its proposal or whether to submit a separate proposal for amendment, leaving its codification proposal on the table, and then, once the substantive change has been adopted, incorporate it into the proposal for codification"*.

rendering applicable pre-established maximum permitted levels of radioactive contamination. The period of validity of such a Regulation is to be as short as possible and must not exceed three months. Within one month of its adoption and after consultation with experts, the Commission is to submit to the Council a proposal for a Regulation to adapt or confirm the provisions of the Regulation previously adopted by the Commission, in particular the establishment of maximum permitted levels of radioactive contamination, based on Article 31 of the Euratom Treaty, in view of the health protection of the population. Therefore, as a matter of urgency, it is appropriate for the Council to reserve the right to exercise directly the power to adopt those adjusted measures within this short timeframe. This is, however, without prejudice to the possibility that, in the long term after the nuclear accident or the radiological emergency, other legal instruments or another legal basis may be used for the purpose of controlling foodstuffs or feedingstuffs being placed on the market, for which this reservation of implementing powers will not apply.

5. It is therefore appropriate to transform the codification of Regulation (Euratom) No 3954/87, Regulation (Euratom) No 944/89 and Regulation (Euratom) No 770/90 into a recast in order to incorporate the necessary amendment.

Proposal for a

**COUNCIL REGULATION (EURATOM)**

**laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency**

**(Recast)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament<sup>7</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>8</sup>,

Whereas:

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- (1) Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency<sup>9</sup> has been substantially amended<sup>10</sup>. Since further amendments are to be made, the said Regulation should be recast in the interests of clarity, together with Commission Regulation (Euratom) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency<sup>11</sup> and Commission Regulation (Euratom) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency<sup>12</sup>.

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<sup>7</sup> OJ C [...], [...], p. [...].

<sup>8</sup> OJ C [...], [...], p. [...].

<sup>9</sup> OJ L 371, 30.12.1987, p. 11.

<sup>10</sup> See Annex IV.

<sup>11</sup> OJ L 101, 13.4.1989, p. 17.

<sup>12</sup> OJ L 83, 30.3.1990, p. 78.

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↓ 3954/87 Recital 1

- (2) Article 2(b) of the Treaty requires that the Council establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied, as further set out in Title Two, Chapter III, of the Treaty.
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↓ 3954/87 Recital 2 (adapted)

- (3) On 2 February 1959, the Council adopted Directives<sup>13</sup> laying down basic safety standards, the text of which was replaced by that of  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 ionizing radiation<sup>14</sup> . Article  50(2)  of that Directive requires Member States to stipulate intervention levels in the event of accidents.
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↓ 3954/87 Recital 3

- (4) Following the accident at the Chernobyl nuclear power-station on 26 April 1986, considerable quantities of radioactive materials were released into the atmosphere, contaminating foodstuffs and feedingstuffs in several European countries to levels significant from the health point of view.
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↓ 3954/87 Recital 4 (adapted)

- (5) Measures  were adopted <sup>15</sup> to ensure that certain agricultural products are only introduced into the  Union  according to the common arrangements which safeguard the health of the population while maintaining the unified nature of the market and avoiding deflections of trade.
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↓ 3954/87 Recital 5 (adapted)

- (6) The need arises to set up a system allowing the  European Atomic Energy  Community, following a nuclear accident or any other case of radiological emergency which is likely to lead or has led to a significant radioactive contamination of foodstuffs and feedingstuffs, to fix maximum permitted levels of radioactive contamination in order to protect the population.
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↓ 3954/87 Recital 6 (adapted)

- (7) The Commission  is to  be informed of a nuclear accident or of unusually high levels of radioactivity according to Council Decision  87/600/Euratom  of 14 December 1987 on Community arrangements for the early exchange of information
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<sup>13</sup> OJ 11, 20.2.1959, p. 221/59.

<sup>14</sup> OJ L 159, 29.6.1996, p. 1.

<sup>15</sup> Council Regulations (EEC) No 1707/86 (OJ L 146, 31.5.1986, p. 88), (EEC) No 3020/86 (OJ L 280, 1.10.1986, p. 79), (EEC) No 624/87 (OJ L 58, 28.2.1987, p. 101) and (EEC) No 3955/87 ( OJ L 371, 30.12.1987, p.  14).

in the event of radiological emergency<sup>16</sup>, or under the  IAEA  Convention on early notification of a nuclear accident of 26 September 1986.

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↓ 3954/87 Recital 7 (adapted)

- (8) The Commission  should , if the circumstances so require, immediately adopt a Regulation rendering applicable pre-established maximum permitted levels.
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↓ 3954/87 Recital 8 (adapted)

- (9) On the basis of current data available in the field of radiation protection, derived reference levels have been established and these  levels  may be used as a basis for the fixing of maximum permitted levels of radioactive contamination to be applied immediately following a nuclear accident or any other case of radiological emergency which is likely to lead or has led to significant radioactive contamination of foodstuffs and feedingstuffs.
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↓ 3954/87 Recital 9

- (10) Such maximum permitted levels take due account of the latest scientific advice as presently available on an international scale whilst reflecting the need for reassuring the public and avoiding divergences in international regulatory practice.
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↓ 3954/87 Recital 10

- (11) However, it is necessary to take due account of the particular conditions applying and, therefore, to establish a procedure allowing the rapid adaptation of these pre-established levels to maximum permitted levels appropriate to the circumstances of any particular nuclear accident or any other case of radiological emergency which is likely to lead or has led to significant radioactive contamination of foodstuffs and feedingstuffs.
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↓ 3954/87 Recital 11 (adapted)

- (12) A Regulation rendering applicable maximum permitted levels  should  also maintain the unity of the  Internal  Market and avoid deflections of trade within the  Union .
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↓ 3954/87 Recital 12

- (13) In order to facilitate the adaptation of maximum permitted levels, procedures should be provided for allowing the consultation of experts including the Group of Experts referred to in Article 31 of the Treaty.

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<sup>16</sup>  OJ L 371, 30.12.1987, p.  76.

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↓ 944/89 Recital 3 (adapted)

- (14) The foodstuffs to be considered ☒ as minor foodstuffs ☒ are those of minor dietary importance which make only a marginal contribution to food consumption by the population.
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↓ new

- (15) It is appropriate for the Council to reserve the right to exercise directly the power to adopt a Regulation to timely endorse measures proposed by the Commission in the first month after a nuclear accident or a radiological emergency. The relevant proposal for the adaptation or confirmation of the provisions laid down in the Regulation adopted by the Commission, in particular the establishment of maximum permitted levels of radioactive contamination, should be based on Article 31 of the Treaty, in view of the health protection of the population. This is without prejudice to the possibility that in the long term after the accident or the radiological emergency other legal instruments or another legal basis may be used for the purpose of controlling foodstuffs or feedingstuffs being placed on the market.
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↓ 3954/87 Recital 13 (adapted)

- (16) Compliance with the maximum permitted levels ☒ should ☒ be the subject of appropriate checks,
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↓ 3954/87

HAS ADOPTED THIS REGULATION:

*Article 1*

1. This Regulation lays down the procedure for determining the maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs which may be placed on the market following a nuclear accident or any other case of radiological emergency which is likely to lead to or has led to significant radioactive contamination of foodstuffs and feedingstuffs.

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↓ 3954/87 (adapted)  
→<sub>1</sub> Corrigendum, OJ L 18,  
22.1.1988, p. 74

2. For the purposes of this Regulation, ☒ the following definitions shall apply: ☒
- (a) “foodstuffs” means products which are intended for human consumption either immediately or after processing;
- (b) “feedingstuffs” means products which are intended only for animal nutrition.



## Article 2

1. In the event of the Commission receiving — in particular according to either the  European Atomic Energy  Community arrangements for the early exchange of information in case of a radiological emergency or under the  IAEA Convention  of 26 September 1986 on early notification of a nuclear accident — official information on accidents or on any other case of radiological emergency, substantiating that the maximum  permitted  levels  for foodstuffs laid down  in Annex I  or the maximum permitted levels for feedingstuffs laid down in Annex III  are likely to be reached or have been reached, it  shall  immediately adopt, if the circumstances so require, a Regulation rendering applicable those maximum  permitted  levels.

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↓ 3954/87

2. The period of validity of any Regulation within the meaning of paragraph 1 shall be as short as possible and shall not exceed three months, subject to the provisions of Article 3(4).

## Article 3

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↓ 3954/87 (adapted)

1. After consultation with experts, which shall include the group of experts  referred to in Article 31 of the Treaty, hereinafter “group of experts” , the Commission shall submit to the Council a proposal for a Regulation to adapt or confirm the provisions of the Regulation referred to in Article 2(1)  of this Regulation  within one month of its adoption.

2. When submitting the proposal for a Regulation referred to in paragraph 1 , the Commission shall  take into account the basic standards laid down in accordance with Articles 30  and  31 of the Treaty, including the principle that all exposures shall be kept as low as reasonably achievable, taking the aspect of the protection of the health of the general public and economic and social factors into account.

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↓ 3954/87

3. The Council shall, acting by a qualified majority, take a decision on the proposal for a Regulation referred to in paragraphs 1 and 2 within the time limit set out in Article 2(2).

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↓ 3954/87 (adapted)

4. In the event that the Council does not decide within this time limit, the levels set out in  Annexes I and III  shall continue to apply until the Council does decide or until the Commission withdraws its proposal because the conditions set out in Article 2(1) no longer apply.

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↓ 3954/87

*Article 4*

The period of validity of any Regulation within the meaning of Article 3 shall be limited. This period may be revised at the request of a Member State or on the initiative of the Commission in accordance with the procedure laid down in Article 3.

*Article 5*

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↓ 3954/87 (adapted)

1. In order to ensure that the maximum permitted levels laid down in Annexes I  and III  take account of any new scientific data becoming available, the Commission shall, from time to time, seek the opinion of experts, which shall include the group of experts.
2. At the request of a Member State or the Commission, the maximum permitted levels laid down in  Annexes I and III  may be revised or supplemented, upon the submission of a proposal from the Commission to the Council in accordance with the procedure laid down in Article 31 of the Treaty.

*Article 6*

1. Foodstuffs or feedingstuffs not in compliance with the maximum permitted levels laid down in a Regulation adopted in accordance with Articles 2 or 3 shall not be placed on the market.

For the purposes of applying this Regulation, foodstuffs or feedingstuffs imported from third countries shall be considered to be placed on the market if, on the customs territory of the Community, they undergo a customs procedure other than a transit procedure.

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↓ 3954/87

2. Each Member State shall provide the Commission with all information concerning the application of this Regulation, in particular concerning cases of non-compliance with the maximum permitted levels. The Commission shall communicate such information to the other Member States.
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↓ 944/89 Art. 1 (adapted)

*Article 7*

A  list of minor foodstuffs is set out in Annex II.

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↓ 2218/89 Art. 2 (adapted)

*Article 8*

Rules for  implementing  this Regulation  and adaptations to the  list of minor foodstuffs  , together with the maximum permitted levels of radioactive contamination to be applied thereto, as set out in Annex II,  and  to  the maximum  permitted  levels for feedingstuffs  set out in Annex III shall be  adopted in accordance with the procedure  referred to  in Article  195(2)  of  Council  Regulation (EC) No  1234/2007<sup>17</sup>  , which shall apply by analogy. To this end  the Commission shall be assisted by  an ad hoc Committee.

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*Article 9*

Council Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and No 770/90 are repealed.

References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex V.

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↓ 3954/87 (adapted)

*Article 10*

This Regulation shall enter into force on the  twentieth  day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

*For the Council*  
*The President*  
[...]

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<sup>17</sup> OJ L 299, 16.11.2007, p. 1.

**ANNEX I**

**MAXIMUM PERMITTED LEVELS FOR FOODSTUFFS (Bq/kg)**

	Foodstuffs <sup>18</sup>			
	☒ Infant ☒ food <sup>19</sup>	Dairy produce <sup>20</sup>	Other foodstuffs except minor foodstuffs <sup>21</sup>	Liquid foodstuffs <sup>22</sup>
Isotopes of strontium, notably Sr-90	75	125	750	125
Isotopes of iodine, notably I-131	150	500	2 000	500
Alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241	1	20	80	20
All other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 <sup>23</sup>	400	1 000	1 250	1 000

<sup>18</sup> The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption. Member States may make recommendations concerning the diluting conditions in order to ensure that the maximum permitted levels laid down in this Regulation are observed.

<sup>19</sup> ☒ Infant ☒ food ☒ is ☒ defined as those foodstuffs intended for the feeding of infants during the first four to six months of life, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly identified and labelled “food preparation for infants”.

<sup>20</sup> Dairy produce is defined as those products falling within the following CN codes including, where appropriate, any adjustments which might be made to them later: 0401, 0402 (except 0402 29 11).

<sup>21</sup> Minor foodstuffs and the corresponding levels to be applied to them ☒ are set out in Annex II ☒.

<sup>22</sup> Liquid foodstuffs as defined in the heading 2009 and in chapter 22 of the combined nomenclature. Values are calculated taking into account consumption of tap-water and the same values should be applied to drinking water supplies at the discretion of competent authorities in Member States.

<sup>23</sup> Carbon 14, tritium and potassium 40 are not included in this group.

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↓ 944/89 Art. 1 and Annex

**ANNEX II**

**LIST OF MINOR FOODSTUFFS**

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↓ 944/89 Art. 2

For the minor foodstuffs set out in this Annex, the maximum permitted levels to be applied are 10 times those applicable to “other foodstuffs except minor foodstuffs” set out in Annex I or pursuant to Regulations adopted on the basis of Article 3.

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↓ 944/89 Art. 1 and Annex  
(adapted)

CN code	Description
0703 20 00	Garlic (fresh or chilled)
0709 ☒ 59 50 ☒	Truffles (fresh or chilled)
0709 90 40	Capers (fresh or chilled)
0711 ☒ 90 70 ☒	Capers (provisionally preserved, but unsuitable in that state for immediate consumption)
☒ ex ☒ 0712 ☒ 39 ☒ 00	Truffles (dried, whole, cut, sliced, broken or in powder, but not further prepared)
0714	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh or dried, whether or not sliced or in the form of pellets; sago pith
0814 00 00	Peel of citrus fruit or melons (including watermelons), fresh, frozen, dried or provisionally preserved in brine, in sulphur water or in other preservative solutions
0903 00 00	Maté
0904	Pepper of the genus <i>Piper</i> ; dried or crushed or ground fruits of the genus <i>Capsicum</i> or of the genus <i>Pimenta</i>
0905 00 00	Vanilla
0906	Cinnamon and cinnamon-tree flowers
0907 00 00	Cloves (whole fruit, cloves and stems)
0908	Nutmeg, mace and cardamons

0909	Seeds of anise, badian, fennel, coriander, cumin or caraway; juniper berries
0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices
1106 20	Flour, meal ☒ and powder ☒ of sago ☒ or of ☒ roots or tubers of heading No 0714
1108 14 00	Manioc (cassava) starch
1210	Hop cones, fresh or dried, whether or not ground, powdered or in the form of pellets; lupulin
1211	Plants and parts of plants (including seeds and fruits), of a kind used primarily in perfumery, in pharmacy or for insecticidal, fungicidal or similar purposes, fresh or dried, whether or not cut, crushed or powdered
1301	Lac; natural gums, resins, gum-resins and ☒ oleoresins (for example, ☒ balsams)
1302	Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products
1504	Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified
1604 30	Caviar and caviar substitutes
1801 00 00	Cocoa beans, whole or broken, raw or roasted
1802 00 00	Cocoa shells, husks, skins and other cocoa waste
1803	Cocoa paste, whether or not defatted
2003 20 00	Truffles (prepared or preserved otherwise than by vinegar or acetic acid)
2006 00	☒ Vegetables, ☒ fruit, nuts, fruit-peel and other parts of plants, preserved by sugar (drained, glacé or crystallized)
2102	Yeasts (active or inactive); other single-cell micro-organisms, dead (but not including vaccines of heading No 3002); prepared baking powders

2936

Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent

3301

Essential oils (terpeneless or not), including concretes and absolutes; resinoids; ☒ extracted oleoresins; ☒ concentrates of essential oils in fats, in fixed oils, in waxes or the like, obtained by enfleurage or maceration; terpenic by-products of the deterpenation of essential oils; aqueous distillates and aqueous solutions of essential oils

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**ANNEX III**

**MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION  
(CAESIUM-134 AND CAESIUM-137) OF FEEDINGSTUFFS**

Animal	Bq/kg <sup>24, 25</sup>
Pigs	1 250
Poultry, lambs, calves	2 500
Other	5 000

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<sup>24</sup> These levels are intended to contribute to the observance of the maximum permitted levels for foodstuffs; they do not alone guarantee such observance in all circumstances and do not lessen the requirement for monitoring contamination levels in animal products destined for human consumption.

<sup>25</sup> These levels apply to feedingstuffs as ready for consumption.





**ANNEX IV**

**Repealed Regulations**

Council Regulation (Euratom) No 3954/87	(OJ L 371, 30.12.1987, p. 11)
Council Regulation (Euratom) No 2218/89	(OJ L 211, 22.7.1989, p. 1)
Commission Regulation (Euratom) No 944/89	(OJ L 101, 13.4.1989, p. 17)
Commission Regulation (Euratom) No 770/90	(OJ L 83, 30.3.1990, p. 78)

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**ANNEX V**

**CORRELATION TABLE**

Regulation (Euratom) No 3954/87	Regulation (Euratom) No 944/89	Regulation (Euratom) No 770/90	This Regulation
Articles 1 to 5			Articles 1 to 5
Article 6(1) first and second sentence			Article 6(1) first and second subparagraphs
Article 6(2)			Article 6(2)
	Article 1		Article 7(1)
	Article 2		Annex II
		Article 1	Article 2(1)
Article 7			Article 8
---	---	---	Article 9
Article 8			Article 10
Annex			Annex I
	Annex		Annex II
		Annex	Annex III
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