



Brussels, 6.8.2013  
COM(2013) 576 final

**Draft proposal for a  
COUNCIL REGULATION**

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

**Draft presented under Article 31 of the Euratom Treaty for opinion of the European  
Economic and Social Committee**

## EXPLANATORY MEMORANDUM

1. On 1 April 1987 the Commission decided<sup>1</sup> to instruct its services 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 supersede the various acts incorporated in it<sup>4</sup>.
3. In its opinion of 27.9.2007 the Consultative Working Party of the legal services set up under the Interinstitutional Agreement of 20 December 1994 on an accelerated working method for official codification of legislative texts<sup>5</sup> stated that the proposal referred to in point 2 confined itself to straightforward codification, without any substantive changes to the acts covered by it.
4. In the course of the legislative procedure relating to that initial codification proposal, it was acknowledged that a provision appearing in the draft 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 have implied a substantive change, and would have therefore gone beyond straightforward codification, it was considered necessary that point 8<sup>6</sup> of the Interinstitutional Agreement of 20 December 1994 - Accelerated working method for

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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> OJ C 102, 4.4.1996, p. 2.

<sup>6</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"*.

official codification of legislative texts - be applied, in the light of the Joint Declaration on that point<sup>7</sup>.

5. In the light thereof, codification of Regulation (Euratom) No 3954/87, Regulation (Euratom) No 944/89 and Regulation (Euratom) No 770/90 was transformed into a recast in order to incorporate the said amendment, and a relevant proposal was submitted to the legislative authority<sup>8</sup>.
6. In its opinion of 4.6.2010 the Consultative Working Party of the legal services, acting in accordance with point 9 of the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>9</sup>, stated that the proposal referred to in point 5 did not comprise any substantive amendments other than those identified as such, and that, as regards the codification of the unchanged provisions of the earlier acts with those substantive amendments, the proposal contained a straightforward codification of the existing texts, without any change in their substance.
7. In the course of the legislative procedure relating to that recast proposal, it became apparent that certain existing provisions contained in Regulation (Euratom) No 3954/87 have now become incompatible with the new "Comitology" system laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. It has therefore been decided to withdraw the recast proposal and to draft a revised proposal of Regulation (Euratom) No 3954/87, which includes its consolidation and the implementation of the new "Comitology" system.
8. On the basis of the experience gained from the nuclear accidents in Chernobyl and in particular in Fukushima, the revised proposal provides that the Commission is assisted by a section of the Standing Committee on the Food Chain and Animal Health - Toxicological Safety of the Food Chain dealing with radioactive contamination of food and feed referred to in Article 58 (1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>10</sup>.
9. Taking into consideration the evolution of the primary and secondary law during the last decades, in particular with regard to food safety under the TFEU, and in order to ensure legal certainty and coherence of all EU legislative measures with regard to the conditions governing imports of food and feed from third countries affected by a nuclear accident or a radiological emergency, the measures that were established in the post-Chernobyl context will need to be aligned with the regime of implementing

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<sup>7</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".

<sup>8</sup> COM(2010) 184 final.

<sup>9</sup> OJ C 77, 28.3.2002, p. 1.

<sup>10</sup> OJ L 31, 1.2.2002, p.1.

powers and procedures defined in the present regulation. This might also imply, where necessary, a change of the legal basis.

10. It should be noted that the Group of Experts referred to in Article 31 of the Euratom Treaty, confirmed in their Opinion dated 21 November 2012 their conclusion in 1998 (Publication Radiation Protection 105), that the maximum permitted levels pre-established for future accidents in Regulation 3954/87 are still valid. However, as soon as new scientific knowledge on doses and risks would be published by ICRP, they considered that it should be checked whether there is a need for a review of these levels. Therefore, the Commission has not changed these maximum permitted levels in its revised proposal<sup>11</sup>.
11. According to the two-stage procedure laid down in Article 31 of the Euratom Treaty, the Commission shall first obtain the opinion of the European Economic and Social Committee on the present draft before submitting a proposal to the Council.

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<sup>11</sup> [http://ec.europa.eu/energy/nuclear/radiation\\_protection/article\\_31\\_en.htm](http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm)

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after obtaining the opinion of the group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States<sup>12</sup>,

Having regard to the opinion of the European Parliament<sup>13</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>14</sup>,

Whereas:

- (1) Article 31 of the Euratom Treaty establishes a two-stage procedure whereby the Commission shall first obtain the opinion of the European Economic and Social Committee on the present draft before submitting a proposal to the Council.
- (2) Council Directive 96/29/Euratom of 13 May 1996 lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation<sup>15</sup>.
- (3) 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. Measures were adopted<sup>16</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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<sup>12</sup> OJ C..p..

<sup>13</sup> OJ C , , p. .

<sup>14</sup> OJ C , , p. .

<sup>15</sup> OJ L 159, 29.6.1996, p. 1.

<sup>16</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).

- (4) Council Regulation (Euratom) No 3954/87<sup>17</sup> lays down maximum permitted levels of radioactive contamination to be applied following a nuclear accident or any other case of radiological emergency which is likely to lead or has led to significant radioactive contamination of food and feed. Those maximum permitted levels are still in line with the latest scientific advice as presently available internationally.
- (5) Following the accident at the Fukushima nuclear power station on 11 March 2011, the Commission was informed that radionuclide levels in certain food products originating in Japan exceeded the action levels in food applicable in Japan. Such contamination may constitute a threat to public and animal health in the Union and therefore measures were adopted imposing special conditions governing the import of feed and food originating in or consigned from Japan, in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (6) There is a need 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 food and feed, to establish maximum permitted levels of radioactive contamination in order to protect the population.
- (7) Maximum permitted levels of radioactive contamination should apply to food and feed originating in the Union or imported from third countries according to the location and circumstances of the nuclear accident or the radiological emergency.
- (8) 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 in the event of radiological emergency<sup>18</sup>, or under the IAEA Convention on early notification of a nuclear accident of 26 September 1986.
- (9) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers<sup>19</sup>.
- (10) The examination procedure should be used for the adoption of acts rendering applicable the pre-established maximum permitted levels of radioactive contamination of food and feed.
- (11) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to certain radiological emergencies which are likely to lead or have led to a significant radioactive contamination of food and feed, imperative grounds of urgency so require.

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<sup>17</sup> OJ L 371, 30.12.1987, p. 11.

<sup>18</sup> OJ L 371, 30.12.1987, p. 76.

<sup>19</sup> OJ L 55, 28.2.2011, p. 13.

- (12) In order to take into account that diets of infants during the first six months period of life may vary significantly, and to allow for uncertainties in the metabolism of infants during the second six months period of life, there is a benefit in extending the application of lower maximum permitted levels for foods for infants, to the whole first 12 months of age.
- (13) In order to facilitate the adaptation of maximum permitted levels, in particular with regard to scientific knowledge, procedures for establishing the maximum permitted levels should include the consultation of the Group of Experts referred to in Article 31 of the Treaty,
- (14) Compliance with the maximum permitted levels should be the subject of appropriate checks,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

This Regulation lays down the maximum permitted levels of radioactive contamination of food as set out in Annex I and the maximum permitted levels of minor food as set out in Annex II, and the maximum permitted levels of radioactive contamination of feed as set out in Annex III, 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 food and feed, and the procedures to render these maximum permitted levels applicable.

#### *Article 2*

##### *Definitions*

For the purposes of this Regulation, the following definitions shall apply:

1. "Food" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans, including drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment, "food" does not include:
  - (a) feed;
  - (b) live animals unless they are prepared for placing on the market for human consumption;
  - (c) plants prior to harvesting;
  - (d) medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council<sup>20</sup> ;

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<sup>20</sup> OJ L 311, 28.11.2001, p. 67.

- (e) cosmetic products within the meaning of Article 2(1)(a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council<sup>21</sup>;
  - (f) tobacco and tobacco products within the meaning of Directive 2001/37/EC of the European Parliament and of the Council<sup>22</sup> ;
  - (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971
  - (h) residues and contaminants.
2. "minor food" as listed in Annex II, means food of minor dietary importance which make only a marginal contribution to food consumption by the population.
  3. "feed" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
  4. "placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

### *Article 3*

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 food, minor food or feed are likely to be reached or have been reached, it shall adopt, if the circumstances so require, an implementing Regulation rendering applicable those maximum permitted levels. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 5(2).
2. On duly justified imperative grounds of urgency relating to *the circumstances of the nuclear accident or the radiological emergency*, the Commission shall adopt an immediately applicable implementing Regulation in accordance with the procedure referred to in Article 5(3).
3. When preparing the draft implementing act referred to paragraphs 1 and 2 and discussing it with the committee referred to in Article 5, 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 protection of the health of the general public and economic and societal factors into account.

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<sup>21</sup> OJ L 342, 22.12.2009, p. 59.

<sup>22</sup> OJ L 194, 18.7.2001, p. 26.



#### *Article 4*

1. As soon as the Commission adopts an implementing Regulation rendering applicable maximum permitted levels, food or feed not in compliance with these maximum permitted levels shall not be placed on the market.

For the purposes of applying this Regulation, food or feed 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.

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.

#### *Article 5*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 (1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>23</sup>. That committee shall be considered as a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

#### *Article 6*

In order to ensure that the maximum permitted levels laid down in Annexes I, II and III take account of any new or additional important data becoming available, in particular with regard to scientific knowledge, adaptations to those Annexes shall be proposed by the Commission after consultation of the Group of Experts referred to in Article 31 of the Treaty establishing the European Atomic Energy Community .

#### *Article 7*

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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<sup>23</sup> OJ L 31, 1.2.2002, p. 1.

*Article 8*

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*  
*[...]*

## ANNEX I

### MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FOOD

The maximum permitted levels to be applied to food shall be the following:

	Food (Bq/kg) <sup>24</sup>			
	Infant food <sup>25</sup>	Dairy produce <sup>26</sup>	Other food except minor food <sup>27</sup>	Liquid food <sup>28</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>29</sup>	400	1 000	1 250	1 000

<sup>24</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>25</sup> Infant food is defined as those foodstuffs intended for the feeding of infants during the first twelve 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 under one of the following names: “infant formula”, “follow-on formula” “infant milk” and “follow-on milk”, in accordance with articles 11 and 12 of Commission Directive 2006/141/EC.

<sup>26</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>27</sup> Minor food and the corresponding levels to be applied to them are set out in Annex II.

<sup>28</sup> Liquid food 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.

<sup>29</sup> Carbon 14, tritium and potassium 40 are not included in this group.

## ANNEX II

### MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF MINOR FOOD

1. List of minor food

CN code	Description
0703 20 00	Garlic (fresh or chilled)
0709 59 50	Truffles (fresh or chilled)
0709 99 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, chilled, frozen 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 31 00	Caviar
1604 32 00	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 90 10	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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2. The maximum permitted levels to be applied to the minor food as listed in paragraph 1, shall be the following

	<b>(Bq/kg)</b>
Isotopes of strontium, notably Sr-90	7500
Isotopes of iodine, notably I-131	20000
Alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241	800
All other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 <sup>30</sup>	12500

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<sup>30</sup> Carbon 14, tritium and potassium 40 are not included in this group.

### ANNEX III

#### **MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FEED**

The maximum permitted levels for caesium-134 and caesium-137 shall be the following:

Animal	Bq/kg <sup>31, 32</sup>
Pigs	1 250
Poultry, lambs, calves	2 500
Other	5 000

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<sup>31</sup> These levels are intended to contribute to the observance of the maximum permitted levels for food; 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>32</sup> These levels apply to feed 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	
Article 1(1)	Article 1		Article 1	
Article 1(2)		Article 1	Article 1	
Article 2(1)			Article 2	
Article 2(2)			Article 3(1) and 3(2)	
Article 3(1)			-	
Article 3(2)			-	
Article 3(3) and (4)			Article 3(3)	
Article 4			-	
Article 5(1)			-	
Article 5(2)			Article 6	
Article 6(1)			-	
Article 6(2)		Article 4(1)		
	Article 2		Article 4(2)	
			Annex II(2)	
			Annex III	
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Article 7			Article 5	
---			Article 5	
Article 8			-	
Annex			Article 7	
		Annex		Article 8
				Annex I
				Annex II(1)
			Annex III	
			Annex III	
---		Annex	Annex IV	
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		Article 1	Annex V	
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