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COM(2013) 943 final

2013/0451 (NLE)

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**

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

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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"*.

<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*

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<sup>11</sup> will need to be aligned with the regime of implementing powers and procedures defined in the present regulation. This might also imply, where necessary, a change of the legal basis.

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*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.

<sup>11</sup> The latest were: Council Regulation (EC) No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (Codified version) (OJ L 201, 30.7.2008, p.1) and Council Regulation (EC) No 1048/2009 of 23 October 2009 amending Regulation (EC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (OJ L 290, 6.11.2009, p.4).

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>12</sup>.

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<sup>12</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)

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**

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>13</sup>,

Having regard to the opinion of the European Parliament<sup>14</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>15</sup>,

Whereas:

- (1) Council Directive 96/29/Euratom<sup>16</sup> lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.
- (2) 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 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.
- (3) 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.
- (4) 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

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

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

<sup>15</sup> OJ C , , p. .

<sup>16</sup> 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 (OJ L 159, 29.6.1996, p. 1.)

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

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.

- (5) 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.
- (6) 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.
- (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<sup>18</sup>, or under the IAEA Convention on early notification of a nuclear accident of 26 September 1986.
- (8) 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.
- (9) 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.
- (10) In order to ensure that food and feed exceeding the maximum permitted levels are not placed on the market of the EU, compliance with these levels should be the subject of appropriate checks.
- (11) In order to ensure uniform conditions for the implementation of this Regulation as regards rendering applicable the pre-established maximum permitted levels, 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>.
- (12) 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.
- (13) 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>18</sup> Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of radiological emergency (OJ L 371, 30.12.1987, p. 76).

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

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, 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> ;
  - (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" means food of minor dietary importance which makes 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;

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<sup>20</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

<sup>21</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

<sup>22</sup> Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

- 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.

### *Article 4*

1. As soon as the Commission adopts an implementing Regulation rendering applicable maximum permitted levels, food or feed not in compliance with those 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 Union, 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.

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

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.

#### *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*  
[...]