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NOTE

from:	General Secretariat of the Council
to:	Delegations
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Subject:	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

Delegations will find attached the revised text of the above proposal. This document will be considered by the WPAQ on 9 July 2014.

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 States¹,

Having regard to the opinion of the European Parliament²,

Having regard to the opinion of the European Economic and Social Committee³,

Whereas:

- (1) Council Directive **2013/59/Euratom**⁴ lays down basic safety standards for the protection against the dangers arising from **exposure to** ionising 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 feeding stuffs 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.

¹ OJ C..p..

² OJ C , , p. .

³ OJ C , , p. .

⁴ Council Directive **2013/59/Euratom** of **5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.01.2014).**

- (3) Council Regulation (Euratom) No 3954/87⁵ 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. **The rationale and the assumptions which underline the maximum permitted levels of radioactive contamination of food have been reviewed by the Group of Expert referred to in Article 31 of the Euratom Treaty and are described in Publication RP 105 entitled "EU Food Restriction Criteria for Application after an Accident"**⁶.
- (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 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 **regarding those products that could be placed on the market** 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.

⁵ 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).

⁶ **RP 105 is available on the following website:**
http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm

- (7) The Commission is to be informed of a nuclear accident or of unusually high levels of radioactivity according to Council Decision 87/600/Euratom⁷, 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 **the circumstances of the nuclear accidents or the radiological emergency scientific knowledge**, procedures for **reviewing the implementing regulations may establishing the maximum permitted levels should** include the consultation **by the Commission** 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 **⁸ 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 powers⁹** [which **is to should** apply for the purpose of this Regulation, notwithstanding the fact that **even though** it does not **refer explicitly to mention** Article 106a of the Euratom Treaty].

⁷ 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).

⁸ **Regulation (EU) No 182/2011⁸ 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**

⁹ **OJ L 55, 28.2.2011, p. 13.**

- (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.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down:

- (a) 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
- (b) the procedure to **adopt or subsequently amend implementing regulations rendering the** maximum permitted levels applicable.

Article 2

Definitions

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

- 1) ‘food’ (or ‘**foodstuff**’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘**Food**’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

‘Food’ shall 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 Council¹⁰ ~~Directives 65/65/EEC (1) and 92/73/EEC (2)~~;
 - (e) cosmetics within the meaning of Article 2(1)(a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council¹¹ ~~Directive 76/768/EEC (3)~~;
 - (f) tobacco and tobacco products within the meaning of Directive 2001/37/EC of the European Parliament and of the Council¹² ~~Directive 89/622/EEC (4)~~;
 - (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 contaminants¹³;
 - (i) [water intended for human consumption, in particular after the point of compliance as defined in Article 5 of Directive 2013/51/Euratom¹³].
- 2) "minor food" means food of minor dietary importance which makes only a marginal contribution to food consumption by the population;
- 3) "feed" (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals as defined in regulations 183/2005 and 767/2009;

¹⁰ 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).

¹¹ 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).

¹² 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).

¹³ [Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption].

- 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 **as defined in regulation 142/2009 art 3.14 and in regulation 178/2009 art 3.7.**
- 5) **"emergency" means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, food- and feedsafety, property or the environment, or a hazard that could give rise to such serious adverse consequences;**

Article 3

Applicable maximum permitted levels

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, which is likely to lead or has led to radioactive contamination of substantiating that the maximum permitted levels for food, minor food or feed set out in Annexes I, II and III are likely to be reached or have been reached, **the Commission** shall adopt, if the circumstances so require, an implementing Regulation rendering applicable maximum permitted levels **to the potentially contaminated food and feed products that could be placed on the market. The maximum permitted levels set out in the implementing Regulation shall not exceed those set out in Annexes I, II and III [without opinion of the Article 31 group of experts].** That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 5(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).

2. The period of validity of implementing Regulations adopted under paragraph 1 shall be as short as possible. The duration of the first implementing Regulation adopted following a nuclear accident or radiological emergency shall not exceed three months.

Implementing Regulations shall be periodically reviewed by the Commission, and if appropriate, amended ~~in accordance with the justification principle~~ on the basis of the nature and location of the accident and of the evolution of the level of radioactive contamination effectively measured.

3. When preparing the draft implementing Regulation referred to in paragraph 1, or reviewing it, the Commission shall take into account the basic standards laid down in accordance with Articles 30 and 31 of the Treaty, including the justification principle and the optimisation principle, with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors.

When reviewing the implementing Regulations, the Commission may seek the opinion of the Group of Experts referred to in Article 31 of the Treaty establishing the European Atomic Energy Community, in particular in the event of a nuclear accident or a radiological emergency causing such a widespread contamination of food consumed in the EU that the rationale and assumptions behind the maximum permitted levels set out in Annexes I, II and III are no longer valid.

- 3a. Without prejudice to the objective pursued by this Regulation, implementing Regulations may allow at EU level for derogations to [or below] the maximum permitted levels [set out in Annexes I, II and III / set out therein] for specific food or feed. Those derogations based on cultural and societal considerations shall be objectively justified and shall only apply to food or feed which are of [minor importance] at the Community level is produced and consumed locally in a Member State.

Article 4

Restrictive measures

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 **intended for import into the Union imported** from third countries shall be **deemed as intended for placing considered to be placed** on the market **when it arrives at any entry point into the EU, unless the importer provides evidence to the contrary. The final decision shall be one for the competent authority at the point of entry to the Union 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 **through the Urgent Radiological Information Exchange system (ECURIE) or the Rapid Alert System for Food and Feed** with all information concerning the application of this Regulation. **The Commission shall communicate such information to other Member States, in particular concerning cases** of non-compliance with the maximum permitted levels **shall be notified through the Rapid Alert System for Food and Feed (RASFF). The Commission shall communicate such information to the other Member States.**
3. **In addition to § 1 and 2, and if required by the circumstances, the Commission might impose additional measures and special conditions governing the import of food and feed such as declaration of consignments and prior notification of their arrival**

Article 5
Committee

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 Council¹⁴. That committee shall be considered as a committee within the meaning of Regulation (EU) No 182/2011 ~~and its members composition shall ensure that the committee has the necessary expertise in the field of radiation protection~~.
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
Reporting

In case of a nuclear accident or any other case of a radiological emergency, the Commission shall submit to the European Parliament and to the Council a report on the implementation of the measures undertaken pursuant to this Regulation and notified to the Commission according to Article 4.2.

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 **IV**.

¹⁴ 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).

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 0

The maximum contamination levels set out in Annexes I to III were derived from Report 105 (EU Food Restriction Criteria for Application after an Accident, Radiation Protection 105 of 1998). These are based in particular on the following assumptions:

1. It is assumed that 10% of food is contaminated; different assumptions apply to infants under one year.
2. The basis for dose estimates are the dose co-efficients of the radionuclides for ingestion, an average annual consumption quantity for certain food groups and the assumed percentage of contaminated food.
3. The dose criterion is based on an additional dose of 5 mSv for adults as well as for infants.
4. Sum formulae should be used to set maximum permitted levels and to review compliance with these levels.

ANNEX I

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FOOD

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

<u>Isotope group/Food group</u>	Food (Bq/kg) ¹⁵			
	Infant food ¹⁶	Dairy produce ¹⁷	Other food except minor food ¹⁸	Liquid food ¹⁹
<u>Sum of</u> Isotopes of strontium, notably Sr-90	75	125	750	125
<u>Sum of</u> Isotopes of iodine, notably I-131	150	500	2 000	500
<u>Sum of</u> Alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241	1	20	80	20
<u>Some of</u> All other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 ²⁰	400	1 000	1 250	1 000

¹⁵ 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.

¹⁶ 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 **as such**.

¹⁷ 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).

¹⁸ Minor food and the corresponding levels to be applied to them are set out in Annex II.

¹⁹ 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 at the discretion of competent authorities in Member States]**.

²⁰ 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
<u>1211</u>	<u>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</u>
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

2. The maximum permitted levels to be applied to the minor food as listed in paragraph 1, shall be the following

<u>Isotope group</u>	(Bq/kg)
<u>Sum of I</u> isotopes of strontium, notably Sr-90	7500
<u>Sum of I</u> isotopes of iodine, notably I-131	20000
<u>Sum of A</u> alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241	800
<u>Sum of A</u> all other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 ²¹	12500

²¹ 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 **the sum of** caesium-134 and caesium-137 shall be the following:

<u>Animal Feed for</u>	Bq/kg^{22, 23}
Pigs	1 250
Poultry, lambs, calves	2 500
Other	5 000

²² 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.

²³ These levels apply to feed as ready for consumption.

ANNEX IV

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
Article 1(2)			Article 2
Article 2(1)			Article 3(1) and 3(2)
Article 2(2)			-
Article 3(1)			-
Article 3(2)			Article 3(3)
Article 3(3) and (4)			-
Article 4			-
Article 5(1)			Article 6
Article 5(2)			-
Article 6(1)			Article 4(1)
Article 6(2)			Article 4(2)
	Article 2	Article 1	Annex II(2)
---	---	---	Annex III
Article 7			Article 5
			-
---	---	---	Article 7
Article 8			Article 8
Annex			Annex I
	Annex		Annex II(1)
		Annex	Annex III
---	---	---	Annex IV
---	---	---	Annex V