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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: 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, and repealing Council Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90

COUNCIL REGULATION (EURATOM) 2016/...

of ...

laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Council Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90

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,

Having regard to the opinion of the European Parliament¹,

Having regard to the opinion of the European Economic and Social Committee²,

¹ Opinion of ... (not yet published in the Official Journal).

² OJ C 226, 16.7.2014, p. 68.

Whereas:

- (1) Council Directive 2013/59/Euratom¹ 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 food and feed in several European countries to levels that were significant from the point of view of health. Measures were adopted to ensure that certain agricultural products are only introduced into the Union in accordance with the common arrangements which safeguard the health of the population while maintaining the unified nature of the market and avoiding deflections of trade.

¹ 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, 17.1.2014, p. 1).

- (3) Council Regulation (Euratom) No 3954/87¹ 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 basis for the establishment of the maximum permitted levels set out in this Regulation has been reviewed and described in the Commission Radiation Protection Publication 105 (EU Food Restriction Criteria for Application after an Accident). In particular, those levels are based on a reference level of 1 mSv per year for the increment in individual effective dose by ingestion and on the assumption that 10 % of food consumed annually is contaminated. However, different assumptions apply to infants under one year.
- (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 could constitute a threat to public and animal health in the Union and therefore measures were adopted imposing special conditions governing the import of food and feed originating in or consigned from Japan, in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council².

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 (OJ L 371, 30.12.1987, p. 11).

² 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).

- (5) There is a need to set up a system allowing the 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 products to be placed on the market in order to protect the population.
- (6) Like other food, drinking water is ingested directly or indirectly and therefore plays a role in the consumer's overall exposure to radioactive substances. With regard to radioactive substances, quality control of water intended for human consumption is already provided for in Council Directive 2013/51/Euratom¹, with the exclusion of mineral waters and waters which are medicinal products. This Regulation should apply to food, minor food and feed which could be placed on the market following a nuclear accident or any other case of radiological emergency, and not to water intended for human consumption for which Directive 2013/51/Euratom applies. However, in the case of a radiological emergency, Member States are free to choose to refer to the maximum levels for liquid food set out in this Regulation in order to manage the use of water intended for human consumption.
- (7) Maximum permitted levels of radioactive contamination should apply to food and feed originating in the Union or imported from third countries on the basis of the location and circumstances of the nuclear accident or other radiological emergency.

¹ 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 (OJ L 296, 7.11.2013, p. 12).

- (8) The Commission is to be informed of a nuclear accident or of unusually high levels of radioactivity under Council Decision 87/600/Euratom¹ or under the International Atomic Energy Agency (IAEA) Convention on Early Notification of a Nuclear Accident of 26 September 1986.
- (9) In order to take into account that diets of infants during their first six months may vary significantly and that there are uncertainties in the metabolism of infants during the second six-month period as well, it is appropriate to extend the application of lower maximum permitted levels for foods for infants to the first twelve months.
- (10) In order to facilitate the adaptation of applicable maximum permitted levels, in particular with regard to the circumstances of the nuclear accident or other radiological emergency, procedures for reviewing the implementing Regulations should include the consultation by the Commission of the group of experts referred to in Article 31 of the Treaty.
- (11) In order to ensure that food and feed exceeding the applicable maximum permitted levels are not placed on the Community market, compliance with these levels should be the subject of appropriate checks.

¹ 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).

- (12) In order to ensure uniform conditions for the implementation of this Regulation as regards rendering applicable 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 Council¹ which is to apply for the purpose of this Regulation notwithstanding the fact that it does not refer explicitly to Article 106a of the Treaty.
- (13) The Commission should be assisted by the Standing Committee on Plants, Animals, Food and Feed. Member States should ensure that, where draft implementing acts based on this Regulation are discussed by that Committee, their representatives have, or can rely on, adequate expertise in radiological protection.
- (14) The examination procedure should be used for the adoption of acts rendering applicable maximum permitted levels of radioactive contamination of food and feed.
- (15) 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.

¹ 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 (OJ L 55, 28.2.2011, p. 13).

- (16) This Regulation should constitute a *lex specialis* for the procedure to adopt and subsequently amend implementing Regulations laying down applicable maximum permitted levels of radioactive contamination following a case of radiological emergency. Where it is evident that food or feed originating in the Union or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission is allowed to adopt additional emergency measures pursuant to Regulation (EC) No 178/2002. The Commission should ensure that this Regulation and Regulation (EC) No 178/2002 are implemented in a harmonised way. Where possible, applicable maximum permitted levels and additional emergency measures should be integrated in a single implementing Regulation based on this Regulation and Regulation (EC) No 178/2002.
- (17) Furthermore, general rules for the performance of official controls to verify compliance with rules aiming, inter alia, to prevent, eliminate or reduce to acceptable levels risks to humans and animals are laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council¹.

¹ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

- (18) When preparing or reviewing implementing Regulations, the Commission should take into account, inter alia, the following circumstances: location, nature and extent of the nuclear accident or other radiological emergency within or outside the Community; nature, extent and spread of the identified or projected release of radioactive substances in air, water and soil and in food and feed within or outside the Community; radiological risks of the identified or potential radioactive contamination of food and feed and the resulting radiation doses; type and quantity of the contaminated food and feed which might be brought onto the market in the Community; maximum permitted levels for contaminated food and feed set in third countries; importance of this food and feed for providing the population with an adequate food supply; consumer expectations regarding the safety of food and possible changes to consumers' eating habits as a result of a radiological emergency.
- (19) In duly justified cases, any Member State should have the possibility to request to be allowed to derogate temporarily from the maximum permitted levels of radioactive contamination in respect of specified food or feed consumed on its territory. Implementing Regulations should specify the food and feed to which the derogations apply, the types of radionuclides concerned, as well as the geographical scope and duration of the derogations,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down the maximum permitted levels of radioactive contamination of:

- (a) food, as set out in Annex I;
- (b) minor food, as set out in Annex II; and
- (c) 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.

This Regulation also lays down the procedure to adopt or subsequently amend implementing Regulations laying down the applicable maximum permitted levels.

Article 2
Definitions

For the purposes of this Regulation, the following definitions 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.

'Food' includes drink, chewing gum and any substance 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 point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council¹;

¹ 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).

- (e) cosmetic products within the meaning of point (a) of Article 2(1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council¹;
 - (f) tobacco and tobacco products within the meaning of, respectively, points (1) and (4) of Article 2 of Directive 2014/40/EU of the European Parliament and of the Council²;
 - (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;
 - (i) water intended for human consumption within the meaning of point (1) of Article 2 of Directive 2013/51/Euratom;
- (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;

¹ 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).

² Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

- (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;
- (5) 'radiological 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, property or the environment, or a hazard that could give rise to such serious adverse consequences.

Article 3

Applicable maximum permitted levels

1. If the Commission receives — in particular either under the Community arrangements for the early exchange of information in the event of a radiological emergency, or under the IAEA Convention on Early Notification of a Nuclear Accident of 26 September 1986 — official information on a nuclear accident or on any other case of radiological emergency which is likely to lead to or has led to significant radioactive contamination of food and feed, it shall adopt an implementing Regulation rendering applicable maximum permitted levels to the potentially contaminated food or feed that could be placed on the market.

Without prejudice to Article 3(4), the applicable maximum permitted levels set out in such an implementing Regulation shall not exceed those set out in Annexes I, II and III. 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 other 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 following a nuclear accident or any other case of radiological emergency shall not exceed three months.

Implementing Regulations shall be periodically reviewed by the Commission and, if appropriate, amended 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 or reviewing implementing Regulations, the Commission shall take into account the basic standards laid down pursuant to 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 implementing Regulations, the Commission shall consult the group of experts referred to in Article 31 of the Treaty if a nuclear accident or any other case of radiological emergency causes such widespread contamination of food or feed consumed in the Community that the rationale and assumptions underpinning the maximum permitted levels set out in Annexes I, II and III to this Regulation are no longer valid. The Commission may seek the opinion of that group of experts in any other case of contamination of food or feed consumed in the Community.

4. Without prejudice to the health protection objective pursued by this Regulation, the Commission may, by means of implementing Regulations, allow any Member State, at its request and in the light of exceptional circumstances prevailing in that Member State, to derogate temporarily from the maximum permitted levels in respect of specified food or feed consumed on its territory. Those derogations shall be based on scientific evidence and be duly justified by the circumstances, in particular societal factors, prevailing in the Member State concerned.

Article 4

Restrictive measures

1. When 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, as from the date specified in that implementing Regulation.

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, it is placed under 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. The Commission shall communicate such information to the other Member States. Any case of non-compliance with the applicable maximum permitted levels shall be notified through the Rapid Alert System for Food and Feed (RASFF).

Article 5
Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be 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
Reporting

In the event of a nuclear accident or any other case of a radiological emergency which is likely to lead to or has led to significant radioactive contamination of food and feed, the Commission shall submit to the European Parliament and to the Council a report. The report shall cover the implementation of the measures undertaken pursuant to this Regulation and notified to the Commission in accordance with Article 4(2).

Article 7

Repeal

Council Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) 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.

Article 8

Entry into force

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 ...,

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 not exceed the following:

Isotope group/ Food group	Food (Bq/kg) ¹			
	Infant food ²	Dairy produce ³	Other food except minor food ⁴	Liquid food ⁵
Sum of isotopes of strontium, notably Sr-90	75	125	750	125
Sum of isotopes of iodine, notably I-131	150	500	2 000	500

¹ 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.

² Infant food is defined as food intended for the feeding of infants during the first twelve months of life which meets, in itself, the nutritional requirements of this category of persons and is put up for retail sale in packages which are clearly identified and labelled as such.

³ Dairy produce is defined as products falling within the following CN codes including, where appropriate, any adjustments which might subsequently be made to them: 0401 and 0402 (except 0402 29 11).

⁴ Minor food and the corresponding levels to be applied to them are set out in Annex II.

⁵ Liquid food is defined as products falling within heading 2009 and Chapter 22 of the Combined Nomenclature. Values are calculated taking into account consumption of tap-water and the same values could be applied to drinking water supplies at the discretion of competent authorities in Member States.

Isotope group/ Food group	Food (Bq/kg) ¹			
	Infant food ²	Dairy produce ³	Other food except minor food ⁴	Liquid food ⁵
Sum of alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239 and Am-241	1	20	80	20
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137 ¹	400	1 000	1 250	1 000

¹ 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 fruit 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 cardamoms
0909	Seeds of anise, badian, fennel, coriander, cumin or caraway; juniper berries
0910	Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices

CN code	Description
1106 20	Flour, meal and powder of sago or of roots or tubers of heading 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, except plants or parts of plants used for food production
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 crystallised)

CN code	Description
2102	Yeasts (active or inactive); other single-cell micro-organisms, dead (but not including vaccines of heading 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 point 1 shall not exceed the following:

Isotope group	Bq/kg
Sum of isotopes of strontium, notably Sr-90	7 500
Sum of isotopes of iodine, notably I-131	20 000
Sum of alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239 and Am-241	800
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137 ¹	12 500

¹ 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 not exceed the following:

Feed for	Bq/kg ^{1, 2}
Pigs	1 250
Poultry, lambs, calves	2 500
Other	5 000

¹ 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.

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