Council Regulation (Euratom) 2016/52 of 15 January 2016 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 Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90

COUNCIL REGULATION (Euratom) 2016/52

of 15 January 2016

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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,

Having regard to the opinion of the European Parliament[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Whereas:

(1) Council Directive 2013/59/Euratom[(3)] 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.

(3) Council Regulation (Euratom) No 3954/87[(4)] 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

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dose by ingestion and on the assumption that 10 % of food consumed annually is contaminated. However, different assumptions apply to infants under 1 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 Council[(5)].

(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/Euratom[(6)], 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.

(8) The Commission is to be informed of a nuclear accident or of unusually high levels of radioactivity under Council Decision 87/600/Euratom[(7)] 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 6 months may vary significantly and that there are uncertainties in the metabolism of infants during the second 6-month period as well, it is appropriate to extend the application of lower maximum permitted levels for foods for infants to the first 12 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.

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(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.

(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 Council[(8)] 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.

(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 Council[(9)].

(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

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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;

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(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 Council[(10)];

(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 Council[(11)];

(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 Council[(12)];

(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;

(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