Basic information

2013/0451(NLE) NLE - Non-legislative enactments Regulation	Procedure completed
Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency **Subject** 3.10.08.01 Feedingstuffs, animal nutrition 3.10.10 Foodstuffs, foodstuffs legislation 3.60.04 Nuclear energy, industry and safety 3.70.08 Radioactive pollution 3.70.10 Man-made disasters, industrial pollution and accidents 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	HERRANZ GARCÍA Esther (PPE)	10/07/2014
	Shadow rapporteur TĂNĂSESCU Claudiu Ciprian (S&D) GIRLING Julie (ECR) PAULSEN Marit (ALDE) JUARISTI ABAUNZ Josu (GUE/NGL) RIVASI Michèle (Verts/ALE) PEDICINI Piernicola (EFDD)	

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	

	AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	

Former committee for opinion	Former rapporteur for opinion	Appointed
EMPL Employment and Social Affairs		
ITRE Industry, Research and Energy		
AGRI Agriculture and Rural Development		

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
JURI Legal Affairs	HAUTALA Heidi (Verts/ALE)	20/01/2015

Council of the European Union

European Commission

Commission DG	Commissioner
Energy	ARIAS CAÑETE Miguel

Key events

Date	Event	Reference	Summary
10/01/2014	Legislative proposal published	COM(2013)0943	Summary
25/02/2014	Committee referral announced in Parliament		
20/10/2014	Resumption of business from the previous parliamentary term		
26/05/2015	Vote in committee		
02/06/2015	Committee report tabled for plenary, 1st reading/single reading	A8-0176/2015	Summary
09/07/2015	Decision by Parliament	T8-0267/2015	Summary
09/07/2015	Results of vote in Parliament		
15/01/2016	Act adopted by Council after consultation of Parliament		
15/01/2016	End of procedure in Parliament		
20/01/2016	Final act published in Official Journal		

Technical information

Procedure reference	2013/0451(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consultation of Parliament
Legislative instrument	Regulation
Legal basis	Euratom Treaty A 032 Euratom Treaty A 031
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/00327

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE546.837	04/02/2015	
Amendments tabled in committee		PE551.762	06/03/2015	
Specific opinion	JURI	PE552.009	31/03/2015	
Committee report tabled for plenary, 1st reading/single reading		A8-0176/2015	02/06/2015	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0267/2015	09/07/2015	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2013)0943	10/01/2014	Summary
Commission response to text adopted in plenary	SP(2015)554	24/09/2015	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1556/2014	25/03/2014	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2016/0052
OJ L 013 20.01.2016, p. 0002

Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency

2013/0451(NLE) - 10/01/2014 - Legislative proposal

PURPOSE: to lay down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

PROPOSED ACT: Council Regulation.

ROLE OF THE EUROPEAN PARLIAMENT: the Council adopts the act after consulting the European Parliament but without being obliged to follow its opinion.

BACKGROUND: following the accident at the **Chernobyl nuclear power-station** on 26 April 1986, Council Regulation (Euratom) No 3954/87 laid 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.

The codification of Council Regulation (Euratom) No 3954/87 was initiated by the Commission, and a relevant proposal was submitted to the legislative authority.

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. 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.

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. 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.

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.

The Commission considers it necessary 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.

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**.

CONTENT: this proposal seeks to lay down the **maximum permitted levels of radioactive contamination of food**, the maximum permitted levels of minor food, and the maximum permitted levels of radioactive contamination of feed, 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.

In the event of the Commission receiving 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**.

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 examination procedure**.

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.

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. That committee shall be considered as a committee within the meaning of Regulation (EU) No 182/2011.

Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency

2013/0451(NLE) - 15/01/2016 - Final act

PURPOSE: to lay down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

NON-LEGISLATIVE ACT: Council Regulation (Euratom) 2016/52 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.

CONTENT: this Regulation lays down the **maximum permitted levels of radioactive contamination of food, minor food and feed** 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.

Applicable maximum permitted levels: if the Commission receives 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.

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.

The period of validity of implementing Regulations 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 3 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.

When reviewing implementing Regulations, the Commission shall consult the **group of experts** referred to in Article 31 of the Treaty.

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.

Restrictive measures: 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.

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 (RAFF).

Committee procedure: the Commission shall 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.

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.

ENTRY INTO FORCE: 9.2.2016.

Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency

2013/0451(NLE) - 02/06/2015 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Esther HERRANZ GARCÍA (EPP, ES) on the 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 committee approved the Commission proposal as amended below:

Legal basis: Members proposed changing the legal basis to Article 168(4)(b) and Article 114 of the Treaty on the Functioning of the European Union, meaning that that ordinary legislative procedure would apply in this area.

Definitions: as regards the definitions of ‘food’, ‘feed’ and ‘placing on the market’ set out in the regulation, it is proposed to refer to Regulation (EC) No 178/2002 laying down the general principles and requirements of food law to avoid any future discrepancy with the definition provided by the Commission in its proposal.

Members also suggested that it is necessary to consider the possible contamination of packages and introduced the definition of ‘radiological emergency" situations.

Practices which consist of **blending** foodstuffs containing concentrations above those permitted by the rules on maximum permitted levels of radioactive contamination in food and feed with uncontaminated or mildly contaminated foodstuffs, so as to obtain a product that complies with these rules, shall not be authorised.

Maximum permitted levels of radioactive contamination: the maximum permitted levels should be made **public and regularly revised** to take due account of the latest scientific advances and advice as presently available internationally, to reflect the need to reassure the public and to provide it with a high level of protection, and to avoid divergences in international regulatory practice.

The adoption of the maximum permitted levels under this Regulation should be based on the **protection requirements for the most critical and vulnerable population groups**, in particular children and people in isolated geographic areas or those practising subsistence farming. The maximum permitted levels should be the same for the entire population and should be based on the lowest levels.

An amendment clarifies the Commission text by referring to the **parameters used** to determine the maximum permitted levels laid down in the annexes. The EU has extensive radioactivity protection where food is concerned, with levels far below those permitted internationally

The maximum permitted levels listed in Annexes I to III have been revised and are set out in the Commission’s Radiological Protection Publication 105. Specifically, they are based on a **reference level** of 1 mSv per year in addition to the individual dose as ingested, and suppose that 10 % of the food consumed annually is contaminated.

Implementing acts: in the event of the Commission receiving official information on accidents or on any other case of radiological emergency that contaminates food and feed, it shall adopt, in the shortest time possible, an implementing Regulation laying down maximum permitted levels of radioactivity that may not exceed those laid down in the Annexes to this Regulation.

In drawing up that act, the Commission shall be assisted by an **independent group of public health experts** chosen on the basis of their knowledge and expertise in radiological protection and food safety. The Commission shall make public the composition of the committee of experts and its members' declarations of interests.

Review of the implementing acts and modification of the maximum permitted levels: the implementing acts shall be adopted in line with the nature and scope of the radiation and shall be reviewed as many times as is necessary with regard to the manner in which the contamination develops.

The Commission shall undertake to carry out the first review within **one month at the latest following a nuclear accident or radiological emergency** in order to modify, if necessary, the maximum permitted levels of radioactivity and the list of radionuclide

Nuclear liability regime: the Commission shall put in place a nuclear liability regime that is to address the concerns of all the Member States which might be affected by a nuclear accident; this system shall provide for appropriate compensation in case of nuclear accidents.

Controls regarding the respect of maximum permitted levels: Member States shall monitor compliance with the maximum permitted levels of radioactive contamination within their territories. They shall maintain a system of official controls for foodstuffs and feedingstuffs, and undertake other activities as appropriate in the circumstances, including public communication on food and feed safety and risks.

Information concerning the application of the Regulation: each Member State shall provide the Commission with all information concerning the application of this Regulation, in particular concerning: (i) the regular scheduling of checks on the maximum permitted levels on its national territory; (ii) cases of non-compliance with the maximum permitted levels; (iii) the identification of the national competent services in charge of the controls.

Cases of non-compliance with the maximum permitted levels shall be **notified via the rapid alert system** referred to in Regulation (EC) No 178/2002 of the European Parliament and of the Council. Member States shall provide information to the public, mainly by means of an online service, about the maximum permitted levels, emergency situations and cases of non-compliance with the maximum permitted levels. It shall also be notified about foodstuffs that could accumulate higher concentrations of radioactivity, and, in particular, about the product type, brand, origin and date of analysis.

Exportation of contaminated feed: the Commission shall impose penalties on Member States which themselves fail to impose penalties for the placing on the market or exportation of feed exceeding the maximum permitted levels of contamination.

Compensation to farmers: the Commission shall submit to the European Parliament and the Council, by 31 March 2017, a report on the appropriateness of a **mechanism** for compensating farmers whose foodstuffs have been contaminated beyond the maximum permitted levels of radioactive contamination. The report shall, if appropriate, be accompanied by a legislative proposal setting up such a mechanism.

Reports: the Commission shall submit to the European Parliament and the Council:

- by 31 March 2017, a report on the pertinence of the maximum permitted levels of radioactive contamination set in the Annexes;
- a report accompanied, where necessary, by a **proposal to adapt those annexes** and revise, if necessary, the list of radionuclides, after consultation of the Group of Experts in order to ensure that permitted levels laid down in the Annexes to this Regulation take account of any new or additional important data becoming available;
- a report giving details of the measures taken and the information notified in **the event of a nuclear accident or other cause of a radiological emergency** leading to contamination of food and feed.

Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency

2013/0451(NLE) - 09/07/2015 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 365 votes to 255, with 53 abstentions, a legislative resolution on the 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.

Parliament adopted its position at first reading following the ordinary legislative procedure. The amendments adopted in plenary amended the Commission proposal as follows:

Legal basis: Members proposed changing the legal basis to Article 168(4)(b) and Article 114 of the Treaty on the Functioning of the European Union so as to give Parliament the power of codecision. This would mean that the **ordinary legislative procedure** would apply in this area.

Definitions: as regards the definitions of 'food', 'feed' and 'placing on the market' set out in the regulation, it is proposed to refer to Regulation (EC) No 178/2002 laying down the general principles and requirements of food law to avoid any future discrepancy with the definition provided by the Commission in its proposal.

Members also suggested that it is necessary to consider the possible contamination of packages and introduced the definition of 'radiological emergency" situations.

The definition of 'minor food' has been deleted.

Practices which consist of **blending** foodstuffs containing concentrations above those permitted by the rules on maximum permitted levels of radioactive contamination in food and feed with uncontaminated or mildly contaminated foodstuffs, so as to obtain a product that complies with these rules, shall not be authorised.

Maximum permitted levels of radioactive contamination: the maximum permitted levels should be made **public and regularly revised** to take due account of the latest scientific advances and advice as presently available internationally, to reflect the need to reassure the public and to provide it with a high level of protection, and to avoid divergences in international regulatory practice.

The adoption of the maximum permitted levels under this Regulation should be based on the **protection requirements for the most critical and vulnerable population groups**, in particular children and people in isolated geographic areas or those practising subsistence farming. The maximum permitted levels should be the same for the entire population and should be based on the lowest levels.

An amendment clarifies the Commission text by referring to the **parameters used** to determine the maximum permitted levels laid down in the annexes. The EU has extensive radioactivity protection where food is concerned, with levels far below those permitted internationally

The maximum permitted levels listed in Annexes I to III have been revised and are set out in the Commission's Radiological Protection Publication 105. Specifically, they are based on a **reference level** of 1 mSv per year in addition to the individual dose as ingested, and suppose that 10 % of the food consumed annually is contaminated.

Implementing acts: in the event of the Commission receiving official information on accidents or on any other case of radiological emergency that contaminates food and feed, it shall adopt, in the shortest time possible, an implementing Regulation laying down maximum permitted levels of radioactivity that may not exceed those laid down in the Annexes to this Regulation.

When food or feed **originating in the Union or imported from third countries** poses a serious risk to human or animal health or to the environment, the Commission should, by means of implementing acts, adopt additional measures to ensure a high level of human and animal health protection.

Group of experts: in drawing up an implementing act, the Commission shall be assisted by an **independent group of public health experts** chosen on the basis of their knowledge and expertise in radiological protection and food safety. The Commission shall make public the composition of the committee of experts and its members' declarations of interests.

Review of the implementing acts and modification of the maximum permitted levels: the implementing acts shall be adopted in line with the nature and scope of the radiation and shall be reviewed as many times as is necessary with regard to the manner in which the contamination develops.

The Commission shall undertake to carry out the first review within **one month at the latest following a nuclear accident or radiological emergency** in order to modify, if necessary, the maximum permitted levels of radioactivity and the list of radionuclide

Nuclear liability regime: the Commission shall put in place a nuclear liability regime that is to address the concerns of all the Member States which might be affected by a nuclear accident; this system shall provide for appropriate compensation in case of nuclear accidents.

Controls regarding the respect of maximum permitted levels: Member States shall monitor compliance with the maximum permitted levels of radioactive contamination within their territories. They shall maintain a system of official controls for foodstuffs and feedingstuffs, and undertake other activities as appropriate in the circumstances, including public communication on food and feed safety and risks.

Information concerning the application of the Regulation: each Member State shall provide the Commission with all information concerning the application of this Regulation, in particular concerning: (i) the regular scheduling of checks on the maximum permitted levels on its national territory; (ii) cases of non-compliance with the maximum permitted levels; (iii) the identification of the national competent services in charge of the controls.

Cases of non-compliance with the maximum permitted levels shall be **notified via the rapid alert system** referred to in Regulation (EC) No 178/2002 of the European Parliament and of the Council.

Members insisted that, in the event of a nuclear accident or radiological emergency which requires the maximum permitted levels to be applied, the public should be informed of the levels in force, both by the Commission and by each Member State. Moreover, Member States shall provide information to the public, mainly by means of an online service, about the maximum permitted levels, emergency situations and cases of non-compliance with the maximum permitted levels. It shall also be notified about foodstuffs that could accumulate higher concentrations of radioactivity, and, in particular, about the product type, brand, origin and date of analysis.

Exportation of contaminated feed: the Commission shall impose penalties on Member States which themselves fail to impose penalties for the placing on the market or exportation of feed exceeding the maximum permitted levels of contamination.

Compensation to farmers: the Commission shall submit to the European Parliament and the Council, by 31 March 2017, a report on the appropriateness of a **mechanism** for compensating farmers whose foodstuffs have been contaminated beyond the maximum permitted levels of radioactive contamination. The report shall, if appropriate, be accompanied by a legislative proposal setting up such a mechanism.

Reports: the Commission shall submit to the European Parliament and the Council:

- by 31 March 2017, a report on the pertinence of the maximum permitted levels of radioactive contamination set in the Annexes;
- a report accompanied, where necessary, by a **proposal to adapt those annexes** and revise, if necessary, the list of radionuclides;
- a report giving details of the measures taken and the information notified in **the event of a nuclear accident or other cause of a radiological emergency** leading to contamination of food and feed.