Basic information

2012/0074(NLE) NLE - Non-legislative enactments Directive	Procedure completed
Protection of public health: radioactive substances in water intended for human consumption **Subject** 3.60.04 Nuclear energy, industry and safety 3.70.04 Water control and management, pollution of waterways, water pollution 3.70.08 Radioactive pollution 4.20 Public health 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	RIVASI Michèle (Verts/ALE)	09/09/2011
	Shadow rapporteur MIKOLÁŠIK Miroslav (PPE) TĂNĂSESCU Claudiu Ciprian (S&D) PANAYOTOV Vladko Todorov (ALDE) ROSBACH Anna (ECR) WILS Sabine (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	MERKIES Judith A. (S&D)	12/09/2011

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
JURI Legal Affairs	LICHTENBERGER Eva (Verts/ALE)	08/10/2012

Council of the European Union

Council configuration	Meetings	Date
General Affairs	3268	2013-10-22

European Commission	Commission DG	Commissioner
	Energy	OETTINGER Günther

Key events

Date	Event	Reference	Summary
28/03/2012	Legislative proposal published	COM(2012)0147	Summary
20/04/2012	Committee referral announced in Parliament		
23/01/2013	Vote in committee		
05/02/2013	Committee report tabled for plenary, 1st reading/single reading	A7-0033/2013	Summary
12/03/2013	Decision by Parliament	T7-0068/2013	Summary
12/03/2013	Results of vote in Parliament		
22/10/2013	Act adopted by Council after consultation of Parliament		
22/10/2013	End of procedure in Parliament		
07/11/2013	Final act published in Official Journal		

Technical information

Procedure reference	2012/0074(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consultation of Parliament
Legislative instrument	Directive
Legal basis	Euratom Treaty A 031-p2 Euratom Treaty A 031 Euratom Treaty A 032
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/09351

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Specific opinion	JURI	PE500.425	07/11/2012	
Amendments tabled in committee		PE500.579	18/12/2012	
Committee opinion	ITRE	PE491.256	20/12/2012	
Committee draft report		PE489.702	16/01/2013	

Amendments tabled in committee		PE504.067	22/01/2013	
Committee report tabled for plenary, 1st reading/single reading		A7-0033/2013	05/02/2013	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0068/2013	12/03/2013	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2012)0147	28/03/2012	Summary
Commission response to text adopted in plenary	SP(2013)306	30/04/2013	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1312/2012	23/05/2012	

Additional information

Source	Document	Date
European Commission	EUR-Lex	
European Commission	EUR-Lex	

Final act

Directive 2013/0051
OJ L 296 07.11.2013, p. 0012 Summary

Protection of public health: radioactive substances in water intended for human consumption

2012/0074(NLE) - 28/03/2012 - Legislative proposal

PURPOSE : to lay down requirements on radioactive substances in water intended for human consumption.

PROPOSED ACT : Council Directive.

BACKGROUND : drinking water contamination by radioactive substances may occur through accidental releases of radioactivity or through improper disposal practices. Water systems that are vulnerable to this type of contamination undergo extensive monitoring for radioactive contamination to ensure that the water is safe for drinking. There are many regions in Europe where the geological and hydrological features are such that the presence of naturally occurring radioactive substances is of concern.

In order to protect human health, the Council adopted Directive 98/83/EC on the quality of water intended for human consumption. The requirements for monitoring tritium and total indicative dose under Council Directive 98/83/EC have not been implemented, pending the adoption of amendments to Annexes II (monitoring) and III (specifications for the analysis of parameters).

However, indicator parameters set out in Annex I Part C relating to radioactivity and tritium and the related monitoring provisions in Annex II to Directive 98/83/EC actually fall within the scope of the basic standards as set out in Article 30 of the Euratom Treaty. As a result, the Commission proposes to incorporate the requirements for monitoring levels of radioactivity into specific legislation under the Euratom Treaty.

IMPACT ASSESSMENT : no impact assessment was undertaken.

LEGAL BASIS : Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community.

CONTENT : the proposal lays down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. It sets out parametric values, frequencies and methods for monitoring radioactive substances.

Scope: parametric values for radon and tritium and parametric values for total indicative dose, for other radioactive substances, in water intended for human consumption are set out in the proposal. The Commission notes that it adopted in June 2011 a draft proposal laying down requirements with regard to radioactive substances in water intended for human consumption based on Article 31 of the Euratom Treaty. On 27 October 2011 the EESC adopted an opinion on this draft Commission proposal, calling for the inclusion of radon gas within the scope of the Directive. It recalls that in 1998 radon gas had been excluded from the scope of the Directive in view of the fact that it constitutes a risk of inhalation rather than of ingestion as drinking water. The Commission agrees with the EESC recommendation and has now made provision for the inclusion of radon gas in the Directive.

In order to address the specific feature of radon gas, it is included as a separate indicator parameter, while the long-lived decay products of radon are included in the evaluation of total indicative dose as defined in Directive 98/83/EC.

The EESC also advocated mirroring to the largest possible extent the general provisions of Directive 98/83/EC, so as to offer one coherent policy. This would require, amongst other, the inclusion of bottled waters. The Commission agrees with this recommendation but also needs to allow for the fact that after adoption of the 1998 Directive, specific legislation was adopted for the monitoring of bottled waters, in the overall context of food safety. Hence the new Commission proposal includes on the one hand bottled water within the scope of the Directive, on the other hand refers to the monitoring criteria laid down in Regulation (EC) No 852/2004.

The Commission will propose the deletion of tritium and total indicative dose from the list of indicator parameters in part C of Annex I to Directive 98/83 /EC and the repeal of all references to these parametric values.

General obligations: Member States must take all measures necessary to establish an appropriate monitoring programme to ensure that water intended for human consumption complies with the parametric values established in accordance with the Directive.

Parametric values: parametric values applicable for the monitoring of radioactive substances in water intended for human consumption must be set in accordance with Annex I. For water put into bottles or containers intended for sale this shall be without prejudice to the principles of hazard analysis and critical control points (HACCP) as required by Regulation (EC) No 852/2004.

Monitoring: Member States shall ensure regular monitoring of water intended for human consumption in accordance with Annex II in order to check that the concentrations of radioactive substances do not exceed the parametric values laid down.

Sampling: sampling locations are specified in the proposal. Samples representative of the quality of the water consumed throughout the year shall be taken and analysed in accordance with the methods set out in Annex III.

Remedial action and notification of consumers: any failure to comply with the parametric values laid down must be immediately investigated in order to identify its cause. Member States must assess whether the failure poses a risk to human health, and take remedial action to restore the quality of the water. Where the risk to human health cannot be regarded as trivial, the Member State shall ensure that consumers are notified.

BUDGETARY IMPLICATIONS : the proposal has no implication for the Community budget.

Protection of public health: radioactive substances in water intended for human consumption

2012/0074(NLE) - 05/02/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Michèle RIVASI (Greens/EFA, FR), and amended the proposal for a Council directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

The Commission is called upon to alter its proposal accordingly, pursuant to Article 293(2) of the Treaty on the Functioning of the European Union and Article 106a of the Euratom Treaty.

The main amendments suggested by the committee are as follows:

Amendment of legal basis: Members want the proposal to follow the **ordinary legislative procedure** and be based upon **Article 192(1)** of the Treaty on the Functioning of the European Union and not upon Articles 31 and 32 Treaty establishing the European Atomic (Euratom), as proposed by the Commission.

The report underlines that radionuclides in water intended for human consumption are currently dealt with under the Directive 98/83/EC (Drinking Water Directive). In order to ensure legal certainty and consistency of the Union legislation on drinking water, it proposes that **the legal basis should be the same as that for Directive 98/83/EC** to treat radionuclides on the same footing as all other carcinogenic contaminants.

Parametric values: these are based on the scientific knowledge available, taking into account the **precautionary principle**. They must ensure that water intended for human consumption can be consumed safely on a life-long basis, taking as reference the **most vulnerable citizens**.

Non-compliance with a parameter that has an indicator function: in this event, the Member State concerned should: (i) determine the cause (ii) assess the level of the risk to human health including in the long-term and the possibilities for intervention and (iii) on the basis of these findings, take action to ensure the water supply complies with the quality criteria laid down in the directive as soon as possible.

This remedial action may go as far as shutting down the facility concerned if the quality of water requires such action. Priority should be given to **action**, which rectifies the problem at source.

Information for consumers: consumers should be informed immediately of:

- **the risks, and the measures already taken** by the authorities and the time necessary for the remedial action to take effect ;
- **the quality of water** intended for human consumption via easily accessible publications. Members want updated information regarding areas at risk from potential sources of radioactive contamination to be made available to consumers at all times by local administrations.

Natural mineral water: the Commission should, at the latest two years after entry into force of the directive, present a proposal to revise Directive 2009 /54/EC, in order to align the control requirements for natural mineral waters to the requirements provided for in this Directive and in Directive 98/83/EC.

Monitoring programmes: each Member State should establish robust monitoring programmes to check on a regular basis, that water intended for human consumption meets the requirements of the Directive. In particular, Members want Member States:

- to ensure that the measures taken to implement the Directive do not, under any circumstances, have the effect of allowing any deterioration in the present quality of water intended for human consumption;
- to develop new technologies which would minimise the time needed to isolate nuclear waste from the environment following a natural disaster ;
- to take all measures necessary to ensure that radioactive waste from filtered drinking water is disposed of according to the provisions in force;
- to carry out risk assessments of radioactive waste deposits that could have an impact on ground water or other sources of drinking water that could be endangered by natural disasters.

Samples and analysis: in line with the **'polluter pays'** principle, if monitoring shows contamination to come from an artificial source, it should be the person responsible who meets the costs, rather than the water operator or the public.

Natural radiation levels and radiation from human activity: Members propose that natural radiation levels and contamination from human activities be **managed in a differentiated manner,** on the basis of distinct dosimetric criteria and bearing in mind different groups affected, especially **in terms of age.**

With regard to natural radioactivity in drinking water, the report notes that reference concentrations proposed by the Commission have been calculated using the dose coefficients for adults. However, calculations show that for other age-groups, especially **infants less than one year old**), these reference concentrations would lead to exceeding the total indicative dose (TID). In order to be consistent within the proposal, and to assure a level of protection corresponding to **0.1 mSv TID for all age groups,** the most vulnerable group of population must be taken as basis for the calculations.

With regard to the radiological impact of normal levels of human activity, the maximum reference dose should be **lowered to 0.01 mSv/year**, corresponding to 10% of the acceptable natural dose.

Review of Annexes: Members consider that **at least every five years**, the Commission shall review all the Annexes on parametric values, references for radioactive substances and sampling and analysis, in the light of scientific and technical progress and make amendments through **delegated acts**.

Protection of public health: radioactive substances in water intended for human consumption

2012/0074(NLE) - 12/03/2013 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 582 votes to 24 with 63 abstentions, a legislative resolution on the proposal for a Council directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

Parliament adopted its postion in first reading following the ordinary legislative procedure. It amended the Commission proposal as follows:

Amendment of the legal basis: Parliament wants the proposal **to follow the ordinary legislative procedure** and be based upon Article 192(1) of the Treaty on the Functioning of the European Union and not upon Articles 31 and 32 Treaty establishing the European Atomic (Euratom), as proposed by the Commission.

Accordingly, the Directive shall apply to water intended for human consumption **as defined in Article 2 of Directive 98/83/EC** on the quality of water intended for human consumption and concerns **harmonised requirements in respect of the quality of water intended for human consumption,** with the aim of safeguarding the health of the general public against the adverse effects of the contamination of such water by radioactive substances.

Parametric values: these are based on the scientific knowledge available, taking into account the precautionary principle. They must ensure that water intended for human consumption can be consumed safely on a life-long basis, taking as reference the most vulnerable citizens.

Non-compliance with a parameter that has an indicator function: in this event, the Member State concerned should: (i) determine the cause (ii) assess the level of the risk to human health including in the long-term and the possibilities for intervention and (iii) on the basis of these findings, take action to ensure the water supply complies with the quality criteria laid down in the directive as soon as possible.

This remedial action may go as far as shutting down the facility concerned if the quality of water requires such action. Priority should be given to action, which rectifies the problem at source.

Information for consumers: consumers should be informed immediately of:

- **the risks, and the measures already taken** by the authorities and the time necessary for the remedial action to take effect ;
- **the quality of water intended for human consumption via easily accessible publications**. Members want updated information regarding areas at risk from potential sources of radioactive contamination to be made available to consumers at all times by local administrations.

Natural mineral water: the Commission should, at the latest two years after entry into force of the directive, present a proposal to revise Directive 2009 /54/EC, in order to align the control requirements for natural mineral waters to the requirements provided for in this Directive and in Directive 98/83/EC.

Monitoring programmes: each Member State should establish robust monitoring programmes to check on a regular basis, that water intended for human consumption meets the requirements of the Directive. In particular, Members want Member States:

- to ensure that the measures taken to implement the Directive **do not, under any circumstances, have the effect of allowing any deterioration in the present quality of water** intended for human consumption;
- to develop **new technologies** which would minimise the time needed to isolate nuclear waste from the environment following a natural disaster ;
- to take all measures necessary to ensure that **radioactive waste from filtered drinking water** is disposed of according to the provisions in force;
- to carry out **risk assessments** of radioactive waste deposits that could have an impact on ground water or other sources of drinking water that could be endangered by natural disasters.

For its part, the Commission should carry out:

- a study on the cocktail effects of other chemical substances combined with radioactive substances in water intended for human and update the relevant legislation based on the results;
- an evaluation of the implementation of the current Water Framework Directive in the Member States.

Samples and analysis: an amendment states that the system of analytical quality control system must be subject to **random checks**, at least once a year.

In line with the '**polluter pays**' principle, if monitoring shows contamination to come from an artificial source, it should be the person responsible who meets the costs, rather than the water operator or the public.

Natural radiation levels and radiation from human activity: Parliament proposes that natural radiation levels and contamination from human activities be **managed in a differentiated manner**, on the basis of distinct dosimetric criteria and bearing in mind different groups affected, especially in terms of age.

- With regard to **natural radioactivity in drinking water**, the calculation shall be performed for the population group most exposed to risk (children less than a year old) in order to ensure compliance with the **total indicative dose of 0,1 mSv,** regardless of the age of the consumer.
- With regard to the radiological impact of normal levels of human activity, the maximum reference dose should be lowered to **0.01 mSv/year**, corresponding to 10% of the acceptable natural dose.

Review of Annexes: Parliament considers that at least every five years, the Commission shall review all the Annexes on parametric values, references for radioactive substances and sampling and analysis, in the light of scientific and technical progress and make amendments through delegated acts.

Protection of public health: radioactive substances in water intended for human consumption

2012/0074(NLE) - 22/10/2013 - Final act

PURPOSE: to lay down the requirements for monitoring levels of radioactive substances in water intended for human consumption.

LEGISLATIVE ACT: Council Directive 2013/51/Euratom laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

CONTENT: the directive lays down **requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption**. It lays down parametric values and frequencies and methods for monitoring radioactive substances.

The directive does not apply to:

- natural mineral waters recognised as such by the competent national authorities, in accordance with Directive 2009/54/EC;
- waters which are medicinal products within the meaning of Directive 2001/83/EC.

Since this Directive provides for minimum rules, **Member States should be free to adopt or maintain more stringent measures** in the field covered by this Directive, without prejudice to the free movement of goods in the internal market as defined by the case-law of the Court of Justice.

Monitoring programmes: the directive foresees that Member States shall take all measures necessary to establish an appropriate monitoring programme for water intended for human consumption, to ensure that in the event of non-compliance with the parametric values laid down pursuant to this Directive:

- it shall be **assessed** whether that poses a risk to human health which requires action; and,
- **remedial action** shall be taken, where necessary, to improve the quality of water to a level which complies with requirements for the protection of human health from a radiation protection point of view.

Monitoring and analysis: the directive obliges Member States to take all measures necessary to ensure that monitoring for radioactive substances in water intended for human consumption is undertaken, in order to check whether the values of radioactive substances comply with the parametric values laid down in the Directive.

Monitoring shall be undertaken so as to ensure that the measured values obtained are representative of the quality of the water consumed throughout the year.

Remedial action and notification of the general public: in the case of any failure to comply with a parametric value, **an inquiry** shall immediately investigate in order to identify the cause.

Where a failure to comply with a parametric value poses a risk to human health which requires action, the Member State shall take remedial action and ensure that the general public concerned is: i) **notified** of the risk and the remedial action taken; and ii) **advised** on any additional precautionary measures that may be needed.

ENTRY INTO FORCE: 27/11/2013.

TRANSPOSITION: 28/11/2015.