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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

EXPLANATORY MEMORANDUM

1. JUSTIFICATION OF THE PROPOSAL

Water is one of the most comprehensively regulated areas of Community environmental legislation. Early European water policy began in the 1970s with the adoption of political programmes as well as legally binding legislation.

On 3 November 1998 the Council adopted Directive 98/83/EC on the quality of water intended for human consumption. This new Directive had to be transposed into national legislation by the end of the year 2000, and had to be complied with by the end of 2003.

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.

So far 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). Technical requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption have been finalised for about six years now, after a consultation process involving the Group of Experts provided for under Article 31 Euratom, the Committee established under the Drinking Water Directive and the consultation of the Committee of Member State representatives established under Articles 35-36 of the Euratom Treaty.

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, it is justified to incorporate the requirements for monitoring levels of radioactivity into specific legislation under the Euratom Treaty in order to maintain the uniformity, coherence and completeness of radiation protection legislation at Community level.

Therefore the Commission adopted on 27 June 2011 a draft proposal laying down requirements for the protection of the health of the general public 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 amongst others for the inclusion of radon gas within the scope of the Directive. The EESC referred to a Commission Recommendation (2001/928/Euratom) for the protection against radon gas in drinking water. 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 draft proposal for a Euratom Directive focussed on the change of the legal basis, without technical amendments, but 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 EC 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.

Taking into account the implementation of the general principle in legal theory and practice that establishes that a law governing a specific subject matter overrides a law which only governs general matters ("*lex specialis derogat legi generali*"), the provisions of the Directive under the Euratom Treaty supersede those of the Directive 98/83/EC as regards radioactive substances in drinking water. In a second step, 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.

2. SUBSIDIARITY AND PROPORTIONALITY

- Legal basis

The provisions of this Directive are related to the basic standards for the protection of the health of workers and the general public. Consequently, the legal base chosen is the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof.

- Subsidiarity principle

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community. As the Community's legislative powers under Title II Chapter III of the Euratom Treaty are exclusive in nature, they are not subject to the principle of subsidiarity.

- Proportionality principle

The proposal complies with the proportionality principle for the following reason(s):

The proposal sets out minimum harmonised standards for monitoring radon, tritium and total indicative dose and adapts the requirements of Directive 98/83/EC related to radioactivity to the latest scientific and technical progress.

- Choice of instruments

While the Community is responsible for establishing uniform rules in the radiation protection field in order to achieve a high level of health protection of workers and the general public, it falls on the Member States to transpose into their national legislation such rules and to implement them.

A directive is therefore best suited to create a common approach on defining requirements for radioactivity parameters for monitoring the quality of water intended for human consumption in the light of scientific and technical progress.

As a consequence, harmonised requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption are defined.

3. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

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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 Commission¹ drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, in accordance with Article 31 of the Treaty,

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

After consulting the European Parliament³,

Whereas:

- (1) The ingestion of water is one of the pathways of incorporation of radioactive substances into the human body. In accordance with Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation⁴, the contribution to the exposure of the population as a whole from practices which involve a risk from ionizing radiation must be kept as low as reasonably achievable.
- (2) In view of the importance for human health of the quality of water intended for human consumption, it is necessary to lay down at Community level quality standards which have an indicator function and provide for the monitoring of the compliance with those standards.
- (3) Indicator parameters have already been set out in Annex I, Part C relating to radioactive substances, as well as the related monitoring provisions in Annex II to Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption⁵. However, those parameters fall within the scope of the basic standards defined in Article 30 of the Euratom Treaty.

¹ OJ C , , p.

² OJ C , , p.

³ OJ C , , p.

⁴ OJ L 159, 29.6.1996, p. 1

⁵ OJ L 330, 5.12.1998, p. 32

- (4) The requirements for monitoring levels of radioactivity in water intended for human consumption should therefore be adopted in specific legislation that ensures the uniformity, coherence and completeness of radiation protection legislation under the Euratom Treaty.
- (5) The provisions of this Directive adopted under the Euratom Treaty should supersede those of the Directive 98/83/EC as regards the contamination of drinking water by radioactive substances.
- (6) In the event of non-compliance with a parameter that has an indicator function, the Member State concerned should assess whether that non-compliance poses any risk to human health and, where necessary, take remedial action to restore the quality of the water.
- (7) Consumers should be adequately and appropriately informed of the quality of water intended for human consumption.
- (8) It is necessary to exclude from the scope of this Directive natural mineral waters and waters which are medicinal products, since special rules for those types of water have been established in Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters⁶ and 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 use⁷. The monitoring of waters put into bottles or containers intended for sale, other than natural mineral waters, for the purpose of checking that the levels of radioactive substances comply with the parametric values laid down in this Directive should be done in accordance with the principles of hazard analysis and critical control points (HACCP) as required by Regulation (EC) No 852/2004⁸.
- (9) Each Member State should establish monitoring programmes to check that water intended for human consumption meets the requirements of this Directive.
- (10) The methods used to analyse the quality of water intended for human consumption should be such as to ensure that the results obtained are reliable and comparable.
- (11) Commission Recommendation 2001/928/Euratom of 20 December 2001 on the protection of the public against exposure to radon in drinking water supplies⁹ deals with the radiological quality of drinking water supplies regarding radon and long-lived radon decay products, and it is appropriate to include these radionuclides in the scope of this Directive.

⁶ OJ L 164, 26.6.2009, p. 45

⁷ OJ L 311, 28.11.2001, p. 67

⁸ OJ L 226, 25.6.2004, p. 3

⁹ OJ L 344, 28.12.2001, p.85

HAS ADOPTED THIS DIRECTIVE:

Article 1
Subject matter

This 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 sets out parametric values, frequencies and methods for monitoring radioactive substances.

Article 2
Definitions

For the purposes of this Directive, definitions laid down in Article 2 of Council Directive 98/83/EC shall apply.

Article 3
Scope

This Directive shall apply to water intended for human consumption with the exemptions set out in Article 3(1) of Directive 98/83/EC and laid down in accordance with Article 3(2) of that Directive.

Article 4
General obligations

Without prejudice to the provisions laid down in Article 6(3)a of Directive 96/29/Euratom, Member States shall 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 this Directive.

Article 5
Parametric values

Member States shall set parametric values applicable for the monitoring of radioactive substances in water intended for human consumption 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.

Article 6
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 in accordance with Article 5.

Article 7
Sampling locations

Member States may take samples:

- (a) in the case of water supplied from a distribution network, at the point within the supply zone or at the treatment works if it can be demonstrated that such sampling gives the same or higher measured value of the parameters concerned;
- (b) in the case of water supplied from a tanker, at the point at which it emerges from the tanker;
- (c) in the case of water put into bottles or containers intended for sale, at the point at which the waer is put into the bottles or containers;
- (d) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking.

Article 8
Sampling and analysis

1. 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.
2. Member States shall ensure that all laboratories analysing samples of water intended for human consumption have a system of analytical quality control. They shall ensure that that system is subject to occasional checks by an independent controller approved by the competent authority for that purpose.

Article 9
Remedial action and notification of consumers

1. Member States shall ensure that any failure to comply with the parametric values laid down in accordance with Article 5 is immediately investigated in order to identify its cause.
2. Where a failure to comply with the parametric values laid down in accordance with Article 5 occurs, the Member State shall assess whether the failure poses a risk to human health. In the event that there is such a risk, the Member State shall take remedial action to restore the quality of the water.
3. Where the risk to human health cannot be regarded as trivial, the Member State shall ensure that consumers are notified.

Article 10
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*one year after the date referred to in Article 11-*

specific date to be inserted by the Publications Office] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 11
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 12
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

Parametric values for radon and tritium and parametric values for Total Indicative Dose, for other radioactive substances, in water intended for human consumption

Radioactivity

Parameter	Parametric value	Unit	Notes
Radon	100	Bq/l	
Tritium	100	Bq/l	
Total indicative dose	0,10	mSv/year	(Note 1)

Note 1: Excluding tritium, potassium -40, radon and short-lived radon decay products

ANNEX II

Monitoring of radioactive substances

1. General principles and monitoring frequencies

A Member State is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied on the basis of other monitoring that the levels of both tritium and of the calculated total indicative dose are well below the parametric value. Monitoring drinking water for radon is not required where a Member State is satisfied on the basis of other monitoring that the levels of radon are well below the parametric value. In these cases, it shall communicate the grounds for its decision to the Commission, including the results of the other monitoring carried out.

2. Radon and Tritium

Monitoring of drinking water for radon or tritium shall be carried out where a source of radon or tritium is present within the catchment and it cannot be shown on the basis of other surveillance programmes or investigations that the level of radon or tritium is well below its parametric indicator value 100 Bq/l. Where monitoring for radon or tritium is required, it shall be carried out at the audit frequency.

3. Total Indicative Dose

Monitoring of drinking water for Total Indicative Dose (TID) shall be carried out where a source of artificial or enhanced natural radioactivity is present within the catchment and it cannot be shown on basis of other surveillance programmes or investigations that the level of TID is well below its parametric indicator value 0.1 mSv/year. Where monitoring for artificial radionuclide levels is required, it shall be carried out at the audit frequency indicated in the table. Where monitoring for natural radionuclide levels is required, Member States shall define the frequency of the monitoring having regard to all relevant information available on temporal variations of natural radionuclide levels in different types of waters. Depending on the expected variations, monitoring frequency may vary from a single check measurement to the audit frequency. Where only a single check for natural radioactivity is required, a re-check shall be required at least where any change occurs in relation to the supply likely to influence the concentrations of radionuclides in the drinking water.

Where methods for removing radionuclides from drinking water have been applied in order to ensure that a parametric value is not exceeded, monitoring shall be carried out at the audit frequency.

Where results of other surveillance programmes or investigations than those required as provided in the first paragraph of this point are used to ensure compliance with this Directive, the Member State shall communicate the grounds for its decision to the Commission, including the relevant results of these monitoring programmes or investigations.

4. The audit frequency of monitoring shall be as set out in the following table:

TABLE
Audit frequency of monitoring for water intended for human consumption supplied from a distribution network

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m ³	Number of samples per year (Notes 3)
≤ 100	(Note 4)
$> 100 \leq 1\ 000$	1
$> 1\ 000 \leq 10\ 000$	1 + 1 for each 3 300 m ³ /d and part thereof of the total volume
$> 10\ 000 \leq 100\ 000$	3 + 1 for each 10 000 m ³ /d and part thereof of the total volume
$> 100\ 000$	10 + 1 for each 25 000 m ³ /d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: As far as possible, the number of samples should be distributed equally in time and location.

Note 4: The frequency is to be decided by the Member State concerned.

ANNEX III

Sampling and analysis methods

1. Screening for compliance with total indicative dose (TID)

Member States may use screening methods for gross alpha activity and gross beta activity to monitor for the parametric indicator value for TID, excluding tritium, potassium-40, radon and short-lived radon decay products.

If the gross alpha and the gross beta activity are less than 0.1 Bq/l and 1.0 Bq/l respectively, the Member State may assume that the TID is less than the parametric indicator value of 0.1 mSv/year and no radiological investigation is needed unless it is known from other sources of information that specific radionuclides are present in the water supply and are liable to cause a TID in excess of 0.1 mSv/year.

If the gross alpha activity exceeds 0.1 Bq/l or the gross beta activity exceeds 1.0 Bq/l, analysis for specific radionuclides shall be required. The radionuclides to be measured shall be defined by Member States taking into account all relevant information about likely sources of radioactivity. Since elevated levels of tritium may indicate the presence of other artificial radionuclides, tritium, gross alpha activity and gross beta activity should be measured in the same sample.

In replacement of gross alpha and gross beta activity screening discussed above, Member States may decide to use other reliable screening methods for radionuclides to indicate the presence of radioactivity in drinking water. If one of the activity concentrations exceeds 20% of its reference concentration or the tritium concentration exceeds its parametric value of 100 Bq/l, an analysis of additional radionuclides shall be required. The radionuclides to be measured shall be defined by Member States taking into account all relevant information about likely sources of radioactivity.

2. Calculation of the Total Indicative Dose (TID)

The TID is the committed effective dose for one year of intake resulting from all the radionuclides whose presence in a water supply has been detected, both of natural and artificial origin, excluding tritium, potassium-40, radon and short-lived radon decay products. The TID shall be calculated from the radionuclide concentrations and the dose coefficients for adults laid down in Annex III, Table A of Directive 96/29/Euratom or more recent information recognised by the competent authorities in the Member State. Where the following formula is satisfied, Member States may assume that the TID is less than the parametric indicator value of 0.1 mSv/year and no further investigation shall be required:

$$\sum_{i=1}^n \frac{C_i(obs)}{C_i(ref)} \leq 1 \quad (1)$$

where

$C_i(obs)$ = observed concentration of radionuclide i

$C_i(ref)$ = reference concentration of radionuclide i

n = number of radionuclides detected.

Where the formula is not satisfied, the parametric value shall only be regarded as having been exceeded if the radionuclides are persistently present at similar activity concentrations for a full year. Member States shall define the extent of resampling necessary to ensure that the measured values are representative for an average activity concentration for a full year.

Reference concentrations for radioactivity in drinking water¹

Origin	Nuclide	Reference concentration
Natural	U-238 ²	3.0 Bq/l
	U-234 ²	2.8 Bq/l
	Ra-226	0.5 Bq/l
	Ra-228	0.2 Bq/l
	Pb-210	0.2 Bq/l
	Po-210	0.1 Bq/l
Artificial	C-14	240 Bq/l
	Sr-90	4.9 Bq/l
	Pu-239/Pu-240	0.6 Bq/l
	Am-241	0.7 Bq/l
	Co-60	40 Bq/l
	Cs-134	7.2 Bq/l
	Cs-137	11 Bq/l
	I-131	6.2 Bq/l

¹ This table includes the most common natural and artificial radionuclides. Reference concentrations for other radionuclides can be calculated using the dose coefficients for adults laid down in Annex III, Table A of Directive 96/29/Euratom, or more recent information recognised by the competent authorities in the Member State, and by assuming an intake of 730 litres per year.

² One milligram (mg) of natural uranium contains 12.3 Bq of U-238 and 12.3 Bq of U-234. This table allows only for the radiological properties of uranium, not for its chemical toxicity.

3. Performance characteristics and methods of analysis

For the following radioactivity parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a limit of detection specified.

Parameters	Limit of detection (Note 1)	Notes
Radon	10 Bq/l	Note 2, 3
Tritium	10 Bq/l	Note 2, 3
Gross alpha	0.04 Bq/l	Note 2, 4
Gross beta	0.4 Bq/l	Note 2, 4
U-238	0.02 Bq/l	Note 2, 6
U-234	0.02 Bq/l	Note 2, 6
Ra-226	0.04 Bq/l	Note 2
Ra-228	0.08 Bq/l	Note 2, 5
Pb-210	0.02 Bq/l	Note 2
Po-210	0.01 Bq/l	Note 2
C-14	20 Bq/l	Note 2
Sr-90	0.4 Bq/l	Note 2
Pu-239/Pu-240	0.04 Bq/l	Note 2
Am-241	0.06 Bq/l	Note 2
Co-60	0.5 Bq/l	Note 2
Cs-134	0.5 Bq/l	Note 2
Cs-137	0.5 Bq/l	Note 2
I-131	0.5 Bq/l	Note 2

Note 1: the limit of detection shall be calculated according to ISO 11929-7, Determination of the detection limit and decision thresholds for ionizing radiation measurements-Part 7: Fundamentals and general applications, with probabilities of errors of 1st and 2nd kind of 0.05 each

Note 2: measurement uncertainties shall be calculated and reported as complete standard uncertainties, or as expanded standard uncertainties with an expansion factor of 1.96, according to the ISO Guide for the Expression of Uncertainty in Measurement (ISO, Geneva 1993, corrected reprint Geneva, 1995)

Note 3: the limit of detection for radon and for tritium is 10% of its parametric value of 100 Bq/l

Note 4: the limit of detection for gross alpha and gross beta activities are 40% of the screening values of 0.1 and 1.0 Bq/l respectively

Note 5: This Limit of Detection applies only to routine screening; for a new water source for which it is plausible that Ra-228 exceeds 20% of the reference concentration, the limit of detection for the first check shall be 0.02 Bq/l for Ra-228 nuclide specific measurements. This shall also apply where a subsequent re-check is required.

Note 6: The low value of the specified detection limit for U is due to taking into account the chemotoxicity of uranium.