Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption

COUNCIL DIRECTIVE 2013/51/EURATOM

of 22 October 2013

laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption

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 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 establishing the European Atomic Energy Community,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the European Parliament,

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[(2)], the contribution to the exposure of the general public as a whole from practices which involve a risk from ionising 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 to provide for the monitoring of compliance with those standards.

(3) Council Directive 98/83/EC[(3)] sets out indicator parameters relating to radioactive substances in Annex I, Part C and related monitoring provisions in Annex II thereto. However, those parameters fall within the scope of the basic standards defined in Article 30 of the Euratom Treaty.

(4) The requirements for monitoring levels of radioactive substances 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) Since the Community is competent to adopt the basic safety standards for the protection of the health of workers and general public against the dangers arising from ionising radiations, the provisions of this Directive supersede those of Directive 98/83/EC as

regards the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

(6) As recognised by the Court of Justice in its case-law, the tasks imposed on the Community by Article 2(b) of the Euratom Treaty to establish uniform safety standards to protect the health of workers and of the general public do not preclude, unless explicitly stated in those standards, a Member State from providing for more stringent measures of protection. 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.

(7) Parametric values should not be regarded as limit values. In the event that monitoring of water intended for human consumption indicates non-compliance with a parametric value, the Member State concerned should consider whether that poses a risk to human health which requires action and, where necessary, take remedial action to improve the quality of the water to a level which complies with the requirements for the protection of human health from a radiation protection point of view.

(8) Monitoring of waters intended for human consumption put into bottles or containers intended for sale, other than natural mineral waters, for the purpose of checking whether the levels of radioactive substances comply with the parametric values laid down pursuant to this Directive, should be carried out in accordance with the principles of hazard analysis and critical control points (HACCP) as required by Regulation (EC) No 852/2004 of the European Parliament and of the Council[(4)] and without prejudice to the principles of official controls laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council[(5)].

(9) The general public should be adequately and appropriately informed of the quality of water intended for human consumption.

(10) 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[(6)] and Directive 2001/83/EC of the European Parliament and of the Council[(7)].

(11) Each Member State should establish monitoring programmes to check that water intended for human consumption meets the requirements of this Directive.

(12) 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.

(13) Taking into consideration the large geographical variability in the natural occurrence of radon, the Commission adopted Recommendation 2001/928/Euratom[(8)], which deals with the quality of water intended for human consumption regarding radon and long-lived radon decay products. It is appropriate to include these radionuclides in the scope of this Directive.

(14) In order to maintain the high quality of water intended for human consumption in view of its importance for human health, it is necessary for Annexes II and III to be regularly updated in the light of scientific and technical progress.

(15) While it is for Member States to define the sampling and analysis frequencies for water intended for human consumption put into bottles or containers intended for sale, it is advisable for those Member States required to monitor water intended for human consumption for radon or tritium or to establish the Indicative Dose (ID), to carry out sampling and analysis at least once per year,

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 lays down parametric values and frequencies and methods for monitoring radioactive substances.

Article 2

Definitions

For the purposes of this Directive the following definitions apply:

(1) ‘water intended for human consumption’ means:

(a) all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, a tanker, or in bottles or containers;

(b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form;

(2) ‘radioactive substance’ means any substance that contains one or more radionuclides the activity or concentration of which cannot be disregarded as far as radiation protection is concerned;

(3) ‘indicative dose’ or ‘ID’ means the committed effective dose for one year of ingestion resulting from all the radionuclides whose presence has been detected in a supply of water intended for human consumption, of natural and artificial origin, but excluding tritium, potassium-40, radon and short-lived radon decay products;

(4) ‘parametric value’ means the value of radioactive substances in water intended for human consumption above which Member States shall assess whether the presence of radioactive substances in water intended for human consumption poses a risk to human health which requires action and, where necessary, shall take remedial action

to improve the quality of water to a level which complies with the requirements for the protection of human health from a radiation protection point of view.

Article 3

Scope and exemptions

1 This Directive applies to water intended for human consumption.

2 This Directive does not apply to:

a natural mineral waters recognised as such by the competent national authorities, in accordance with Directive 2009/54/EC;

b waters which are medicinal products within the meaning of Directive 2001/83/EC.

3 Member States may exempt from this Directive:

a water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the general public concerned;

b water intended for human consumption from an individual supply providing on average less than 10 m^3 a day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.

4 Member States that have recourse to the exemptions provided for in paragraph 3(b) shall ensure that:

a the general public concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption;

b when a potential danger to human health arising from the quality of such water is apparent, the general public concerned promptly be given appropriate advice.

Article 4

General obligations

Without prejudice to the provisions laid down in point a of Article 6(3) of Directive 96/29/Euratom[(9)], 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:

(a) it shall be assessed whether that poses a risk to human health which requires action and,

(b) 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.

Article 5

Parametric values and points of compliance

1 Member States shall set parametric values applicable for the monitoring of radioactive substances in water intended for human consumption in accordance with Annex I.

2 Where monitoring of water intended for human consumption is undertaken in accordance with the requirements of Annex II of this Directive the point of compliance shall be:

a in the case of water supplied from a distribution network, the point at which it emerges from the taps where the water is normally taken;

b in the case of water supplied from a tanker, the point at which it emerges from the tanker;

c in the case of water put into bottles or containers intended for sale, the point at which the water is put into the bottles or containers;

d in the case of water used in a food-production undertaking, the point where the water is used in the undertaking.

3 The definition of points of compliance in paragraph (2)(a) is without prejudice to the choice of a sampling point, which may be any point within the supply zone or at the treatment works provided there is no adverse change in the concentration value between the sampling point and the point of compliance.

Article 6

Monitoring and analysis

1 Member States shall take all measures necessary to ensure that monitoring for radioactive substances in water intended for human consumption is undertaken in accordance with the monitoring strategies and frequencies set out in Annex II, in order to check whether the values of radioactive substances comply with the parametric values laid down pursuant to Article 5(1).

Member States shall ensure that monitoring is undertaken so as to ensure that the measured values obtained are representative of the quality of the water consumed throughout the year. For water intended for human consumption that is put into bottles or containers intended for sale, this shall be without prejudice to the principles of HACCP as required by Regulation (EC) No 852/2004 and to the principles of official controls as laid down in Regulation (EC) No 882/2004.

2 Monitoring for the ID shall be carried out, and analytical performance characteristics shall be in accordance with the requirements set out in Annex III.

3 Member States shall ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject to checking by an external organisation approved by the competent authority for that purpose.

Article 7

Remedial action and notification of the general public

1 Member States shall ensure that any failure to comply with a parametric value laid down pursuant to Article 5(1) is immediately investigated in order to identify the cause.

2 Where a failure to comply with a parametric value occurs, the Member State shall assess whether the failure poses a risk to human health which requires action.

3 In the event that such a risk referred to under paragraph 2 exists, the Member State shall:

a take remedial action in order to comply with requirements for the protection of human health from a radiation protection point of view; and

b 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 for the protection of human health in respect of radioactive substances.

Article 8

Transposition into national law

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 November 2015 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 The 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 9

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 10

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 22 October 2013.

For the Council

The President

L. LINKEVIČIUS

ANNEX I

PARAMETRIC VALUES FOR RADON, TRITIUM AND ID OF WATER INTENDED FOR HUMAN CONSUMPTION

Parameter	Parametric value	Unit	Notes
Radon	100	Bq/l	(Note 1)
Tritium	100	Bq/l	(Note 2)
ID	0,1	mSv	

Note 1:

(a) Member States may set a level for radon which is judged inappropriate to be exceeded and below which optimisation of protection should be continued, without compromising water supply on a national or regional scale. The level set by a Member State may be higher than 100 Bq/l but lower than 1 000 Bq/l. In order to simplify national legislation, Member States may choose to adjust the parametric value to this level.

(b) Remedial action is deemed to be justified on radiological protection grounds, without further consideration, where radon concentrations exceed 1 000 Bq/l.

Note 2: Elevated levels of tritium may indicate the presence of other artificial radionuclides. If the tritium concentration exceeds its parametric value, an analysis of the presence of other artificial radionuclides shall be required.

ANNEX II

MONITORING OF RADIOACTIVE SUBSTANCES

1. **General principles and monitoring frequencies**

All parameters for which parametric values must be set pursuant with Article 5(1) shall be subject to monitoring. However, no monitoring of a specific parameter shall be required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of water intended for human consumption in concentrations which could exceed the corresponding parametric value.

In case of naturally occurring radionuclides, where previous results have shown that the concentration of radionuclides is stable, the frequency, in derogation from the minimum sampling requirements set out in point 6, is to be decided by the Member State, taking into consideration the risk to human health. A Member State is not required to monitor water intended for human consumption for radon or tritium or to establish the ID where it is satisfied on the basis of representative surveys, monitoring data or other reliable information that, for a period of time to be determined by them, the levels of radon, tritium or of the calculated ID will remain below the respective parametric values listed in Annex I. In that case, it shall communicate the grounds for its decision to the Commission and provide the Commission with the necessary documentation supporting that decision, including the findings of any surveys, monitoring or investigations carried out. In this context, the provisions with regard to the minimum sampling and analysis requirements set out in point 6 of this Annex do not apply.

2. **Radon**

Member States shall ensure that representative surveys are undertaken to determine the scale and nature of likely exposures to radon in water intended for human consumption originating from different types of ground water sources and wells in different geological areas. The surveys shall be designed in such a way that underlying parameters, and especially the geology and hydrology of the area, radioactivity of rock or soil, and well type, can be identified and used to

direct further action to areas of likely high exposure. Monitoring of radon concentrations shall be undertaken where there is reason to believe, on the basis of the results of the representative surveys or other reliable information, that the parametric value laid down pursuant to Article 5(1) might be exceeded.

3. **Tritium**

Member States shall ensure that monitoring of tritium in water intended for human consumption is carried out where an anthropogenic source of tritium or other artificial radionuclides is present within the catchment area and it cannot be shown on the basis of other surveillance programmes or investigations that the level of tritium is below the parametric value listed in Annex I. Where monitoring for tritium is required, it shall be carried out at the frequencies indicated in the table appearing in point 6 of this Annex. If the concentration of tritium exceeds its parametric value, an investigation of the presence of other artificial radionuclides shall be required.

4. **Indicative dose**

Monitoring of water intended for human consumption for the ID shall be carried out where a source of artificial or elevated natural radioactivity is present and it cannot be shown on the basis of other representative monitoring programmes or other investigations that the level of ID is below the parametric value listed in Annex I. Where monitoring for artificial radionuclide levels is required, it shall be carried out at the frequency indicated in the table appearing in point 6 of this Annex. Where monitoring for natural radionuclide levels is required, each Member State shall define the frequency of the monitoring of either gross alpha activity, gross beta activity or individual natural radionuclides depending on the screening strategy adopted by it (according to Annex III). The monitoring frequency may vary from a single check measurement to the frequencies indicated in the table appearing in point 6 of this Annex. Where only a single check for natural radioactivity is required, a recheck shall be required at least where any change occurs in relation to the supply likely to influence the concentrations of radionuclides in water intended for human consumption.

5. **Water treatment**

Where treatment to reduce the level of radionuclides in water intended for human consumption has been taken, monitoring shall be carried out at the frequencies indicated in the table appearing in point 6 to ensure the continued efficacy of that treatment.

6. **Minimum sampling and analysis frequencies**

The minimum sampling and analysis frequency for the monitoring of water intended for human consumption supplied from a distribution network or from a tanker or used in a food production undertaking shall be as set out in the following table:

TABLE

Minimum sampling and analysis frequencies for monitoring of water intended for human consumption supplied from a distribution network or from a tanker or used in a food production undertaking

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 and 4)**
volume ≤ 100	(Note 5)
100 < volume ≤ 1 000	1
1 000 < volume ≤ 10 000	1

	+ 1 for each 3 300 m^3/d and part thereof of the total volume
10 000 < volume ≤ 100 000	3 + 1 for each 10 000 m^3/d and part thereof of the total volume
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: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned.

Note 5: The frequency is to be decided by the Member State concerned.

Member States shall define sampling frequencies for water intended for human consumption put into bottles or containers intended for sale. In so doing Member States may take into consideration the volume of water produced.

7. Averaging

Where a parametric value is exceeded in a particular sample, Member States shall define the extent of resampling necessary to ensure that the measured values are representative of an average activity concentration for a full year.

ANNEX III

MONITORING FOR INDICATIVE DOSE AND ANALYTICAL PERFORMANCE CHARACTERISTICS

1. Monitoring for compliance with the ID

Member States may use various reliable screening strategies to indicate the presence of radioactivity in water intended for human consumption. These strategies may include screening for certain radionuclides, or screening for an individual radionuclide, or gross alpha activity or gross beta activity screening.

(a) screening for certain radionuclides, or screening for an individual radionuclide

If one of the activity concentrations exceeds 20 % of the corresponding derived value or the tritium concentration exceeds its parametric value listed in Annex I, 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.

(b) screening strategies for gross alpha activity and gross beta activity

Member States may use screening strategies for gross alpha activity and gross beta activity[(10)] to monitor for the parametric indicator value for ID.

For this purpose gross alpha activity or gross beta activity screening levels shall be set. The recommended screening level for gross alpha activity is 0,1 Bq/l. The recommended screening level for gross beta activity is 1,0 Bq/l.

If the gross alpha activity and gross beta activity are less than 0,1 Bq/l and 1,0 Bq/l respectively, the Member State may assume that the ID is less than the parametric value of 0,1 mSv and radiological investigation is not needed unless it is known from other sources of information that specific radionuclides are present in the water that are liable to cause an ID in excess of 0,1 mSv.

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.

Member States may set alternative screening levels for gross alpha activity and gross beta activity where they can demonstrate that the alternative levels are in compliance with an ID of 0,1 mSv.

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.

2. **Calculation of the ID**

The ID shall be calculated from the measured radionuclide concentrations and the dose coefficients 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, on the basis of the annual intake of water (730 l for adults). Where the following formula is satisfied, Member States may assume that the ID is less than the parametric value of 0,1 mSv and no further investigation shall be required:

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

where

$C_i(obs)$ = observed concentration of radionuclide *i*
$C_i(der)$ = derived concentration of radionuclide *i*
n = number of radionuclides detected.

DERIVED CONCENTRATIONS FOR RADIOACTIVITY IN WATER INTENDED FOR HUMAN CONSUMPTION[0]

Origin	Nuclide	Derived concentration
Natural	U-238[b]	3,0 Bq/l
	U-234[b]	2,8 Bq/l
	Ra-226	0,5 Bq/l
	Ra-228	0,2 Bq/l
	Pb-210	0,2 Bq/l

a This table includes values for the most common natural and artificial radionuclides; these are precise values, calculated for a dose of 0,1 mSv, an annual intake of 730 litre and using the dose coefficients laid down in Annex III, Table A of Directive 96/29/Euratom; derived concentrations for other radionuclides can be calculated on the same basis, and values can be updated on the basis of more recent information recognised by the competent authorities in the Member State.

b This table allows only for the radiological properties of uranium, not for its chemical toxicity.

	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

a This table includes values for the most common natural and artificial radionuclides; these are precise values, calculated for a dose of 0,1 mSv, an annual intake of 730 litre and using the dose coefficients laid down in Annex III, Table A of Directive 96/29/Euratom; derived concentrations for other radionuclides can be calculated on the same basis, and values can be updated on the basis of more recent information recognised by the competent authorities in the Member State.

b 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 parameters and radionuclides, the method of analysis used must, as a minimum, be capable of measuring activity concentrations with a limit of detection specified below:

Parameters and radionuclides	**Limit of detection (Notes 1, 2)**	**Notes**
Tritium	10 Bq/l	Note 3
Radon	10 Bq/l	Note 3
gross alpha activity	0,04 Bq/l	Note 4
gross beta activity	0,4 Bq/l	Note 4
U-238	0,02 Bq/l	
U-234	0,02 Bq/l	
Ra-226	0,04 Bq/l	
Ra-228	0,02 Bq/l	Note 5
Pb-210	0,02 Bq/l	
Po-210	0,01 Bq/l	
C-14	20 Bq/l	
Sr-90	0,4 Bq/l	
Pu-239/Pu-240	0,04 Bq/l	
Am-241	0,06 Bq/l	
Co-60	0,5 Bq/l	
Cs-134	0,5 Bq/l	

Cs-137	0,5 Bq/l	
I-131	0,5 Bq/l	

Note 1: The limit of detection shall be calculated according to the ISO standard 11929: Determination of the characteristic limits (decision threshold, detection limit and limits of the confidence interval) for measurements of ionising radiation — Fundamentals and application, 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.

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

Note 4: The limit of detection for gross alpha activity 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 initial screening for ID for a new water source; if initial checking indicates that it is not plausible that Ra-228 exceeds 20 % of the derived concentration, the limit of detection may be increased to 0,08 Bq/l for routine Ra-228 nuclide specific measurements, until a subsequent re-check is required.

(**1**) OJ C 24, 28.1.2012, p. 122.

(**2**) 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 radiation (OJ L 159, 29.6.1996, p. 1).

(**3**) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

(**4**) Regulation (EC) No 852/2004 2004 of the European Parliament and of the Council of the 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

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

(**6**) Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (OJ L 164, 26.6.2009, p. 45).

(**7**) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**8**) Commission Recommendation 2001/928/Euratom of 20 December 2001 on the protection of the public against exposure to radon in drinking water supplies (OJ L 344, 28.12.2001, p. 85).

(**9**) 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 radiation (OJ L 159, 29.6.1996, p. 1).

(**10**) Where appropriate gross beta activity may be replaced by residual beta activity after subtraction of the K-40 activity concentration.