

**L.N. 8 of 2016**

**FOOD SAFETY ACT  
(CAP. 449)**

**Protection of Public Health (Radioactive Substances in Water  
intended for Human Consumption) Regulations, 2016**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Parliamentary Secretary for Health has made the following regulations:-

Citation, scope  
and  
commencement.

**1.** (1) The title of these regulations is the Protection of Public Health (Radioactive Substances in Water intended for Human Consumption) Regulations, 2016.

(2) These regulations implement the provisions of 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.

(3) The purpose of these regulations is to lay down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption as well as laying down parametric values and frequencies and methods for monitoring radioactive substances.

(4) These regulations shall come into force on 1 January 2016.

**2.** For the purposes of these regulations, unless the context otherwise requires:

"competent authority" means the Superintendent of Public Health or a person authorised to act on his behalf;

"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;

"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;

"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;

"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; and

(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.

**3.** (1) These regulations apply to water intended for human consumption. Scope and exemptions.

(2) These regulations do not apply to:

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

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

(3) The competent authority may exempt from these regulations:

(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<sup>3</sup> a day, or serving fewer than fifty persons, unless the water is supplied as part of a commercial or public activity.

(4) The competent authority that has recourse to the

exemptions provided for in sub-regulation (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; and

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

Monitoring programme.

**4.** The competent authority 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 these regulations -

(a) it shall be assessed whether that non-compliance 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.

Setting of parametric values.

**5.** (1) The competent authority shall set parametric values applicable for the monitoring of radioactive substances in water intended for human consumption in accordance with Schedule I.

(2) Where monitoring of water intended for human consumption is undertaken in accordance with the requirements of Schedule II, 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 sub-regulation (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.

6. (1)(a) The competent authority shall take all measures necessary to ensure that monitoring for radioactive substances in water intended for human consumption is undertaken by the water utilities and, or private water suppliers in accordance with the monitoring strategies and frequencies set out in Schedule II, in order to check whether the values of radioactive substances comply with the parametric values laid down pursuant to regulation 5(1).

Monitoring for radioactive substances in water.

(b) The competent authority shall ensure that monitoring is undertaken by the water utilities and, or private water suppliers 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 Schedule III.

(3) The competent authority 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.

7. (1) It is the duty of the water utilities and, or private water suppliers to immediately inform the competent authority with any non-compliance and, or failures to the parametric values laid down pursuant to regulation 5(1) and Schedule I.

Duty to inform the competent authority.

(2) The water utilities and, or private water suppliers are to carry out the necessary monitoring in accordance to the frequencies laid down in Schedule II.

(3) Upon failure to comply with the provisions of sub-regulations (1) and (2), the water utilities and, or private water suppliers shall be in breach of these regulations.

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Failure to  
comply with a  
parametric  
value.

8. (1) The competent authority shall ensure that any failure to comply with a parametric value laid down pursuant to regulation 5(1) is immediately investigated in order to identify the cause.

(2) Where a failure to comply with a parametric value occurs, the competent authority shall assess whether the failure poses a risk to human health which requires action.

(3) In the event that such a risk referred to in sub-regulation (2) exists, the competent authority shall:

(a) order the water utilities and, or private water suppliers to 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.

(4) The notifications referred to in sub-regulation (3)(b) are to be issued by the competent authority based on the detailed information which is to be provided to it by the water utility and, or private water supplier.

(5) The competent authority shall always have the right to issue such notifications to the public immediately once such a non-compliance becomes known.

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## SCHEDULE 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	0,10	mSv	

Note 1:

(a) The competent authority 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 the competent authority may be higher than 100 Bq/l but lower than 1 000 Bq/l. In order to simplify national legislation, the competent authority 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.

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 SCHEDULE II

## MONITORING OF RADIOACTIVE SUBSTANCES

## 1. General principles and monitoring frequencies

All parameters for which parametric values must be set pursuant with regulation 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 it, 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 paragraph 6, is to be decided by the competent authority, taking into consideration the risk to human health. The

competent authority is not required to request water utilities and, or private water suppliers 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 it, the levels of radon, tritium or of the calculated ID will remain below the respective parametric values listed in Schedule 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 paragraph 6 of this Schedule do not apply.

## 2. Radon

The competent authority 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 regulation 5(1) might be exceeded.

## 3. Tritium

The competent authority 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 Schedule I. Where monitoring for tritium is required, it shall be carried out at the frequencies indicated in the table appearing in paragraph 6 of this Schedule. 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 Schedule I. Where monitoring for artificial radionuclide levels is required, it shall be carried out at the frequency indicated in the table appearing in paragraph 6 of this Schedule. Where monitoring for natural radionuclide levels is required, the competent authority 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 Schedule III). The monitoring frequency may vary from a single check measurement to the frequencies indicated in the table appearing in paragraph 6 of this Schedule. 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 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 by the water utility and, or private water supplier, monitoring shall be carried out at the frequencies indicated in the table appearing in paragraph 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 by private water suppliers 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 <sup>3</sup>	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 <sup>3</sup> /d and part thereof of the total volume
10 000 < volume ≤ 100 000	3 + 1 for each 10 000 m <sup>3</sup> /d and part thereof of the total volume
volume > 100 000	10 + 1 for each 25 000 m <sup>3</sup> /d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area and, or a private water supply 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. The competent authority 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 competent authority concerned.

Note 5: The frequency is to be decided by the competent authority. The competent authority shall define sampling frequencies for water intended for human consumption put into bottles or containers intended for sale. In so doing the competent authority may take into consideration the volume of water produced.

## 7. Averaging

Where a parametric value is exceeded in a particular sample, the competent authority shall define the extent of re-sampling necessary to ensure that the measured values are representative of an average activity concentration for a full year.

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## SCHEDULE III

### MONITORING FOR INDICATIVE DOSE AND ANALYTICAL PERFORMANCE CHARACTERISTICS

#### 1. Monitoring for compliance with the ID

The competent authority may require the water utilities and, or private water suppliers to 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 Schedule I, an analysis of additional radionuclides shall be required. The radionuclides to be measured shall be defined by the competent authority taking into account all relevant information about likely sources of radioactivity;

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

the competent authority may require the water utility and, or private water supplier to use screening strategies for gross alpha activity and gross beta activity\* 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 competent authority 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.

The competent authority 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.

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

The radionuclides to be measured shall be defined by the competent authority 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 authority in the Member State, on the basis of the annual intake of water (730 l for adults). Where the following formula is satisfied, the competent authority may assume that the ID is less than the parametric value of 0,1 mSv and no further investigation shall be required:

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

[-]

where

$C_i(\text{obs})$  = observed concentration of radionuclide  $i$

$C_i(\text{der})$  = derived concentration of radionuclide  $i$

$n$  = number of radionuclides detected.

Derived concentrations for radioactivity in water  
intended for human consumption <sup>(2)</sup>

Origin	Nuclide	Derived Concentration
Natural	U-238 <sup>(3)</sup>	3,0 Bq/l
	U-234 <sup>(3)</sup>	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

(2) 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 authority in the Member State.

(3) 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.

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