

2015 No. 363

FOOD

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015

<i>Made</i>	- - - -	<i>28th October 2015</i>
<i>Laid before the Scottish Parliament</i>		<i>30th October 2015</i>
<i>Coming into force</i>	- -	<i>28th November 2015</i>

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and all other powers enabling them to do so.

In accordance with section 48(4A) and (6) of that Act, the Scottish Ministers have had regard to relevant advice given by Food Standards Scotland(b).

There has been consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c).

Citation and commencement

1. These Regulations may be cited as the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015 and come into force on 28th November 2015.

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- (a) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Section 6(4) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c.40), paragraph 10(3) of Schedule 5 to the Food Standards Act 1999 (c.28) (“the 1999 Act”) and S.I. 2002/794. Section 6(4A) was inserted by paragraph 3(2) of the schedule to the Food (Scotland) Act 2015 (asp 1). Section 16(1)(e) was amended by section 34(1) of the Food (Scotland) Act 2015. Sections 17(1) and 48(1) were amended by paragraph 8 of Schedule 5 to the 1999 Act. Section 17(1) was also amended by paragraph 12 of Schedule 5 to the 1999 Act. Section 26(3) was amended by paragraph 1 of Schedule 6 to the 1999 Act. Section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990. By virtue of section 40(2) of the 1999 Act, amendments made by Schedule 5 to that Act are to be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46). The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of that Act. In so far as not transferred, and in so far as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by S.I. 2005/849.
- (b) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act. Section 48(6) was added by paragraph 3(1) of the schedule to the Food (Scotland) Act 2015.
- (c) OJ L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ L 188, 18.7.2009, p.14).

Amendment of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007

2.—(1) The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007(a) are amended in accordance with Regulations 3 to 5.

Amendment of regulation 2 (interpretation)

3.—(1) At the appropriate position in regulation 2(1) (interpretation), insert—

““Directive 96/29” means Council Directive 96/29/Eurotom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation(b);

“Directive 2013/51” means Council Directive 2013/51/Eurotom laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption(c);”.

(2) In regulation 2(2), for “2009/54, 98/83 or 2003/40” substitute “96/29, 98/83, 2003/40, 2009/54 and 2013/51”.

Amendment of regulation 16 (enforcement)

4.—(1) At the end of regulation 16(2)(c) (enforcement)(d), omit “and”.

(2) After regulation 16(2)(d), insert—

(e) carry out additional monitoring in accordance with Parts 1 and 2 of Schedule 12 to check whether the water complies with the relevant parametric values specified in the table in Part 3 of that Schedule;

(f) for the purpose of monitoring spring water and bottled drinking water required by sub-paragraph (e), carry out sampling and analysis in accordance with Schedule 13 to check compliance with the parametric value for indicative dose specified in the table in Part 3 of Schedule 12;

(g) for the purpose of carrying out the sampling and analysis required by sub-paragraph (f), take samples at the point at which the water is put into the bottle; and

(h) if necessary, take the remedial measures specified in Part 1 of Schedule 12.”.

Amendment of Schedules

5. After Schedule 11, insert—

(a) S.S.I. 2007/483, as relevantly amended by S.S.I. 2009/273 and S.S.I. 2010/89. S.S.I. 2010/89 was itself amended by S.S.I. 2010/127 and S.S.I. 2011/94.

(b) OJ L 159, 29.6.1996, p.1.

(c) OJ L 296, 7.11.2013, p.12.

(d) Regulation 16(2) was added by S.S.I. 2010/89.

Monitoring for radioactive substances in spring water and bottled
drinking water

PART 1

General

General

1. Each food authority must monitor spring water and bottled drinking water for radon, tritium and indicative dose in accordance with this Schedule.

Indicative dose

2. Each food authority must monitor spring water and bottled water for indicative dose if a source of artificial or elevated natural radioactivity is present and it cannot be shown on the basis of representative monitoring programmes or other investigations that the level of indicative dose is below the parametric value specified in the table in Part 3.

3. Sampling must be carried out at the frequencies specified in the table in Part 2.

4. A food authority may use various reliable screening strategies to monitor for the parametric indicator value for indicative dose.

5. Subject to paragraph 7, if a food authority screens for gross alpha activity and gross beta activity and—

- (a) the screening level for gross alpha activity is or exceeds 0.1 Bq/l; or
- (b) the screening level for gross beta activity is or exceeds 1.0 Bq/l,

that food authority must investigate the presence of other radionuclides as determined by the food authority, taking into account all relevant information about likely sources of radioactivity.

6. If a food authority screens for an individual radionuclide or certain radionuclides and—

- (a) one of the activity concentrations exceeds 20% of the corresponding derived value;
or
- (b) where applicable, the concentration of tritium exceeds the parametric value specified in the table in Part 3,

the food authority must investigate the presence of radionuclides, as determined by the food authority, taking into account all relevant information about likely sources of radioactivity.

7. Paragraph 5 does not prohibit a food authority from screening at alternative levels for gross alpha activity and gross beta activity if it can demonstrate that the alternative levels are in compliance with an indicative dose of 0.1mSv.

8. If the gross alpha activity and gross beta activity are less than 0.1 Bq/l and 1.0 Bq/l respectively, a food authority may assume that the indicative dose is less than the parametric value of 0.1 mSv in which case further radiological investigation is not required unless it is known from other sources of information that specific radionuclides are present in the water that are liable to cause an indicative dose at or in excess of 0.1 mSv.

Tritium

9. Each food authority must monitor spring water and bottled drinking water for tritium if an artificial source of tritium or other artificial radionuclide(s) 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 specified in the table in Part 3.

10. Sampling must be carried out at the frequencies specified in the table in Part 2.

11. If the concentration of tritium exceeds the parametric value specified in the table in Part 3, the food authority must investigate the presence of other artificial radionuclides.

Radon

12. Each food authority must provide representative surveys to determine the scale and nature of likely exposure to radon in spring water and bottled drinking water originating from different types of ground water sources and wells in different geological areas.

13. The representative surveys must be designed in such a way that underlying parameters, including 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.

14. Sampling must be carried out at the frequencies specified in the table in Part 2.

15. Each food authority must monitor spring water and bottled drinking water for radon if there is a reason to believe, on the basis of the results of the representative surveys or other reliable information, that the parametric value for radon specified in the table in Part 3 might be exceeded.

Exemption from monitoring

16. A food authority may apply to Food Standards Scotland for an exemption from the requirement to monitor spring water or bottled drinking water for radon, tritium or indicative dose if—

- (a) it is satisfied on the basis of representative surveys, monitoring data or other reliable information provided by the food business operator that, for a minimum period of five years, the parameter in question will remain below its respective parametric value specified in the table in Part 3; and
- (b) it provides Food Standards Scotland with a copy of the representative surveys, monitoring data or other reliable information referred to in sub-paragraph (a),

and if it agrees with the food authority's recommendation, Food Standards Scotland may grant the exemption for such period and subject to such conditions as it thinks fit.

Treatment of bottled drinking water

17. Where bottled drinking water has been treated to reduce the level of radionuclides, the food authority must carry out monitoring at the frequencies indicated in the table in Part 2 to ensure the continued efficacy of that treatment.

Averaging

18. If a parametric value specified in the table in Part 3 is exceeded in a sample of spring water or bottled drinking water, the food authority must take further samples, as appropriate, having regard to any guidance issued by Food Standards Scotland to ensure that the measured values are representative of an average activity concentration for a full year.

Remedial action

19.—(1) If a food authority determines that spring water or bottled drinking water does not comply with the parametric concentrations or values set out in this Schedule, the food authority must—

- (a) immediately investigate the non-compliance in order to identify the cause;
- (b) assess whether the non-compliance poses a risk to human health which requires action;
- (c) require the business operator to take remedial action as soon as possible to restore the quality of the water and, where necessary, protect human health;
- (d) in respect of any parameter specified in the tables in Parts 2 and 3, notify the general public of the remedial action taken, unless the food authority considers that non-compliance with the parametric value is trivial; and
- (e) in respect of any parameter specified in the table in Part 2, notify the general public of the risks and remedial action taken and advise the general public of any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.

(2) If spring water or bottled drinking water constitutes a potential danger to human health, irrespective of whether it meets the relevant parametric values in this Schedule, a food authority must—

- (a) prohibit or restrict the supply of that water in its area or take such other action as is necessary to protect human health; and
- (b) inform the general public promptly of that fact and provide advice where necessary.

(3) In performing the functions in paragraph (2), the food authority must have regard to any risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.

PART 2

Minimum sampling and analysis frequencies

<i>Volume of water bottled each day</i> <i>m³⁽¹⁾</i>	<i>Number of samples per year⁽²⁾</i>
volume ≤ 100	1
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

⁽¹⁾ The volumes are calculated as averages taken over a calendar year.

⁽²⁾ As far as possible, the number of samples should be distributed equally in time and location.

PART 3

Parametric values for radon, tritium and indicative dose

<i>Item</i>	<i>Parameter</i>	<i>Unit of Measurement</i>	<i>Parametric Value</i>
1.	Radon	Bq/l	100 ⁽¹⁾
2.	Tritium	Bq/l	100 ⁽²⁾
3.	indicative dose	mSv	0.10

⁽¹⁾ Remedial action is deemed to be justified on radiological protection grounds, without further consideration, where radon concentrations exceed 1000 Bq/l.

⁽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.

SCHEDULE 13

Regulation 16(2)(f)

Sampling and analysis for indicative dose in spring water and bottled drinking water

PART 1

General

Analysis of samples

1. Each food authority must ensure that each sample is analysed and indicative dose calculated in accordance with Annex III to Directive 2013/51 and this Schedule.

2. For each radionuclide specified in the second column of Table 1 in Part 2, the derived concentration is shown in the third column of that table and the dose coefficient for calculating the indicative dose is specified in Table A of Annex III to Directive 96/29 as referenced in Annex III to Directive 2013/51.

3. For each parameter specified in the first column of Table 2 in Part 2, the method of analysis must be one that is capable of detecting the parameter at the limit of detection specified in the second column of that table.

PART 2

Methods of analysis and performance characteristics⁽¹⁾

Table 1

Derived concentrations for radioactivity in spring water or bottled drinking water

<i>Origin</i>	<i>Nuclide</i>	<i>Derived concentration</i>
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 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 litres and using the dose coefficients laid down in Table A of Annex III to Directive 96/29; 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.

⁽²⁾ This table allows only for the radiological properties of uranium, not for its chemical toxicity.

Table 2**Performance characteristics and methods of analysis**

<i>Parameters radionuclides</i>	Limit of detection ^{(1) (2)}
Tritium	10 Bq/l ⁽³⁾
Radon	10 Bq/l ⁽³⁾
gross alpha activity	0.04 Bq/l ⁽⁴⁾
gross beta activity	0.4 Bq/l ⁽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 ⁽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

⁽¹⁾ The limit of detection is 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.

⁽²⁾ Measurement uncertainties are 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.

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

⁽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.

⁽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.”.

MAUREEN WATT

Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
28th October 2015

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (“the 2007 Regulations”) by implementing in relation to spring water and drinking water in a bottle, Council Directive 2013/51/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ L 296, 7.11.13, p.12).

Regulation 3 makes consequential amendments to the interpretation provisions in regulation 2 of the 2007 Regulations.

Regulation 4 amends regulation 16 of the 2007 Regulations to specify the monitoring and sampling requirements required by Food Authorities.

Regulation 5 inserts two new Schedules to the 2007 Regulations, Schedule 12 which provides for monitoring for radioactive substances in spring water and bottled drinking water and Schedule 13 which provides for sampling and analysis for indicative dose in spring water and bottled drinking water.

A full Business and Regulatory Impact Assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.

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