



**PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT
THE NATURAL MINERAL WATER, SPRING WATER AND BOTTLED DRINKING WATER
(SCOTLAND) AMENDMENT REGULATIONS 2015**

**THE TRANSPOSITION OF COUNCIL DIRECTIVE 2013/51/EURATOM ON RADIATION
MONITORING.**

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| Type of measure: | Secondary |
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1. Title of Proposal

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

Radiation Monitoring

2. Purpose and intended effect

(i) Objectives

In 2013 the European Council agreed a new Directive under the Euratom Treaty: Council Directive 2013/51/Euratom¹ (the “Directive”). The Directive sets out parametric values, frequencies and performance characteristics for analytical methods for monitoring radioactive substances in water intended for human consumption.

Full compliance with the Directive is required by 28 November 2015. The policy objective is to transpose EU requirements into Scottish regulations. This is in line with scientific recommendations² that legislative measures should be set for the monitoring of radon levels in water.

It is currently not a requirement to test for radon in bottled drinking waters. Government intervention is necessary as the Directive now requires analysis for radon if the Indicative Dose (ID) is exceeded. The current legislation stipulates that any radiation analyses which appear abnormal prompts follow up testing to establish the radionuclides present. Radon analysis may be done voluntarily by the bottled drinking water industry in line with HACCP and risk assessment of a source.

We understand that pre-existing industry data on ID might allow us to make representations to the Commission for a 5 year derogation from the sampling requirements as provided for in Annex II of the Directive.

The intended effect of the regulations is to contribute to ensuring consumer safety in minimising the risk of radiological contamination from consumption of spring and other bottled drinking waters (not natural mineral water, which is subject to other more specific EU requirements).

(ii) Background

On 13 October 2013, Directive 2013/51/Euratom (‘The Directive’) was published. The Directive details the requirements for the protection of the health of the general public regarding radioactive substances in water intended for human consumption. It has been established under Article 31 of the Treaty establishing the European Atomic Energy Community (The Euratom Treaty).

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0051&from=EN>

² <http://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/radioactivity-drinking-water>

The Directive includes the standards (parametric values) for Indicative Dose and tritium. These standards supersede those currently found in the Drinking Water Directive regarding monitoring of radioactivity in water intended for human consumption.

Significantly the Directive also specifies one new standard for radon monitoring in water for human consumption. It does not specify monitoring frequencies for radiation in bottled drinking water and states that the monitoring is based solely on individual risk assessment. It is therefore up to each Member State to decide on minimum monitoring frequencies as none are set for bottled drinking water in the Directive.

In the absence of historical radiological data, industry will need to carry out alpha and beta analysis to satisfy the requirements of the Directive

However, consumer protection will continue to be safeguarded on the basis of data which demonstrates that alpha and beta radiation levels in bottled drinking water in Scotland and the rest of the UK are significantly low.

Risk assessment is not solely based on analysis of a water sample. Other information sources will contribute to the assessment of risk. This includes knowledge of the geology and operational monitoring of alpha and beta radiation.

In addition, the Drinking Water Quality Regulator for Scotland Inspectorate) has sponsored a research project to collate information on radon occurrence in water supplies in order to help their stakeholders, including local authorities, to carry out risk assessments.

(iii) Rationale for Government intervention

On 13 October 2013, Directive 2013/51/Euratom ('the Directive') was published. If the ID exceeds the parametric value for alpha radiation, there is a new requirement for radon monitoring. Monitoring is not required where it can be demonstrated to the competent authority on the basis of representative surveys, monitoring data or other reliable information that the levels of ID, tritium or radon will remain below the respective parametric values detailed in the Directive. In this case, a business can apply for an exemption from monitoring.

The new radiation monitoring requirements supersede those currently detailed in the Drinking Water Directive, therefore, Government intervention is required in order to update the regulations in Scotland.

This will allow Scottish industry to compete on an equal basis with the rest of Europe in line with the Scottish Government's productivity and participation targets and work towards realisation of Scotland's full economic potential.

(iv) By legislating for radiation testing of certain categories of bottled water this will also help to meet the outcome of "We live longer, healthier lives" as part of the Scottish Government's National Performance Framework.

This BRIA is for the Scottish Regulations. Similar work and accompanying consultation exercises will be carried out in England by Defra, and in Wales and Northern Ireland by the Food Standards Agency.

3. Consultation

(i) Within Government

The consultation package has been discussed with Scottish Government officials from the Public Health Division and the Agriculture, Food, Drink and Rural Communities Directorate.

The Drinking Water Quality Regulator is also aware of our proposals on radioactivity monitoring and is included in the list of interested parties for the consultation (in relation to private and public water supplies interests).

In July 2013 and again in December 2014 Local Authority Lead Food Officers in Scotland were made aware by letter of the proposals to update and consolidate the 2007 regulations and given details of the requirements of Directive 2013/51/Euratom.

In April 2015, interested parties in Scotland were made aware of our proposals and invited to a stakeholder meeting on 4 June to discuss them. Those who attended included a representative from Scottish Local Authority Enforcement officers and a Public Analyst from Aberdeen.

Prior to consultation Defra held various meetings with and informed UK Trade Bodies of the radioactivity requirements during 2014 and 2015.

In addition, during the development of the consultation package Defra has been liaising with DWI officials as Directive 2013/51/Euratom also relates to drinking water not in bottles and to water used in food production. Scottish Government DWI officials are aware of our proposals and have been sent the consultation package.

(ii) Public Consultation

In addition to the 4 June stakeholder meeting, a 4 week public consultation is being carried out in Scotland from 21 September to 16 October 2015.

(iii) Business

Defra issued several information letters to and held several meetings with affected UK Trade Bodies during 2014 and 2015 and industry stakeholders in Scotland were informed about the proposals and the in a letter dated 29 April 2015.

FSS has held initial discussions with seven Scottish producers of either bottled drinking water or spring water - one currently carries out monitoring for radioactivity - further discussions will be held with that producer during the public consultation period to develop our proposals/costings further and obtain feedback from other stakeholders.

4. Options

Option 1 – Do nothing. Failure to include the requirements of Council Directive 2013/51/Euratom ('the Directive') in the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No.2) Regulations 2007 would constitute a failure to comply with EU obligations.

Option 2 -Introduce the changes required by Council Directive 2013/51/Euratom.

This option transposes wording contained in the Directive which:

- i) requires that the analysis of radon in bottled drinking water is based solely on risk assessment, and;
- ii) enables firms to be exempt from formal analysis on the basis of representative surveys and other reliable information.

It addresses the obligation that the UK has to the Commission in terms of meeting transposition deadline of 28 November 2015.

This provides consistency for Scottish industry across the EU and ensures consumers benefit from the monitoring for radioactivity.

(i) Sectors and groups affected

Businesses producing spring water and bottled drinking water will be the main groups affected

Enforcers - enforcement of the rules on bottled waters is the responsibility of Local Authority Environmental Health Departments.

Consumers - will be affected by the new monitoring requirements in that consumer confidence should increase after this change as it will be understood that bottled water produced in the EU will be monitored for radioactivity. The amended Regulations will ensure that consumers can have confidence in the quality of products on sale.

(ii) OPTION APPRAISAL: COSTS AND BENEFITS

Option 1- Do Nothing

There are no costs to either industry or consumers. However, the Commission has powers to apply financial sanctions to the UK where, following infringement proceedings for a breach of EU law, the Court of Justice has found that delivery of Official Controls, are inappropriate or inadequate. Such financial sanctions may comprise of both a daily penalty (of up to circa €700,000 per day so as to induce the remedy of the breach) and a lump sum (based on assessment of the effects of the breach for which the minimum is currently €9,446,000). FSS would be required to pay a percentage of any UK fine if the infraction related to a devolved matter. Fines are extremely rare and the European Commission works hard with Member States to avoid financial penalties wherever possible.

There would be no familiarisation costs to either industry or enforcers.

Option 2 – provide for the implementation of Council Directive 2013/51/Euratom**(a) Benefits - Non-Monetised**

This policy has been introduced by the European Commission to protect consumers from radiological contamination from potable water sources, and now includes radon, in line with expert scientific advice. The health risks from inhalation of radon have long been known. The risks associated with ingestion have not been as extensively documented because most of the radon in water will escape before it is ingested. The level where remedial action is required for water is 1000 Bq/l. This accounts for radon loss before ingestion. Nonetheless, if radon is ingested in significant levels, it can damage the lining of the stomach.

There is therefore, some benefit to consumer health from the new safeguards that will be put in place in terms of the assessment of risk of the presence of radon. However the risk from the presence of radioactivity to consumer health is considered to be very low.

**(b) Costs
Business**

The Directive only requires monitoring of radon if the ID exceeds the parametric value in the Directive. The monitoring of tritium is only required where there is the possibility of a source of tritium or other artificial radionuclides in the area. Following the establishment of the ID, if the screening values are not exceeded, no further investigation is required and monitoring in line with HACCP³ is proposed.

When initially discussed with bottled drinking water businesses, they advised Defra that they did not consider that the requirements of the Directive would be too onerous as radiation levels in sources of spring water are relatively stable. Radon levels vary little over time, although heavy rainfall can reduce levels. This is possibly as result of dilution by surface water.

The Directive does not stipulate minimum frequencies for monitoring bottled drinking water. To ensure a consistent and effective monitoring regime, FSS considers that wherever it is the case that monitoring of ID, tritium or radon is required it shall be done in accordance with the minimum frequencies already detailed in the Directive.

Member States are able to set minimum frequencies and the Directive enables this to be based on volume of production if so desired. Following a cross departmental meeting with the FSA policy leads across the UK, the Drinking Water Inspectorate and the FSA Radiological team in November 2014, it was agreed that HACCP principles already in place presently provide the safety assurance required for radon detection and remedial action.

Monetised Direct One-Off Costs to Industry

³ All food businesses must have a food safety management system based on Hazard Analysis and Critical Control Points (HACCP) principles.

The BSDA Soft Drinks Annual Report for 2014 indicates that 60% of bottled drinking water consumed in the UK is natural mineral water. 32% is spring water and the remaining 8% is other types of bottled drinking water (water which is not marketed as spring or natural mineral water)⁴. These figures are not available on a country-wide basis, but indicate that spring water accounts for less than half of the annual bottled drinking water consumption in the UK.

From a survey and other local authority and industry engagement we understand there are currently six spring water producers in Scotland and we estimate there are also six bottled water producers. Stakeholders are asked to comment on this assumption below.

We estimate the cost of analysis for total alpha / beta, tritium and radon analysis is £138 for each test plus costs for transporting and containing the sample at 2015 costs. The sample volume is not significant as costs are not dependent upon volume.

If testing is required, each business is required to take one sample for alpha / beta analysis.

We assume that each of the 6 spring and 6 bottled businesses tests a water sample for total alpha / beta at the rate of £138 this leads to a one off cost to the Scottish industry of £1656 (plus transport costs) in 2015. These figures will be checked at consultation.

Q 1 Are spring water and bottled water producers and local authorities prepared to share pre-existing Indicative Dose monitoring data with FSS to support a case to enable the use of the derogation from the sampling requirements in the Directive?

Q 2 Is the assumption of the size of the bottled water market in Scotland accurate?

Q 3 Are the assumptions on the one-off monetised costs associated with radon monitoring accurate?

Ongoing costs will vary but are not envisaged for this new regulatory requirement. Industry has informed us that they check alpha and beta radiation levels every 2 years, or in line with risk assessment. If acceptable historical information is available as mentioned previously, any readings for gross alpha or beta activity which are in excess of those prescribed in the regulation⁵, prompt follow up investigation at additional cost.

⁴ Of the 8% of bottled drinking water, 3% is municipally sourced according to the Natural Hydration Council. This indicates that the remaining 5% is naturally sourced but has been treated. .

⁵ <http://www.legislation.gov.uk/uksi/2007/2785/contents/made>

Q 4: Are the assumptions on the ongoing costs associated with radon monitoring accurate?

Learning and Dissemination Costs to Businesses

The natural mineral water industry is exempt from the requirements of the Directive. The requirement for radon monitoring was first notified to businesses in 2013 by Defra to UK trade associations. Local Authorities in Scotland were provided with an update on this issue on 16 December 2014 and industry stakeholders were updated on 29 April 2015⁶. There are no direct implications or familiarisation costs for the natural mineral water industry and as such no corresponding impact is included in the costs to business. In addition, the UK natural mineral water industry has been notified of the exemption via their trade associations previously.

As cited before, we are aware of six spring water businesses in Scotland and approximately six bottled water producers who will need to be aware of the new requirements. Consultation with industry has indicated it would take one full time production manager / director in the manufacturing industry per business 2 hours in total to learn and disseminate information about this regulation. This involves 1.5 hours for learning and 0.5 hours for dissemination. The median hourly pay rate for full time production managers/directors is around £26.64 (ASHE Provisional 2013 Estimates in 2013 prices uplifted to 2015 prices using HM Treasury deflator figures⁷, with a 30% overhead uplift in accordance with the UK standard cost model)⁸. Therefore the total one-off familiarisation cost to 12 spring water businesses in Scotland translates to an equivalent annual cost of £639 (2015 prices, 2015 Net Present Value).

Q 5 Are the assumptions on the costs to industry associated with familiarisation with regard to radon monitoring regulation accurate?

Q 6 Are the assumptions on the costs to industry associated with risk assessment for radon accurate?

Non - monetised costs

Costs to Enforcers

Learning and Dissemination Costs

Local Authority Environmental Health Officers will also need to become familiar with the new monitoring and enforcement requirements for radon. Similar to industry

⁶ <https://www.food.gov.uk/sites/default/files/ENF-E-14-038.pdf>

⁷ <https://www.gov.uk/government/publications/gdp-deflators-at-market-prices-and-money-gdp-march-2013>

⁸ <http://www.berr.gov.uk/files/file44503.pdf> http://www.statistics.gov.uk/downloads/theme_labour/ASHE-2009/2009_occ4.pdf

professionals, it is estimated that it would take one Environmental Health Officer per local authority 2 hours in total to learn and disseminate information about this regulation. This involves 1.5 hours for learning and 0.5 hours for dissemination. The median hourly pay rate for an Environmental Health Officer is around £22.80 (ASHE Provisional 2013 Estimates in 2013 prices uplifted to 2015 prices using HM Treasury deflator figures⁹, with a 30% overhead uplift in accordance with the UK standard cost model)¹⁰.

There are 32 local authorities in Scotland.¹¹, the total one-off familiarisation cost to enforcement bodies in Scotland translates to one-off equivalent annual cost of £1,459 in 2015 (2015 prices, 2015 Net Present Value). This is likely to be a conservative estimate as Local Authorities have already been advised of the new radon monitoring requirements.

Q 7 Are the assumptions on the costs to Enforcers associated with familiarisation with regard to the radiation monitoring regulation accurate?

On-going costs are likely to be marginal. Enforcers must continue to monitor businesses to ensure compliance with other regulatory requirements. Costs for enforcement of this policy cannot be separated from costs of monitoring compliance with other policies, and therefore have not been monetised.

5. Scottish Firms Impact Test

We have begun to engage with several different sized and located spring and bottled water businesses in Scotland – those most likely to be affected by the proposed changes and will continue to do so during the public consultation period.

(i) Competition Assessment

The proposed legislation will apply to all businesses and individuals involved in the UK bottled water trade equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition. Using the Competition and Markets Authority competition assessment framework developed by the former Office of Fair Trading¹², it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. We assert that this policy will not limit the number or range of suppliers directly or

⁹ <https://www.gov.uk/government/publications/gdp-deflators-at-market-prices-and-money-gdp-march-2013>

¹⁰ <http://www.berr.gov.uk/files/file44503.pdf>

¹¹ <http://www.lbro.org.uk/resources/docs/mapping-p3-info.pdf>

¹² https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284451/OFT1113.pdf The Competition and Markets Authority is now responsible for this area of work.

indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

(ii) Test run of business forms

No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

During the consultation period we will ascertain with the Justice Directorate whether the new regulations will have any legal aid implications.

7. Enforcement, sanctions and monitoring

(i) Enforcement

Enforcement of the amended regulations will be the responsibility of Local Authorities. In Scotland, Enforcement Officers from Local Authority Environmental Health Departments will need to familiarise themselves with the new requirements and ensure they are adhered to. Enforcement action is only pursued where informal action has been unsuccessful.

(ii) Sanctions

Regulation 20 of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No.2) Regulations 2007 lays down that the penalty on summary conviction for an offence under the Regulations is a fine not exceeding level 5 on the standard scale.

The proposals outlined in this BRIA do not introduce new sanctions or penalties in the proposed draft regulations but are broadening the scope of these to reflect additional EU requirements for monitoring for radiation in bottled drinking water and spring water (not natural mineral water) contained in Directive 2013/51/Euratom.

(iii) Monitoring

The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

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