

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

Summary Report Of Responses To Consultation from Stakeholders

Food Standards Scotland issued a consultation on the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015 from 21 September 2015 to 16 October 2015. The purpose of the consultation was to provide interested parties and stakeholders with the opportunity to comment on the proposed regulations and the associated partial Business and Regulatory Impact Assessment (BRIA).

- 1 The regulations transpose Directive 2013/51/EURATOM imposing requirements for radiation testing of all bottled water, with the exception of natural mineral waters. The European Directive lays down general principles for monitoring radioactive substances in bottled drinking water as well as specifying the technical rules on the methods and frequencies of sampling.
- 2 The key proposals on which the consultation sought views were:
 - Monitoring procedures and frequencies
 - Suggesting a period of 5 years as an appropriate time to exempt a supply of water from monitoring of either radon or tritium or the calculated ID
 - Assumptions on the size of the bottled water market in Scotland and associated volumes of production.
- 3 FSS invited stakeholders to comment on the BRIA and, in particular, if they agreed with the impact of the proposed Regulations and, if not, provide comments and supporting evidence on any cost implications that may arise.
4. FSS considered responses to stakeholders' comments and these are summarised in the last column of the table.-
5. FSS is grateful to those stakeholders who responded to this consultation - these stakeholders are listed at the end of the document.

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Q1. As a bottled drinking water producer, do you have any concerns with the issue of radon contamination?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	Through historic gross alpha and gross beta test results and risk management, Highland Spring Group does not have any concerns with radon contamination.	Noted
British Soft Drinks Association	E-mail	BSDA bottled water producer members in Scotland do not have any concerns with the issue of radon contamination.	Noted
AG Barr	E-mail	A G Barr do not have any concerns with the issue of radon contamination of the Strathmore source. This has been confirmed by recent analysis by an accredited laboratory which shows compliance with the Directive 2013/51/Euratom.	Noted
Cott Beverages Ltd	E-mail	No.	Noted

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Q2. Where further investigation of tritium or gross alpha activity/ gross beta activity is necessary, and where screening for ID is undertaken using certain radionuclides, are the common artificial and natural radionuclides detailed in Figure 2 sufficient or should others be included specifically for Scotland. Please provide any reasoning for your suggestions.			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	The list of common radionuclides listed is sufficient.	Noted
British Soft Drinks Association	E-mail	BSDA consider that the list of radionuclides is sufficient.	Noted
AG Barr	E-mail	A G Barr consider that the list of radionuclides is sufficient. Recent analysis of the Strathmore source by an accredited laboratory show compliance with the Directive 2013/51/EURATOM and no further investigation is necessary.	Noted
Cott Beverages Ltd	E-mail	We are not experts regarding specific nuclides, therefore cannot offer constructive feedback. As the list will have been drawn up by experts in this field and based on field data, we would assume that it's fit for purpose.	Noted

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**Q3. Do you agree that where monitoring of radioactive substances is required for a bottled drinking water, monitoring should be carried out in line with the minimum frequencies detailed in Figure 3?
If not, please suggest what minimum frequencies should apply and whether the frequency of monitoring should differ depending on the radioactive parameter being monitored**

Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	The frequencies stated in Figure 3 are acceptable.	Noted
British Soft Drinks Association	E-mail	These frequencies seem appropriate, however it needs to be very clear that this monitoring is only required if there is an indication of a problem.	Noted
AG Barr	E-mail	These frequencies seem appropriate, however it needs to be very clear that this monitoring is only required if there is an indication of a problem.	Noted
Cott Beverages Ltd	E-mail	As the levels of radiation should be fairly static, then testing should be kept to a minimum.	Noted

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Q4. Are the volumes quoted realistic for bottled water production? – if not, please provide us with figures you think are appropriate.

Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	The volumes quoted are realistic. The smallest Highland Spring Group bottling plant bottles 4 million litres per year and the largest plant bottles 292 million litres per year.	Noted
British Soft Drinks Association	E-mail	The volumes do appear realistic.	Noted
AG Barr	E-mail	The volumes do appear realistic.	Noted
Cott Beverages Ltd	E-mail	The upper volumes are very high. For instance 100,000m ³ is equal to 100,000,000L of water, this equates to 6.25 million 8x2L cases per day.	Noted. We will consider this point further.

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Q5. Is the period of five years an appropriate time to exempt a supply of water from the monitoring of either radon or tritium or the calculated ID? If not, what length of time is appropriate and why?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	The exemption time of 5 years is appropriate however the definition of <i>'Monitoring would, however, be required following any significant event which could affect radiation levels e.g. an earth tremor or vibration'</i> needs to state the trigger value. For example, the British Geological Survey records on average 8-10 earth tremors within a 5km radius of our Ochil's site per year. To-date we have not seen any adverse effect to any boreholes from any tremors.	This would not be a concern provided you had evidence that this background seismic activity does not affect radioactivity levels. Our understanding is that a link between seismic events and radon release is inconclusive, and it would be difficult to define a seismic threshold above which monitoring needs to change – we will be making reference to this in guidance. The monitoring that Highland Spring should do to maintain their exemption should be analysed for any trends and if levels are stable then that should suffice.
British Soft Drinks Association	E-mail	BSDA members consider that for spring waters a permanent derogation should be given subject to certain conditions being met. If water is considered acceptable in year 1 and there is stable geography, unless there is	Our consultation letter explained that exemptions lasting longer than 5 years would cause potential problems regarding record keeping and ensuring that any events e.g. seismic activity during recent years had been properly taken into

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		<p>some sort of geographical activity, and annual measurement of TDI and alpha & beta counts remain satisfactory, an exemption should stand indefinitely. For 'bottled waters' of mains supplied drinking water, if a derogation is in place for the water as drinking water from the public supply it would seem sensible that the derogation will also apply to the product being packed as bottled water.</p> <p>There needs to be a consistency of approach between local authorities on the criteria that are required to satisfy a request for a derogation across the whole of the UK.</p> <p>Guidance on these requirements would be welcomed.</p>	<p>account. FSS will keep this under review.</p> <p>On the public supply, Scotland effectively exempts Scottish Water from calculating TID unless gross alpha and gross beta exceed certain limits. The tritium sample frequency has been reduced to one per supply per year, based on the fact that no tritium has been detected in the past 3 years.</p> <p>So in Scotland the testing regime for bottled water would be less onerous – only for gross alpha and gross beta, if these don't reveal a problem.</p> <p>FSS intends to work with other administrations across the UK to produce draft guidance on these issues which will be subject to consultation.</p>
AG Barr	E-mail	<p>A G Barr consider that for the Strathmore Source a permanent derogation should be given. We have an extensive hydrogeological report on the</p>	<p>Our consultation letter explained that exemptions lasting longer than 5 years would cause potential problems regarding record keeping and ensuring that any events e.g.</p>

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		<p>aquifer that shows the source has stable geography and it is also in a low risk area with reference to Radon. If water is considered acceptable in year 1 and there is a stable geography, unless there is some sort of geographical activity, and annual measurement of TDI and alpha & beta counts remain satisfactory, an exemption should stand indefinitely. This exemption is already in place for Natural Mineral Water sources and Spring Waters should be treated likewise.</p> <p>There needs to be a consistency of approach between local authorities on the criteria that are required to satisfy a request for a derogation across the whole of the UK. Guidance on these requirements would be welcomed.</p>	<p>seismic activity during recent years had been properly taken into account. FSS will keep this under review.</p> <p>Potential producers of natural mineral waters are required to provide information on radiological parameters at the onset of recognition and are specifically exempt from the EURATOM Directive requirements. Whilst formal monitoring frequencies are not stipulated for natural mineral waters in the bottled drinking water regulations, there is a requirement for the food authority to carry out periodic checks to ensure that the composition and other essential characteristics of the water remain stable. It is acknowledged that radiological parameters are not explicitly required to be checked. However, the fact that other essential characteristics of the water are to remain stable implies that radiological parameters should be checked periodically and this</p>
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			<p>would be done on a risk basis.</p> <p>The EU legislation makes distinctions between the types of bottled drinking water, and therefore it is not appropriate to extend the same requirements for radiological monitoring in spring water to natural mineral water and <i>vice versa</i>.</p> <p>FSS intends to work with other administrations across the UK to produce draft guidance on these issues which will be subject to consultation.</p>
Cott Beverages Ltd	E-mail	<p>Testing every 5 years seems reasonable, with the caveat of additional testing if there are potential changes to the supply, ie seismic activity and/or changes regarding man-made activity. Do the minimum testing regimes change if there is a local issue, such as another Chernobyl, and would these be communicated to bottlers at such a time? Would these be in place for a number of years post any incident?</p>	<p>In the event of a nuclear accident, additional monitoring will be required but this would be dealt with under separate, emergency legislation.</p>

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Q BRIA1. 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?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	Highland Spring Group is prepared to share historic radiation / ID monitoring data with FSS in order to support a case for derogation.	Noted
British Soft Drinks Association	E-mail	BSDA members are willing to share historical data regarding Indicative Dose monitoring and also hydrogeological information that would enable derogations to be granted.	Noted
AG Barr	E-mail	AG Barr is willing to share historical data regarding Indicative Dose monitoring and also hydrogeological information that would enable derogations to be granted. The company has already informed both the FSS and the local Forfar EHO of the recent findings with respect to radon and radionuclide analysis.	Noted
Cott Beverages Ltd	E-mail	No comment offered	

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Q BRIA2. Is the assumption of the size of the bottled water market in Scotland accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	<p>Highland Spring currently has 4 bottling plants in Scotland.</p> <p>Ochil's PH4 1QA – bottles spring water and bottled drinking water</p> <p>The Gleneagles Plant PH4 1QF – bottles spring water</p> <p>Fells G66 7JQ bottles bottled drinking water</p> <p>Braes of Glenlivet AB37 9JS – bottles natural mineral water and drinking water</p> <p>Highland Spring cannot comment on any other bottled water producers sites</p>	Noted
British Soft Drinks Association	E-mail	No Comment Made	
AG Barr	E-mail	No Comment Made	
Cott Beverages Ltd	E-mail	No comment offered	

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Q BRIA3. Are the assumptions on the one-off monetised costs associated with radon monitoring accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	<p>No they are not accurate. Highland Spring Group currently contract radiation testing through a commercial laboratory. The cost for testing gross alpha and gross beta is currently £56.51 per test plus transport and packaging. The cost for testing gross alpha, gross beta and radon is £80.89 per test plus transport and packaging.</p> <p>In order to comply with the proposals, each Spring Water borehole would have to be individually tested and Bottled Drinking water would have to be tested at the point of bottling. The Highland Spring Group sites within Scotland which bottle Spring Water have 8 production boreholes. Therefore the one-off costs associated with the testing of these would be £452.08. In addition the sites which bottle Bottled Drinking Water would require 3 one-off tests at a cost of £169.53.</p>	<p>Noted – testing for Radon will only be required if results for gross Alpha and Beta are a concern.</p> <p>Noted - spring waters and bottled drinking waters are all to be tested at the point of bottling.</p> <p>It is important to note that results of sampling levels must be equivalent to levels at the point of bottling, allowing for radioactive decay.</p>
British Soft Drinks Association	E-mail	The basic cost of one radon analysis	Noted

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		<p>is approximately £140, however the sampling has to be carried out to a strict protocol and time is an important factor, specific containers for the collection of samples are required and samples would need to be couriered to the testing laboratories, the total cost is therefore likely to be double this.</p> <p>If there were any issues raised from this analysis then further testing would be required, these tests are considerably more expensive.</p>	
AG Barr	E-mail	<p>The actual cost of performing radon and radionuclide analysis, for the Strathmore source, using an accredited laboratory was £428 (ex Vat). Sampling was carried out under strict protocol, time is an important factor with regard to this type of investigation to ensure accurate results. Samples were delivered to the laboratory (PHE England) by Barr personal immediately after sampling. The results were compliant with the new legislation and indicated that no further analysis would be required.</p>	Noted
Cott Beverages Ltd	E-mail	No comment offered	

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Q BRIA4. Are the assumptions on the ongoing costs associated with radon monitoring accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	No they are not accurate. The current Highland Spring Group regime for testing gross alpha and gross beta is annually for every Spring Water borehole. This has been determined by risk assessment. We would expect to maintain this frequency of testing and the associated costs on-going.	Noted - spring waters and bottled drinking waters are all to be tested at the point of bottling. These on-going costs are linked to the food business operators own risk assessment as part of their food safety and management system.
British Soft Drinks Association	E-mail	We believe the assumptions are a fair summary.	Noted
AG Barr	E-mail	We believe the assumptions are a fair summary.	Noted
Cott Beverages Ltd	E-mail	No comment offered	

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Q BRIA5. Are the assumptions on the costs to industry associated with familiarisation with regard to radon monitoring regulation accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	No they are not accurate. The time taken in the physical sampling of boreholes / products has not been taken into account in the costing. Due to their location, it is estimated that it takes 30 minutes per sample in total.	Noted – Further sampling would only apply if specific radon testing is required. Unlike microbiological testing which applies at source, radioactivity monitoring is carried out at the point of bottling.
British Soft Drinks Association	E-mail	These would appear reasonable.	Noted.
AG Barr	E-mail	These would appear reasonable.	Noted.
Cott Beverages Ltd	E-mail	No comment offered	

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Q BRIA6. Are the assumptions on the costs to industry associated with risk assessment for radon accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	No they are not accurate. The costs do not take into account the need for the involvement of a Hydrogeologist in the risk assessment process. Highland Spring contracts a 3 rd party Hydrogeologist at a total cost of approximately £2000 to do this.	These on-going costs are linked to the food business operators own risk assessment as part of their food safety and management system.
British Soft Drinks Association	E-mail	Risk assessment costs do not seem to be covered as such in the impact assessment. For most small and even medium sized companies the assessments are likely to be carried out by external consultants with probable costs between 1 to 3 thousand pounds.	As above.
AG Barr	E-mail	Risk assessment costs do not seem to be covered as such in impact assessment. For most small and even medium sized companies the assessments are likely to be carried out by external consultants with probable costs between 1 to 3 thousand pounds.	As above.
Cott Beverages Ltd	E-mail	No comments offered	

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Q BRIA7. Are the assumptions on the costs to enforcers associated with familiarisation with regard to radon monitoring regulation accurate?			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	Highland Spring Group is unable to comment on this cost.	Noted
British Soft Drinks Association	E-mail	N/A	
AG Barr	E-mail	N/A	
Cott Beverages Ltd	E-mail	No comments offered	

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OTHER COMMENTS:			
Respondent	Method of Response	Comment	Response
Highland Spring Group	E-mail	Understands that this amendment to the regulation is to ensure compliance with the Euratom Directive, however it would be useful to have a consolidated regulation for ease of use by industry.	Noted. FSS plans to launch a public consultation on proposed consolidated regulations during January 2016.
AG Barr	E-mail	Understands that this amendment to the regulation is to ensure compliance with the Euratom Directive, however it would be useful to have a consolidated regulation for ease of use by industry.	Noted. FSS plans to launch a public consultation on proposed consolidated regulations during January 2016.

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ACTIONS TO BE IMPLEMENTED:

- FSS intends to work with other administrations across the UK to provide guidance on these regulations which will take into account relevant issues as described in this summary.

List of Respondents:

1	Highland Spring Group	31	60
2	British Soft Drinks Association	32	61
3	AG Barr	33	62
4	Cott Beverages Ltd	34	63
5	The Royal Environmental Health Institute of Scotland (No substantive comments)	35	64
6	Environmental Health Department, East Ayrshire Council (No substantive comments)	36	65
7	Scottish Environment Protection Agency (No substantive comments)	37	66
8		38	67
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