FOOD STANDARDS SCOTLAND CONSULTATION
The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015

Date consultation launched:	Closing date for responses:
21 September 2015	16 October 2015

Who will this consultation be of most interest to?

Producers and consumers of natural mineral water, spring water and bottled water.
Enforcement officers responsible for the enforcement of the Regulations in this sector.

What is the subject of this consultation?

The transposition of Directive 2013/51/EURATOM imposing requirements for radiation testing of certain categories of bottled water

What is the purpose of this consultation?

To give stakeholders the opportunity to comment on the draft Regulations and provide information on the costs and benefits detailed in the partial Business and Regulatory Impact Assessment for radiation monitoring requirements.

Responses to this consultation should be sent to:

Stewart Herd
Regulatory Policy Branch
FOOD STANDARDS SCOTLAND
Tel: 01224 285154
Fax: 01224 285168

Please note our new postal address:
Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL
Email: stewart.herd@fss.scot

Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation?	Yes ☒	No ☐ See Annex A for reason.

Food hygiene information scheme

If you would prefer to receive future consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.

Positive About Disabled People

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

DETAIL OF CONSULTATION

Introduction

1. The exploitation, production, labelling and marketing of bottled drinking water is governed by EU law[1]. The primary purpose of EU legislation is to protect the health of consumers, prevent consumers from being misled and to ensure fair trading and free movement of bottled drinking water across the EU.

2. Three categories of bottled drinking water are described under the EU regime:

- Natural mineral water;
- Spring water
- Other bottled drinking water (covering all waters which do not bear the reserved descriptions: Natural mineral water or Spring water).

3. Each of these categories of water is subject to separate rules on treatment, bottling, marketing and labelling, advertising, sale and monitoring.

4. There are three EU Directives that govern the exploitation, production, marketing requirements and permitted treatments for all three types of bottled drinking water produced and marketed both in the EU and the European Economic Area (EEA).

5. These Directives have been transposed by The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007[2] (the "2007 Regulations")

I. Council Directive 98/83/EC relating to the quality of water intended for human consumption[3]
II. Council Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of Natural mineral waters and the conditions for using ozone enriched air for the treatment of Natural mineral waters and Spring waters[4]
III. Council Directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of Natural mineral water (recast) [5]

6. In addition, Commission Regulation (EU) No. 115/2010[6] laying down the conditions for use of activated alumina for the removal of fluoride from Natural mineral waters and Spring waters is directly applicable, and took effect across the EU as soon as it was published in 2010. Accompanying enforcement provisions have been included in an amendment to the 2007 Regulations.

7. These pieces of EU legislation have been given effect in Scotland by the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007 (as amended).

[1] http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0020_en.htm
[2] http://www.legislation.gov.uk/ssi/2007/483/pdfs/ssi_20070483_en.pdf
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF
[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:126:0034:0039:EN:PDF
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0045:0058:EN:PDF
[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0013:0015:EN:PDF

8. In the near future, FSS intends to carry out a separate consultation exercise on proposals intended to:

- Consolidate all Scottish amendments to the 2007 Regulations on natural mineral water, spring water, and bottled drinking water into a single Scottish Statutory Instrument
- Remove a national provision which calls for the re-calcification up to 60mg/l for any bottled or spring water which had been softened or de-salinated
- Clarify the permitted treatments for spring water.

9. However, due to the need to implement the provisions of Directive 2013/51/EURATOM by 28 November 2015, this consultation focuses on new EU radiation testing requirements for certain categories of bottled water.

Key proposal:

The transposition of Directive 2013/51/EURATOM imposing requirements for radiation testing of certain categories of bottled water

10. FSS would like to seek views on proposals to implement Directive 2013/51/EURATOM ('the Euratom Directive')[7] in so far as it relates to bottled drinking water. All bottled drinking water is covered by the Directive, with the exception of natural mineral water.

11. The Euratom 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.

12. Parametric values are set for radon, tritium and the indicative dose (ID). The ID is the effective dose of radiation that the body may receive from consuming water (and covers other radionuclides). These values have an "*indicator function*"[8]; i.e. they are not intended to be limits. Rather, if any particular parametric value is exceeded, further investigation is required. Exceeding a parametric value should not be considered a safety risk, without first conducting a thorough investigation.

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

Background

14. The level of radiation in bottled drinking water is not considered to be an issue for Scottish producers, this is supported by data from the British Soft Drinks Association (BSDA), The European Federation of Bottled Drinking Waters (EFBW) and the Food Standards Agency (FSA).

15. In 2002, the FSA published a report demonstrating that levels of natural radioactivity found in UK-produced natural mineral water, spring water and bottled drinking water were not significant[9]. A more recent survey was published by the FSA on 28 August 2014[10], prompted by the publication of the Euratom Directive. It indicated that there is no

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:296:0012:0021:EN:PDF
[8] Paragraph 2 of introductory text to Directive 2013/51 Euratom
[9] http://tna.europarchive.org/20080609145551/http:/www.food.gov.uk/science/surveillance/fsis2004branch/fsis6704
[10] https://www.food.gov.uk/sites/default/files/fsis-01-14-radioactivity-in-bottled-water.pdf

radiological risk to health from consuming UK-produced bottled drinking water. None of the samples breached any of the levels detailed in the Euratom Directive.

16. The monitoring of tritium and "*total indicative dose*" (TID)[11], (which is calculated on the basis of gross alpha[12] and gross beta radiation levels) is already required by the Drinking Water Directive for spring water and other bottled drinking waters, but more detailed requirements on this are now included in the Euratom Directive. The monitoring of radon is currently not required.

New radiological monitoring requirements

17. The requirements in the Euratom Directive for monitoring radioactive substances supersede those laid down in the Drinking Water Directive. Under the Euratom Directive, ID, tritium and radon are subject to monitoring in accordance with the monitoring strategies and frequencies set out in Annex II of the Directive. Note, the terminology has changed in the Euratom Directive from "TID" to "ID" but the terms mean the same thing. The key purpose of monitoring is to check whether the levels of radioactive substances in a given water supply comply with the parametric values specified. For bottled drinking water, compliance with parametric values must be checked at the point at which the water is put into bottles. **If the gross alpha activity and gross beta activity are less than 0.1 Bq/l and 1.0 Bq/l respectively, it may be assumed that the ID is less than the parametric value of 0.1 mSv and radiological investigation, including radon monitoring, 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**.

Monitoring of radon, if required

18. Radon monitoring is a new requirement stemming from the EU at some initial cost to industry (detailed in Annex 1). However, radon monitoring is only necessary where there is reason to believe (on the basis of representative surveys or other reliable information), that the levels will exceed the parametric values laid down in the Euratom Directive. The Euratom Directive gives discretion to Member States to define the sampling and analysis frequencies for monitoring radon in bottled drinking water. FSS proposes that any radon monitoring, if required, shall be conducted according to the minimum frequencies stipulated in Figure 3 as discussed in paragraph 29.

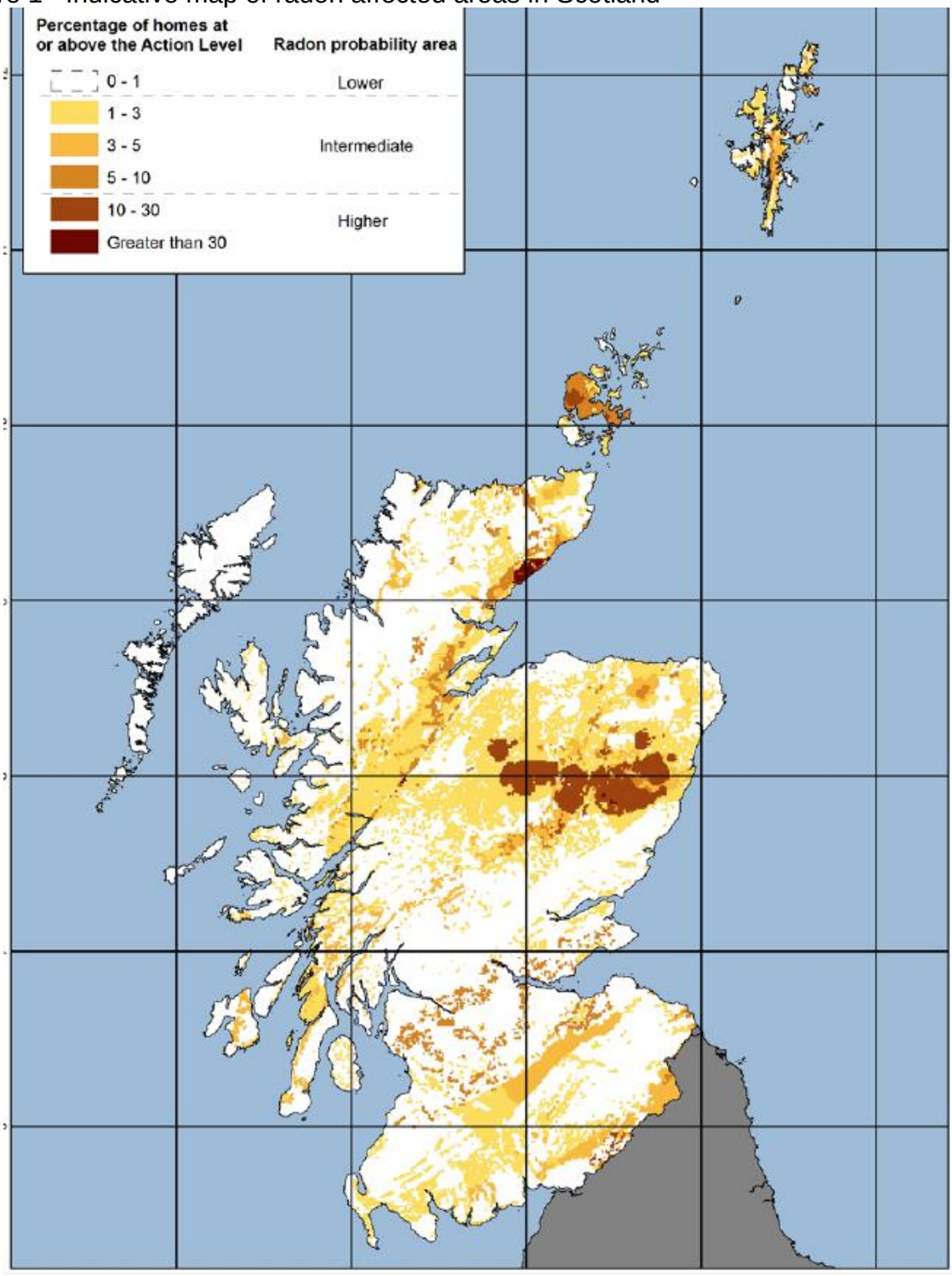
19. Member States must ensure that representative surveys are undertaken to determine the scale and nature of likely exposure to radon in water. FSS considers that this undertaking is the responsibility of both the business and the Local Authority, and that consideration of the presence of radon should be included in the risk assessments undertaken for the suitability of a particular source for a bottled drinking water.

20. Each geographical site for a source of spring water is different. A risk assessment should already include a review of land ownership and land use (current and historic) for the water basin. It should also include data on contaminants, pollution incidents, legal controls applicable to protecting water from pollution and evaluation of the risk for each land use or natural risk. Existing risk assessments should already provide an indication of the radiological safety of a particular water source; they may or may not cover the incidence of radon, depending on hydrogeological assessment.

[11] TID is only measured if the screening value for gross alpha or beta radiation is exceeded.
[12] The gross alpha analysis is an initial screening test for radioactive particles, which can occur naturally.

21. It is a reasonable assumption that a business producing spring water or bottled drinking water will first use existing information to inform and assess the prevalence of naturally occurring radon from the British Geological Survey, the Scottish Environment Protection Agency or the Health and Safety Executive. The map in Figure 1 shows the areas at risk of radon in air[13], based on monitoring of houses, which reflects the underlying geology. It is envisaged that such maps will help Local Authorities and businesses determine the risk of radon in a particular catchment area used in the production of bottled drinking water.

Figure 1– Indicative map of radon affected areas in Scotland



The darker the area, the higher percentage of homes affected (Public Health England). This is indicative of the underlying rock strata emitting radon gas.

[13] The radon air maps provide information on radon which is being released from the underlying rock strata

Q1. As a bottled drinking water producer, do you have any concerns with the issue of radon contamination?

Monitoring of tritium, if required

22. Tritium is an indicator of artificial sources of radiation. Paragraph 3 of Annex II of the Euratom Directive requires that tritium is monitored where there is a man-made source of tritium or other artificial radionuclides within the catchment area. If it cannot be shown on the basis of surveillance programmes or investigations that the level of tritium is below the relevant parametric value, monitoring is required and should be conducted according to the minimum frequencies stipulated in Figure 3. Figure 3 is the table referred to after paragraph 6 of Annex II to the Euratom Directive but adjusted to remove text related to supply zones as discussed in paragraph 31.

23. Where the concentration of tritium exceeds the parametric value, the Euratom Directive requires further analysis of other artificial radionuclides. These other radionuclides are not defined; however, Annex III of the Euratom Directive provides a list of the most common artificial and natural radionuclides and their derived concentrations (shown in Figure 2). Derived concentrations are based on an annual intake of 730 litres of water, using dose coefficients laid down in Directive 96/29 Euratom[14], which lays down Basic Safety Standards arising from ionising (harmful) radiation. The list shown at Figure 2 is not exhaustive. However, FSS consider that these radionuclides provide a suitable minimum baseline to guide further radiological analysis. If further sampling is required, details of such sampling will be agreed on a case-by case basis with the Local Authority, in consultation with FSS.

Figure 2: from ANNEX III of the Euratom Directive – "Derived Concentrations for radioactivity in water intended for human consumption" (1)

Origin	Nuclide	Derived concentration Bq/l
Natural	U-238 (2)	3.0
	U-234 (2)	2.8
	Ra-226	0.5
	Ra-228	0.2
	Pb - 210	0.2
	Po - 210	0.1
Artificial	C-14	240
	Sr-90	4.9
	Pu-239 / Pu 240	0.6
	Am-241	0.7
	Co-60	40
	Cs-134	7.2
	Cs-137	11
	I-131	6.2

(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 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. If any of the radionuclides in the table are exceeded, remedial action is necessary and the public must be notified.

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

[14] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996L0029&from=EN

Monitoring of Indicative Dose

24. Monitoring of bottled drinking water for the ID must 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 (Paragraph 4, Annex II of the Euratom Directive). Where monitoring for artificial radionuclide levels is required, this must be carried out at the minimum frequencies detailed in Figure 3, as discussed in paragraph 31.

25. Article 6 of the Euratom Directive requires that monitoring for ID is carried out in accordance with the screening strategies detailed in Annex III of the Euratom Directive. Member States are able to use "*various reliable screening strategies*" to indicate the presence of radioactivity, either;

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

(b) screening strategies for gross alpha activity and gross beta activity [note that the screening value detailed in the Drinking Water Directive for gross alpha is 0.5 Bq/l and in the Euratom Directive it is 0.1Bq/l].

26. In the case that the screening method for ID is the analysis of certain radionuclides or individual radionuclides, if a particular radionuclide activity exceeds 20 % of the derived value detailed in Figure 2, then full analysis of all the radionuclides detailed in Figure 2 is required; with gross alpha and beta activity measured in the same sample.

27. If gross alpha and gross beta activity is measured for the purpose of compliance with the ID, and is less than the stipulated screening values of 0.1 Bq/l and 1.0 Bq/l respectively, the Euratom Directive allows Member States to assume that the parametric value for the ID has not been breached, and no further investigation is required.

28. If monitoring for ID is required, it should be conducted according to the minimum frequencies stipulated in Figure 3 as discussed in paragraph 29.

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.

Frequency of monitoring

29. In general, monitoring of radioactive substances in bottled drinking water is required in the following two instances:

a) To check whether levels of radioactive substances comply with the parametric values laid down in the Euratom Directive in which case it should be carried out in accordance with a food safety management plans based on Hazard and Critical Control Point Principles (HACCP), as required by the EU Food Hygiene Regulation 852/2004(EC); and

b) If initial monitoring indicates that levels of radioactive substances may exceed the relevant parametric values, further monitoring will be required in accordance with the sampling and analysis frequencies to be defined by each Member State.

30. Annex II, paragraph 6, of the Euratom Directive lays down minimum frequencies for monitoring radioactive substances in water supplied from a distribution network or a tanker or used in a food production undertaking - see the table after paragraph 6 of the Directive, but gives Member States the discretion to define sampling frequencies for monitoring bottled drinking water in relation to:

a) radon;

b) The ID where monitoring for natural radionuclides is required; in this instance the frequency of monitoring can either be:

- a single check measurement for natural radioactivity, with a recheck required if any change occurs in relation to the water supply which is likely to influence the concentration of radionuclides; or

- the minimum frequencies set out in Figure 3;

c) Naturally occurring radionuclides, where previous monitoring results have shown that the concentration of radionuclides is stable; in this instance Member States have discretion to derogate from the minimum sampling and analysis frequencies set out in Figure 3.

31. Please note, the position for monitoring tritium or artificial radionuclide levels is more clear cut as monitoring must be carried out according to the minimum frequencies stipulated in Figure 3 (as provided for in paragraphs 3 and 4 of Annex II to the Euratom Directive).

32. In defining minimum sampling and analysis frequencies, Member States may take into consideration the volume of water produced. The monitoring frequencies for bottled drinking water should follow a risk-based approach using the principles of HACCP under Regulation 852/2004 and official control principles under Regulation 882/2004. FSS, along with the Defra and the FSA radiological teams, considers that the volumes and minimum sampling and analysis frequencies laid down in Figure 3 (the table referred to in the Euratom Directive above but adjusted to remove text related to supply zones) represents an appropriate level of monitoring for monitoring bottled drinking water (where monitoring is required).

33. 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 Euratom Directive Figure 3 with adjusted text to ensure a consistent and effective monitoring regime. FSS ’s view is that the Euratom Directive is explicit in its requirements for monitoring radiological substances, and that **such monitoring is only required if it is demonstrated that parametric values are exceeded**. The monitoring frequencies which have been stipulated in Figure 3 provide a robust and risk-assessed monitoring programme if elevated parametric values are identified and these appear equally relevant to bottled drinking water as they do to other water sources intended to be sold for human consumption.

34. FSS does not consider that setting alternative monitoring frequencies for bottled drinking water is appropriate. If monitoring is required, we see no scientific basis for deviating from the monitoring regime already stipulated (see question 3). This view is supported by the Defra and FSA.

Figure 3: (Minimum sampling and analysis frequencies for monitoring of water intended for human consumption from bottled water.)

Volume of water bottled each day (Note 1) m^3	***Number of samples per year (Note 3)***
volume ≤ 100	***1 (Note 3)***
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: The volumes are calculated as averages taken over a calendar year.
Note 2: As far as possible, the number of samples should be distributed equally in time and location.

Note 3: For volumes bottled which are less than or equal to 100 m^3, the number of annual samples is un-defined. FSS considers a single annual sample is appropriate in this case.

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.

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

35. In circumstances where the prescribed concentration or value for total indicative dose, tritium or, as the case may be, radon is exceeded in a sample taken, we propose that FSS will specify, by written notice to the monitoring local authority, the extent of resampling necessary to ensure that the measured values are representative of an average activity concentration for a full year.

Derogating from minimum monitoring requirements

36. **Under Annex II of the Euratom Directive monitoring is not required if the Local Authority (as competent authority) can establish that the calculated ID, tritium or radon will remain below the corresponding parametric values specified in Annex I of the Euratom Directive, for a certain period of time. Monitoring would, however, be required following any significant event which could affect radiation levels e.g. an earth tremor or vibration.**

37. FSS intends to seek to apply this derogation for a period of 5 years in the new regulations. As such, it would be helpful if spring water and bottled drinking water businesses and local authorities could supply relevant data on ID monitoring, which they have, in order to support a case to the European Commission. See Q 1 in the BRIA

38. Local Authorities would retain their option of non-statutory monitoring, if required, in the interests of food safety.

Time period for derogating from minimum monitoring requirements

39. A period of five years is being proposed as the timeframe for allowing an exemption from monitoring so long as sufficient data is provided to satisfy Local Authorities that the presence of calculated ID and/or tritium and/or radon in a given water supply is unlikely, or will remain below the prescribed parametric values during this period. FSS considers that this should be a rolling exemption; whereby businesses will be required to provide the Local Authority with up-to-date operational monitoring data in order to continue to rely on the exemption from monitoring for subsequent five year periods. Exemptions lasting longer than five 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 account.

40. A five year period for applying the exemption is considered long enough to reduce the burdens of monitoring on industry and local authorities where risk is deemed unlikely or where the risk of breaching a parametric value is low, but not so long that there is a possibility that levels of radioactive substances could change during this time.

Q5. Is the period of five years an appropriate length of 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?

Consultation Process

41. A stakeholder meeting on our proposals was held on 4 June and we have been reflecting on the comments raised. Some of these points have prompted us to ask some additional questions which has contributed to the delay in issuing the consultation documents. Stakeholder feedback will be taken into account when finalising the SSI and BRIA. A four week consultation is now being launched to provide interested parties with the opportunity to comment on these proposals. A shortened consultation period is required to ensure the instrument is in place to meet the European deadline of 28 November 2015 to transpose the requirements of Directive 2013/51/EURATOM and align implementation dates with other parts of the UK.

42. **We would welcome your comments on;**

- The proposed Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015, attached as Annex B.

- The Partial Business and Regulatory Impact Assessment (BRIA) attached as Annex C on radiation monitoring requirements.

43. The purpose of a BRIA is to assess and record the likely costs and benefits of the forthcoming provisions for individuals involved in the bottled water trade, retailers, consumers and enforcement bodies.

44. Details of assumptions made and the envisaged costs and benefits associated with the proposal and FSS would like stakeholders' comments on whether these assumptions, costs and benefits are accurate. We are particularly keen to hear from Small and Medium Enterprises (SMEs') on any likely impact and would encourage them to comment on all aspects of this proposal. More detailed costing calculations and conclusions will be published in our final BRIA which will be informed by stakeholder comments.

45. Comments from any interested party are welcome. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed legislation.

Responses

46. This is a shortened 4 week consultation and therefore responses are required by close **16 October 2015**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents). If you are replying by post please note our new address details.

47. We will summarise all comments received and the official response to each will be published on the FSS website within 3 months following the end of the consultation period.

48. Thank you on behalf of Food Standards Scotland for participating in this public consultation.

Questions asked in this consultation:

Q1. As a bottled drinking water producer, do you have any concerns with the issue of radon contamination?

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.

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.

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

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?

Business & Regulatory Impact Assessment (BRIA) – Radiation Monitoring

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?

Q BRIA2. Is the assumption of the size of the bottled water market in Scotland accurate?

Q BRIA3. Are the assumptions on the one-off monetised costs associated with radon monitoring accurate?

Q BRIA4. Are the assumptions on the ongoing costs associated with radon monitoring accurate?

Q BRIA5. Are the assumptions on the costs to industry associated with familiarisation with regard to radon monitoring regulation accurate?

Q BRIA6. Are the assumptions on the costs to industry associated with risk assessment for radon accurate?

Q BRIA7. Are the assumptions on the costs to enforcers associated with familiarisation with regard to radon monitoring regulation accurate?

Yours sincerely,

Stewart Herd
Regulatory Policy Branch

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Scottish Statutory Instrument – The Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) Amendment Regulations 2015

Annex C: Partial Business & Regulatory Impact Assessment - Radiation Monitoring

Annex D: List of Interested Parties

Annex E: Data Protection Form

Annex F: Consultation Feedback Questionnaire

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the principle of openness, our office in Pilgrim House in Aberdeen will hold a copy of the completed consultation. FSS will publish a summary of responses, which may include full name. Disclosure of any other personal data would be made only upon request for the full consultation response. If you do not want this information to be released please email openness@fss.scot or return by post to the address given on page. In accordance with the provisions of Freedom of Information Act (Scotland) 2002/ Environmental Information (Scotland) Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with FSS. However, we will take into account your views when making this decision.

3. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

4. A list of interested parties to whom this letter is being sent appears in Annex F.

5. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf

9. The consultation criteria from that code should be included in each consultation and are listed overleaf:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 — Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 — Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

10. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

11. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Business & Regulatory Impact Assessment at Annex C.

Comments on the consultation process itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts by sending an email to openness@fss.scot or return by post to the address given on page 1.