



Department
for Environment
Food & Rural Affairs

www.gov.uk/defra

Consultation on: The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2016

October 2015



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Executive summary

New regulations, The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2016 (“the regulations”) will be laid before Parliament to revoke the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (SI 2007/2785¹) (“the 2007 regulations”), and relevant amending instruments. The regulations are likely to come into force in early 2016.

Geographical extent

These regulations will apply in England only. Separate regulations will be made in Scotland, Wales and Northern Ireland.

Purpose

This consultation seeks views on proposals to consolidate and update existing legislation governing the exploitation, bottling and marketing of natural mineral water, spring water and other bottled drinking water. The following proposals are discussed:

- Consolidation of existing legislation which has been amended a number of times;
- Removal of unnecessary burdens on business which are not laid down in the overarching EU legislation (referred to as “gold-plating”);
- Replacement of criminal offences with administrative sanctions (i.e. improvement notices) to enable local authorities to take a more proportionate enforcement approach; and
- Application of new monitoring requirements for radioactive substances laid down in Directive 2013/51/EURATOM.

Audience

We would like to hear from anyone with an interest in the bottled drinking water sector, including but not limited to food business operators (FBOs), public analysts, trade associations, members of the public and Local Authorities.

Format

This consultation document is divided into sections covering the proposals described above.

Annex 1 in the body of this document details the financial implications of the new regulations and seeks further views.

Questions are included throughout the document and are summarised again, for ease, at Annex 2 which has been separately uploaded onto the Defra public consultation hub: ‘citizen space’².

¹ <http://www.legislation.gov.uk/uksi/2007/2785/contents/made>

² <https://consult.defra.gov.uk/>

Annex 3 is also separately uploaded onto citizen space and is a specific data collection exercise aimed at businesses, in order to inform the development and nature of guidance needs.

The responses to the consultation questions will assist in the final drafting of the regulations and guidance in England and will check the accuracy of assumptions that have been made.

Responding to this consultation

This consultation will run for 4 weeks from Friday 2 October to Friday 30 October 2015. Any responses or enquiries relating to this consultation should be sent to the following email address:

Bottled.Water@defra.gsi.gov.uk

Confidentiality & data protection

Information provided in response to this consultation document, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

Introduction

1. The exploitation, production, labelling and marketing of bottled drinking water is governed by EU law. The primary purpose of EU food and drink composition law is to protect the health of consumers, prevent consumers from being misled and to ensure fair trading and free movement of food and drink across the EU.
2. There are very few rules on food and drink which are national. The harmonisation of food requirements, including those that apply to bottled drinking water, improves the free movement of goods across EU Member States. It also provides a level of consistency amongst the bottled water industry operating in the EU and the international industry who may wish to import bottled drinking water into the EU using the marketing terms 'natural mineral water' or 'spring water'.
3. The consistent application of EU requirements enhances consumer protection, laying down the conditions for prevention and intervention in the event of threats to public health. This is of utmost significance to consumers who are afforded a level of safety, assurance and consistency in understanding the categories of bottled drinking water products sold and produced across all EU Member States.
4. Three categories of bottled drinking water are described under EU law:
 - i) Natural mineral water;
 - ii) Spring water; and
 - iii) Other bottled drinking water / table water (covering all waters which do not bear the marketing terms: natural mineral water or spring water).
5. Each of these categories of water is subject to their own rules on treatment, bottling, marking / labelling, advertising, sale and monitoring.
6. The following EU Directives govern the exploitation, production, treatment and marketing of the three categories of bottled drinking water produced and marketed in, or imported into, the EU. They have been transposed into the 2007 regulations.
 - I. Council Directive 98/83/EC³ relating to the quality of water intended for human consumption;
 - II. Council Directive 2003/40/EC⁴ 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;
 - III. Council Directive 2009/54/EC⁵ of the European Parliament and of the Council on the exploitation and marketing of natural mineral water (recast).

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>

7. In addition, Commission Regulation (EU) No.115/2010⁶ ('Regulation 115/2010') lays down the conditions for using activated alumina to remove fluoride from natural mineral water and spring water. Unlike the EU Directives, Regulation 115/2010 is directly applicable and binding in its entirety on Member States which is why the requirements have not been transposed into the 2007 regulations. However, the enforcement provisions in the 2007 regulations were updated in 2010 in order to reflect Regulation 115/2010.
8. In 2011, the Coalition Government committed to reducing the burden that legislation can impose on stakeholders by publishing a list of deregulatory measures in England as part of "The Red Tape Challenge" ('RTC')⁷. In relation to the 2007 regulations, this meant consolidating and removing a national measure on the minimum hardness (the level of calcium carbonate) of bottled drinking water which has been softened or desalinated. This is referred to as 'the RTC commitment'. See Part 1 for further information.
9. In addition to the outstanding RTC commitment from the last Parliament, Defra is proposing to change the enforcement approach to one involving administrative rather than criminal sanctions, in line with other recent food regulations. See Part 1 for further information.
10. The regulations will also transpose new requirements in Council Directive 2013/51/EURATOM⁸ ('Euratom Directive') on radioactive substances, which places obligations on Member States and businesses to test and monitor for radioactive substances in drinking water in order to protect public health. The radiation monitoring requirements supersede those currently detailed in Council Directive 98/83/EC⁹, which covers the quality of water intended for human consumption. See Part 2 for further information.

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0013:0015:EN:PDF>

⁷ <https://www.gov.uk/government/news/government-sets-hospitality-food-and-drink-businesses-free-from-regulation>

⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:296:0012:0021:EN:PDF>

⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0083&from=EN>

Part 1: Deregulation exercise

1. A programme of work has been initiated by Defra to consolidate the existing regulatory regime for bottled drinking water and remove unnecessary burdens on business.
2. This section of the consultation document seeks views on the following deregulatory measures:
 - i. Consolidation of the 2007 regulations;
 - ii. Removal of gold-plating (unnecessary burdens on business which are not laid down in the overarching EU legislation);
 - iii. Replacement of criminal offences with administrative sanctions (i.e. the issue of improvement notices) to enable local authorities to take a more proportionate approach to enforcement in line with other food regulations.

i) Consolidation of the 2007 regulations

3. The 2007 regulations have been amended four times since their publication, namely to reflect new EU requirements.
4. The following list details the amendments that have been made to the 2007 regulations:
 - i) The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2009 (SI 1598)¹⁰: implementation of Directive 2009/54/EC;
 - ii) The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2010, (SI 433)¹¹: enforcement provisions for Commission Regulation 115/2010;
 - iii) The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) (No.2) Regulations 2010, (SI 896)¹²: to correct errors in SI 433; and
 - iv) The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) (Amendment) Regulations 2011, (SI 451)¹³: to account for the Secretary of State for Environment, Food and Rural Affairs being responsible for carrying out the relevant functions in the regulations.
5. The amendments to the 2007 regulations do not exist in one single statutory instrument. As such, Defra proposes to consolidate the legislation so that all legal requirements are contained in the one statutory instrument making them more user-friendly.

¹⁰ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/218815/uksi_20091598_en.pdf

¹¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/218816/uksi_20100433_en.pdf

¹² https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/218817/uksi_20100896_en.pdf

¹³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/218818/data.pdf

ii) Removal of gold-plating

6. The second proposal for deregulation is to remove the minimum 'hardness' level currently applied to spring water and bottled drinking water which has been softened or desalinated.
7. Paragraph 1(d) in Schedule 2 to the 2007 regulations requires that: "***in the case of water prepared from water which has been softened or desalinated, its hardness is not below a minimum concentration of 60 mg Ca/l.***"
8. The rule is a national rather than EU requirement, seeking to preserve the purported beneficial cardiovascular health effects of hard water (i.e. water with a high concentration of calcium carbonate / lime-scale). The effect of the rule is that if spring water or bottled drinking water fails to meet the minimum hardness requirement of 60mg/l for calcium, after it has been softened or desalinated, remineralisation with calcium or blending with hard water is required to ensure that the level of calcium is increased to 60mg/l.
9. The original requirement for a minimum hardness level in drinking water was governed by Directive 80/778/EEC¹⁴ on the advice from the World Health Organisation (WHO). In 1998, this Directive was replaced by Directive 98/83/EC¹⁵, which removed the requirement for minimum hardness from EU law. Consequently, many Member States removed this provision from their regulations when they transposed the new Directive.
10. The UK retained the on Government advice at the time. Similar regulatory requirements have applied in Scotland, Wales and Northern Ireland since 1999.
11. In 2010, the Scientific Advisory Committee on Nutrition (SACN)¹⁶ recommended that there is "*insufficient evidence to suggest that there is a beneficial effect of hard water on cardiovascular disease risk, to support the retention of a statutory minimum hardness for bottled water which has been softened or desalinated*"¹⁷.
12. As such, the removal of this requirement is justified based on scientific evidence and as a result, it is not considered necessary to maintain this national measure at cost to industry which has no associated identified health benefits for consumers. Public Health England (PHE)¹⁸ has confirmed that the evidence base has not changed since it was considered by SACN in 2010.

¹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31980L0778&from=EN>

¹⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31980L0778&from=EN>

¹⁶ <https://www.gov.uk/government/groups/scientific-advisory-committee-on-nutrition>

¹⁷ http://www.sacn.gov.uk/pdfs/sacn_position_statement_hard_water_and_cardiovascular_disease.pdf

¹⁸ <https://www.gov.uk/government/organisations/public-health-england>

13. A number of key producers and trade organisations of varying sizes, as well as local authorities were asked about the minimum hardness provision. All parties to date appear content with the removal of this national requirement.

Q1. Are you in favour of removing the minimum hardness provision? Please advise if you will benefit from the removal of this national measure.

iii) Replacing criminal sanctions with administrative sanctions

14. The general approach to food enforcement is risk-based and consistent with good practice. Where there is not a significant risk to human health, enforcement officers from a local authority will work with businesses in their area to ensure compliance with regulatory requirements. They do this through visits, the timing of which is determined on a risk assessed basis as well as through collaborative relationships under the primary authority principles¹⁹. Enforcement action is only pursued where informal action has been unsuccessful or in the case of serious and/or persistent breaches of statutory requirements.
15. In the food sector, the use of improvement notices is the key enforcement tool to ensure compliance with regulatory requirements. Recent food composition and labelling regulations, such as The Food Information Regulations 2014²⁰ and The Fish Labelling Regulations 2013²¹ contain provisions applying section 10 of the Food Safety Act 1990²² which sets out the improvement notice regime. This means that, where an authorised officer has reasonable grounds for believing that a person has not complied with particular regulations, he or she may issue an improvement notice requiring that person to take steps within a given time frame in order to become compliant. Defra is proposing to apply the same improvement notice regime to the new regulations.
16. Any notice served under the regulations will need to:
- state the officer's grounds for believing that a person is failing to comply with the regulations;
 - specify the matters which constitute a person's failure to comply;
 - specify the measures which, in the officer's opinion, a person must take in order to secure compliance;

¹⁹ <https://www.food.gov.uk/enforcement/enforcework/compliance/primary-auth>

²⁰ http://www.legislation.gov.uk/uksi/2014/1855/pdfs/uksi_20141855_en.pdf

²¹ http://www.legislation.gov.uk/uksi/2013/1768/pdfs/uksi_20131768_en.pdf

²² http://www.legislation.gov.uk/ukpga/1990/16/pdfs/ukpga_19900016_en.pdf

- require a person to take those measures, or measures which are at least equivalent to them, within such period as may be specified in the notice.
17. Improvement notices will be used as part of the hierarchy of enforcement when informal measures are no longer appropriate and the contravention or issue should be elevated to formal enforcement action.
18. In order to ensure an effective, proportionate and dissuasive enforcement regime, any failure to comply with an improvement notice within a specified time period (where there has been no successful appeal) will be a criminal offence. This offence already exists in section 10(2) of The Food Safety Act 1990.
19. The following criminal offences will also continue to apply to the regime on bottled drinking water:
- obstructing an authorised officer in the course of his enforcement functions;
 - failing (without reasonable cause) to give an authorised officer any assistance or information which that authorised officer may reasonably require for the performance of his enforcement functions;
 - furnishing information which a person knows to be false or misleading in a material particular;
 - recklessly furnishing information which is false or misleading in a material particular.
20. These offences are laid down in section 33 of the Food Safety Act 1990²³.

Q2. Do you agree with the proposals for a more proportionate enforcement regime? If not, please provide detail.

Appeals against improvement notices

21. Businesses will have the opportunity to appeal against an improvement notice. Appeals will be heard by a newly formed body of the General Regulatory Chamber's First-tier Tribunal²⁴.
22. The First-tier Tribunal is a specialist judicial body empowered to deal with a wide range of issues which might form the substance of appeals, and to ensure cases are dealt with in the interests of justice and minimising parties' costs. The composition of a tribunal is a matter for the Senior President of Tribunals to decide, and may include non-legal members with suitable expertise or experience in the issues in an appeal in addition to Tribunal Judiciary.
23. The General Regulatory Chamber operates under the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009²⁵ which provide flexibility for

²³ <http://www.legislation.gov.uk/ukpga/1990/16/section/33>

²⁴ <https://www.gov.uk/courts-tribunals/first-tier-tribunal-general-regulatory-chamber>

dealing with individual cases.

24. Rule 2 of the General Regulatory Chamber Rules states its overriding objective as being to deal with a case fairly and justly. This includes dealing with a case in ways which are proportionate to the importance of the case, the complexity of the issues and the anticipated costs and resources of the parties. The rules give the Tribunal judge wide case management powers in order to achieve these objectives.
25. The Tribunal may also hear an appeal either orally in a court room or determined on the papers only. This latter written procedure is used if both parties agree that the Tribunal may determine the appeal on the papers without holding a full hearing and the Tribunal is satisfied that it can determine the issues without one.
26. Under the rules, the Tribunal has the power to award costs against a party where it considers that a party has acted unreasonably in bringing, defending or conducting the proceedings.
27. Currently, no fees are being charged by the Tribunal to bring an appeal. The Lord Chancellor has the capacity to charge fees for appeals to the Tribunal, for example an application fee. Where he is proposing to introduce fees he is required to consult the Senior President of Tribunals. Following this, any such proposal would be subject to secondary legislation that would need to be debated and agreed by both Houses of Parliament before it would take effect.
28. Any party to a case has a right to appeal to the Upper Tribunal on points of law arising from a decision of the First-tier Tribunal. The right may only be exercised with the permission of the First-tier Tribunal or the Upper Tribunal. Where permission is given, the further appeal would be made to the Upper Tribunal.

²⁵ <http://www.justice.gov.uk/downloads/guidance/courts-and-tribunals/tribunals/tribunals-rules-2009-at010411.pdf>.

Questions asked on behalf of the Tribunals Procedure Committee

Q3. Do you consider the General Regulatory Chamber of the First-tier Tribunal to be appropriate for these appeals? Please give reasons for your response.

Q4. Do you consider that the rules of the General Regulatory Chamber of the First -tier Tribunal²⁶ will suit the handling of these appeals against improvement notices? Please explain your answer. Please give the specific rule changes that you propose and your reasons for doing so.

²⁶ <http://www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/rules.htm>

Part 2: Radiation monitoring

1. This part of the consultation document seeks views on Defra's proposals to implement Directive 2013/51/EURATOM ('the Euratom Directive')²⁷ 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**.
2. 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.
3. 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*"²⁸; 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.
4. If remedial action is required following an investigation, the Euratom Directive stipulates that the general public must be notified of the risk as well as the remedial action which has been taken. The general public must also be advised of any additional precautionary measures that may be needed.

Background

5. The level of radiation in bottled drinking water is not likely to be an issue for English producers, as confirmed by British Soft Drinks Association (BSDA), The European Federation of Bottled Drinking Waters (EFBW) and the Food Standards Agency (FSA) in 2014.
6. In 2002, the FSA published a report demonstrating that levels of natural radioactivity and uranium found in UK-produced natural mineral water, spring water and bottled drinking water were not significant²⁹. A more recent survey was published by the FSA on 28 August 2014³⁰, prompted by the publication of the Euratom Directive. It confirmed that there is no radiological risk to health from consuming UK-produced bottled drinking water. None of the samples which were analysed breached any of the legal limits detailed in the Euratom Directive.
7. The monitoring of tritium and "*total indicative dose*" (TID)³¹, (which is a combination of gross alpha³² and gross beta radiation levels) is already required by the Drinking

²⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:296:0012:0021:EN:PDF>

²⁸ Paragraph 2 of introductory text to Directive 2013/51 Euratom

²⁹ <http://tna.europarchive.org/20080609145551/http://www.food.gov.uk/science/surveillance/fsis2004branch/fsis6704>

³⁰ <https://www.food.gov.uk/sites/default/files/fsis-01-14-radioactivity-in-bottled-water.pdf>

³¹ TID is only measured if the screening value for gross alpha or beta radiation is exceeded.

Water Directive for spring water and other bottled drinking waters, but detail on monitoring frequencies and other specifics have not been covered. The monitoring of radon is also currently exempt.

New radiological monitoring requirements

8. The requirements in the Euratom Directive for monitoring radioactive substances supersede those laid down in the Drinking Water Directive. Under the Euratom Directive, radon, tritium and ID 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 effectively 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.

Monitoring of radon

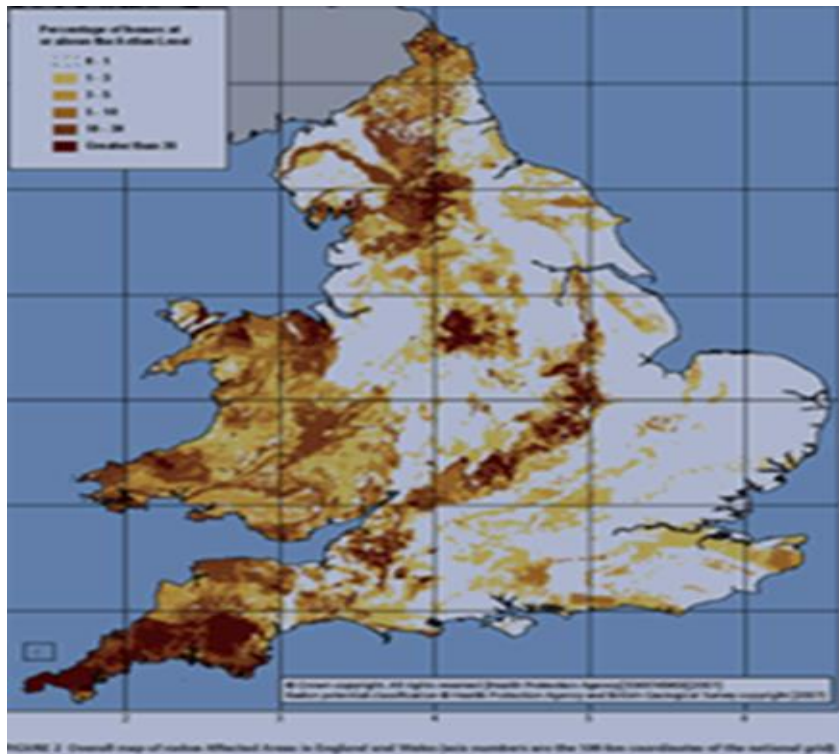
9. Radon monitoring is a new requirement stemming from the EU at some initial cost to industry (detailed in Annex 1). However, radon monitoring is only necessary where there is reason to believe (on the basis of representative surveys or other reliable information), that the levels will exceed the parametric 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. Defra proposes that any radon monitoring, if required, shall be conducted according to the minimum frequencies stipulated in Figure 3 as discussed in paragraph 25.
10. Member States must ensure that representative surveys are undertaken to determine the scale and nature of likely exposure to radon in water. Defra considers that this undertaking is the responsibility of both the business and the local authority. For example, 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.
11. 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 therefore already provide an indication of the radiological safety of a particular water source; the risk assessment may or may not cover the incidence of radon, as this would depend on the hydrogeological assessment.
12. In order to check the incidence of radon at the point at which the water is put into bottles, it is a reasonable assumption that a business producing spring water or bottled drinking water will first assess the hydrogeology of the catchment area, as

³² The gross alpha analysis is an initial screening test for radioactive particles, which can occur naturally.

well as any historical alpha radiation levels. Existing information on the prevalence of naturally occurring radon from the British Geological Survey, the Environment Agency or the Health and Safety Executive will also assist in identifying risk.

13. The map in Figure 1 shows the areas at risk of radon in air³³, based on geological data. 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 England and Wales



The dark areas show the high the concentration of radon in air. This is indicative of the underlying rock strata emitting radon gas (Source: Public Health England).

Q5. As a bottled drinking water producer, do you have any concerns with the issue of radon contamination?

Monitoring of tritium

14. 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, as discussed in paragraph 25.

³³ The radon air maps provide information on radon which is being released from the underlying rock strata

15. 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 Euratom³⁴, which lays down basic safety standards arising from ionising (harmful) radiation. The list shown at Figure 2 is not exhaustive, however, Defra consider that these radionuclides provide a suitable minimum baseline to guide further radiological analysis. If further sampling is required, details of such sampling should be agreed on a case by case basis with the local authority in consultation with Defra.

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.

Monitoring of indicative dose

16. 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

³⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996L0029&from=EN>

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 25.

17. 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 current screening value specified for gross alpha is 0.5Bq/l³⁵ and in the Euratom Directive it is 0.1Bq/l].

18. 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.

19. 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.

20. If monitoring for ID is required, it should be conducted according to the minimum frequencies stipulated in Figure 3, as discussed in paragraph 25.

Q6 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 England? Please provide any reasoning for your suggestions.

Frequency of monitoring

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

- 1) 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 Hazard and Critical Control Point principles (HACCP), as required by the EU Food Hygiene Regulation 852/2004(EC); and

³⁵ http://www.who.int/water_sanitation_health/dwq/GDW9rev1and2.pdf (paragraph 9.4)

- 2) If it cannot be shown from initial monitoring that levels of radioactive substances will not exceed the relevant parametric values, further monitoring is required in accordance with the sampling and analysis frequencies to be defined by each Member State (discussed in paragraph 25)
22. 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 (Figure 3), 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.
23. 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).
24. 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. Defra along with FSA and Food Standards Scotland (FSS) radiological experts consider that the volumes and minimum sampling and analysis frequencies laid down in Figure 3 could represent an appropriate level of monitoring for monitoring bottled drinking water (where monitoring is required).
25. Defra considers that wherever it is the case that monitoring of radon, tritium or ID is required it shall be done in accordance with the minimum frequencies already detailed in the Euratom Directive (shown in Figure 3) to ensure a consistent and effective monitoring regime. Defra'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.
26. Defra 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 8). This view is supported by the FSA and FSS.

Figure 3: Annex II (Minimum sampling and analysis frequencies for monitoring of water intended for human consumption supplied from a distribution network or from a tanker or used in a food production undertaking)

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m³ / (litres)	Number of samples per year (Notes 3 and 4)
volume ≤ 100	1 (Note 5)
100 < volume ≤ 1 000	1
1 000 < volume ≤ 10 000	1 + 1 for each 3 300 m³ /d and part thereof of the total volume
10 000 < volume ≤ 100 000	3 + 1 for each 10 000 m³ /d and part thereof of the total volume
volume > 100 000	10 + 1 for each 25 000 m³ /d and part thereof of the total volume
<p>Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.</p> <p>Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.</p> <p>Note 3: As far as possible, the number of samples should be distributed equally in time and location.</p> <p>Note 4: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned.</p> <p>Note 5: For volumes [of production] which are less than or equal to 100 m³/ litres, the number of annual samples is un-defined. Defra consider a single annual sample is appropriate in this case.</p>	

Q7. 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 volume and the radioactive parameter being monitored

Averaging

27. Under the Euratom Directive, if a parametric value is exceeded in a sample of spring water or bottled drinking water, the food authority must undertake further sampling to ensure that the measured values are representative of an average activity concentration for a full year. The extent of resampling is at the discretion of each Member State.
28. Defra considers that at least two further samples are required at three monthly intervals in order to check the validity of the original result and ensure that sampling is representative of an average activity concentration for a full year. We propose to outline this position in guidance.

Q8. Do you agree with the proposed guidance on averaging? Please give reasons for your response.

Exemption from minimum monitoring requirements

29. Under Annex II of the Euratom Directive monitoring is not required if the local authority (as the competent authority) can establish that radon or tritium or the calculated ID will remain below the corresponding parametric values specified in Annex I of the Euratom Directive for a certain period of time.
30. Defra intends to apply this exemption in the new regulations. As such, the local authority will need to consider representative surveys, monitoring data and other reliable information to establish that, for a particular timeframe, the levels of radon and / or tritium and/ or ID will remain or are expected to remain below the parametric values. Local authorities will be required to submit this documentation to Defra. Defra will in turn submit the documentation to the European Commission in accordance with the obligation stipulated in the Euratom Directive.
31. Local authorities would retain their option of non-statutory monitoring, if required, in the interests of food safety.
32. Exemptions should be considered on a case-by-case basis. At this stage, it is not considered appropriate for there to be an England-wide exemption under the regulations, given that water supplies in certain areas in England are more likely to contain radon or tritium than others and that unconventional shale gas extraction may or may not affect radiological risk³⁶.

³⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/329744/PHE-CRCE-002_for_website_protected.pdf (section 5.4 - radon in water)

Time period for derogating from minimum monitoring requirements

33. A period of five years³⁷ is proposed as the timeframe for allowing an exemption from monitoring (this is in line with World Health Organisation guidelines³⁸) so long as sufficient data is provided to satisfy local authorities that the presence of radon and / or tritium and / or calculated ID in a given water supply is unlikely, or will remain below the prescribed parametric values during this period. Defra consider 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. Defra considers that 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.
34. 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.

Q9. Do you agree that a period of five years is 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

35. Defra consider that these exemptions should no longer apply, if abstraction activity is near an unconventional oil and gas site which has been hydraulically fractured, or if there is a significant local geological event which could affect radiation levels, e.g. an earth tremor. In this case, it is proposed that monitoring would be required to establish baseline data which would confirm whether in fact an exemption could be granted for a further period of five years, or whether monitoring for radiological parameters is required at the frequencies outlined in Figure 3. We propose to outline this position in guidance.

Q10. Do you agree with the proposed guidance on exemptions?

³⁷ The Drinking Water Inspectorate currently provide exemptions for 5 years in guidance on radiation monitoring for tritium and TID (paragraph 4.29): [http://dwi.defra.gov.uk/stakeholders/guidance-and-codes-of-practice/WS\(WQ\)%20Regulations%20October2008.pdf](http://dwi.defra.gov.uk/stakeholders/guidance-and-codes-of-practice/WS(WQ)%20Regulations%20October2008.pdf)

³⁸ http://www.who.int/water_sanitation_health/dwg/GDW9rev1and2.pdf (paragraph 9.6.4)

Part 3: Other proposed changes

1. In this part of the consultation document, other proposed changes are discussed. The regulations will be similar in layout to the 2007 regulations. However, in line with Government guidance on effective transposition of EU legislation³⁹ a “copy-out” approach will be taken whereby the regulations will adopt the same wording as is detailed in the EU Directives.
2. As part of the consolidation exercise, Defra will be making changes in relation to:
 - i) the appeal process when a natural mineral water recognition is either refused or withdrawn;
 - ii) the sampling requirements which apply to local authorities as part of their official control obligations;
 - iii) the Co-ordination of Regulatory Enforcement (Enforcement Action) Order 2009 (CORE) to ensure the service of improvement notices under section 10 of the Food Safety Act 1990 for the purpose of enforcing the requirements of the new regulations is regarded as “enforcement action” for the purposes of the primary authority scheme.

i) Appeal process for recognition of natural mineral water

3. Under the 2007 regulations, a local authority may decline to grant or withdraw formal recognition of a natural mineral water extracted in England if it is satisfied that the legal requirements for recognition are not met. Similarly, the Secretary of State also has a power in the 2007 regulations to decline to grant or withdraw recognition of a natural mineral water extracted in a non-EEA country but marketed in England if satisfied that the legal requirements for recognition are not met. A person aggrieved by the decision of the local authority or, as the case may be; the Secretary of State may appeal to the Secretary of State for a review of that decision.
4. Defra is proposing to modify this appeal procedure so that, under the regulations, all appeals relating to a refusal to grant or withdrawal of a recognition in England will be made to an independent person appointed for that purpose by the Secretary of State. This will ensure impartiality in the appeal process and it is envisaged that an appointed person will be an expert in the field or will have the relevant expertise and knowledge to fully understand and consider the issues in dispute.

³⁹ <https://www.gov.uk/government/publications/implementing-eu-directives-into-uk-law>

5. The appointed person will consider the appeal and any representations made by the local authority or the Secretary of State (as the case may be) and report in writing to the Secretary of State with a recommended course of action.
6. Under the current appeal procedure in regulation 4 of the 2007 regulations, no time limits are prescribed for bringing an appeal to the Secretary of State or for the Secretary of State to report back to the appellant on the results of an appeal. Defra is proposing to clarify this position in the regulations so that:
 - a person aggrieved by a decision of the local authority or Secretary of State (as the case may be) to refuse to grant or to withdraw a recognition must appeal to the appointed person within **6 months** of being notified of that decision; and
 - the appointed person must consider the appeal and representations from the relevant authority and issue a written report to the Secretary of State within **3 months** of the appeal first being made.

Q11. Do you agree the appeal procedure should be subject to time limits?

If so, do you consider that the time limits proposed are reasonable?

ii) Sampling

7. The Food Safety (Sampling and Qualifications) England Regulations 2013⁴⁰ ('the 2013 regulations') specify the qualifications and experience required to act as a public analyst, a food analyst or a food examiner for the purposes of the Food Safety Act 1990.
8. The 2013 regulations ensure that there are sufficient numbers of suitably qualified and experienced staff to carry out official control work in line with European requirements on official controls⁴¹, and that food business operators, who are the subject of enforcement action should have access to an expert second opinion when sampling and analysis is undertaken.
9. The 2013 regulations also specify the procedures to be followed when a sample has been procured under section 29 of the Food Safety Act 1990 for chemical or microbiological analyses, and prescribe the form of the certificate of analysis and/or examination. However, the 2013 regulations exclude the 2007 regulations from these procedural requirements because detailed sampling provisions already exist in the 2007 regulations for taking samples of bottled drinking water.

⁴⁰ <http://www.legislation.gov.uk/uksi/2013/264/contents/made>

⁴¹ http://ec.europa.eu/food/safety/official_controls/index_en.htm

10. Consideration is now being given to applying the 2013 regulations in full to the bottled drinking water regime and deleting the requirements currently found in regulations 17 and 18 of the 2007 regulations, from the new regulations.

11. The procedural requirements in the 2007 regulations and the 2013 regulations are the same, save for the following differences:

- i. The 2013 regulations contain the following additional requirements which do not apply under the 2007 regulations:
 - If a sample consists of sealed containers and opening them would impede a proper analysis, the authorised officer must divide the sample into parts by putting the containers into three lots, and each lot is treated as being a part – regulation 7(2) of the 2013 regulations.
 - If the division of a sample into parts is not reasonably practicable or is likely to impede a proper analysis, the authorised officer must as soon as is reasonably practicable give notice to the owner that the undivided sample will be analysed and submit it for analysis – regulation 7(4) of the 2013 regulations.
- ii. In the 2007 regulations, if any analysis of a sample is being relied on for the purpose of prosecution, the Government Chemist must carry out a secondary analysis of that sample and provide a certificate of analysis. In the 2013 regulations, there is greater flexibility as the Government Chemist may direct a food analyst to analyse the sample – regulation 8(3) of the 2013 regulations.
- iii. In the 2007 regulations, on receipt of a certificate of analysis from the Government Chemist the authorised officer must supply a copy of it to the prosecutor immediately – regulation 18(5). This requirement is less stringent in the 2013 regulations; under regulation 8(5) the authorised officer must supply a copy as soon as reasonably practicable.
- iv. The 2007 regulations contain a prescriptive requirement on the delivery of samples - regulation 17(8). Delivery may be to a person or person's agent or by registered post or recorded delivery. If it is not possible (after reasonable enquiry) to ascertain the name and address of the person who should be given the sample, an authorised officer may retain the sample. The 2013 regulations do not contain any requirements on delivery of samples.
- v. The 2007 regulations contain an additional notification requirement at regulation 17(9). If it appears that water was exploited or bottled by a person who is not someone required to be given a sample under regulation 17 but their name and UK address is displayed on the bottle, the authorised officer must notify that person within 3 days of taking a sample that a sample has been procured and where the sample was taken or, as the case may be, from whom the sample was purchased. The 2013 regulations do not contain this requirement.

12. The implications of removing the existing requirements on sampling from the 2007 regulations and relying solely on the 2013 regulations are as follows:

- Prescriptive rules on permitted methods of delivery for samples will be lost (unless we retain this as a standalone requirement in the new regulations);
- The notification requirement in regulation 17(9) of the 2007 regulations will no longer apply (unless we retain this as a standalone requirement in the new regulations);
- The provision of the certificate of analysis to the prosecutor in the event enforcement proceedings are commenced would be required “as soon as reasonably practicable” rather than “immediately”;
- The Government Chemist would be able to direct another food analyst to carry out a secondary analysis if required;
- New requirements will apply under the 2013 regulations that have not previously applied under the 2007 regulations in relation to the protocol for dividing samples which cannot be opened or which, if opened, would impede proper analysis.

Q12. Do you have any concerns with this proposal to apply the requirements in the Food Safety (Sampling and Qualifications) (England) Regulations 2013 to the bottled drinking water regime?

iii) Primary authority

13. The ‘primary authority’ is a statutory scheme, which was established by the Regulatory Enforcement and Sanctions Act 2008 (RESA) to drive greater consistency and certainty for businesses regulated by local authorities. It enables a partner business to form a legally recognised affiliation with a nominated local authority (the “primary authority”) which acts as the main point of contact between the business and other local authorities which regulate it. Primary authorities may issue ‘primary authority advice’ upon which businesses can rely.
14. The primary authority has powers to direct local authority action. If an enforcing authority proposes enforcement action which the primary authority deems to be inconsistent with the advice it has provided, the primary authority may ‘block’ that enforcement action.
15. The primary authority is able to share compliance information with enforcing authorities, and may publish plans where this will be of benefit in guiding or co-ordinating the activities of enforcing authorities. Disagreements between local authorities in relation to primary authority advice are resolved through dialogue. If these disagreements cannot be resolved, the Secretary of State is empowered to make a determination on the matter. Defra intends to include the regulations within the primary authority scheme, in line with other food Regulations which have been in force since 2013⁴².

⁴² The Fish Labelling (England) Regulations 2013 and The Fruit Juices and Fruit Nectars (England) Regulations 2013 and the http://www.legislation.gov.uk/ukxi/2014/573/pdfs/ukxi_20140573_en.pdf

16. This will be done by amending the Co-ordination of Regulatory Enforcement (Enforcement Action) Order 2009 (SI 2009/665) (“the 2009 Order”) so that the service of an improvement notice under section 10 of the Food Safety Act 1990 for the purpose of enforcing the requirements of the new Regulations, will be regarded as an “enforcement action” under the primary authority scheme.
17. The key objectives of the primary authority are to increase operational certainty for businesses, reduce burdens associated with regulation and increase compliance by giving businesses clear instructions on how to meet a regulatory requirement in a cost-effective way.

Q 13 – Do you agree that the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2016 should be included in the scope of the primary authority scheme in England?

Q14 – If a primary authority has powers to direct other Local Authorities, are there any circumstances where you consider this requirement should not apply? Please explain your answer.

Annex 1: Cost and benefit analysis

Q15. Do you agree with the estimated cost and benefit analysis for The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2016 described in this Annex? Please explain any answers.

The potential impacts on bottled drinking water businesses, consumers and local authorities are discussed here.

Defra seeks to confirm the cost / benefit analysis that has been prepared in association with new regulations where the following changes will take place:

- 1) *Removal of unnecessary burdens on business which are not laid down in the overarching EU legislation (“gold plating”)***
- 2) *Replacement of criminal offences with administrative sanctions (i.e. the issue of improvement notices) to enable local authorities to take a more proportionate enforcement approach;***
- 3) *Transposition of new testing and monitoring requirements for radioactive substances laid down in Directive 2013/51/EURATOM***

This cost and benefit analysis has been prepared in line with guidance set out in the Green Book and the Better Regulation Framework Manual for public policy appraisal. It uses standard appraisal assumptions of:

10 year time horizon for appraisal of costs and benefits (therefore this analysis covers the period 2016-2024); and 3.5% discount rate for calculating the present value of costs and benefits.

Only additional costs and benefits due to the introduction of new policies are included.

Policy will be implemented as of November 2016 and end estimates are given in 2014 prices and 2016 NPV. Where estimates of cost and data were only available for 2013, they have been uplifted to 2014 prices using HM Treasury deflator figures. All final estimates quoted are in 2014 prices.

1. Removal of unnecessary burdens on business which are not laid down in the overarching EU legislation (“gold plating”)

Direct benefits to businesses

1. In July 2013, and more recently in July 2014, the four main UK trade associations were contacted and asked about the fortification requirement. The British Water Cooler Association (BWCA) was the only trade association at the time to confirm that one of its members, based in England, currently adheres to the national provision of fortification of bottled drinking water to a minimum level of 60mg/l calcium.

2. A detailed survey issued by the FSA and Defra in July 2013 sought an update on any treatments performed on bottled drinking water. The survey was sent to local authorities in order to capture data on small-scale producers who bottle less than 5 million litres per annum. The survey results indicated that no small businesses undertake water softening or de-salination. Based on this information, the assumption is that only one business in England would be affected / benefit as a result of this change in policy.
3. The BWCA advised in email correspondence, that for its member, the annual expenditure on mandatory fortification is between £15K and £20K (2013 price estimates). There are no additional labelling requirements and no costs envisaged for those affected businesses that no longer need to adhere to the minimum hardness requirement. The midpoint of this range is included in the central scenario estimate with an assumed saving of £17,500 a year. Total benefits are estimated to be £0.15m over a 10 year period from 2016-2024 (2014 prices, 2016 NPV).

Benefits to local authorities (non-monetised)

4. We assume that there are no monetised benefits to local authorities from removing the fortification requirement. Monitoring from 2016 will be part of overall controls to verify business compliance with multiple regulations. Time spent to check compliance with the fortification requirement cannot be separated from other checks. Therefore verification control costs arising solely due to the fortification requirement have not been monetised.
5. There has been no food safety or compositional breaches resulting in product recall for failure to adhere to the minimum hardness requirement for bottled drinking water in the past decade. This indicates that monitoring costs for this particular requirement are minimal.

Consumer Costs and Benefits

6. There are no costs or benefits to consumers identified due to removal of the fortification requirement. Notably, the removal of a minimum hardness requirement has no effect on consumer health and safety as the fortification of bottled water no longer has scientifically verified health benefits and is not a significant nutritional contribution to the English diet.
7. The total quantifiable net benefit of this proposal is estimated to be around £0.15m (best estimate), with £0.13m as the minimum estimate and £0.17m as the maximum estimate, in net present value terms over the 10 year appraisal period. Net benefit to businesses of this proposal is £0.15m.

2. Replacement of criminal offences with administrative sanctions (i.e. the issue of improvement notices) to enable local authorities to take a more proportionate enforcement approach

Benefits to businesses and local authorities (non-monetised)

1. There is an assumed benefit to industry and local authorities in terms of moving from the current criminal sanctions regime to the new administrative sanctions regime by way of improvement notices. A criminal offence will only apply in cases where an improvement notice is not complied with or if a person or business intentionally obstructs an authorised officer in the exercise of his or her duties or provides false information. It is anticipated that gains will be made as a result of time saved to businesses and local authorities in resolving issues rapidly. There is presumed to be a reduction in costs which will materialise as only the most serious offences would need to be escalated to a Magistrates' Court, the vast majority being resolved through the issuing of improvement notices.
2. It is acknowledged that the benefits of this measure will be felt only by those businesses that breach regulatory requirements, and there appears not to be any benefit for businesses that are compliant. As many of the front-line criminal offences in relation to bottled drinking water regulations relate to quality issues as well as food safety issues, the changes in enforcement would allow greater levels of cooperative working between business and local authorities to allow businesses time to rectify any quality issues. Making regulatory requirements clearer and enforcement more proportionate to risk should ultimately lead to greater compliance from businesses. Making food law easier to enforce also allows local authorities to make the most effective use of resources.

3. Transposition of new testing and monitoring requirements for radioactive substances laid down in Directive 2013/51/EURATOM

1. Full compliance with the Directive is required by 28 November 2016. The policy objective is to transpose EU requirements into English regulations at the same time as the rest of the UK and the rest of the EU. This is in line with scientific recommendation that radon levels in water should be monitored through legislative measures.
2. The current analysis for total indicative dose of radiation in drinking water specifically exempts radon. It is currently not a mandatory requirement to routinely test for radon in bottled drinking waters. This is not to say that there is a risk of radon remaining undetected. The current legislation stipulates that any radiation analyses which appear abnormal stimulate further testing to establish the abnormality which would establish the type of radiation present. Radon analysis may already be done voluntarily by the bottled drinking water industry in line with Hazard and Critical Control Points (HACCP) and risk assessment of a source.

3. Article 6⁴³ of the Euratom Directive requires that the analysis of radon in bottled drinking water is based on principles of HACCP as required by Food Hygiene Regulation (EC) 853/2004 and to the principles of official controls as laid down in Regulation (EC) 883/2004. Businesses are able to be exempt from formal analysis of radon if representative surveys and other reliable information show that for a period of time the levels of those substances will not exceed the parametric values set out in the Directive.
4. Given that radiation levels in UK produced water are low, we assume that all businesses in England will be able to rely on an exemption from formal analysis and the cost benefit analysis has been prepared on this basis.
5. As the requirement to monitor radon is new, there is an emphasis on radon analysis and associated costs.

Direct costs to businesses

6. The Directive only requires monitoring of radon where there is reason to believe that levels will exceed the parametric values detailed in the Directive. The monitoring of tritium is only required where there is a man-made source of tritium or other artificial radionuclides in the area. Following the establishment of the indicative dose (ID), if the screening values are not exceeded, no further investigation is required and monitoring in line with HACCP is proposed.
7. Businesses have advised Defra that they did not consider that the requirements of the Directive would be too onerous as radiation levels are relatively stable. Further, radon levels vary little over time.
8. The Directive does not stipulate minimum frequencies for monitoring bottled drinking water. To ensure a consistent and effective monitoring regime, Defra consider that wherever it is the case that monitoring of radon, tritium or ID is required; it shall be done in accordance with the minimum frequencies already detailed in the Directive. Defra consider that the requirement to monitor radon, tritium or ID is highly unlikely given that a spring water business would not have chosen a high radiation risk area to exploit a spring water source in the first place.
9. Member States are able to set minimum frequencies for monitoring radioactive substances in bottled drinking water based on volume of production. Following a meeting with the FSA, 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. It was therefore, not considered necessary to set minimum frequencies according to volume of production for the UK.

⁴³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:296:0012:0021:EN:PDF>

One-off costs to business

10. 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 water or natural mineral water). 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.
11. In July 2013, a survey (FSA reference ENF/E/13/029) was conducted by Defra and the FSA on bottled drinking water production. The confidential survey responses indicated that there are currently 34 businesses concerned with spring water production in England.
12. The cost provided by industry for radon analysis is £180 in 2014 terms, equivalent to £183 in 2016 terms (using the HM Treasury deflator). The volume and cost has been provided by the laboratory that was contacted by the BSDA following Defra enquiries, and these costs will be checked at consultation.
13. We assume that each of the 34 businesses tests a water sample at the rate of £183, leading to a one-off cost to the English industry of £6,218 in 2016.

Monetised ongoing costs to business

14. 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. As mentioned previously, any readings for gross alpha or beta activity which are in excess of those currently prescribed in the regulations lead to further investigation at cost. Radon (and/ or any other radiation) contamination would therefore be picked up at this stage and any ongoing costs are therefore not as a direct result of the new regulatory requirement.
15. In addition to the alpha and beta checks, the initial radon analysis in 2016 would provide the evidence of low risk, to compliment representative surveys allowing for the exemption from formal radon monitoring. Therefore there will be no ongoing costs to business.

Learning and dissemination costs

16. Natural mineral water is exempt from the monitoring requirements of the Directive. The requirement for radon monitoring was first notified to businesses in 2013 via an email to trade associations. A further formal update by Defra and the FSA to local authorities and industry was issued on 18 December 2014. Therefore 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.
17. There are approximately 34 businesses in England 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 2016 prices using HM

Treasury deflator figures, with a 30% overhead uplift in accordance with the UK standard cost model). Therefore the total one-off familiarisation cost to 34 businesses in England translates to one-off cost of £1,812 (2016 prices, 2016 Net Present Value).

Non – monetised costs to businesses

18. Detail on the considerations that are required when conducting a risk assessment for radon will be provided in a DWI report covering the impact of the Directive requirements for radon in drinking water supplies. This is due for publication later in 2015. The report will present radon hazard identification maps for both ground waters and surface waters which will further inform spring water businesses about the risk of radon in their source water.
19. Currently we do not have information on the cost of specific risk assessment for radon and therefore we have not monetised them. As mentioned earlier, current risk assessments may already cover radon although there is no legal obligation for them to do so. Additional costs are likely to be marginal and will not increase the costs to business above £1m gross annual costs per year. Notably, the risk of detecting radon in excess of parametric values, in a bottle of drinking water remains extremely low.

Q16. Please provide detail on any additional costs for risk assessment in relation to radon specifically

Local authority learning and dissemination costs

20. Local authority Trading Standard Officers will also need to become familiar with the new monitoring and enforcement requirements for radon. Similar to industry professionals, it is estimated that it would take one Trading Standards Officer, per local authority, 2 hours in total to learn and disseminate information about this regulations. This involves 1.5 hours for learning and 0.5 hours for dissemination. The median hourly pay rate for a Trading Standards Officer is around £18.80 (ASHE Provisional 2013 Estimates in 2013 prices uplifted to 2016 prices using HM Treasury deflator figures, with a 30% overhead uplift in accordance with the UK standard cost model).
21. Assuming 353 local authorities in England, the total one-off familiarisation cost to enforcement bodies in England translates to one-off equivalent annual cost of £13,276 in 2016 (2016 prices, 2016 Net Present Value). This is likely to be a conservative estimate as local authorities have been advised of the new radon monitoring requirements on numerous occasions, most recently in correspondence on 1 December 2014.

Local authority enforcement costs

22. 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.

Non-monetised benefits for consumers

23. This policy has been introduced by the EU to protect consumers from radon contamination from potable water sources, 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 action is required in a domestic dwelling is 200 Bq/l air. The level where remedial action is required for water is 1000 Bq/l. The latter figure is higher to account for radon loss before ingestion. Nonetheless, if radon is ingested in significant levels, it can damage the lining of the stomach.
24. 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 to consumer health is currently very low. We do not have the evidence available on the exact impact on consumer health and how much consumers would value this benefit.
25. A summary table of combined costs and benefits is provided below. All costs to businesses listed are direct and in 2016 prices and 2016 NPV terms.

£m	Central Scenario
Learning and dissemination costs for businesses (one -off)	-0.00
Analysis of radon in water sample (initial and ongoing)	-0.01
TOTAL COSTS TO BUSINESS	-0.01
TOTAL BENEFITS TO BUSINESS	0.00
Learning and dissemination costs for government	-0.01
TOTAL COSTS TO BUSINESS AND GOVERNMENT	-0.02
TOTAL BENEFITS TO BUSINESS AND GOVERNMENT	0.00
NET BENEFIT TO BUSINESS	-0.02

Small and micro business assessment

1. This section considers whether small and micro businesses should be exempted from the regulatory requirements. Small businesses are defined as those with up to 49 full-time equivalent (FTE) employees. Micro businesses are types of small businesses with up to 10 FTE employees.
2. It was not possible to find out the number of small and micro businesses specifically in England that are bottled water businesses. However data from the ONS (UK Business: Activity, Size, and Location – 2013' – Tables B3.1 and B3) gives information on Standard Industrial Classification (SIC) 11.07 covering the, 'Manufacture of soft drinks; production of mineral waters, and other bottled waters'. 76% of these businesses (170 businesses) were defined as micro businesses and 18% (40 businesses) as small businesses. Therefore a total of 94% of businesses in this sector are small and micro businesses. We assume that these proportions will remain constant over the period under consideration.

Q19. Are you a small or micro business according to the definition above?

Please provide details of likely impacts of the measures described in this consultation document.

3. We do not propose to seek derogation from the regulatory requirements for small and micro businesses as the Government moratorium exempting micro and start-up business from new domestic regulation for three years does not include domestic regulations which transpose EU legislation or enforcement measures of directly applicable EU legislation⁴⁴.

⁴⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/31584/2011budget_growth.pdf