Title: The Natural Mineral Water, Spring Water and Bottled Water (Wales) Regulations 2015

CONSULTATION SUMMARY PAGE

Date launched: 01 June 2015  Closing date: 24 August 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 consolidation of all Regulations on natural mineral water, spring water and bottled water into a single Statutory Instrument to include the transposition of an EU Directive on radiation monitoring, clarification of permitted treatments for spring water, removal of a fortification requirement that is no longer scientifically justified and a more proportionate enforcement regime.

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 Impact Assessments for
  i) The consolidation of Regulations including the removal of a fortification requirement that is no longer scientifically justified and a more proportionate enforcement regime.
  ii) Clarification of EU Regulations on permitted treatments for Spring Water
  iii) Radiation monitoring requirements

Responses to this consultation should be sent to:
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Impact Assessment included? Yes
The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

1. The exploitation, production, labelling and marketing of bottled drinking water is governed by EU law\(^1\). The primary purpose of the 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, marking and labelling, advertising, sale and monitoring.

Key proposals:
- Consolidate all Regulation on natural mineral water, spring water and bottled water into a single Statutory Instrument
- Introduction of a more proportionate enforcement regime, introducing the serving of Improvement Notices for non-compliance
- Removal of a national provision which calls for the re-calcification up to 60 mg/l for any bottled water or Spring Water which had been softened or desalinated.
- Clarification of permitted treatments for spring water
- Transposition of Directive 2013/51/Euratom imposing requirements for radiation testing of certain categories of bottled water

Consolidate all Regulation on natural mineral water, spring water and bottled water into a single Statutory Instrument

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 outside the European Economic Area (EEA).

5. These Directives have been transposed into The Natural Mineral Water, Spring water and Bottled Drinking Water (Wales) 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

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and the conditions for using ozone enriched air for the treatment of Natural mineral waters and Spring waters\textsuperscript{4}


6. Commission Regulation (EU) No.115/2010\textsuperscript{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 as such, 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 Regulations have been transposed into The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 (as amended). There have been three amendments to the 2007 Regulations in order to reflect changes made at EU level.

- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007: No. 3165 (W. 276)\textsuperscript{7}
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2009: No. 1897 (W. 170)\textsuperscript{8}
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2010: No. 748 (W. 76)\textsuperscript{9}
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2011: No. 400 (W. 57)\textsuperscript{10}

8. The amendments to the 2007 Regulation do not exist in one single SI, which makes them cumbersome and difficult to follow. As such, the FSA proposes to consolidate the legislation so that all legal requirements are contained in the one statutory instrument making them more user-friendly.

\textit{Sampling arrangements}

9. The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 (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 (the Act).

10. The 2013 Regulations specify the procedures to be followed when a sample has been procured under section 30 (Analysis of Samples) of the Act for chemical or microbiological analyses, and prescribes the form of the resultant certificates of analysis and/or examination analysis or examination. The 2013 Regulations excludes the 2007 Regulations in relation to the procedures for taking samples of bottled drinking water.

11. Consideration is now being given to applying the 2013 to the Regulations. Thereby removing the need to carry forward text from the 2007 Regulations; regulation 17: “Arrangements for samples taken for analysis”.

\textsuperscript{7} http://www.legislation.gov.uk/wsi/2007/3165/contents/made  
\textsuperscript{8} http://www.legislation.gov.uk/wsi/2009/1897/contents/made  
\textsuperscript{9} http://www.legislation.gov.uk/wsi/2010/748/contents/made  
\textsuperscript{10} http://www.legislation.gov.uk/wsi/2011/400/contents/made
The 2013 Regulations apply in their entirety to bottled water of all types. As such, it renders the more prescriptive provisions on sample analysis detailed in the 2007 Regulations, unnecessary.

12. The implications of not carrying forward the proposals 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 this is retained as a standalone requirement in the new regulations);
- The notification requirement in regulation 17(9) of the 2007 regulations will no longer apply (unless this is retained 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.

Q1. Do you agree that as the 2013 Regulations already apply, there is no requirement to include more prescriptive requirements on sampling for bottled water?

In your response, please consider the outlined consequences.

Introduction of a more proportionate enforcement regime, introducing the use of Improvement Notices for non-compliance

13. 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 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 basis as well as through collaborative relationships under the primary authority principles. Enforcement action is only pursued where informal action has been unsuccessful or in the case of serious and/or persistent breaches of the statutory requirements.

14. In the food sector, the use of improvement notices is a key enforcement tool and recent food composition and labelling regulations, such as The Food Information Regulations 2014 and The Fish Labelling Regulations contain provisions applying section 10 of the Food Safety Act 1990 (as amended) 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 serve an improvement notice.

15. The notice should:

- 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 so to comply;

11 http://www.food.gov.uk/enforcement/enforcwork/compliance/primary-auth
specify the measures which, in the officer's opinion, a person must take in order to secure compliance;
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.

16. Appeals against the content of an Improvement Notice in Wales are heard by the Magistrates’ Court.

17. This would 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. However, to ensure an effective, proportionate and dissuasive enforcement system, any failure to comply with an Improvement Notice within a specified time period (where there has been no successful appeal) is a criminal offence. This offence already exists in section 10(2) of The Food Safety Act 1990.

19. Regulation 10 (1) (b) of 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.”

20. The rule, which is a national rather than EU requirement, sought to preserve the purported beneficial cardiovascular health effects of hard water (i.e. water with a high concentration of calcium carbonate/limescale). The effect of the rule is that if spring water or bottled drinking water fails to meet the minimum hardness requirement of 60mg/l after it has been softened or desalinated, remineralisation or blending with hard water is required to ensure that the level of calcium is increased to 60mg/l.

21. The original requirement for a minimum hardness level in drinking water was governed by Directive 80/778/EEC14 (“The Drinking Water Directive”), on advice from the World Health Organisation15 which suggested that fortification could have health benefits for consumers, based on evidence which suggested that hard water may reduce the risk of cardiovascular disease and that calcium (and magnesium) are the main minerals that give water its hardness.

22. The UK and other Member States were therefore required to include this provision in national legislation and this approach was, at the time, supported by advice from the then Health Department; The Department of Health and Social Security’s (DHSS) Committee on Medical Aspects (COMA) in food policy.

23. In 1998, The Drinking Water Directive was updated (by Directive 98/83/EC16), 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.

Q2. Do you agree with the proposals for a more proportionate enforcement regime?

Removal of a national provision which calls for the re-calcification up to 60 mg/l for any bottled water or Spring Water which had been softened or desalinated.

15 http://www.who.int/water_sanitation_health/dwq/chemicals/hardness.pdf
24. The UK retained the requirement for minimum hardness on the above mentioned health grounds. This was done as a national provision in SI 1999 No. 1540\(^{17}\) (as amended) as well as in the 2007 Regulations (as amended). The retention of this minimum hardness provision was on the basis of further advice from DHSS officials that in terms of cardio-vascular disease, there is a protective effect of hard water. Similar regulatory requirements have applied in Scotland, Wales and Northern Ireland since 1999.

25. In 2010, the Scientific Advisory Committee on Nutrition (SACN) recommended that: “There is currently 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”\(^{18}\).

26. As the SACN advice now supersedes the advice from COMA, it is valid to consider that the removal of this requirement is an evidence based option. Maintaining this national measure at cost to industry which has no associated health benefits for consumers and without scientific justification is not considered acceptable.

Q3. Are you in favour of removal of the minimum hardness provision?

Q4. Are you aware of any businesses in Wales currently fortifying water in relation to the existing regulation?

Clarification of permitted treatments for spring water

27. Since the 1980’s, the EU has prohibited disinfection treatment for Natural Mineral Water (Directive 80/777 EC). This is in order to preserve the naturally present microbial flora found at the water source as well as to maintain the integrity of the original purity of the water source.

28. In 1996, the position changed as a result of Council Directive 96/70 EC\(^{19}\) and spring water became subject to the same restrictions on treatments as natural mineral water. Disinfection treatments were prohibited for all products marketed as natural mineral water or as spring water.

29. Due to the UK’s interpretation of the EU Regulations, this position has not been reflected in national legislation in Wales, or elsewhere in the UK, and producers continue to use disinfection treatments in the production of spring water.

30. The UK interpretation was called into question by other Member States. As a result of this, the UK met with the EU Commission, which was content to allow the UK to remedy national legislation in line with the correct interpretation of EU requirements.

31. FSA Wales proposes updating the Regulations in Wales to ensure that it is clear that the prohibition on disinfection applies to both natural mineral water and spring water.

32. In Wales, not all businesses that produce bottled spring water use disinfection treatment. Those that do have been treating spring water with Ultra Violet (UV) light. It is a harmless treatment which de-activates the DNA (genetic make-up) of organisms so that they cannot reproduce, and its use in this particular food production sector is to


provide additional (not essential) safeguards. The FSA is not aware of any other disinfection treatment used in the production of bottled spring water.

33. As some businesses already had UV disinfection units in place, they have continued to use them if they considered that UV treatment was an additional safeguard in their business.

34. In order to assess the national position on using UV disinfection in spring water production and to ensure that all Welsh businesses can be compliant with legislation which accurately implements EU requirements for marketing spring water across the EU, informal but extensive engagement has already taken place UK-wide with a number of trade associations and small businesses (via Local Authorities), and food safety interests.

35. In the UK, the relevant Competent Authorities (FSA in Wales and Northern Ireland, Food Standards Scotland (FSS) in Scotland and Defra in England) are satisfied that there is no scientific evidence base for disinfection treatments for lawfully produced Spring Water which must demonstrate that it is potable (drinkable at source without the need for any treatment to clean it).

Q5. Will you be affected by the change in policy with regard to UV treatment? If so, how?

Application of new monitoring requirements for radioactive substances laid down in Directive 2013/51/EURATOM.


37. In respect of the new monitoring obligations, the EURATOM Directive introduces a new requirement of analysis of radon and also requires Member States to:

- ensure that monitoring for radioactive substances in drinking water is undertaken;
- check whether the values of radioactive substances in drinking water comply with the parametric values stipulated in the Directive; and
- in the event of non-compliance with the parametric values for radioactive substances assess whether that non-compliance poses a risk to human health which requires action and take remedial action where necessary to improve the quality of the water in order to protect human health.

38. The EURATOM Directive makes it clear that all parameters listed in the EURATOM Directive must be subject to monitoring but does not stipulate the frequency of monitoring required. As such the frequency will need to be determined by each Member State and are to be set in line with Hazard and Critical Control Point principles (HACCP), in accordance with EU Food Hygiene Regulation 852/2004(EC).

39. Despite the general obligation on Member States under the EURATOM Directive to establish appropriate monitoring programmes for radioactive substances in drinking water, the Directive does make an exemption in paragraph 1 of Annex II:

“A Member State is not required to monitor water intended for human consumption for radon or tritium or to establish the ID where it is satisfied on the basis of representative surveys, monitoring data or other reliable information that, for a period of time to be determined by them, the levels of radon, tritium or of the calculated ID will remain below the respective parametric values listed…”

40. FSA, FSS and Defra are proposing to apply this exemption in full in the new regulations which will exempt local authorities from having to carry out monitoring of water for radioactive substances, provided they are satisfied that the levels of radon, tritium or calculated ID will remain below the specified parametric values for a certain period of time. A three year period is proposed for radiation parameters. In this case, a business producing bottled spring water or drinking water in Wales will need to present representative surveys, monitoring date or other reliable information to the Local Authority in order to prove that position. If an assessment is made that monitoring is not required, the decision must be communicated to the competent authority which will then notify the European Commission.

41. Member States are required to transpose the requirements by 28 November 2015.

Q6. Are you aware of any concerns in Wales with the issue of radon contamination in bottled water?

Q7. Do you consider that five years is an appropriate length of time to cover exemption of monitoring requirements for radiation parameters? If not, why not?

Impact Assessment

42. The FSA has prepared three separate Impact Assessments to enable focused responses by those affected by the various proposals.

i) The consolidation of Regulations including the removal of a fortification requirement that is no longer scientifically justified and a more proportionate enforcement regime.

ii) Clarification of EU Regulations on permitted treatments for Spring Water

iii) Radiation monitoring requirements

43. Details of assumptions made and the envisaged costs and benefits associated with each of the proposals are provided and the FSA would like stakeholders’ comments on whether these assumptions, costs and benefits are accurate.

Responses

44. Responses are required by close 24 August 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).

45. Thank you on behalf of the Food Standards Agency for participating in this public consultation.
Questions asked in this consultation:

**Consultation letter**

Q1. Do you agree that, as the 2013 Regulations already apply, there is no requirement to include more prescriptive requirements on sampling for bottled water?

In your response, please consider the outlined consequences.

Q2. Do you agree with the proposals for a more proportionate enforcement regime?

Q3. Are you in favour of removal of the minimum hardness provision?

Q4. Are you aware of any businesses in Wales currently fortifying water in relation to the existing regulation?

Q5. Will you be affected by the change in policy with regard to UV treatment? If so, how?

Q6. Are you aware of any concerns in Wales with the issue of radon contamination in bottled water?

Q7. Do you consider that five years is an appropriate length of time to cover exemption of monitoring requirements for radiation parameters? If not, why not?

**Impact Assessment - Consolidation**

Q IA1.1: Do you agree with the estimated size of the bottled water market in Wales.

Q IA1.2: Do you agree with the estimated costs of learning and dissemination in relation to the consolidation of regulations?
Impact Assessment - Spring Water Treatments

Q IA2.1: Is the assumption of 9 producers of Spring Water in Wales accurate?

Q IA2.2: If you did not complete the survey, please advise us of any relevant information on UV use in the production of Spring Water in Wales.

Q IA2.3 Please advise us of any costs or benefits that will result from the correct implementation of EU Regulations and the subsequent requirement to discontinue using UV decontamination in the production of Spring Water, with particular reference to

- Learning and dissemination costs
- Removal of UV equipment
- Installation of alternative compliant measures
- Re-labelling as a ‘bottled drinking water’
- Brand Value

Impact Assessment – Radiation Monitoring

Q IA3.1: Is the assumption of the size of the market in Wales accurate?

Q IA3.2: Are the assumptions on the one-off monetised costs associated with radon monitoring accurate?

Q IA3.3: Are the assumptions on the ongoing costs associated with radon monitoring accurate?

Q IA3.4: Are the assumptions on the costs to industry associated with familiarisation with regard to radon monitoring regulation accurate?

Q IA3.5: Are the assumptions on the costs to industry associated with risk assessment for Radon accurate?

Q IA3.6: Are the assumptions on the costs to Government associated with familiarisation with regard to radon monitoring regulation accurate?
Annex A – Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information 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 the FSA. However, we will take into account your views when making this decision.

4. 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

5. A list of interested parties to whom this letter is being sent appears in Annex C. 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. A Welsh version of the consultation package can be found at www.food.gov.uk

7. Please contact us if you require this consultation in an alternative format such as Braille or large print.

8. This consultation has been prepared in accordance with HM Government consultation principles21.

21 http://www.bis.gov.uk/policies/bre/consultation-guidance
The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

EXPLANATORY NOTE
(This note is not part of the Regulations)

These Regulations, which apply in Wales, implement and enforce the following European instruments—


(c) Commission 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 (OJ No L 126, 22.5.2003, p 34);

(d) Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters (OJ No L 37, 10.2.2010, p 13); and

They revoke and replace the Natural Mineral Water, Spring Water and Bottled Water (Wales) Regulations 2007 (S.I. 2007/3165) and amending instruments.

Part 1 is introductory and includes relevant definitions.

Part 2 prescribes the conditions for recognising natural mineral water. Regulation 5 enables a food authority to refuse to grant or withdraw recognition of natural mineral water and provides a right to appeal against such a decision. Part 2 also applies restrictions on exploiting natural mineral water springs as well as the treatment, bottling, marking, labelling, advertisement and sale of natural mineral water.

Part 3 applies restrictions on exploiting spring water springs and the treatment, bottling, marking, labelling, advertisement and sale of spring water.

Part 4 applies restrictions on the bottling, marking, labelling, advertisement and sale of drinking water in a bottle.

Part 5 prescribes the requirements for monitoring natural mineral water, spring water and drinking water in a bottle for the purpose of ensuring that the requirements of these Regulations are satisfied.

Regulation 27 prescribes the remedial action that must be taken by a food authority in relation to spring water and drinking water in a bottle in the event of non-compliance with the parametric values for the parameters set out in Schedule 7.

Part 6 provides for enforcement, transitional provisions, revocations and amendments to other legislation. Regulation 29 imposes an obligation on food authorities to execute and enforce the Regulations.

Regulation 30 to 32 and Schedule 10 apply certain provisions of the Food Safety Act 1990 (1990 c.16), with modifications. This includes the application (with modifications) of section 10(1), enabling an improvement notice to be served requiring compliance with specified provisions of the Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence.

Regulation 38 and Schedule 11 make amendments to the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 and the Private Water Supplies (Wales) Regulations 2010.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Food
Standards Agency at Food Standards Agency Wales, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW or from the Agency’s website at www.food.gov.uk/wales.
The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

Made ***

Laid before the National Assembly for Wales ***

Coming into force ***

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The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4)(1), 16(1)(2), 17(1)(3), 26(1) and (3)(4), 31(5) and 48(1)(6) of the Food Safety Act 1990(7) and

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(1) Section 6(4) was amended by section 31 of, and paragraph 6 of Schedule 9 to, the Deregulation and Contracting Out Act 1994 (c. 40), section 40(1) and (4) of, and paragraph 10(1) and (3) of Schedule 5 and Schedule 6 to, the Food Standards Act 1999 (c. 28) (“the 1999 Act”), and S.I. 2002/794.

(2) Section 16(1) was amended by section 40(1) of, and paragraphs 7 and 8 of Schedule 5 to, the 1999 Act.

(3) Section 17(1) was amended by section 40(1) of, and paragraphs 8 and 12(a) of Schedule 5 to, the 1999 Act, and S.I. 2011/1043.

(4) Section 26(3) was partially repealed by section 40(4) of, and Schedule 6 to, the 1999 Act.

(5) Section 31 was amended by section 40(1) of, and paragraph 8 of Schedule 5, to the 1999 Act.

(6) Section 48(1) was amended by section 40(1) of, and paragraph 8 of Schedule 5 to, the 1999 Act.

(7) 1990 c. 16. Functions formerly exercisable by “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by section
These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972(2) and it appears to the Welsh Ministers that it is expedient for the references in these Regulations to the Annexes to the Directives listed in regulation 2(3) to be construed as references to those Annexes as amended from time to time.

The Welsh Ministers have had regard to the relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990(3).

There has been consultation during the preparation and evaluation of the following Regulations, as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(4).

PART 1
Introductory

Title, commencement and application

1.—(1) The title of these Regulations is the Honey (Wales) Regulations 2015.

(2) These Regulations come into force on 28 November 2015 and apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

“the Act” (“XX”) means the Food Safety Act 1990;

“advertisement” (“XX”) means a representation in any form in connection with a trade or business in

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1 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006.
2 Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 and Part 2 of the Schedule to the European Union (Amendment) Act 2008.
3 Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.
order to promote the supply of goods, and “advertise” shall be construed accordingly;

“the Agency” (“XX”) means the Food Standards Agency;

“bottle” (“XX”) the noun, means a closed container of any kind in which water is sold for drinking by humans or from which water sold for drinking by humans is derived, and “bottle”, the verb, and cognate expressions, are to be construed accordingly;


“Directive 2003/40” (“XX”) means Commission 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(2);


“drinking water” (“XX”) means water which is intended for sale for drinking by humans other than—

(a) natural mineral water, or
(b) spring water.

“effervescent natural mineral water” (“XX”) means natural mineral water which, at source or after bottling, gives off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure;

“fluoride removal treatment” (“XX”) means—

(a) a treatment of natural mineral water or spring water with activated alumina in order to remove fluoride which is authorised in accordance with regulations 9(1)(a)(iii) or 15(1)(a)(iii) and Schedule 1, or

(2) OJ No L 126, 22.5.2003, p 34.
(4) OJ No L 296, 7.11.2013, p 12.
(b) in the case of natural mineral water or spring water brought into Wales from another part of the United Kingdom or from another EEA state, a treatment which complies with Articles 1 to 3 of Regulation 115/2010;

“natural mineral water” ("XX") means water which—

(a) is microbiologically wholesome within the meaning of Article 5 of Directive 2009/54,

(b) originates in an underground water table or deposit and emerges from a spring tapped at one or more natural or bore exits,

(c) can be clearly distinguished from drinking water on account of the following characteristics having been preserved intact because of the underground origin of the water, which has been protected from all risk of pollution—

(i) its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects, and

(ii) its original purity, and

(d) is for the time being recognised pursuant to and in accordance with regulation 4;

“ozone-enriched air treatment” ("XX") means—

(a) a treatment with ozone-enriched air which is authorised in accordance with regulations 9(1)(a)(iv) or 15(1)(a)(iv) and Schedule 2, or

(b) in the case of water brought into Wales from other parts of the United Kingdom or from another EEA State, a treatment which complies with Article 5 of Directive 2003/40, as implemented in that part of the United Kingdom or that EEA State;

“parameter” ("XX") means a property, element, organism or substance listed in the second column of any table in Part 2, Part 3 or Part 4 of Schedule 7 or Table 1 in Schedule 8;

“Regulation 115/2010” ("XX") means Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters(1);

“sell” ("XX") includes possess for sale and offer, expose or advertise for sale, and “sale” is to be construed accordingly; and

“spring water” ("XX") means water which is bottled at source and intended for sale for drinking

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(1) OJ No L 37, 10.2.2010, p 13.
by humans in its natural state other than natural mineral water.

(2) Expressions used in these Regulations that are also used in Directive 98/83, Directive 2009/54, Regulation 115/2010 or Directive 2013/51 have the same meaning in these Regulations as they have in those Directives or that Regulation.


(4) Any reference in these Regulations to the marking or labelling of a bottle includes both marking or labelling done before any water is bottled, and marking or labelling after bottling.

Exemptions

3.—(1) These Regulations do not apply to any water which—

(a) is a medicinal product within the meaning of Directive 2001/83 of the European Parliament and of the Council on the Community code relating to medicinal products for human use(1);

(b) is a natural mineral water which is used at source for curative purposes in thermal or hydromineral establishments;

(c) is not intended for sale for drinking by humans; or

(d) is a natural mineral water intended for export to a country other than an EEA State.

(2) These Regulations do not apply to packaged ice portions intended for use in cooling food.

PART 2
Natural mineral water

Recognition as natural mineral water

4.—(1) Natural mineral water may only be sold as natural mineral water if it is recognised in accordance with paragraph (2).

(2) Water is recognised as natural mineral water where—

(a) in the case of water extracted from the ground in Wales, the food authority grants

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recognition in accordance with Part 1 of Schedule 3;
(b) in the case of water extracted from the ground in another part of the United Kingdom, the responsible authority of that part of the United Kingdom recognises it pursuant to Directive 2009/54;
(c) in the case of water extracted from the ground in an EEA State other than the United Kingdom, a responsible authority of that EEA State recognises it pursuant to Directive 2009/54;
(d) in the case of water extracted from the ground in a country other than an EEA State—
   (i) the Agency grants recognition in accordance with Part 2 of Schedule 3; or
   (ii) it has an equivalent recognition, given by a responsible authority of—
      (aa) another part of the United Kingdom; or
      (bb) an EEA State other than the United Kingdom.

(3) The publication in the Official Journal of the European Union of the name of any water as a natural mineral water recognised in the Community for the purposes of Directive 2009/54 is conclusive evidence that that water is recognised for the purposes of that Directive, save where recognition is granted in accordance with Schedule 3.

Declining to grant or withdrawing recognition

5.—(1) Where, in relation to any water that has been recognised under regulation 4(2)(a) or 4(2)(d)(i) it is found that—
   (a) by analysis in accordance with Part 3 of Schedule 3, the requirements of paragraph 12 of that Part are not met;
   (b) the requirements of Schedule 4 are not met; or
   (c) the content of the water is not in accordance with paragraph 1(c) of Part 1 or, as the case may be, paragraph 5(c) of Part 2 of Schedule 3,

the food authority or, as the case may be, the Agency may withdraw that recognition until such time as the requirements concerned are met.

(2) Any person who is aggrieved by a decision of the food authority or, as the case may be, the Agency to decline to grant or withdraw recognition of a water may within 6 months of being notified of the decision appeal against it to a person appointed for the purpose by the Agency.
The appointed person must consider the appeal and any representations made by the food authority or the Agency, as appropriate, and [within 3 months] report in writing with a recommended course of action to the Agency.

(4) The Agency must either—
(a) confirm the decision together with the reasons; or
(b) direct the food authority to grant or restore, or itself restore, as appropriate, recognition of the water in question.

(5) Where the food authority is directed by the Agency under paragraph (4)(b) to grant or restore recognition, it must immediately comply with that direction.

Application to withdraw recognition

6. A person who exploits a spring from which water is extracted which is recognised as natural mineral water in accordance with regulation 4(2)(a) or 4(2)(d)(i), may apply to the food authority or to the Agency, as appropriate, to have that recognition withdrawn.

Notification of changes

7. The food authority must immediately notify the Agency if—
(a) it grants, restores or withdraws recognition of a natural mineral water; or
(b) it is notified of any change to the trade description of a natural mineral water or to the name of a spring from which natural mineral water has been extracted.

Exploitation of natural mineral water springs

8.—(1) No person may exploit a spring for the purpose of marketing the water from it as natural mineral water unless—
(a) the water extracted from that spring is natural mineral water;
(b) the food authority of the area in which the spring is located has given permission for that spring to be exploited; and
(c) the requirements of Schedule 4 are met.

(2) Where it is found during exploitation that natural mineral water is polluted and that bottling of the water would contravene paragraphs 6, 7 or 8 of Schedule 4, no person may exploit the spring from which the water is extracted until the cause of the pollution is eradicated and the bottling of the water would comply with those paragraphs.
Treatment of natural mineral water

9.—(1) No person may subject natural mineral water in its state at source to—

(a) any treatment other than—

(i) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, whether or not preceded by oxygenation, in so far as the treatment does not alter the composition of the water as regards the essential constituents which give it its properties;

(ii) the total or partial elimination of free carbon dioxide by exclusively physical methods;

(iii) a fluoride removal treatment which is authorised in accordance with Schedule 1; or

(iv) an ozone-enriched air oxidation treatment which is authorised in accordance with Schedule 2;

(b) any addition other than the introduction or the re-introduction of carbon dioxide to produce effervescent natural mineral water; or

(c) any disinfection treatment by whatever means, or, subject to paragraph (1)(b), the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water.

(2) Paragraph (1) does not prevent the use of natural mineral water in the manufacture of soft drinks.

Bottling of natural mineral water

10.—(1) No person may bottle natural mineral water—

(a) unless the requirements of Schedule 4 are met;

(b) in a container other than a container which is fitted with closures designed to avoid any possibility of adulteration or contamination; and

(c) which, at the time of bottling, contains any substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.

(2) The methods used for detection for the substances listed in Part 1 of Schedule 5 must conform to the performance characteristics for analysis specified in Part 2 of Schedule 5.
Marking and labelling of natural mineral water

11.—(1) No person may bottle natural mineral water and mark or label it with—

(a) a trade description which includes the name of a locality, hamlet or other place, unless that trade description refers to a natural mineral water, the spring of which is exploited at the place indicated by that name and is not misleading as regards the place of exploitation of the spring;

(b) a trade description which is different from the name of the spring or the place of its exploitation, unless the name of the spring or the place of exploitation is also marked or labelled on the bottle, using letters at least one and a half times the height and width of the largest of the letters used for that trade description;

(c) any indication, designation, trade mark, brand name, picture or other sign, whether figurative or not, the use of which suggests a characteristic which the water does not possess, in particular as regards its origin, the date of authorisation to exploit the spring, the results of analyses or any similar references to guarantees of authenticity;

(d) any indication other than those specified in sub-paragraphs (f) and (g) attributing to the natural mineral water properties relating to the prevention, treatment or cure of a human illness;

(e) any indication listed in the first column of the Table in Schedule 6, except where the natural mineral water meets the criterion so listed and corresponds to the indication;

(f) the indication “may be diuretic”, “XX”, or “may be laxative”, “XX”, or its equivalent in any other language, unless the natural mineral water has been assessed as possessing the property attributed by the indication in accordance with physico-chemical analysis and pharmacological, physiological or clinical examination as appropriate; or

(g) the indication “stimulates digestion”, “XX”, or “may facilitate the hepato-biliary functions”, “XX”, or its equivalent in any other language, unless the natural mineral water has been assessed as possessing the property attributed by the indication in accordance with the physico-chemical analysis and pharmacological, physiological and clinical examination.

(2) No person may bottle natural mineral water and mark or label it with a sales description other than—
(a) “natural mineral water”; or

(b) in the case of an effervescent natural mineral water, one of the following, as appropriate—

(i) “naturally carbonated natural mineral water” to describe water whose content of carbon dioxide from the spring after decanting, if any, and bottling is the same as at source, taking into account where appropriate, the reintroduction of a quantity of carbon dioxide from the same water table or deposit equivalent to that released in the course of those operations and subject to the usual technical tolerances;

(ii) “natural mineral water fortified with gas from the spring” to describe water whose content of carbon dioxide from the same water table or the same deposit after decanting, if any, and bottling is greater than that established at source; or

(iii) “carbonated natural mineral water” to describe water to which has been added carbon dioxide of an origin other than the water table or deposit from which the water comes.

(c) nothing in sub-paragraph (a) prevents a person from using the words “ŵr mwynol naturiol” in addition to the words “natural mineral water”;

(d) nothing in sub-paragraph (b) prevents the use of the words “XX” in addition to “naturally carbonated natural mineral water”, “XX” in addition to “natural mineral water fortified with gas from the spring”, “XX” in addition to “carbonated natural mineral water”; and

(e) Nothing in sub-paragraphs (a), (b), (c) or (d) prevents the use of equivalent words in any other language in addition to Welsh and English.

(3) No person may bottle natural mineral water unless the bottle is marked or labelled with—

(a) a statement of analytical composition indicating the characteristic constituents of the water;

(b) the name of the place where the spring is exploited and the name of the spring;

(c) if it has undergone the treatment of total or partial elimination of free carbon dioxide by exclusively physical methods, the indication “fully de-carbonated” or “partially de-carbonated”, as appropriate;

(d) if it has undergone an ozone-enriched air treatment, the words “water subjected to an
authorised ozone-enriched air oxidation technique”, which must appear in proximity to the analytical composition of characteristic constituents;

(e) if its fluoride concentration exceeds 1.5 mg/l—

(i) the words “contains more than 1.5 mg/l of fluoride; not suitable for regular consumption by infants and children under 7 years of age”, which must appear in immediate proximity to the trade name and in clearly visible characters; and

(ii) the actual fluoride content in relation to the physico-chemical composition, which must be included within the statement referred to in paragraph (3)(a).

(f) nothing in sub-paragraph (c) prevents the use of the indication “XX” in addition to “fully de-carbonated”, or “XX” in addition to “partially de-carbonated”;

(g) nothing in sub-paragraph (d) prevents the use of the words “XX” in addition to “water subjected to an authorised ozone-enriched air oxidation technique”;

(h) nothing in sub-paragraph (e)(i) prevents the use of the words “XX” in addition to “contains more than 1.5 mg/l of fluoride; not suitable for regular consumption by infants and children under 7 years of age”; and

(i) nothing in sub-paragraphs (c), (d), (e)(i), (f), (g) and (h) prevents the use of equivalent words in any other language in addition to Welsh and English.

Advertising of natural mineral water

12.—(1) Where in accordance with regulation 11(1)(b) a bottle containing natural mineral water is required to be marked or labelled with the name of the spring or the place of its exploitation—

(a) the same requirement also applies to any written advertisement for that natural mineral water; and

(b) in any other advertisement, at least equivalent prominence must be given to the place of exploitation or the name of the spring as is given to the trade description.

(2) No person may advertise natural mineral water in contravention of paragraph (1).

(3) No person may advertise natural mineral water under any indication, designation, trade mark, brand name, picture or other sign, whether figurative or not, the use of which suggests a characteristic which the water does not possess, in particular as regards its
origin, the date of authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity.

Sale of natural mineral water

13.—(1) No person may sell water which is bottled and marked or labelled “natural mineral water”, “dŵr mwynol naturiol”, or its equivalent in any other language, unless that water is natural mineral water recognised in accordance with regulation 4(2).

(2) No person may sell bottled natural mineral water if it—

(a) has been extracted from a spring which is exploited in contravention of regulation 8;

(b) has been subjected to any treatment or addition in contravention of regulation 9;

(c) is bottled in contravention of regulation 10;

(d) is marked or labelled in contravention of regulation 11; or

(e) is advertised in contravention of regulation 12.

(3) No person may sell bottled natural mineral water—

(a) which contains—

(i) parasites or pathogenic micro-organisms;

(ii) Escherichia coli or other coliforms and faecal streptococci in any 250ml sample examined;

(iii) sporulated sulphite-reducing anaerobes in any 50ml sample examined; or

(iv) Pseudomonas aeruginosa in any 250 ml sample examined;

(b) where the total colony count of the water at the source from which that water was taken does not comply with paragraph 7 of Schedule 4;

(c) where the revivable total colony count of that water is in excess of that which would result from the normal increase in the bacterial count which it had at source; or

(d) where that water contains any organoleptic defect.

(4) No person may sell natural mineral water from one and the same spring under more than one trade description.
PART 3

Spring water

Exploitation of spring water springs and bottling of spring water

14.—(1) No person may bottle spring water unless—
(a) the requirements of Schedule 4 are met; and
(b) that water meets the requirements of Schedule 7.

(2) Where it is found during exploitation that spring water is polluted and that bottling of the water would contravene paragraphs 6, 7 or 8 of Schedule 4, no person may exploit the spring from which the water is extracted until the cause of the pollution is eradicated and the bottling of the water would comply with those paragraphs.

Treatments and additions for spring water

15.—(1) No person may subject spring water in its state at source to—
(a) any treatment other than—
(i) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, whether or not preceded by oxygenation, in so far as the treatment does not alter the composition of the water as regards the essential constituents which give it its properties;
(ii) the total or partial elimination of free carbon dioxide by exclusively physical methods;
(iii) a fluoride removal treatment which is authorised in accordance with Schedule 1; or
(iv) an ozone-enriched air treatment which is authorised in accordance with Schedule 2;
(b) any addition other than the introduction or the re-introduction of carbon dioxide; or
(c) any disinfection treatment by whatever means, or, subject to paragraph (1)(b), the addition of bacteriostatic elements, or any other treatment likely to change the viable colony count of the spring water.

(2) Paragraph (1) does not prevent the use of spring water in the manufacture of soft drinks.

Marking and labelling of spring water

16.—(1) No person may mark or label a bottle with the description “spring water”, “XX”, or its equivalent
in any other language, unless the water contained in it—

(a) is spring water;
(b) is bottled as specified in regulation 14; and
(c) if treated, has been subjected to a permitted treatment as specified in regulation 15.

(2) No person may mark or label a bottle containing spring water with a trade description which—

(a) includes the name of a locality, hamlet or other place, unless that trade description refers to water the spring of which is exploited at the place indicated by that name and is not misleading as regards the place of exploitation of the spring; or

(b) is different from the name of the spring or the place of its exploitation unless the name of the spring or the place of its exploitation is also marked or labelled on the bottle, using letters at least one and a half times the height and width of the largest of the letters used for that trade description.

(3) No person may mark or label any bottle with the description “spring water”, “XX”, or its equivalent in any other language, unless the bottle is marked or labelled with—

(a) the name of the place where the spring is exploited;
(b) the name of the spring;
(c) if the water has undergone an ozone-enriched air treatment, the words “water subjected to an authorised ozone-enriched air oxidation technique”, which must appear in proximity to the particulars referred to in sub-paragraphs (a) and (b);
(d) nothing in sub-paragraph (c) prevents the use of the words “XX” in addition to “water subjected to an authorised ozone-enriched air oxidation technique”; and
(e) nothing in sub-paragraphs (c) or (d) prevents the use of equivalent words in any other language in addition to Welsh and English.

Advertising of spring water

17. — (1) Where in accordance with regulation 16(2)(b) a bottle containing spring water is required to be marked or labelled with the name of the spring or its place of exploitation in addition to a trade description—

(a) the same requirement also applies to any written advertisement for that spring water; and
(b) in any other advertisement, at least equivalent prominence must be given to the place of exploitation or the name of the spring as is given to the trade description.

(2) No person may advertise spring water in contravention of paragraph (1).

**Sale of spring water**

18.—(1) No person may sell spring water which is bottled or labelled “spring water”, “XX”, or its equivalent in any other language, unless that water is spring water.

(2) No person may sell spring water which—

(a) is bottled in contravention of regulation 14;
(b) has been subjected to any treatment or addition in contravention of regulation 15;
(c) is marked or labelled in contravention of regulation 16; or
(d) is advertised in contravention of regulation 17.

(3) No person may sell spring water from one and the same spring under more than one trade description.

**PART 4**

**Drinking water in a bottle**

**Bottling of drinking water**

19. No person may bottle drinking water unless that water meets the requirements of Schedule 7.

**Marking and labelling of drinking water in a bottle**

20.—(1) No person may mark or label drinking water in a bottle with—

(a) a designation, proprietary name, trade mark, brand name, illustration or other sign, whether emblematic or not, the use of which is liable to cause confusion of the water with a natural mineral water, or
(b) the description “mineral water”, “dŵr mwyol”, or its equivalent in any other language..

**Advertising of drinking water in a bottle**

21. No person may advertise drinking water in a bottle under—

(a) a designation, proprietary name, trade mark, brand name, illustration or other sign, whether emblematic or not, the use of which is liable
to cause confusion of the water with a natural mineral water, or
(b) the description “mineral water”, “dŵr mwynol”, or its equivalent in any other language.

Sale of drinking water in a bottle
22. No person may sell drinking water in a bottle which is—
(a) bottled in contravention of regulation 19; or
(b) marked or labelled in contravention of regulation 20; or
(c) advertised in contravention of regulation 21.

PART 5
Monitoring

CHAPTER 1
Natural mineral water

Monitoring of natural mineral water
23. In the case of natural mineral water, each food authority must carry out periodic checks to ensure that—
(a) the composition, temperature and other essential characteristics of the water remain stable within the limits of natural fluctuation;
(b) without prejudice to subparagraph (a), the composition, temperature and other essential characteristics of the water are unaffected by any variations in the rate of flow;
(c) the viable colony count at source (before the water is subjected to any permitted treatment) is reasonably constant, taking into account the qualitative and quantitative composition of the water considered in the recognition of the water and that it continues to satisfy the requirements of Part 1 of Schedule 3; and
(d) the requirements of Schedule 4 are met in relation to the water.

CHAPTER 2
Spring water and drinking water in a bottle

Monitoring of spring water and drinking water in a bottle
24. In the case of spring water and drinking water in a bottle, each food authority must carry out—
(a) regular monitoring in accordance with Schedule 8 to check whether the water complies with the relevant parametric values in Parts 2 and 3 of Schedule 7;

(b) regular monitoring to check whether the water complies with the relevant parametric values in Part 4 of Schedule 7; and

(c) additional monitoring, on a case-by-case basis, in relation to any property, element, substance or organism other than a parameter specified in Schedule 7, if the food authority has reason to suspect that it may be present in the water concerned in an amount or number which constitutes a potential danger to human health.

Exemptions from monitoring

25. The food authority may exclude a parameter listed in Part 4 of Schedule 7 from monitoring—

(a) if it is satisfied on the basis of representative surveys, monitoring data or other reliable information that, [for a minimum period of five years], the parameter in question is unlikely to be present in a given supply of water at a concentration or value that would exceed the relevant parametric value in Schedule 7;

(b) if it notifies the Agency of that decision and provides the Agency with a copy of the representative surveys, monitoring data or other reliable information referred to in sub-paragraph (a); and

(c) taking into account any guidance issued by the Agency.

Samples and analysis

26. For the purpose of monitoring spring water and drinking water in a bottle, each food authority must—

(a) take samples at the point at which the water is put into the bottle; and

(b) carry out sampling and analysis in accordance with Schedule 9.

Remedial action

27.—(1) If a food authority determines that spring water or drinking water in a bottle does not comply with the parametric concentrations or values set out in Schedule 7, the food authority must—

(a) immediately investigate the non-compliance in order to identify the cause;
(b) assess whether the non-compliance poses a risk to human health which requires action;
(c) require the business operator to take remedial action as soon as possible to restore the quality of the water and, where necessary, protect human health;
(d) notify the general public of the remedial action taken, unless the food authority considers that non-compliance with the parametric value is trivial; and
(e) in respect of any parameter listed in Part 4 of Schedule 7, advise the general public on any additional precautionary measures that may be needed for the protection of human health.

(2) If spring water or drinking water in a bottle constitutes a potential danger to human health, irrespective of whether it meets the relevant parametric values in Schedule 7, a food authority must—
(a) prohibit or restrict the supply of that water in its area or take such other action as is necessary to protect human health; and
(b) inform the general public promptly of that fact and provide advice where necessary.

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

CHAPTER 3
Treatments

Monitoring of certain treatments

28.—(1) Each food authority must carry out periodic checks on any fluoride removal treatment which it has authorised to ensure that the requirements of paragraph 3 of Schedule 1 continue to be satisfied.

(2) Each food authority must carry out periodic checks on any ozone-enriched air treatment which it has authorised to ensure that the requirements of paragraph 4 of Schedule 2 continue to be satisfied.

PART 6
Enforcement and miscellaneous provisions

Enforcement

29. Each food authority must execute and enforce these Regulations in its area.
Improvement notices

30.—(1) The provisions of section 10 of the Act specified in column 1 of Table 1 of Schedule 10 apply for the purpose of these Regulations, with the modifications specified in column 2 of that table to enable an authorised officer of a food authority to serve an improvement notice on any person who is failing to comply with a provision of Regulation 115/2010 mentioned in column 2 of Table 1 of Schedule 10.

(2) Paragraph (1) is without prejudice to the application of section 10 of the Act for purposes other than those specified in paragraph (1).

(3) An authorised officer of a food authority must not serve an improvement notice under section 10(1) of the Act, as applied and modified by this regulation, as read with Schedule 10 if—

(a) the improvement notice would relate to water bottled and marked or labelled before [28 November 2015]; and

(b) the matters constituting the alleged contravention would not have constituted an offence under the Regulations listed in regulation 37.

(4) If spring water or drinking water in a bottle does not meet the requirements of paragraph 1(c) of Part 1 of Schedule 7, an authorised officer of a food authority must not serve an improvement notice under section 10(1) of the Act, as applied and modified by this regulation, as read with Schedule 10 if—

(a) the water in question was bottled or sold in an EEA State other than the United Kingdom; and

(b) the water complied with the law in that EEA State when it was bottled or sold.

Powers of entry

31.—(1) The provisions of section 32 of the Act specified in column 1 of Table 2 of Schedule 10 apply for the purposes of enabling these Regulations, with the modifications specified in column 2 of that table, to enable an authorised officer of a food authority—

(a) to exercise a power of entry to ascertain whether there is, or has been, any contravention of a provision of Regulation 115/2010 mentioned in column 2 of Table 2 of Schedule 10;

(b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of such provisions; and

(c) where exercising a power of entry under the applied section 32 provisions, to exercise the
associated powers in subsections (5) and (6) relating to records.

(2) Paragraph (1) is without prejudice to the application of section 32 of the Act for purposes other than those specified in paragraph (1).

Application of other provisions of the Act

32. The provisions of the Act specified in column 1 of Table 3 of Schedule 10 apply, with the modifications specified in column 2 of that table, for the purposes of these Regulations.

Samples: general

33. The food authority must ensure that each sample is representative of the quality of the water concerned consumed throughout the year in which the sample is taken.

Samples: delivery

34.—(1) An authorised officer of a food authority who has procured a sample under section 29 of the Act and is required to give part of that sample to the owner or any other person may deliver that sample—

(a) directly to the person or the person’s agent; or

(b) by registered post or recorded delivery service.

(2) If, after reasonable enquiry, the authorised officer is unable to ascertain the name and address of the person to whom part of the sample is to be given the authorised officer may, in lieu of giving the part to that person, retain it.

Samples: notification

35.—(1) An authorised officer must serve a notice in accordance with paragraph (2) if it appears that any water, of which the authorised officer has procured a sample under section 29 of the Act for the purpose of analysis by a public analyst, was exploited or bottled by a person (not being a person to whom one part of the sample is required to be given) having a name and an address in the United Kingdom displayed on the bottle.

(2) The authorised officer must, within three days of procuring the sample, send to that person a notice informing him—

(a) that the sample has been procured by the officer; and

(b) where the sample was taken or, as the case may be, from whom it was purchased.

(3) Paragraph (1) does not apply if the authorised officer decides not to have the sample analysed.
Savings and transitional provisions

36.—(1) Any recognition of water as natural mineral water granted under the Natural Mineral Waters Regulations 1985, the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999, or the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 and subsisting on the date that these Regulations come into force shall—

(a) in the case of water extracted from the ground in Wales, be treated as if it were recognition granted by the food authority under regulation 4(2)(a); and

(b) in the case of water extracted from the ground in a county other than an EEA State, be treated as if it were recognition granted by the Agency under regulation 4(2)(d)(i).

(2) The revocation of the Regulations listed in regulation 37 does not affect the validity of any [authorisation, recognition or notification] made or given by the Agency or the food authority as the relevant authority under those Regulations, and any such authorisation, recognition or notification continues in effect.

(3) Where an application has been made under the Regulations listed in regulation 37 to a food authority for a recognition of water as natural mineral water the food authority must process that application to its conclusion as if it had been made under these Regulations.

Revocations

37. The following Regulations are revoked—

(a) The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007(1);

(b) The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2009(2);

(c) The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2010(3);

(d) The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2011(4).

(2) S.I. 2009/1897
(3) S.I. 2010/748
(4) S.I. 2011/400.
Amendments to other legislation

38.—(1) In regulation 3(a) of the Private Water Supplies (Wales) Regulations 2010(1), for “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007” substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.

(2) In Schedule 1 to the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013(2), omit the reference to “The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007”.

Name
Title of Minister, one of the Welsh Ministers
Date

(1) S.I. 2010/66.
(2) S.I. 2013/479, amended by S.I. 2013/2493.
SCHEDULE 1 Regulation 9(1)(a)(iii) and 15(1)(a)(iii)

Conditions for carrying out a fluoride removal treatment

1. No person may carry out fluoride removal treatment on natural mineral water or spring water unless that treatment is authorised by the food authority within whose area the water is extracted.

2. A person seeking authorisation to carry out fluoride removal treatment must—
   (a) apply in writing to the food authority within whose area the water is extracted;
   (b) permit representatives of that authority to examine the proposed method of treatment and place of treatment and take samples for analysis in accordance with regulation 26; and
   (c) provide such information in support of the application as is requested by the food authority.

3. The food authority must assess the application and any supporting information and must authorise the fluoride removal treatment if it is satisfied that—
   (a) Articles 1 to 3 of Regulation 115/2010 are complied with in relation to the treatment; and
   (b) the treatment does not have a disinfectant action.

4. Where the food authority decides to authorise a fluoride removal treatment pursuant to paragraph 3, it must inform the applicant in writing and state the date from which the authorisation for commercial use of the treatment has effect.

5. Where the food authority decides to refuse to authorise a fluoride removal treatment pursuant to paragraph 3, it must inform the applicant in writing, stating its reasons.

6. Where a fluoride removal treatment has been authorised pursuant to paragraph 3, the person carrying out the treatment must, for the purpose of enabling the food authority to assess whether the conditions in paragraph 3 continue to be satisfied—
   (a) permit representatives of the authority to examine the method of treatment and place of treatment and take samples for analysis in accordance with regulation 26; and
   (b) provide such information related to the treatment as is requested by the food authority.
7. Where the food authority is satisfied that the conditions specified in paragraph 3 are no longer fulfilled, it may withdraw authorisation of a fluoride removal treatment by giving the person carrying out the treatment a written notice stating the grounds for withdrawal.

8. A person wishing to carry out fluoride removal treatment may apply to the Agency for a review of a decision by a food authority when that authority has—

(a) informed an applicant under paragraph 5 of its refusal to authorise a fluoride removal treatment under paragraph 3, or

(b) withdrawn an authorisation under paragraph 7.

9. The Agency, upon receiving an application under paragraph 8, must—

(a) make such inquiries into the matter as the Agency considers appropriate;

(b) consider the results of those inquiries and any relevant facts; and

(c) either—

(i) confirm the decision; or

(ii) direct the food authority to grant or restore authorisation of a fluoride removal treatment as appropriate.

10. The food authority must immediately comply with a direction of the Agency under paragraph 9(c)(ii).

SCHEDULE 2 Regulation 9(1)(a)(iv) and 15(1)(a)(iv)

Conditions for carrying out an ozone-enriched air treatment

1. No person may carry out an ozone-enriched air treatment on natural mineral water or spring water unless—

(a) it is for the purpose of separating compounds of iron, manganese, sulphur and arsenic from water in which they occur naturally at source;

(b) prior to treatment the requirements of [paragraphs 3, 4 and 5 of Schedule 4] are satisfied; and

(c) the treatment does not have a disinfectant action.

2. An ozone-enriched air treatment must not—

(a) modify the physico-chemical composition of the water in terms of its characteristic constituents; or
(b) leave residues in the water which could pose a risk to public health, or, in the case of the substances listed below, above the levels specified.

<table>
<thead>
<tr>
<th>Treatment residue</th>
<th>Maximum limit ug/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissolved ozone</td>
<td>50</td>
</tr>
<tr>
<td>Bromate</td>
<td>3</td>
</tr>
<tr>
<td>Bromoform</td>
<td>1</td>
</tr>
</tbody>
</table>

3. A person seeking authorisation to carry out an ozone-enriched air treatment must—
   (a) make an application in writing to the food authority in whose area the water is extracted;
   (b) permit representatives of that authority to examine the proposed method of treatment, and place of treatment and take samples for analysis in accordance with regulation 26; and
   (c) provide such information in support of the application as is requested by the food authority.

4. The food authority must assess the application and any supporting information and must authorise the ozone-enriched air treatment if it is satisfied that—
   (a) the treatment process is justified by the composition of the water at source in terms of compounds of iron, manganese, sulphur and arsenic;
   (b) the person carrying out the treatment is taking all necessary measures to ensure that the treatment is effective and safe; and
   (c) the treatment otherwise complies with paragraphs 1 and 2.

5. Where the food authority decides to authorise an ozone-enriched air treatment pursuant to paragraph 4, it must inform the operator of the treatment in writing stating the date from which the authorisation for commercial use of the treatment has effect.

6. Where the food authority refuses to authorise an ozone-enriched air treatment pursuant to paragraph 4, it must inform the applicant in writing, stating its reasons.

7. Where an ozone-enriched air treatment has been authorised pursuant to paragraph 4, the person carrying out the treatment must, for the purpose of enabling the food authority to assess whether the conditions in paragraph 4(a) and (b) continue to be satisfied—
   (a) permit representatives of the authority to examine the method of treatment and place of treatment and take samples for analysis in accordance with regulation 26; and
(b) provide such information related to the treatment as is requested by the food authority.

8. The food authority may withdraw authorisation of an ozone-enriched air treatment if it is satisfied that the conditions specified in paragraph 4 are no longer fulfilled, by giving the person operating the treatment a written notice stating the grounds for withdrawal.

9. A person wishing to carry out treatment may apply to the Agency for a review of a decision made by the food authority to—
   (a) refuse to authorise a treatment under paragraph 4, or
   (b) withdraw authorisation of a treatment under paragraph 8,
upon being informed of that decision under paragraph 6 or paragraph 8.

10. The Agency, upon receiving an application under paragraph 9, must—
   (a) make such inquiries into the matter as the Agency considers appropriate;
   (b) consider the results of those inquires and any relevant facts; and
   (c) either—
       (i) confirm the decision; or
       (ii) direct the food authority to grant or restore authorisation of an ozone-enriched air treatment as appropriate.

11. The food authority must immediately comply with a direction of the Agency under paragraph 10(c)(ii).

SCHEDULE 3 Regulations 4(2)(a), 4(2)(d)(i) and 5(1)(a)

Recognition of natural mineral water

PART 1

Natural mineral water extracted from the ground in Wales

1. A person seeking to have water which is extracted from the ground in Wales recognised as natural mineral water for the purposes of Article 1 of Directive 2009/54 must apply in writing to the food authority within whose area the water is extracted, giving the following particulars—
   (a) those specified in paragraph 10 of Part 3;
(b) any other information showing that the matters specified in paragraphs 11 and 12, as read with paragraph 13 of Part 3 are established; and

c) such evidence as is satisfactory to show that the water contains no substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.

2. In so far as particulars of the anions, cations, non-ionised compounds or trace elements specified in the first column of the tables in Part 4 of this Schedule are required to be given pursuant to sub-paragraph (b) of paragraph 1, the concentration of each such anion, cation, non-ionised compound or trace element must be expressed in those particulars in the unit of measurement specified opposite to it in the second column of the tables in that Part.

3. Where such particulars have been given, the food authority must assess them and must recognise the water to which the particulars relate as natural mineral water if it is satisfied that—

(a) the water is natural mineral water which complies with paragraph 3 of Section 1 of Annex I of Directive 2009/54;

(b) the characteristics of the water have been assessed in accordance with—

(i) the points numbered 1 to 4 set out in paragraph 2(a) of Section 1 of Annex I of Directive 2009/54,

(ii) the requirements and criteria listed in Part 3 of this Schedule / Section II of Annex I of Directive 2009/54 , and

(iii) recognised scientific methods.

4. The food authority must, on recognising a natural mineral water in accordance with paragraph 3, publish an announcement of such recognition and the grounds on which it has been granted in the London Gazette.

PART 2

Natural mineral water extracted from the ground in a country other than an EEA State

5. A person seeking to have a water which is extracted from the ground in a country other than an EEA State recognised as a natural mineral water for the purposes of Article 1 of Directive 2009/54 must apply in writing to the Agency, giving the following particulars—

(a) those specified in paragraph 10 of Part 3;
(b) any other information showing that the matters specified in paragraphs 11 and 12, as read with paragraph 13, of Part 3 are established; and

(c) such evidence as is satisfactory to show that the water contains no substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.

6. In so far as particulars of any of the anions, cations, non-ionised compounds or trace elements specified in the first column of the tables in Part 4 of this Schedule are required to be given pursuant to sub-paragraph (b) of paragraph 5 the concentration of each such anion, cation, non-ionised compound or trace element must be expressed in those particulars in the unit of measurement specified opposite to it in the second column of the tables in that Part.

7. The Agency must recognise such a water if the responsible authority of the country in which the water is extracted has certified that—

(a) it is satisfied—

(i) that the requirements in paragraphs 11 and 12 of Part 3 are established,

(ii) with the evidence given pursuant to sub-paragraph (c) of paragraph 1; and

(b) periodic checks are made to ascertain that—

(i) the water is natural mineral water which complies with paragraph 3 of Section I of Annex I of Directive 2009/54;

(ii) the characteristics of the water are assessed in accordance with—

(aa) points numbered 1 to 4 set out in paragraph 2(a) of Section I of Annex I of Directive 2009/54;

(bb) the requirements and criteria listed in [Part 3/Section II of Annex I of Directive 2009/54]; and

(cc) recognised scientific methods, and

(iii) the provisions of Schedule 4 are being applied by the person exploiting the spring.

8. Recognition of such water lapses after a period of five years unless the responsible authority of the country in which the water is extracted has renewed the certification required by paragraph 7.

9. The Agency must, on recognising water in accordance with this Part of this Schedule publish an announcement of such recognition in the [London Gazette, the Edinburgh Gazette and the Belfast Gazette].
PART 3
Requirements and criteria for recognition as a natural mineral water

10. Geological and hydrological surveys must include the following particulars—
   (a) the exact site of the catchment with an indication of its altitude, on a map with a scale of not more than 1:1,000;
   (b) a detailed geological report on the origin and nature of the terrain;
   (c) the stratigraphy of the hydrogeological layer;
   (d) a description of the catchment operations; and
   (e) the demarcation of the area or details of other measures protecting the spring against pollution.

11. Physical, chemical and physico-chemical surveys must establish—
   (a) the rate of flow of the spring;
   (b) the temperature of the water at source and the ambient temperature;
   (c) the relationship between the nature of the terrain and the nature and type of minerals in the water;
   (d) the dry residues at 180°C and 260°C;
   (e) the electrical conductivity or resistivity, with the measurement temperature being specified;
   (f) the hydrogen ion concentration (pH);
   (g) the anions and cations;
   (h) the non-ionised elements;
   (i) the trace elements;
   (j) the radio-actinological properties at source;
   (k) where appropriate, the relative isotope levels of the constituent elements of water, oxygen (16O–18O) and hydrogen (protium, deuterium, tritium); and
   (l) the toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.

12. Microbiological analysis at source must show—
   (a) the absence of parasites and pathogenic micro-organisms;
   (b) quantitative determination of the revivable colony count indicative of faecal contamination, demonstrating an absence of—
      (i) *Escherichia coli* and other coliforms in 250ml at 37°C and 44.5°C,
      (ii) faecal streptococci in 250 ml,
(iii) sporulated sulphite-reducing anaerobes in 50ml, and

(iv) *Pseudomonas aeruginosa* in 250 ml; and

(c) the revivable total colony count per ml of water—

(i) at 20 to 22ºC in 72 hours on agar-agar or an agar-gelatine mixture, and

(ii) at 37ºC in 24 hours on agar-agar.

13.—(1) Subject to sub-paragraph (2), clinical and pharmacological analyses must be carried out in accordance with scientifically recognised methods and should be suited to the particular characteristics of the natural mineral water and its effect on the human organism, such as diuresis, gastric and intestinal functions, compensation for mineral deficiencies.

(2) Clinical analyses may, in appropriate cases, take the place of analyses referred to in sub-paragraph (1), provided that the consistency and concordance of a substantial number of observations enable the same results to be obtained.

**PART 4**

Particulars of anions, cations, non-ionised compounds and trace elements

**Table A**

<table>
<thead>
<tr>
<th>Anions</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Borate BO$_3^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Carbonate CO$_3^{2-}$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Chloride Cl$^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Fluoride F$^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Hydrogen Carbonate HCO$_3^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Nitrate NO$_3^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Nitrite NO$_2^-$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Phosphate PO$_4^{3-}$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Silicate SiO$_2^{2-}$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Sulphate SO$_4^{2-}$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Sulphide S$^{2-}$</td>
<td>mg/l</td>
</tr>
</tbody>
</table>

**Table B**

<table>
<thead>
<tr>
<th>Cations</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium Al</td>
<td>mg/l</td>
</tr>
<tr>
<td>Ammonium NH$_4^+$</td>
<td>mg/l</td>
</tr>
<tr>
<td>Calcium Ca</td>
<td>mg/l</td>
</tr>
<tr>
<td>Magnesium Mg</td>
<td>mg/l</td>
</tr>
<tr>
<td>Potassium K</td>
<td>mg/l</td>
</tr>
<tr>
<td>Sodium Na</td>
<td>mg/l</td>
</tr>
</tbody>
</table>
Table C

<table>
<thead>
<tr>
<th>Non-ionised compounds</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total organic carbon C</td>
<td>mg/l</td>
</tr>
<tr>
<td>Free carbon dioxide CO₂</td>
<td>mg/l</td>
</tr>
<tr>
<td>Silica SiO₂</td>
<td>mg/l</td>
</tr>
</tbody>
</table>

Table D

<table>
<thead>
<tr>
<th>Trace elements</th>
<th>Unit of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium Ba</td>
<td>µg/l</td>
</tr>
<tr>
<td>Bromine (total) Br</td>
<td>µg/l</td>
</tr>
<tr>
<td>Cobalt Co</td>
<td>µg/l</td>
</tr>
<tr>
<td>Copper Cu</td>
<td>µg/l</td>
</tr>
<tr>
<td>Iodine (total) I</td>
<td>µg/l</td>
</tr>
<tr>
<td>Iron Fe</td>
<td>µg/l</td>
</tr>
<tr>
<td>Lithium Li</td>
<td>µg/l</td>
</tr>
<tr>
<td>Manganese Mn</td>
<td>µg/l</td>
</tr>
<tr>
<td>Molybdenum Mo</td>
<td>µg/l</td>
</tr>
<tr>
<td>Strontium Sr</td>
<td>µg/l</td>
</tr>
<tr>
<td>Zinc Zn</td>
<td>µg/l</td>
</tr>
</tbody>
</table>

SCHEDULE 4 Regulations 5 and 14

Exploitation and bottling requirements for natural mineral water and spring water

1. Equipment for exploiting the water must be so installed as to avoid any possibility of contamination and to preserve the properties corresponding to those ascribed to it which the water possesses at source.

2. The spring or outlet must be protected against the risks of pollution.

3. The catchment, pipes and reservoirs must be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water.

4. The conditions of exploitation, particularly the washing and bottling equipment, must meet hygiene requirements. In particular, the containers must be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the water.

5.—(1) Subject to sub-paragraphs (2) and (3), water must not be transported in containers other than those authorised for distribution to the ultimate consumer.

(2) Natural mineral water may be transported from the spring to the bottling plant in a container which is not for distribution to the ultimate consumer if on or
before 17 July 1980 water from that spring was so transported.

(3) Water distributed to the ultimate consumer in a bottle marked or labelled with the description “spring water” may be transported from the spring to the bottling plant in a container which is not for distribution to the ultimate consumer if, on or before 13 December 1996, water from that spring was so transported.

6.—(1) The revivable total colony count of the water at source, determined according to sub-paragraph (2), must conform to the normal viable colony count of that water and must not show that the source of that water is contaminated.

(2) The colony count is that determined per ml of water—

(a) at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture; and

(b) at 37°C in 24 hours on agar-agar.

7.—(1) After bottling, the total colony count of the water at source may not exceed—

(a) 100 per ml at 20 to 22°C in 72 hours on agar-agar or on agar-gelatine mixture; and

(b) 20 per ml at 37°C in 24 hours on agar-agar.

(2) The total colony count must be measured within the period of 12 hours following bottling, the water being maintained at 4°C +/- 1°C during the period before which it is measured.

8. Water must be free from—

(a) parasites and pathogenic micro-organisms;

(b) Escherichia coli and other coliforms and faecal streptococci in any 250 ml sample examined;

(c) sporulated sulphite-reducing anaerobes in any 50ml sample examined; and

(d) Pseudomonas aeruginosa in any 250 ml sample examined.
SCHEDULE 5 Regulation 10
Constituents of natural mineral water

PART 1
Maximum limits for constituents of natural mineral water

<table>
<thead>
<tr>
<th>Constituents</th>
<th>Maximum limits (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimony</td>
<td>0.0050</td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.010 (as total)</td>
</tr>
<tr>
<td>Barium</td>
<td>1.0</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.003</td>
</tr>
<tr>
<td>Chromium</td>
<td>0.050</td>
</tr>
<tr>
<td>Copper</td>
<td>1.0</td>
</tr>
<tr>
<td>Cyanide</td>
<td>0.070</td>
</tr>
<tr>
<td>Fluoride</td>
<td>5.0</td>
</tr>
<tr>
<td>Lead</td>
<td>0.010</td>
</tr>
<tr>
<td>Manganese</td>
<td>0.50</td>
</tr>
<tr>
<td>Mercury</td>
<td>0.0010</td>
</tr>
<tr>
<td>Nickel</td>
<td>0.020</td>
</tr>
<tr>
<td>Nitrate</td>
<td>50</td>
</tr>
<tr>
<td>Nitrite</td>
<td>0.1</td>
</tr>
<tr>
<td>Selenium</td>
<td>0.010</td>
</tr>
</tbody>
</table>

Note
1. The constituents described above refer to constituents naturally present in the water at source and not to substances present as the result of contamination.
PART 2
Performance characteristics for analysing the constituents in Part 1

<table>
<thead>
<tr>
<th>Constituents</th>
<th>Accuracy of parametric value in %</th>
<th>Precision of parametric value</th>
<th>Detection limit of parametric value in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimony</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Arsenic</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Barium</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Cadmium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Chromium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Copper</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Cyanide</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Fluoride</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Lead</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Manganese</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Mercury</td>
<td>20</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Nickel</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Nitrate</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Nitrite</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Selenium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

Notes

1. The method of analysis used to measure the concentration of the constituents in Part 1 must be capable of measuring concentrations equal to the parametric value with the specified accuracy, precision and detection limits.

2. Regardless of the sensitivity of the method of analysis, the result must be expressed to at least the same number of decimal places as the maximum limit set out in Part 1 for the particular constituent being analysed.

3. Accuracy is the systematic error and represents the difference between the average value of a large number of repeated measurements and the exact value.

4. Precision represents the random error and is expressed in general as the standard deviation (within a batch and between batches) of a sample of results from the average.

5. Acceptable precision is equal to twice the relative standard deviation.

6. The detection limit is—
   (a) three times the relative standard deviation within a batch of a natural sample containing a low concentration of the constituent; or
   (b) five times the relative standard deviation within a batch of a virgin sample.

7. The method should make it possible to determine cyanide in all its forms.
### SCHEDULE 6 Regulation 11(1)(e)
Labelling indications for natural mineral water

<table>
<thead>
<tr>
<th>Indication</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low mineral content</td>
<td>Mineral salt content, calculated as a fixed residue, not greater than 500 mg/l</td>
</tr>
<tr>
<td>Very low mineral content</td>
<td>Mineral salt content, calculated as a fixed residue, not greater than 50 mg/l</td>
</tr>
<tr>
<td>Rich in mineral salts</td>
<td>Mineral salt content, calculated as a fixed residue, greater than 1500 mg/l</td>
</tr>
<tr>
<td>Contains bicarbonate</td>
<td>Bicarbonate content greater than 600 mg/l</td>
</tr>
<tr>
<td>Contains sulphate</td>
<td>Sulphate content greater than 200 mg/l</td>
</tr>
<tr>
<td>Contains chloride</td>
<td>Chloride content greater than 200 mg/l</td>
</tr>
<tr>
<td>Contains calcium</td>
<td>Calcium content greater than 150 mg/l</td>
</tr>
<tr>
<td>Contains magnesium</td>
<td>Magnesium content greater than 50 mg/l</td>
</tr>
<tr>
<td>Contains fluoride</td>
<td>Fluoride content greater than 1 mg/l</td>
</tr>
<tr>
<td>Contains iron</td>
<td>Bivalent iron content greater than 1 mg/l</td>
</tr>
<tr>
<td>Acidic</td>
<td>Free carbon dioxide content greater than 250 mg/l</td>
</tr>
<tr>
<td>Contains sodium</td>
<td>Sodium content greater than 200 mg/l</td>
</tr>
<tr>
<td>Suitable for a low-sodium diet</td>
<td>Sodium content less than 20 mg/l</td>
</tr>
</tbody>
</table>
Requirements for spring water and drinking water in a bottle including prescribed concentrations or values of parameters

PART 1

Requirements for spring water and drinking water in a bottle

1. Water satisfies the requirements of this Schedule if—
   (a) the water does not contain—
       (i) any micro-organism (other than a parameter) or parasite, or
       (ii) any property, element or substance (other than a parameter),
       at a concentration or value which would constitute a potential danger to human health.
   (b) the water does not contain any substance (whether or not a parameter) at a concentration or value which, in conjunction with any other property, element, substance or organism it contains (whether or not a parameter), would constitute a potential danger to human health; and
   (c) the water does not contain concentrations or values of any of the parameters listed in the Tables in Part 2, Part 3 and Part 4 of this Schedule in excess of the prescribed concentrations or values.

2. The concentrations or values of the parameters listed in the Tables in Part 2, Part 3 and Part 4 of this Schedule must be read in conjunction with the notes thereto.
**PART 2**

Parametric values for microbiological and chemical parameters

**Table A: Microbiological Parameters**

<table>
<thead>
<tr>
<th>Item</th>
<th>Parameter</th>
<th>Units of Measurement</th>
<th>Maximum Concentration or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><em>Escherichia coli</em> (<em>E. coli</em>)</td>
<td>number/250 ml</td>
<td>0/250 ml</td>
</tr>
<tr>
<td>2.</td>
<td>Enterococci</td>
<td>number/250 ml</td>
<td>0/250 ml</td>
</tr>
<tr>
<td>3.</td>
<td><em>Pseudomonas aeruginosa</em></td>
<td>number/250 ml</td>
<td>0/250 ml</td>
</tr>
<tr>
<td>4.</td>
<td>Colony count 22°C</td>
<td>number/ml</td>
<td>100/ml (notes 1 and 2)</td>
</tr>
<tr>
<td>5.</td>
<td>Colony count 37°C</td>
<td>number/ml</td>
<td>20/ml (notes 1 and 3)</td>
</tr>
</tbody>
</table>

**Notes**

1. The total viable colony count should be measured within 12 hours of bottling, with the sample water being kept at a constant temperature during that 12 hour period. Any increase in the total viable colony count of the water between 12 hours after bottling and the time of sale should not be greater than that normally expected.

2. In 72 hours on agar-agar or an agar-gelatine mixture.

3. In 24 hours on agar-agar.

**Table B: Chemical Parameters**

<table>
<thead>
<tr>
<th>Item</th>
<th>Parameter</th>
<th>Units of Measurement</th>
<th>Maximum Concentration or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acrylamide</td>
<td>µg/l</td>
<td>0.10 (note 1)</td>
</tr>
<tr>
<td>2.</td>
<td>Antimony</td>
<td>µg Sb/l</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>Arsenic</td>
<td>µg As/l</td>
<td>10</td>
</tr>
<tr>
<td>4.</td>
<td>Benzene</td>
<td>µg/l</td>
<td>1.0</td>
</tr>
<tr>
<td>5.</td>
<td>Benzo (a) pyrene</td>
<td>µg/l</td>
<td>0.010</td>
</tr>
<tr>
<td>6.</td>
<td>Boron</td>
<td>mg/l</td>
<td>1.0</td>
</tr>
<tr>
<td>7.</td>
<td>Bromate</td>
<td>µg/l BrO₃/l</td>
<td>10</td>
</tr>
<tr>
<td>8.</td>
<td>Cadmium</td>
<td>µg Cd/l</td>
<td>5</td>
</tr>
<tr>
<td>9.</td>
<td>Chromium</td>
<td>µg Cr/l</td>
<td>50</td>
</tr>
<tr>
<td>10.</td>
<td>Copper</td>
<td>mg Cu/l</td>
<td>2</td>
</tr>
<tr>
<td>11.</td>
<td>Cyanide</td>
<td>µg CN/l</td>
<td>50</td>
</tr>
<tr>
<td>12.</td>
<td>1,2-dichloroethane</td>
<td>µg/l</td>
<td>3.0</td>
</tr>
<tr>
<td>13.</td>
<td>Epichlorohydrin</td>
<td>µg/l</td>
<td>0.10 (note 1)</td>
</tr>
<tr>
<td>14.</td>
<td>Fluoride</td>
<td>mg F/l</td>
<td>1.5</td>
</tr>
<tr>
<td>15.</td>
<td>Lead</td>
<td>µg Pb/l</td>
<td>10</td>
</tr>
<tr>
<td>16.</td>
<td>Mercury</td>
<td>µg Hg/l</td>
<td>1</td>
</tr>
<tr>
<td>17.</td>
<td>Nickel</td>
<td>µg Ni/l</td>
<td>20</td>
</tr>
<tr>
<td>18.</td>
<td>Nitrate</td>
<td>mg NO₃/l</td>
<td>50 (note 2)</td>
</tr>
<tr>
<td>19.</td>
<td>Nitrite</td>
<td>mg NO₂/l</td>
<td>0.5 (note 2)</td>
</tr>
<tr>
<td>20.</td>
<td>Pesticides and related products:</td>
<td>µg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- individual substances</td>
<td>µg/l</td>
<td>0.10 (notes 3 and 4)</td>
</tr>
<tr>
<td></td>
<td>- total substances</td>
<td>µg/l</td>
<td>0.50 (notes 3 and 5)</td>
</tr>
<tr>
<td>21.</td>
<td>Polycyclic aromatic Hydrocarbons</td>
<td>µg/l</td>
<td>0.1 sum of concentrations of specified compounds</td>
</tr>
</tbody>
</table>
22. Selenium µg Se/l 10
23. Tetrachloroethene and Trichloroethene µg/l 10 (note 7)
24. Trichloromethane, Dichlororbromomethane, Dibromochloromethane and Tribromomethane µg/l 100 (note 7)
25. Vinyl chloride µg/l 0.50 (note 1)

Notes

1. The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

2. The concentration (mg/l) of nitrate divided by 50 added to the concentration (mg/l) of nitrite divided by 3 must not exceed 1.

3. “Pesticides” means:
   — organic insecticides,
   — organic herbicides,
   — organic fungicides,
   — organic nematocides,
   — organic acaricides,
   — organic algicides,
   — organic rodenticides,
   — organic slimicides, and
   — related products (inter alia, growth regulators) and their relevant metabolites, degradation and reaction products.

Only those pesticides which are likely to be present in a given water need to be monitored.

4. The maximum concentration applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the maximum concentration is 0.030 µg/l.

5. The maximum concentration for “total substances” refers to the sum of the concentrations of all individual pesticides detected and quantified in the monitoring procedure.

6. The specified compounds are benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(ghi)perylene, indeno(1,2,3-cd) pyrene.

7. The maximum concentration specified applies to the sum of the concentrations of the specified parameters.

PART 3

Parametric values for indicator parameters

<table>
<thead>
<tr>
<th>Item</th>
<th>Parameter</th>
<th>Units of Measurement</th>
<th>Maximum Concentration or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Aluminium</td>
<td>µg/l</td>
<td>200</td>
</tr>
<tr>
<td>2.</td>
<td>Ammonium</td>
<td>mg/l</td>
<td>0.50</td>
</tr>
<tr>
<td>3.</td>
<td>Chloride</td>
<td>mg/l</td>
<td>250 (note 1)</td>
</tr>
<tr>
<td>4.</td>
<td>Clostridium perfringens</td>
<td>number/100ml</td>
<td>0 (note 2)</td>
</tr>
<tr>
<td>Item</td>
<td>Parameter</td>
<td>Unit of Measurement</td>
<td>Maximum Concentration or Value</td>
</tr>
<tr>
<td>------</td>
<td>-----------</td>
<td>---------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>5.</td>
<td>Colour</td>
<td>Mg/1 Pt/Co scale</td>
<td>20</td>
</tr>
<tr>
<td>6.</td>
<td>Conductivity</td>
<td>μS cm⁻¹ at 20°C</td>
<td>2500 (note 1)</td>
</tr>
<tr>
<td>7.</td>
<td>Hydrogen ion concentration</td>
<td>pH units</td>
<td>4.5 (minimum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>9.5 (maximum) (note 1)</td>
</tr>
<tr>
<td>8.</td>
<td>Iron</td>
<td>μg/l</td>
<td>200</td>
</tr>
<tr>
<td>9.</td>
<td>Manganese</td>
<td>μg/l</td>
<td>50</td>
</tr>
<tr>
<td>10.</td>
<td>Odour</td>
<td>Dilution number</td>
<td>3 at 25°C</td>
</tr>
<tr>
<td>11.</td>
<td>Oxidisability</td>
<td>mg/l O₂</td>
<td>5 (note 3)</td>
</tr>
<tr>
<td>12.</td>
<td>Sulphate</td>
<td>mg/l</td>
<td>250 (note 1)</td>
</tr>
<tr>
<td>13.</td>
<td>Sodium</td>
<td>mg/l</td>
<td>200</td>
</tr>
<tr>
<td>14.</td>
<td>Taste</td>
<td>Dilution number</td>
<td>3 at 25°C</td>
</tr>
<tr>
<td>15.</td>
<td>Colony Count 22°</td>
<td>No abnormal change</td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Coliform bacteria</td>
<td>number/250ml</td>
<td>0</td>
</tr>
<tr>
<td>17.</td>
<td>Total Organic Carbon</td>
<td>No abnormal change</td>
<td></td>
</tr>
<tr>
<td>18.</td>
<td>Turbidity</td>
<td>Acceptable to consumers and no abnormal change</td>
<td></td>
</tr>
</tbody>
</table>

Notes

1. The water must not be aggressive.
2. Necessary only if the water originates from or is influenced by surface water.
3. This parameter need not be measured if the TOC is analysed.
4. This parameter need not be measured for supplies of less than 10 000m³ a day.

PART 4
Parametric values for radon, tritium and ID

Table D:

<table>
<thead>
<tr>
<th>Item</th>
<th>Parameter</th>
<th>Unit of Measurement</th>
<th>Maximum Concentration or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Radon</td>
<td>Bq/l</td>
<td>100 (Note 1)</td>
</tr>
<tr>
<td>2.</td>
<td>Tritium</td>
<td>Bq/l</td>
<td>100 (Note 2)</td>
</tr>
<tr>
<td>3.</td>
<td>Indicative Dose</td>
<td>mSv</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Notes

1. Remedial action is deemed to be justified on radiological protection grounds, without further consideration, where radon concentrations exceed 1000 Bq/l
2. Elevated levels of tritium may indicate the presence of other artificial radionuclides. If the tritium concentration exceeds its parametric value, an analysis of the presence of other artificial radionuclides is required.
SCHEDULE 8  Regulation 24(a)

Monitoring of spring water and drinking water in a bottle

PART 1

Check monitoring

Sampling

1. A food authority must undertake check monitoring in accordance with this Part.

2. Check monitoring means sampling spring water and drinking water in a bottle for each parameter listed in Table 1 in the circumstances listed in that table in order—

(a) to determine whether the water complies with the parametric concentrations or values in Schedule 7;

(b) to provide information on the organoleptic and microbiological quality of the water; and

(c) in the case of drinking water in a bottle, to establish the effectiveness of the treatment of the water, including disinfection.

Table 1

<table>
<thead>
<tr>
<th>Volume of water produced for offering for sale in bottles or containers each day (m³)</th>
<th>Circumstances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium</td>
<td>Necessary only when used as flocculant.</td>
</tr>
<tr>
<td>Ammonium</td>
<td>In all supplies</td>
</tr>
<tr>
<td>Colour</td>
<td>In all supplies</td>
</tr>
<tr>
<td>Conductivity</td>
<td>In all supplies</td>
</tr>
<tr>
<td>Clostridium perfringens (including spores)</td>
<td>Necessary only if the water originates from or is influenced by surface water.</td>
</tr>
<tr>
<td>Escherichia coli (E. Coli)</td>
<td>In all supplies</td>
</tr>
<tr>
<td>Hydrogen ion concentration</td>
<td>In all supplies</td>
</tr>
<tr>
<td>Iron</td>
<td>Necessary only when used as flocculant.</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Necessary only when chloramination is used as a disinfectant.</td>
</tr>
</tbody>
</table>
Odour In all supplies
*Pseudomonas aeruginosa* In all supplies
Taste In all supplies
Colony count 22ºC and 37ºC In all supplies
Coliform bacteria In all supplies
Turbidity In all supplies

**Frequency of sampling**

3. Sampling must be carried out at frequencies specified in Table 2.

**Table 2**

<table>
<thead>
<tr>
<th>Volume of water produced for offering for sale in bottles or containers each day (m³)(1)</th>
<th>Number of samples per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 10</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 10 ≥ 60</td>
<td>12</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>1 for each 5 m³ and part thereof of the total volume</td>
</tr>
</tbody>
</table>

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

**PART 2**

Audit monitoring

**Sampling**

4.—(1) A food authority must undertake audit monitoring in accordance with this Part.

(2) Audit monitoring means sampling spring water and drinking water in a bottle for each parameter listed in Part 2 and 3 of Schedule 7 (other than parameters already being sampled under check monitoring) in order to—

(a) provide the information necessary to determine whether the water complies with the parametric concentrations or values in Schedule 7; and

(b) check that, if disinfection is used in the case of drinking water in a bottle, disinfection by-products are kept as low as possible without compromising disinfection.

**Frequency of sampling**

5. Sampling must be carried out at frequencies specified in Table 3.
Table 3

<table>
<thead>
<tr>
<th>Volume of water produced for offering for sale in bottles or containers (m$^3$)</th>
<th>Number of samples per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 10</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 10 ≥ 60</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>1 for each 100 m$^3$ and part thereof of the total volume</td>
</tr>
</tbody>
</table>

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

SCHEDULE 9 Regulation 26(b)

Sampling and analysis

PART 1

General

Analysis of samples

1.—(1) The food authority must ensure that each sample is analysed in accordance with this paragraph.

(2) For each parameter specified in the first column of Table 1 in Part 2 of this Schedule the method of analysis is specified in the second column of that table.

(3) For each parameter specified in the first column of Table 2 in Part 2 of this Schedule the method is one that is capable of—

(a) measuring concentrations and values with the trueness and precision specified in the second and third columns of that table; and

(b) detecting the parameter at the limit of detection specified in the fourth column of that table.

(4) For hydrogen ion, the method of analysis must be capable of measuring a value with a trueness of 0.2pH unit and a precision of 0.2 pH unit.

(5) The method of analysis used for odour and taste parameters must be capable of measuring values equal to the parametric value with a precision of 1 dilution number at 25 ºC.

(6) For these purposes—

“limit of detection” (“XX”) is—

(a) three times the relative within-batch standard deviation of a natural sample containing a low concentration of the parameter; or
(b) five times the relative within-batch standard deviation of a blank sample;

“precision” (“XX”) (the random error) is twice the standard deviation (within a batch and between batches) of the spread of results about the mean;

“trueness” (“XX”) (the systematic error) is the difference between the mean value of the large number of repeated measurements and the true value.

Authorisation of alternative methods of analysis

2.—(1) The Agency may authorise a method different from that set out in paragraph 1 if satisfied that it is at least as reliable.

(2) An authorisation may be time-limited and may be revoked at any time.

Sampling and analysis by persons other than food authorities

3.—(1) A food authority may enter into an arrangement for any person to take and analyse samples on its behalf.

(2) A food authority must not enter into an arrangement under paragraph (1) unless—

(a) it is satisfied that the task will be carried out promptly by a person competent to perform it; and

(b) it has made arrangements that ensure that any breach of these Regulations is communicated to it immediately, and any other result is communicated to it within 28 days.
PART 2
Analytical methods

Table 4
Prescribed methods of analysis

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium perfringens</em> (including spores)</td>
<td>Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar* at 44 ±1°C for 21± 3 hours. Count opaque yellow colonies that turn pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.</td>
</tr>
<tr>
<td>Coliform bacteria</td>
<td>BS-EN ISO 9308-1</td>
</tr>
<tr>
<td>Colony count 22°C – enumeration of culturable microorganisms</td>
<td>BS-EN ISO 6222</td>
</tr>
<tr>
<td>Colony count 37°C – enumeration of culturable microorganisms</td>
<td>BS-EN ISO 6222</td>
</tr>
<tr>
<td>Enterococci</td>
<td>BS-EN ISO 7899-2</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (<em>E. Coli</em>)</td>
<td>BS-EN ISO 9308-1</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>BS-EN ISO 12780</td>
</tr>
</tbody>
</table>

*Use the following method to make m-CP agar:

Make a basal medium consisting of—
- Tryptose: 30.0g
- Yeast extract: 20.0g
- Sucrose: 5.0g
- L-cysteine hydrochloride: 1.0g
- MgSO₄.7H₂O: 0.1g
- Bromocresol purple: 40.0mg
- Agar: 15.0g
- Water: 1,000.0ml

Dissolve the ingredients of basal medium, adjust pH to 7.6 and autoclave at 121 ºC for 15 minutes. Allow the medium to cool.

Dissolve—
- D-cycloserine: 400.0mg
- Polymyxine-B sulphate: 25.0mg
- Indoxl-b-D-glucoside: 60.0mg

into sterile water and add it to the medium.

Add to the medium—
- Filter-sterilised 0.5% phenolphthalein diphosphate solution: 20.0ml
- Filter-sterilised 4.5% FeCl₃.6H₂O: 2.0ml
Table 5
Prescribed performance characteristics for methods of analysis

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Trueness % of prescribed concentration or value specification</th>
<th>Precision % of prescribed concentration or value specification</th>
<th>Limit of detection % of prescribed concentration or value specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Ammonium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Antimony</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Arsenic</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Benzene</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Benzo(a)pyrene</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Boron</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Bromate</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Cadmium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Chloride</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Chromium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Colour</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Conductivity</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Copper</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Cyanide(i)</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>1,2-dichloroethane</td>
<td>25</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>Fluoride</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Iron</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Lead</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Manganese</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Mercury</td>
<td>20</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Nickel</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Nitrate</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Nitrite</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Pesticides and related products(ii)</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Polycyclic aromatic hydrocarbons(iii)</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Selenium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Sodium</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Sulphate</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Tetrachloroethene(iv)</td>
<td>25</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>Tetrachloromethane</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Trichloroethene(iv)</td>
<td>25</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>Trihalomethanes</td>
<td>25</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>Total:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turbidity(i)</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Turbidity(vi)</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

Notes:

(i) The method of analysis should determine total cyanide in all forms.

(ii) The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned.
(ii) The performance characteristics apply to the individual substances specified at 25% of the parametric value in Part 1 of Table B in Schedule 1.

(iv) The performance characteristics apply to the individual substance specified at 50% of the parametric value in Part 1 of Table B in Schedule 1.

(v) The performance characteristics apply to the prescribed value of 4 NTU.

(vi) The performance characteristics apply to the specification of 1 NTU for surface waters or ground waters influenced by surface water.
Table 1

<table>
<thead>
<tr>
<th>Provision of the Act</th>
<th>Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 10(1) and (2) (improvement notices)</td>
<td>For subsection (1) substitute—</td>
</tr>
<tr>
<td></td>
<td>“(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with any provision specified in paragraph (1AA) or is carrying out either a fluoride removal treatment or an ozone-enriched air treatment that has a disinfectant action, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—</td>
</tr>
<tr>
<td></td>
<td>(a) state the authorised officer’s grounds for believing that the person is failing to comply with the relevant provision;</td>
</tr>
<tr>
<td></td>
<td>(b) specify the matters which constitute the person’s failure so to comply;</td>
</tr>
<tr>
<td></td>
<td>(c) specify the measures which, in the officer’s opinion, the person must take in order to secure compliance; and</td>
</tr>
<tr>
<td></td>
<td>(d) require the person to take those measures or measures that are at least equivalent to them, within such period as may be specified in the notice.</td>
</tr>
<tr>
<td></td>
<td>(1AA) The provisions referred to in subsection (1) are—</td>
</tr>
<tr>
<td></td>
<td>(a) any of regulations 8 to 22 of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015; and</td>
</tr>
<tr>
<td></td>
<td>(b) any of the following provisions of Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters(1)—</td>
</tr>
<tr>
<td></td>
<td>(i) Article 1.2 (requirement that any fluoride removal treatment be performed in accordance with the technical requirements set out in the Annex);</td>
</tr>
<tr>
<td></td>
<td>(ii) the first sentence of Article 2</td>
</tr>
</tbody>
</table>

(1) OJ No L 37, 10.2.2010, p 13.
(requirement that the release of residues into natural mineral water or spring water as a result of any fluoride removal treatment be as low as technically feasible according to the best practices and not pose a risk to public health);

(iii) the second sentence of Article 2 (requirement to ensure compliance with the first sentence of Article 2, operators implement and monitor the critical processing steps set out in the Annex);

(iv) Article 3.1 (requirement that the application of any fluoride removal treatment be notified to the competent authorities at least three months prior to use); and

(v) Article 4 (requirement that the label on natural mineral water or spring water subjected to any fluoride removal treatment include specified information in proximity to the statement of the analytical composition).”.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Powers of entry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provision of the Act</strong></td>
<td><strong>Modifications</strong></td>
</tr>
<tr>
<td>Section 32(1) to (7) (powers of entry)</td>
<td>In subsection (1), for paragraphs (a) to (c) substitute—</td>
</tr>
<tr>
<td></td>
<td>“(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there is or has been on the premises a contravention of any of the following provisions of Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters—</td>
</tr>
<tr>
<td></td>
<td>(i) Article 1.2 (requirement that any fluoride removal treatment be performed in accordance with the technical requirements set out in the Annex);</td>
</tr>
<tr>
<td></td>
<td>(ii) the first sentence of Article 2 (requirement that the release of residues into natural mineral water or spring water as a result of any fluoride removal treatment be</td>
</tr>
</tbody>
</table>
as low as technically feasible according to the best practices and not pose a risk to public health);

(iii) the second sentence of Article 2 (requirement to ensure compliance with the first sentence of Article 2, operators implement and monitor the critical processing steps set out in the Annex);

(iv) Article 3.1 (requirement that the application of any fluoride removal treatment be notified to the competent authorities at least three months prior to use); and

(v) Article 4 (requirement that the label on natural mineral water or spring water subjected to any fluoride removal treatment include specified information in proximity to the statement of the analytical composition); and

(b) to enter any business premises, whether within or outside the authority’s area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention within that area of any of such provisions;”.

Table 3
Other provisions of the Act

<table>
<thead>
<tr>
<th>Provision of the Act</th>
<th>Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2(1) (extended meaning of “sale” etc.)</td>
<td>In subsection (1), for “this Act” substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.</td>
</tr>
<tr>
<td></td>
<td>In subsection (2), for “This Act” substitute “The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.</td>
</tr>
<tr>
<td>Section 3 (presumptions that food intended for human consumption)</td>
<td>In subsection (1), for “this Act” substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.</td>
</tr>
<tr>
<td>Section 20 (offences due to fault of another person)</td>
<td>For “any of the preceding provisions of this part” substitute “section 10(2) as applied by regulation 30 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015.”</td>
</tr>
</tbody>
</table>

(1) Section 2(1) was amended by the section 40(1) of, and paragraph 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28).
Section 21(1) and (5)(1) (defence of due diligence)  
In subsection (1), for “any of the preceding provisions of this Part” substitute “section 10(2) as applied by regulation 30 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,”.

Section 22 (defence of publication in the course of business)  
For “any of the preceding provisions of this Part” substitute “regulations 12, 17 and 21 of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.

Section 29 (procurement of samples)  
In paragraph (b)(ii), after “under section 32 below”, insert “as applied by regulation 31 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.

Section 30(6) and (8) (which relates to evidence of certificates given by a food analyst or examiner)  
For “this Act” substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.

Section 33 (obstruction etc. of officers)  
In subsection (1), for “this Act” (in each place where it occurs) substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”.

Section 35(1)(2) and (2) (punishment of offences)  
In subsection (1), after “section 33(1) above” insert “, as applied and modified by regulation 32 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,”

After subsection (1), insert—

“(1AA) A person guilty of an offence under section 10(2), as applied by regulation 30 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 shall be liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.”.

In subsection (2)—

in the opening words, for “any other offence under this Act” substitute “an offence under section 33(2), as applied by regulation 32 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,”; and

in paragraph (b), for “the relevant amount” substitute “the statutory maximum”.

Section 36 (offences by bodies corporate)  
In subsection (1), for “this Act” substitute “section 10(2) as applied by regulation 30 of, and Schedule 10 to, the Natural Mineral Water,

(1) Section 21(2) was amended by S.I. 2004/3279.

(2) Section 35(1) is to be amended by section 280(2) of, and paragraph 42 of Schedule 26 to, the Criminal Justice Act 2003 (c. 44) from a date to be appointed.
| Section 36A(1) (offences by Scottish partnerships) | Spring Water and Bottled Drinking Water (Wales) Regulations 2015”. For “this Act” substitute “section 10(2) as applied by regulation 30 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015, or regulation [x] of those Regulations”. |
| Section 37(1) and (6) (appeals) | For subsection (1) substitute— (1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 30 of, and Schedule 10 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015, may appeal to a magistrates’ court.” In subsection (6)— for “(3) and (4)” substitute “(1)”; and in paragraph (a), omit “or to the sheriff”. |
| Section 39 (appeals against improvement notices) | For subsection (1) substitute— “On an appeal against an improvement notice served under section 10(1), as applied and modified by regulation 30 of, and Schedule 10 to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015, the magistrates’ court may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the magistrates’ court may in the circumstances think fit.”. In subsection (3), omit “for want of prosecution” |
| Section 44 (protection of officers acting in good faith) | For “this Act” (in each place where it occurs) substitute “the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015”. |

(1) Section 36A was inserted by section 40(1) of, and paragraph 16 of Schedule 5 to, the Food Standards Act 1999.
Title: The natural mineral water, spring water and bottled drinking water regulations (Wales) 2015

Lead department or agency: Food Standards Agency Wales
Other departments or agencies: Food Standards Scotland
Food Standards Agency Northern Ireland
Defra

Impact Assessment (IA)
Date: 01/05/2014
Stage: Consultation
Source of intervention: EU
Type of measure: Primary legislation
Contact for enquiries: John Hirst 02920 678940

Summary: Intervention and Options
IA 1 – Consolidation of Regulations

Cost of Preferred (or more likely) Option

<table>
<thead>
<tr>
<th>Total Net Present Value</th>
<th>Business Net Present Value</th>
<th>Net cost to business per year (EANCB on 2009 prices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- £0.001 m</td>
<td>- £0.001m</td>
<td>£0.000m</td>
</tr>
</tbody>
</table>

What is the problem under consideration? Why is government intervention necessary?
Consolidating all regulations on natural mineral water, spring water and bottled drinking water into a single Statutory Instrument, including a change in enforcement to the use of Improvement Notices in most cases of non-compliance and the removal of a national measure which calls for the re-calcification up to 60 mg/l for any bottled water (not natural mineral water) or spring water which has been softened or de-salinated. Government intervention is required because currently the number of statutory instruments and amendments has the potential to cause confusion, the enforcement regime does is less flexible that is desirable, and the original motivation for the re-calcification measure is no longer scientifically valid. The intended effect is to remove this regulation with cost savings for firms.

What are the policy objectives and the intended effects?
The policy objective is to ensure that food regulation is proportionate and based on the most up-to-date scientific evidence. The effect is to make access to regulation in this area more straightforward, to implement a more proportionate enforcement regime and to remove a burden from food businesses that is not required for the protection of public health.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)
Option 1 (baseline) – Do nothing. – businesses would continue to UV treat products marketed as spring water
Option 2 – Consolidate the regulations including the new enforcement regime and remove the national requirement for refortification of softened spring or bottled water.

Will the policy be reviewed? No  If applicable, set review date: n/a

Does implementation go beyond minimum EU requirements?
No

Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.
Micro Yes | < 20 Yes | Small Yes | Medium Yes | Large Yes
Traded: 0 | Non-traded: 0

What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent)
Traded: 0
Non-traded: 0

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY: __________________________ Date: __________________________
### Policy Option 1

**Description:** Option 1 Do nothing – businesses would continue to UV treat products marketed as spring water.

#### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2015</th>
<th>PV Base Year 2015</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Low:  High: Best Estimate: 0.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**

None. This is the baseline which all other options are appraised against.

**Other key non-monetised costs by ‘main affected groups’**

None. This is the baseline which all other options are appraised against.

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised benefits by ‘main affected groups’**

None. This is the baseline which all other options are appraised against.

**Other key non-monetised benefits by ‘main affected groups’**

None. This is the baseline which all other options are appraised against.

#### Key assumptions/sensitivities/risks

Discount rate (%): 3.5

UK companies may be disadvantaged if UK Regulation imposes requirements that are not imposed by other Member States. The bottled water sector would be disadvantaged in relation to other sectors if the move to civil sanctions is not pursued.

#### BUSINESS ASSESSMENT (Option 1)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) (£m):</th>
<th>In scope of OITO?</th>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs:</td>
<td>Yes/No</td>
<td>IN/OUT/Zero net cost</td>
</tr>
<tr>
<td>Benefits:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Description:** Option 2 – Consolidate the regulations including the new enforcement regime and remove the national requirement for refortification of softened spring or bottled water.

### Description and scale of key monetised costs by ‘main affected groups’

Affected businesses will incur costs from staff learning and disseminating information regarding the new regulations. This one-off cost is estimated to be £418 in 2015.

**Local Authorities will incur costs from staff learning and disseminating information regarding the new regulations. This one-off cost is estimated to be £426 in 2015.**

### Other key non-monetised costs by ‘main affected groups’

There will be verification control costs arising solely due to the minimum hardness requirement.

### Description and scale of key monetised benefits by ‘main affected groups’

No monetised benefits have been identified.

### Other key non-monetised benefits by ‘main affected groups’

There is a benefit to businesses and government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime by way of compliance notice.

There is a benefit from reduced costs to businesses and government from moving to a more proportionate enforcement regime regarding bottled water regulation violations.

### Key assumptions/sensitivities/risks

UK companies may be disadvantaged if UK Regulation imposes requirements that are not imposed by other Member States, The bottled water sector would be disadvantaged in relation to other sectors if the move to civil sanctions is not pursued.

### BUSINESS ASSESSMENT (Option 2)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: 0.0</td>
</tr>
</tbody>
</table>
Evidence Base

Executive Summary

Policy Issue

1. This policy proposal aims to consult on the consolidation of all regulations on natural mineral waters, spring water and bottled water into a single statutory instrument. This will include a move to the use of civil sanctions (Improvement Notices) for most non-compliances, and the removal of a national measure on minimum calcium content of waters which have been softened or de-salinated. In addition, two separate exercises are being conducted in parallel which cover other EU commitments for bottled drinking water. The overarching aim is to ensure that government intervention results in a single SI, consistent across all UK administrations, where there is no need for further amendments.

Rationale for Government Intervention

i. Consolidation of existing Regulations

2. There are four EU regulations which, in combination, detail the exploitation; production; marketing requirements; and permitted treatments for all three types of bottled drinking water produced both in the EU and outside EEA.

- 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 Waters2;

3. These regulations have been transposed into The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 (as amended). There have been three amendments to the 2007 Regulations in order to reflect changes made at EU level.

- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007: No. 3165 (W. 276)5
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2009: No. 1897 (W. 170)6
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2010: No. 748 (W. 76)7
- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2011: No. 400 (W. 57)8

4. This makes it difficult for stakeholders to follow the statutory requirements as they do not exist in a single official document and it is necessary to cross refer four separate Statutory Instruments (SIs). It will be necessary to make a new Statutory Instrument to transpose those aspects of EU Regulation dealt with in the other Impact Assessments included in the overall consultation package, and therefore it is prudent to carry out the consolidation of all existing Regulations as part of this process.

5. A single SI covering all regulation in this area will be of advantage to both existing businesses and new entrants to the market. It will also be an advantage to enforcement authorities that enforce the Regulations.

**ii. Enforcement Regimes**

6. Traditionally, enforcement of regulations on food composition and labelling has been done on a risk based approach. Bottled drinking water is defined as a food and subject to the same risk based approach to enforcement. Where there is not a significant risk to human health, enforcement officials will work with firms to ensure that they can comply with legal requirements. Enforcement action is often only pursued where informal action has been unsuccessful.

7. The new approach to all the recent food regulations in Wales and therefore the new bottled drinking water regulation that results, allows for the greater use of informal action. However, where this fails or where there is repeated breach of regulatory requirements, Improvement Notices will be issued. This would be followed up by a criminal offence in those cases where an Improvement Notice is not complied with.

**iii. Fortification of Waters**

8. The 2007 regulations contain a national provision which calls for the re-calcification up to 60 mg/l for any bottled water or spring water which had been softened or de-salinated. While this was no longer required by EU regulations\(^9\), the UK retained the requirement for minimum hardness as a national provision in SI 1999 No. 1540 (as amended)\(^10\), as well as its replacement SI 2007 No. 3165 (W. 276) (as amended)\(^11\). This was done on health grounds, based on advice at the time, from the Department of Health Committee On Medical Aspects of Food Policy which claimed that calcium helped prevent coronary heart disease. The original EU requirement was therefore maintained as a national provision.

9. More recent (2010) national scientific evidence\(^12\) shows the national provision no longer has a scientific basis, as the validity of the original evidence is disputed. Therefore the original measure imposes a scientifically unjustifiable regulatory burden on businesses.

**Devolved Administrations**

10. Similar exercises are being carried out in England, Northern Ireland. In Scotland, there is no proposal to move to Improvement Notices. This is consistent with the UK picture in other recent regulations.

**Policy Objectives and Intended Effects**


\(^10\) http://www.legislation.gov.uk/uksi/1999/1540/contents/made


\(^12\) http://www.sacn.gov.uk/pdfs/sacn_position_statement_hard_water_and_cardiovascular_disease.pdf
11. The overall objective of the proposed policy is to simplify regulations, reducing the burden of regulation for businesses. Simplification can be achieved by consolidating a number of existing Regulations into a single Statutory Instrument, by removing purely national fortification measures which are a direct cost to business, are no longer scientifically valid and exceed the requirements of EU legislation as well as the move to a more proportionate enforcement system which uses improvement notices to manage breach of regulations.

12. The policy option was discussed at length during a pre-consultation phase with a number of key producers and trade organisations of varying size, as well as local authority enforcement officials. The assumptions used are based on in depth discussion with the sector.

Options Considered, including Alternatives to Regulation

13. Other than a ‘do nothing’ option, There is only one option proposed. Consolidation requires regulatory action. The changes to existing regulation to allow a more proportionate enforcement regime require regulatory action. There is no scientific justification for continuing the fortification requirement, but this can only be removed by regulation. Therefore alternatives to regulation, i.e. voluntary measures, would not be appropriate.

Policy Option 1 (baseline): do nothing - A number of Regulations and amendments still apply to natural mineral water, spring water and bottled water. The current enforcement regime will remain in place where frontline criminal offences exist for breach of regulatory requirements; there is no scope for the use of a more proportionate enforcement regime. Regulations continue to require fortification of waters which have been softened or de-salinated. This is no longer scientifically justified.

Policy Option 2: Regulation on all categories of bottled water is consolidated into a single Statutory Instrument, which imposes a more proportionate enforcement regime and removes the minimum hardness requirement for bottled and spring waters.

Expected Level of Business Impact

14. This 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:

- A 10 year time horizon for appraisal of costs and benefits (therefore this analysis covers the period 2015-2024); and
- A 3.5% discount rate for calculating the present value of costs and benefits.

15. Only additional costs and benefits due to the introduction of Policy Option 2 are included.

16. Policy will be implemented as of November 2015 and end estimates are given in 2014 prices and 2015 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.

17. The FSA, Defra and Food Standards Scotland will be consulting on the support for proposed action in relation to the removal of the minimum calcium content provision. It is envisaged that consultation responses will confirm that regulations will no longer require firms to fortify waters which have been softened or desalinated to a level of 60mg/l calcium.
Policy Option 2 - Regulation on all categories of bottled water is consolidated into a single Statutory Instrument, which imposes a more proportionate enforcement regime and removes the minimum hardness requirement for bottled and spring waters.

18. This section details the costs and benefits of Policy Option 2:

I. Consolidation of regulation for natural mineral waters, spring water and bottled drinking water into a single Statutory Instrument

II. A more proportionate enforcement regime.

III. Removal of requirement for mandatory fortification with calcium (‘minimum hardness’); and

19. We assess the potential impacts on bottled drinking water businesses and Government.

   i. **Consolidation of regulations**

   **Benefits to industry**

20. There may be benefits to industry in terms of simplification as a result of the consolidations. Any new entrants into the sector would only need to familiarise themselves with one statutory instrument as opposed to the four at present. It is difficult to estimate how many new businesses will enter the sector over the next ten years (which is the expected lifespan of the policy) and therefore this benefit is not monetised.

**Benefits to Enforcement**

21. There may be benefits to enforcement bodies and businesses in terms of simplification as a result of the consolidations. After the change, any new entrants into the sector would only need to familiarise themselves with one statutory instrument as opposed to the four at present. The FSA does not record the number of new entrant officers and therefore it is not possible to separate new entrants out from the data on numbers of food law enforcement officers. We are therefore unable to monetise the benefits at this time for the reduced familiarisation.

   ii. **A more proportionate enforcement regime**

   **Benefits to businesses and Government**

22. There is a benefit to industry and Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime by way of compliance notice. This would be followed up by a criminal offence in those cases where a compliance notice is not complied with. It is anticipated that the gains will originate from time saved to businesses and Government officials 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 magistrate court, the vast majority being resolved through the issuing of improvement notices.

23. It is acknowledged that the benefits of this measure are felt by those businesses who breach regulatory requirements; however, a trade association member has confirmed that 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 enforcement officials to allow the firm 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 enforcement officers to make the most effective use of resources as confirmed by the head of better regulation and consultation at the FSA in 2007.

24. Information provided in the FSA food law annual report for 2012/2013 shows that there were 63 food standards prosecutions concluded in England. Formal enforcement actions data shows that for period 2012/2013, prosecutions in the UK decreased by 4% and the use of improvement notices decreased by 20%, showing a general trend of reduction in enforcement action. This could be due to the reduction in budgets at Local Authority level and the local decisions to divert focus and resource towards food safety as opposed to quality issues (confirmed to FSA and Defra officials by Enforcement Officials during 2010 – and 2013). No data was available as to how many prosecutions were due to breaches of the 2007 regulations on bottled water but figures are likely to be extremely low or possibly none at all, hence savings from this measure are close to zero. As data was not available, it was not possible to monetise the potential benefit and it was not proportional to gather this data prior to consultation.

**iii. Removal of minimum hardness requirement**

*Direct benefits to businesses*

25. In July 2013, and again more recently in July 2014, the four main UK trade associations were contacted and asked about the minimum hardness requirement. The British Water Cooler Association (BWCA) was the only trade association to confirm that one of its members (based in England) currently adheres to the national provision of fortification (back up to a minimum of 60mg/l calcium). Furthermore, a detailed survey issued by the FSA and Defra sought an update on any treatments performed on bottled drinking water. The survey was sent to Local Authorities in order to aid the capture of data on small scale producers who bottle less than 5 million litres per annum. The survey results indicate that no small businesses undertake water softening or de-salination. Therefore the assumption is that only one business in the UK would be affected / benefit, if the minimum hardness requirement was removed.

26. There are therefore no costs or benefits envisaged to industry in Wales due to the removal of the refortification requirement for softened water.

*Direct cost and benefits to Government*

27. We assume that there are no benefits to Government from removing the minimum hardness requirement. Under Policy Option 1, the monitoring from 2015 will be part of overall controls to verify business compliance with multiple regulations. Time spent to check compliance with the minimum hardness requirement cannot be separated from other checks. Therefore verification control costs arising solely due to the minimum hardness requirement have not been monetised.

28. The removal of the minimum hardness requirement would also likely to be marginal as enforcers must continue to monitor businesses to ensure compliance with other regulations. There has been no food safety or compositional breach 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.

*Learning and dissemination costs for all measures*

29. Affected businesses will need to become familiar with the new regulations. It is estimated that it would take two full time production manager / director in the manufacturing industry
per business 2 hours in total to learn about this regulation and disseminate information to key staff (1.5 hours for learning and 0.5 hours for dissemination). The median hourly pay rate for full time production managers/directors is around £26.12 (ASHE Provisional 2014 Estimates in 2014 prices\(^\text{13}\), with a 30% overhead uplift in accordance with the UK standard cost model)\(^\text{14}\). Assuming eight affected bottled water firms\(^\text{15}\), the total one-off learning and dissemination cost to businesses in Wales is £418, which translates to an equivalent annual cost of £49 in 2015 (2014 prices, 2014 Net Present Value\(^\text{16}\)[NPV]).

30. Government officials were first advised about the changes to be made in a letter issued by the FSA on 2 July 2013 (reference 2013 ENF/W/13/020\(^\text{17}\)), and on numerous occasions since then including at Food Labelling and Standards Focus Group meetings as well as via the web forum ‘knowledge hub’. Therefore, the time assumed for familiarisation and dissemination of information about the regulatory changes is only one hour in comparison to the usual two hours.

31. Local authority trading standard officers will also need to become familiar with the new regulation. It is estimated that it would take one trading standards officer one hour to read the regulations and disseminate information to key staff (0.5 hours to read and 0.5 hours to disseminate information). The median hourly pay rate for a trading standards officer is around £19.37 (ASHE Provisional 2014 Estimates in 2014 prices\(^\text{18}\), with a 30% overhead uplift in accordance with the UK standard cost model)\(^\text{19}\). There are 22 local authorities in Wales. The total one-off familiarisation cost to enforcement bodies in Wales of £426, which translates to an equivalent annual cost of £50 in 2015 (2014 prices, 2014 NPV).

Q IA1.1: Do you agree with the estimated size of the bottled water market in Wales.
Q IA1.2: Do you agree with the estimated costs of learning and dissemination in relation to the consolidation of regulations?

Consumer Costs and Benefits

32. There are no costs or benefits to consumers identified due to consolidation of regulations, the movement to a more proportionate enforcement regime and removal of the minimum hardness requirement. Notably, the removal of a minimum hardness requirement has no effect on consumer health and safety as fortification of bottled water has no scientifically verified health benefits\(^\text{20}\).


\(^{15}\)Zenith International 2009 Global Bottled Water report estimated 129 bottled water brand / producers in the UK. No breakdown is provided of how many of these firms are based in Wales. In the ONS definition of the sector, Standard Industrial Classification (SIC) 11.07 covers the, ‘Manufacture of soft drinks; production of mineral waters, and other bottled waters’. The ONS (IDBR data, 2014) considers there are 15 firms in this category based in Wales, out of 250 in the UK (a proportion of 6%). Applying this proportion to the number of bottled water brand producers in the UK, we assume that 8 bottled water firms are based in Wales (rounded to an integer value).

\(^{16}\)Net Present Value is the difference between the Present Value of a stream of costs and a stream of benefits.

\(^{17}\)https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/enfw13020.pdf


Summary Table of Costs and Benefits over 10 years

<table>
<thead>
<tr>
<th></th>
<th>£m</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td>0.001</td>
</tr>
<tr>
<td>Learning and dissemination costs for industry</td>
<td>0.000</td>
</tr>
<tr>
<td>Learning and dissemination costs for local authorities</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>TOTAL BENEFITS</strong></td>
<td>0.000</td>
</tr>
<tr>
<td><strong>NET PRESENT VALUE</strong></td>
<td>-0.001</td>
</tr>
<tr>
<td><strong>EANCB</strong></td>
<td>0.0</td>
</tr>
</tbody>
</table>

Summary

33. Under Policy Option 2, there is a consolidation of all regulations on natural mineral waters, spring water and bottled water into a single statutory instrument. This will include a move to the use of civil sanctions (Improvement Notices) for most non-compliances, and the removal of a national measure on minimum calcium content of waters which have been softened or de-salinated.

34. The total quantifiable net benefit of Policy Option 2 is estimated to be around -£844, in net present value terms over the 10 year appraisal period. Net benefit to businesses of Policy Option 2 is -£418.

35. The non-monetised benefits for society are the reduced costs to businesses and government from moving to a more proportionate enforcement regime regarding bottled water regulation violations. Therefore the estimated net benefit to society of Policy Option 2 is likely to be higher than demonstrated in this impact assessment.

Consultation

36. In support of this policy proposal and as part of a public commitment, we will be consulting with relevant stakeholders on the proposal to remove the national measure on fortification of waters that have been softened or de-salinated. We will also seek evidence on the type, and magnitude of, costs and benefits incurred by industry as a result of the proposed changes. Any additional evidence provided will be used to refine the figures for the final impact assessment. However, these proposals were designed under consultation with a number of key producer organisations, which represent the interests of the UK bottled water industry so we expect minimal changes and confidence in the scale of benefits expected.
**Title:** The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Wales) 2015 (1) Radon monitoring

**Lead department or agency:**
Food Standards Agency Wales

**Other departments or agencies:**
Food Standards Scotland
Food Standards Agency Northern Ireland
Defra

**Summary: Intervention and Options**

**Cost of Preferred (or more likely) Option**

<table>
<thead>
<tr>
<th>Total Net Present Value</th>
<th>Business Net Present Value</th>
<th>Net cost to business per year (EANCB on 2009 prices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- £0.004m</td>
<td>£0.004m</td>
<td>£0.000m</td>
</tr>
</tbody>
</table>

**What is the problem under consideration? Why is government intervention necessary?**

Council Directive 2013/51/Euratom lays down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. There are new rules for radiation monitoring in ‘spring water’ and other bottled drinking water – except ‘natural mineral water’. A completely new requirement for radon monitoring in all potable water, including bottled drinking water, has been introduced. Minimum monitoring frequencies for bottled drinking water are not stipulated and are to be set in line with HACCP principles, by each Member State. As consumers will have incomplete information about the risks they face, they will not be able to make a fully informed purchasing decision. Therefore government intervention is necessary to address this market failure.

**What are the policy objectives and the intended effects?**

The policy objective is to ensure that The UK meets its obligations under the EU Treaties. The effect is to transpose the requirements of Council Directive 2013/51/Euratom as they refer to monitoring of radiation in bottled drinking water other than “natural mineral water”.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

Option 1 (baseline) – Do nothing. Do not transpose the Directive.
Option 2 – Transpose the Directive and regulate in Wales for the implementation and enforcement of its provisions.

**Will the policy be reviewed? No If applicable, set review date: n/a**

<table>
<thead>
<tr>
<th>Does implementation go beyond minimum EU requirements?</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.</td>
<td>Micro</td>
</tr>
<tr>
<td>What is the CO₂ equivalent change in greenhouse gas emissions? (Million tonnes CO₂ equivalent)</td>
<td>Traded:</td>
</tr>
</tbody>
</table>

*I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.*

Signed by the responsible SELECT SIGNATORY: ............................................................ Date: ..........................................................

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1 According to EU legislation, three types of bottled drinking water exist: Natural Mineral Waters, Spring Water and all other types of bottled drinking water (water not marketed as either spring or natural mineral water).
Description: **Option 1 Do nothing – businesses would continue to UV treat products marketed as spring water.**

### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2014</th>
<th>PV Base Year 2014</th>
<th>Time Period Years 10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: 0.0</td>
</tr>
</tbody>
</table>

#### COSTS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>High</td>
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<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Best Estimate</td>
<td></td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

None. This is the baseline which all other options are appraised against

Other key non-monetised costs by ‘main affected groups’

None. This is the baseline which all other options are appraised against

#### BENEFITS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
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<td>Low</td>
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<td>Optional</td>
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</tr>
<tr>
<td>Best Estimate</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

None. This is the baseline which all other options are appraised against

Other key non-monetised benefits by ‘main affected groups’

None. This is the baseline which all other options are appraised against

### Key assumptions/sensitivities/risks

**Discount rate (%)** 3.5

By not transposing the EU Directive, the UK will lay itself open to infraction proceedings from the EU. Costs
Description: Option 2 – implement EU law.

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>2015</td>
<td>10</td>
<td>Low: -0.004, High: -0.004, Best Estimate: -0.004</td>
</tr>
</tbody>
</table>

COSTS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.004</td>
<td>0.00</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

Affected businesses will incur costs from staff learning and disseminating information regarding the new regulations. This one-off cost is estimated to be £797 in 2015.

Local Authorities will incur costs from staff learning and disseminating information regarding the new regulations. This one-off cost is estimated to be £867 in 2015.

Firms will need to conduct an initial analysis of radon in water samples, at a total cost of £2,746 in 2015.

Other key non-monetised costs by ‘main affected groups’

There is a potential (though unexpected) non-monetised cost of specific risk assessments for radon.

BENEFITS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

There are no monetised benefits expected from this option.

Other key non-monetised benefits by ‘main affected groups’

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.

Key assumptions/sensitivities/risks

<table>
<thead>
<tr>
<th>Discount rate(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5</td>
</tr>
</tbody>
</table>

Formal radon monitoring will not be required, meaning that there are unlikely to be any on-going costs.

BUSINESS ASSESSMENT (Option 2)

| Direct impact on business (Equivalent Annual) £m: |
| Costs: 0.004 | Benefits: 0.000 | Net: 0.00 |
Evidence Base

Executive Summary

Policy Issue

1. This policy proposal aims to consult on the impact of transposing Council Directive 2013/51/Euratom Laying Down Requirements For The Protection Of The Health Of The General Public With Regard To Radioactive Substances In Water Intended For Human Consumption.

2. In addition, two separate exercises are being conducted in parallel which cover consolidation of current regulations and other EU commitments for bottled drinking water. The overarching aim is to ensure that government intervention results in a single SI, consistent across all UK administrations, where there is no need for further amendments. In Wales, this measure is being taken by making The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Wales) 2015.

Background


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

5. Significantly the Directive also specifies one new standard for radon monitoring in water for human consumption. It also does not specify monitoring frequencies for radiation in bottled drinking water and states that the monitoring is based solely on individual risk assessment.

6. It is therefore up to each Member State to decide on minimum monitoring frequencies as none are set for bottled drinking water in the Directive. At this stage it is not clear what other Member States are doing on minimum frequency of monitoring. However, some enquiries have been made with Member States as well as the Commission (who have not issued any guidance in relation to setting minimum monitoring frequencies). They have re-emphasised (January 2015) that ‘Hazard and Critical Control Point’ (HACCP)¹ principles are used to inform monitoring.

Proposals for radon monitoring

7. As there is little data on national radon levels in groundwater, it is proposed that industry will need to conduct a single radon analysis to compliment any historical data which would enable the Local Authority to satisfy itself that the risk of radon is low.

8. Although formal / legal monitoring is not stipulated for radiation, monitoring is highly likely to continue by the industry itself, and any risk of radon will be captured by analysis of alpha and beta radiation.

9. Consumer protection therefore will continue to be safeguarded on the basis of data which demonstrates that alpha and beta radiation levels in bottled drinking water in England and the rest of the UK are significantly low.

10. Guidance will be issued by FSA Wales which will suggest the approach that could be taken in relation to radiation analysis. Proposals will be checked at consultation.

11. The formal monitoring of radon is a completely new regulatory requirement stemming from the EU at some initial cost to industry. Costs are incurred by the requirement for the UK industry to conduct initial risk assessments on various sources used for spring water and other bottled drinking water (not water marketed as natural mineral water), specifically for radon.

12. Risk assessment for radon is not solely based on analysis of a water sample. Other information sources will contribute to the assessment of risk. This includes knowledge of the geology, data on naturally occurring radon levels and operational monitoring of alpha and beta radiation. But as radon monitoring is a new requirement, it is not clear what extra assessments may be necessary. This will be checked during consultation and financial data will be updated accordingly.

13. Therefore in relation to radon monitoring, a completely new risk assessment may not be necessary if the initial risk assessment showed that the risk of radon contamination was considered to be low owing to the natural geology of the catchment area.

14. There is no legislative mandate for what is covered in a risk assessment for radon. It is a reasonable assumption that a producer, will first use existing information to inform and assess the prevalence of naturally occurring radon from the British Geological Survey or the Environment Agency.

15. The Drinking Water Inspectorate (DWI) have sponsored a research project looking at collating the information on radon occurrence in water supplies in order to help their stakeholders, including local authorities, to carry out risk assessments. This is due to report later and the information will be used to inform the policy development in relation to bottled drinking water monitoring.

16. Therefore in relation to radon monitoring, a completely new risk assessment may not be necessary if the initial risk assessment showed that the risk of radon contamination was considered to be low owing to the natural geology of the catchment area. There is no legislative mandate for what is covered in a risk assessment for radon. It is a reasonable assumption that a firm may further investigate the wider catchment of the area and assess information on naturally occurring radon from the British Geological Survey or the Environment Agency.

Rationale for Government Intervention

17. On 13 October 2013, Directive 2013/51/Euratom (‘the Directive’) was published. A completely new requirement for radon monitoring in all potable water, including bottled drinking water\(^2\), has been introduced. Minimum monitoring frequencies for bottled drinking water are not stipulated and are to be set in line with HACCP principles, by each Member State. Monitoring is not required where it can be demonstrated to the competent

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\(^2\) According to EU legislation, three types of bottled drinking water exist: Natural Mineral Waters, Spring Water and all other types of bottled drinking water (water not marketed as either spring or natural mineral water).
authority on the basis of representative surveys, monitoring data or other reliable information that the levels of radon, tritium or the TID will remain below the respective parametric values detailed in the Directive. In this case, a business can apply for an exemption from monitoring.

18. The new radiation monitoring requirements supersede those currently detailed in the Drinking Water Directive.

19. Therefore, Government intervention is required in order to update regulations in Wales. Regulations which implement and provide enforcement provisions for EU legislation are the responsibility of the Food Standards Agency (FSA) in Wales and Northern Ireland, Defra in England and Food Standards Scotland (FSS) in Scotland.

20. As the Directive does not prescribe monitoring frequencies, the intention is to make full use of the exemption provisions where appropriate.

Other UK Administrations

21. This Impact Assessment is for the Wales Regulations. Similar and parallel Regulations, and accompanying consultation exercises, will be carried out in England by Defra, In Northern Ireland by FSA and in Scotland by Food Standards Scotland.

Policy Objectives and Intended Effects

22. Full compliance with the Directive is required by 28 November 2015. The policy objective is to transpose EU requirements into regulations in Wales at the same time as the rest of the UK and the rest of the EU. This is in line with scientific recommendations\(^3\) that radon levels in water should be monitored through legislative measures.

23. Government intervention is necessary as 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 un-detected; 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 be done voluntarily by the bottled drinking water industry in line with HACCP and risk assessment of a source.

24. The intended effect of the regulation is consistency of application of requirements throughout the UK. This is intended to contribute to ensuring consumer safety in minimising the risk of radon contamination from consumption of spring and other bottled drinking waters (not natural mineral water, which is subject to other more specific EU requirements).

Options Considered, including Alternatives to Regulation

25. Other than the 'Do nothing' option, there is only one option proposed: Transposition of EU Directives and enforcement provisions for EU Regulations require regulatory measures. Alternatives to regulation, i.e. voluntary measures, would not be appropriate.

Policy Option 1 (baseline): do nothing

\(^3\) http://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/radioactivity-drinking-water
26. The baseline used is the current situation. By not transposing the EU Directive, the UK will lay itself open to infraction proceedings from the EU. Costs

**Policy Option 2: Transpose Directive 2013/51/Euratom.**

27. This option transposes wording contained in the Directive which:
   i) requires that the analysis of radon in bottled drinking water is based solely on risk assessment, and;
   ii) enables firms to be exempt from formal analysis on the basis of representative surveys and other reliable information.

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

**Expected Level of Business Impact**

29. This 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:

- A 10 year time horizon for appraisal of costs and benefits (therefore this analysis covers the period 2015-2024); and
- A 3.5% discount rate for calculating the present value of costs and benefits.

30. Only additional costs and benefits due to the introduction of Policy Option 2 are included. Policy will be implemented as of November 2015 and end estimates are given in 2015 prices and 2015 NPV terms.

31. Policy will be implemented as of November 2015 and end estimates are given in 2015 prices and 2015 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.

**Policy Option 2 - Transpose Directive 2013/51/Euratom.**

32. This section details the costs and benefits of Policy Option 2:

33. Radon is a colourless and odourless gaseous by-product of radium. It is difficult to analyse owing to its short half-life of 3.8 days. As there is currently no requirement to test for this gas in water for human consumption, it will be necessary to seek further evidence during consultation on the practicalities involved with analysis.

34. When initially discussed with bottled drinking water businesses, they advised that they did not consider that the requirements of the Directive would be too onerous as radiation levels in sources of spring water are relatively stable. Radon levels vary little over time,

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Where estimates of cost and data were only available for 2013, they have been uplifted to 2014 prices using HM Treasury deflator figures.

5. The time taken for half the radioactive atoms to decay.
although heavy rainfall can reduce levels. This is possibly as result of dilution by surface water.

35. The Directive does not stipulate minimum frequencies for monitoring bottled drinking water. These analyses would need to be conducted at a frequency based on an assessed level of risk for a particular source of spring water.

36. Member States are able to set minimum frequencies and the Directive enables this to be based on volume of production if so desired. Following a cross departmental meeting with the FSA leads across the UK, the Drinking Water Inspectorate and the FSA Radiological team in November 2014, it was agreed that HACCP principles already in place presently provide the safety assurance required for radon detection and remedial action; it was not considered necessary to set minimum frequencies according to volume of production.

Monetised Direct One-Off Costs to Businesses

37. The BSDA Soft Drinks Annual Report for 2014 indicates that 60% of bottled drinking water consumed in the UK is natural mineral water. 32% is spring water and the remaining 8% is other types of bottled drinking water (water which is not marketed as spring or natural mineral water)\(^6\). 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.

38. In July 2013, a survey was conducted by FSA and Defra on bottled drinking water production. The survey responses indicated that there are currently 15 spring water businesses in Wales.

39. The cost provided by industry for radon analysis is £180 in 2014 terms, equivalent to £183 in 2015 terms (using the HM Treasury deflator\(^7\)). 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.

40. The sample volume is not significant as costs are not dependent upon volume. The above figure for a 500 ml sample is purely for exemplary purpose to allow the calculation of low / medium and high scenarios. It is the pre-preparation\(^8\) of the sample that has cost implications as advised to Defra by LGC\(^9\). This will be further checked during consultation. The sample volume will vary according to the analytical methods used. For example, for gamma-ray spectrometry, sample sizes can vary between 25 ml – 3 litres. The cost of this analysis is unknown as currently industry is not required to test for radon and the methods of analysis have only recently been published. Until this testing has taken place, it is not possible to provide detail on variation on costs. This will be checked at consultation.

41. However if we assume that each of the 15 businesses tests a water sample at the rate of £183, this leads to a one off cost to the Welsh industry of £2,746 in 2015.

\(^6\) Of the 8% of bottled drinking water, 3% is municipally sourced according to the Natural Hydration Council. This indicates that the remaining 5% is naturally sourced but has been treated.


\(^8\) The Environmental Protection Agency in America has published a paper on two test methods for radon analysis in water which detail pre-preparation of samples and costs.

\(^9\) http://www.lgcgroup.com/
Q 3.1: Is the assumption of the size of the market in Wales accurate?
Q 3.2: Are the assumptions on the one-off monetised costs associated with radon monitoring accurate?

42. 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 prescribed in the regulation\(^\text{10}\), stimulate further investigation at cost. Radon (and/or any other radiation) contamination would therefore be picked up at this stage and thus any ongoing costs are therefore, not as a direct result of the new regulatory requirement.

43. In addition to the alpha and beta checks, the initial radon analysis in 2015 would provide the evidence of low risk, to compliment representative surveys allowing for the exemption for formal radon monitoring, to be applied for. Therefore it is assumed that there will be no ongoing costs to business.

Q 3.3: Are the assumptions on the ongoing costs associated with radon monitoring accurate?

Learning and Dissemination Costs to Businesses

44. The natural mineral water industry is exempt from the requirements of the Directive. The requirement for radon monitoring was first notified to businesses in 2013 via an email to trade associations. A further formal update by Defra and the FSA to local authorities and industry alike was issued on 18 December 2014\(^\text{11}\). There are no direct implications or familiarisation costs for the natural mineral water industry and as such no corresponding impact is included in the costs to business. In addition, the UK natural mineral water industry has been notified of the exemption via their trade associations on numerous occasions.

45. As cited before, there are approximately 15 spring water businesses in Wales that 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 £26.56 (ASHE Provisional 2014 Estimates in 2014\(^\text{12}\).3 prices uplifted to 2015 prices using HM Treasury deflator figures\(^\text{13}\), with a 30% overhead uplift in accordance with the UK standard cost model)\(^\text{14}\). Therefore the total one-off familiarisation cost to 15 spring water businesses in Wales is £797, which translates to an equivalent annual cost of £93 (2015 prices, 2015 Net Present Value).

\(^{11}\) [https://www.food.gov.uk/sites/default/files/ENF-E-14-038.pdf](https://www.food.gov.uk/sites/default/files/ENF-E-14-038.pdf)
Q 3.4: Are the assumptions on the costs to industry associated with familiarisation with regard to radon monitoring regulation accurate?

Non – Monetised Costs

i. Risk Assessment for Radon

46. Detail on the considerations and costs that are required when conducting a risk assessment for radon will be provided in a Drinking Water Inspectorate (DWI) report covering risk of radon in drinking water supplies due for publication in 2015. A further programme is envisaged of DWI sponsored work resulting in the development of ‘radon groundwater hazard maps’. It is envisaged that these maps will further inform spring water businesses about the risk of radon in their source water.

47. Further information from the spring water\textsuperscript{15} industry will be sought during consultation. However currently we do not have information on the cost of specific risk assessment for radon and therefore 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. It is assumed that 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.

Q 3.5: Are the assumptions on the costs to industry associated with risk assessment for Radon accurate?

Costs to Government

i. Learning and Dissemination Costs

48. 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 regulation. 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 £19.70 (ASHE Provisional 2014 Estimates in 2014\textsuperscript{16} prices uplifted to 2015 prices using HM Treasury deflator figures\textsuperscript{17}, with a 30% overhead uplift in accordance with the UK standard cost model)\textsuperscript{18}.

49. As there are 22 local authorities in Wales, the total one-off familiarisation cost of £867 to enforcement bodies in Wales translates to one-off equivalent annual cost of £101 in 2015 (2015 prices, 2015 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.

\textsuperscript{15} Note that natural mineral water industry is exempt and other table water if it is not spring water is municipally sourced and thus covered by the DWI.


\textsuperscript{17} http://www.berr.gov.uk/files/file44503.pdf

Q 3.6: Are the assumptions on the costs to Government associated with familiarisation with regard to radon monitoring regulation accurate?

ii. Enforcement Costs

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

Non-Monetised Benefits

51. This policy has been introduced by the European Commission 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.

52. 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. It was not proportionate to gather this evidence prior to consultation. The health implications of radon assessment and any further benefits for the consumer will be queried during consultation.

Summary Table

53. A summary table of the costs and benefits is provided below. All costs to businesses listed below are direct costs, and in 2015 prices and 2015 NPV terms.

<table>
<thead>
<tr>
<th>£m</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning and dissemination costs for Government</td>
<td>0.001</td>
</tr>
<tr>
<td>Learning and dissemination costs for businesses</td>
<td>0.001</td>
</tr>
<tr>
<td>Sample testing</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td><strong>0.004</strong></td>
</tr>
<tr>
<td><strong>TOTAL BENEFITS</strong></td>
<td><strong>0.000</strong></td>
</tr>
<tr>
<td><strong>NET BENEFIT</strong></td>
<td><strong>-0.004</strong></td>
</tr>
</tbody>
</table>

Consultation

54. We will be consulting with relevant stakeholders to seek their views on the impact of the policy option described. We will also seek additional evidence on the type and magnitude of costs and benefits incurred by industry as a result of the proposed implementation process. This will help FSA officials assess the accuracy of this cost and benefit analysis. However the extensive pre-consultation suggests that the scale and type of costs described here are unlikely to change significantly.

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19 Figures rounded to 3 d.p. therefore totals in tables do not sum.
Conclusion

55. These proposals were developed in conjunction with a number of key producer organisations representing the interests of the UK bottled water industry. These organisations have advised that the impact of spring water obligations regarding radon analysis in Wales is likely to be minimal. The net cost to firms per year is estimated to be £371 (2009 prices, 2010 NPV). The net cost to firms is estimated to be £3.5k. This is significantly less than £1 million gross annual cost to industry in every year of the policy appraisal period. Although Policy Option 2 results in a net cost to firms, it derives from a direct obligation of the UK to correctly implement EU law.
Title: The natural mineral water, spring water and bottled drinking water regulations (Wales) 2015

Lead department or agency: Food Standards Agency Wales

Other departments or agencies: Food Standards Scotland
Food Standards Agency Northern Ireland
Defra

Summary: Intervention and Options

Cost of Preferred (or more likely) Option

<table>
<thead>
<tr>
<th>Total Net Present Value</th>
<th>Business Net Present Value</th>
<th>Net cost to business per year (EANCB on 2009 prices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- £0.07m</td>
<td>- £0.07m</td>
<td>£0.01m</td>
</tr>
</tbody>
</table>

What is the problem under consideration? Why is government intervention necessary?

Due to a misinterpretation of bottled water legislation the UK is currently under-implementing EU law by allowing the use of disinfection treatment for products marketed as spring water. There are three categories of bottled drinking water; natural mineral water, spring water and bottled drinking water. Only bottled drinking waters can be disinfected according to EU law. Disinfection is not permitted in the categories of spring and natural mineral water. Consumers are not aware that some UK produced spring waters have been disinfected, while the businesses producing these products are aware. This means this market has asymmetric information. Government intervention is necessary to address the EU law under-implementation and market failure by specifically prohibiting disinfection treatment for spring water.

This impact assessment deals with the impacts of Wales implementing EU law, as food composition and labelling are devolved matters. Therefore it is the role of devolved administrations to address these issues for their regions. Defra is consulting to test the accuracy of the assumptions made in this impact assessment.

What are the policy objectives and the intended effects?

The policy objective is to ensure that EU law is fully implemented, The intended effect is that consumers have the right information on bottled water products to make the appropriate purchasing decisions.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 (baseline) – Do nothing – businesses would continue to UV treat products marketed as spring water.
Option 2 – implement EU law on bottled water regulations clarifying that decontamination is not permitted for spring water.

Will the policy be reviewed? No

Does implementation go beyond minimum EU requirements? No

Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.

Micro Yes | < 20 Yes | Small Yes | Medium Yes | Large Yes
-----------|---------|-----------|------------|----------|

What is the CO₂ equivalent change in greenhouse gas emissions? (Million tonnes CO₂ equivalent)

Traded: 0
Non-traded: 0

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY: ___________________________ Date: ___________________________
**Description:** Option 1 Do nothing – businesses would continue to UV treat products marketed as spring water.

### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>2014</td>
<td>10</td>
<td>Low: 0.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High: 0.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: 0.0</td>
</tr>
</tbody>
</table>

#### COSTS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**

None. This is the baseline which all other options are appraised against

**Other key non-monetised costs by ‘main affected groups’**

None. This is the baseline which all other options are appraised against

#### BENEFITS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised benefits by ‘main affected groups’**

None. This is the baseline which all other options are appraised against

**Other key non-monetised benefits by ‘main affected groups’**

None. This is the baseline which all other options are appraised against

**Key assumptions/sensitivities/risks**

Discount rate (%) 3.5

There would be a significant risk of infraction proceedings should this option be pursued.

### BUSINESS ASSESSMENT (Option 1)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>Costs:</th>
<th>Benefits:</th>
<th>Net:</th>
</tr>
</thead>
</table>
**Description:** Option 2 – implement EU law.

### Price Base Year 2014  
**PV Base Year** 2014  
**Time Period Years** 10  
**Net Benefit (Present Value (PV)) (£m)**  
| Low: 0.266 | High: 0.132 | Best Estimate: -0.067 |

### COSTS (£m)  
- **Total Transition (Constant Price)**  
  - Low: 0.235  
  - High: 0.296  
  - Best Estimate: 0.266  
- **Average Annual (excl. Transition) (Constant)**  
  - Low: 0.0  
  - High: 0.0  
  - Best Estimate: 0.0  
- **Total Cost (Present Value)**  
  - Low: 0.235  
  - High: 0.296  
  - Best Estimate: 0.266

### BENEFITS (£m)  
- **Total Transition (Constant Price)**  
  - Low: 0.0  
  - High: 0.0  
  - Best Estimate: 0.0  
- **Average Annual (excl. Transition) (Constant)**  
  - Low: 0.032  
  - High: 0.368  
  - Best Estimate: 0.199  
- **Total Benefit (Present Value)**  
  - Low: 0.032  
  - High: 0.368  
  - Best Estimate: 0.199

### Description and scale of key monetised costs by ‘main affected groups’  
If firms previously used UV treatment on products marketed as spring water, they would be affected by need to: remove UV equipment from business premises (£0.24m); write-off the cost of UV equipment (£0.049m); and take additional hygiene action to ensure water is still safe to drink (£0.183m). Conduction additional microbial sampling (£0.009m)  
There would also be familiarisation costs to Local Authorities (£852) and Industry (£313)

### Other key non-monetised costs by ‘main affected groups’  
Under Policy Option 2, we assume firms that previously used UV treatment will use an extended positive release system (holding product from the market until tests verify that microbiological are indeed met) to ensure that products marketed as spring water are safe to drink. We do not monetise this cost as we do not have this cost data.

### Description and scale of key monetised benefits by ‘main affected groups’  
If firms previously used UV treatment on products marketed as spring water, they would benefit from:  
- Electricity cost savings from not running UV systems (a total present value cost of £0.113m); and  
- Lamp cost savings from not having to buy new UV lamps, dispose of old ones safely and maintain them (a total present value cost of £0.087m).

### Other key non-monetised benefits by ‘main affected groups’  
Consumers who use categories of bottled water to make purchasing decisions will benefit from being better informed about the category of bottled water product they choose to purchase. We currently do not have data on how much consumers actually value this increased information therefore it has not been possible to monetise this benefit.

### Key assumptions/sensitivities/risks  
Discount rate (%) 3.5

We assume that if firms are not able to use UV treatment on products marketed as spring water, they would not re-label products as bottled water. We assume instead that they would take additional action to ensure that the water continues to be safe to drink while continuing to label water as spring water. This assumption has been provided by industry.

### BUSINESS ASSESSMENT (Option 2)  
**Direct impact on business (Equivalent Annual) £m:**  
Costs: 0.03  
Benefits: 0.02  
Net: 0.01
Evidence Base

Executive Summary

1. Rules on the exploitation and production of bottled drinking water are matters of EU competence. The EU legislation has been transposed by ‘The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations’ (2007, as amended), henceforth referred to as the ‘2007 regulations’. There have been three amendments to the 2007 regulations in Wales.

2. There are three legal categories of bottled drinking water according to EU legislation: natural mineral water, spring water and bottled drinking water (also known as table water). EU legislation defines the permitted treatments for each category of bottled drinking water.

3. The UK had interpreted EU legislation on the exploitation of natural mineral water (directive 96/70 EC), to allow disinfection treatment for spring water. This directive had amended the original EU legislation (directive 80/777 EC). The intention of directive 96/70 EC was to ensure that spring waters became subject to the same restrictions on treatments as natural mineral waters. Notably, disinfection treatments became prohibited for spring waters produced and sold in the EU.

4. The EU’s prohibition of disinfection treatment for natural sourced waters, such as natural mineral water and spring water, is in place as the intention is to preserve the naturally present microbial flora which is found at the source of the water.

5. This issue of misinterpretation has meant the UK is under-implementing EU law. Additionally, there is a market failure issue. The spring water producers who currently use UV disinfection know that the treatment is being applied during manufacturing. As there is no legal requirement to label this treatment, consumers assume that spring water has not undergone any disinfection treatment as this is what the EU regulations stipulate. This means there is asymmetric information in the market. This market failure requires government intervention as the market is failing to enable consumers to purchase goods based on accurate information. Consumers may make alternative purchasing decisions if they have accurate information.

6. This impact assessment evaluates the impact in Wales of rectifying this EU law under-implementation. Food composition and labelling are devolved matters and it is the role of other administrations to address these issues for their regions.

7. Policy Option 1 is the baseline, and reflects the current situation where UV treatment of products marketed as spring water continues. However, this option is not viable as the obligation is to address under-implementation of EU law.

8. Under Policy Option 2, the EU law under-implementation is rectified and firms in Wales are prohibited from using UV treatment to disinfect products marketed as spring water.

9. This is a consultation impact assessment. We seek comment only on the accuracy of the assumptions used in this impact assessment.

Summary Table

10. A summary table of the costs and benefits is provided below:

<table>
<thead>
<tr>
<th></th>
<th>Low Scenario</th>
<th>Central Scenario</th>
<th>High Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning and dissemination costs for businesses and government</td>
<td>0.001</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Removal of UV Equipment</td>
<td>0.018</td>
<td>0.024</td>
<td>0.031</td>
</tr>
<tr>
<td>Write off cost of UV equipment</td>
<td>0.024</td>
<td>0.049</td>
<td>0.073</td>
</tr>
<tr>
<td>Additional hygiene action</td>
<td>0.183</td>
<td>0.183</td>
<td>0.183</td>
</tr>
<tr>
<td>Additional microbial sampling over 3 months</td>
<td>0.009</td>
<td>0.009</td>
<td>0.009</td>
</tr>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td>0.235</td>
<td>0.266</td>
<td>0.296</td>
</tr>
<tr>
<td><strong>Benefits</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricity cost savings from not running UV systems</td>
<td>0.016</td>
<td>0.113</td>
<td>0.210</td>
</tr>
<tr>
<td>UV lamp cost savings</td>
<td>0.016</td>
<td>0.087</td>
<td>0.158</td>
</tr>
<tr>
<td><strong>TOTAL BENEFITS</strong></td>
<td>0.032</td>
<td>0.200</td>
<td>0.368</td>
</tr>
<tr>
<td><strong>NET BENEFIT</strong></td>
<td>-0.266</td>
<td>-0.067</td>
<td>0.132</td>
</tr>
</tbody>
</table>

Policy Background

11. There are four EU regulations which in combination detail the exploitation, production, marketing requirements and permitted treatments for bottled drinking waters both produced in the EU and outside the European Economic Area (EEA):

   I. Council directive 98/83/EC relating to the quality of water intended for human consumption⁴;
   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 waters⁵;
   III. Council directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of natural mineral water (recast)⁶; and
   IV. Commission regulation (EU) No.115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters⁷.

12. These regulations have been transposed into national legislation with accompanying enforcement provisions.

Interpretation of EU law

13. The UK is currently under-implementing EU law on bottled water by permitting disinfection treatment of bottled water labelled as ‘spring water’. This is due to an issue of misinterpretation of legislation.

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14. What constitutes a disinfection treatment remains un-defined in EU law. However national legislation in the form of the Water Supply Regulations 2000 and the Private Water Supply Regulations 2009 defines disinfection as ‘a process of water treatment to remove or to render harmless to human health every pathogenic microorganism and pathogenic parasite that would otherwise be present in the water.’

15. In the UK, the treatment which is affected by prohibition of disinfection treatment is solely the use of UV disinfection. The FSA and Defra have conducted investigations into the use of UV disinfection in spring water production as well as consulting with Public Health England, the Food Standards Agency (FSA) Microbiology Division and the Drinking Water Inspectorate, England and Wales. The conclusion is that there is no scientific evidence base for the continued use of UV treatment in the production of spring water. Any use of UV treatment means that the product should be categorised as a bottled drinking water / table water in line with, EU law and existing EU guidance. This would also be in line with consumer perceptions, thereby correcting an asymmetry of information, which represents a market failure.

Current UK regulations

16. In Wales, the European requirements for bottled drinking water were implemented through amended 2007 regulations (2007 No. 3165 (W. 276)). Similar legislation exists in Northern Ireland, Scotland and England.

Devolved Administrations

17. Food composition and labelling are devolved matters. The FSA is responsible for the regulations in Wales which transpose the four EU instruments, referred to earlier. The FSA is responsible for similar regulations in Northern Ireland, Food Standards Scotland in Scotland and Defra in England.

Alternatives to legislation

18. There is no alternative to legislation. The requirements for bottled drinking water are harmonised across the EU and Member States are required to transpose the requirements into their national legislation, along with appropriate enforcement measures.

C. Policy Options

Option 1 (baseline): do nothing

19. The baseline used is the current situation and reflects the current situation where UV treatment of products marketed as spring water continues. However, this option is not viable as the UK is obliged to implement EU law and the expectation from the Commission is that the UK will address the identified under-implementation. Under-implementation of EU rules would continue with risk of infraction costs and risk of direct action from another Member State.

Option 2: Implement EU law.

20. This option implements wording contained in the EU legislation which prohibits the use of disinfection treatment for products marketed as ‘spring water’, using the principles on ‘copy-out’ of EU law in HM Government’s Guidance on Transposition of European Directives. It

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addresses EU law under-implementation, subsequently addressing a market failure and benefitting the consumer in terms of making better informed purchasing choices.

D. Cost and benefit appraisal of decisions

21. This impact assessment has been prepared in line with guidance set out in the Green Book\textsuperscript{12} and the Better Regulation Framework Manual\textsuperscript{13} for public policy appraisal. It uses standard appraisal assumptions of:

- A 10 year time horizon for appraisal of costs and benefits; and
- A 3.5\% discount rate for calculating the present value of costs and benefits

22. Only additional costs and benefits due to the introduction of Policy Options 2 is included. No costs which would have taken place in the absence of Policy Option 2 are included. As Policy 1 shows a net benefit, where a range of estimates have been given the low cost estimates inform the high scenario and the high cost estimates inform the low scenario. The high benefit estimates inform the high scenario and the low benefit estimates inform the low scenario.

23. Policy will be implemented as of November 2015 but end estimates are given in 2014 prices and 2014 NPV. Where estimates of cost and data were only available for 2013, they have been uplifted to 2014 prices using HM Treasury deflator figures\textsuperscript{14}. All final estimates quoted are reflective of 2014 figures.

EU Under-Implementation

24. This section outlines the costs and benefits of addressing UK under-implementation of EU requirements for spring water and the associated market failure. A number of assumptions have been made in terms of assessing the effect on bottled drinking water businesses, consumers and local authority trading standard officers.

25. When the issue is addressed, Welsh regulations will prohibit the use of UV disinfection treatment during the production of spring water. Guidance on the regulatory requirements will be issued, however, it is not foreseen that this guidance should address issues which are not detailed in the EU legislation nor issues which the EU Commission have not offered an opinion on. Businesses will be affected in the following ways:

- Firms can continue to categorise their water as spring water but must be able to safeguard consumer health in compliance with directive 2009/54 EC in the absence of disinfection treatment.
- Should firms wish to maintain the use of disinfection treatments specifically, they must re-categorise their product as a ‘bottled drinking water’ (as opposed to a ‘spring water’).

Costs to businesses

\textsuperscript{11} The guidance states that it: “can also be referred to by, but is not binding on, officials in the devolved administrations.”
26. The FSA and Defra conducted a formal bottled drinking water survey in 2013 with manufacturers of bottled water. Survey results demonstrated that only 6 spring water producers of 9 in Wales still use UV treatment.

27. We are aware that the results of this survey may be incomplete and would ask stakeholders to fill in our knowledge gaps in this area.

Q IA2.1: Is the assumption of 9 producers of spring water in Wales accurate?

Q IA2.2: If you did not complete the survey, please advise us of any relevant information on UV use in the production of Spring Water in Wales.

Q IA2.3 Please advise us of any costs or benefits that will result from the correct implementation of EU Regulations and the subsequent requirement to discontinue using UV decontamination in the production of Spring Water, with particular reference to

- Learning and dissemination costs
- Removal of UV equipment
- Installation of alternative compliant measures
- Re-labelling as a ‘bottled drinking water’
- Brand Value

Learning and dissemination costs

28. In January 2015 affected businesses will need to become familiar with the new regulations. It is estimated that it would take one full time production manager / director per manufacturing business approximately 2 hours in total to learn about this regulation and disseminate information to key staff (1.5 hours for learning and 0.5 hours for dissemination). The median hourly pay rate for full time production managers/directors is around £26.12 (ASHE Provisional 2014 Estimates in 2014 prices15, with a 30% overhead uplift in accordance with the UK standard cost model)16. Assuming six affected spring water firms, the total one-off learning and dissemination cost to businesses in Wales of £313, which translates to an equivalent annual cost of £36 (2014 prices).

Removal of UV equipment

29. Installation of UV equipment is assumed to have been considered as an investment. As UV treatment is no longer allowed in the production of spring water it must be removed safely without affecting the hygienic production of spring water. The British Soft Drink Association has indicated that the associated cost for removal of UV equipment includes a one of costs of between £3 and £5k per business (2013 prices). A mid – point average figure of £4k is assumed, along with a figure of £3k for a low scenario and £5k for a high scenario.

30. Defra has been advised in confidence by a supplier of UV installations that the initial cost of a small UV unit (270W) is likely to have been in the region of £4k. However, a large 3.5kW UV system has an initial cost of £12k. It is not known if any Welsh producers have such a large unit in place. These estimates were provided in 2013 prices. We assume a central

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31. These systems would be removed at a total central estimate cost of £73k (£4k removal cost and £8k unit cost for six businesses). The high scenario estimate is £43k (£3k removal cost and £4k unit cost for six businesses) and the low scenario estimate is £104k (£5k removal cost and £12k unit cost). All estimates here are in 2013 prices; but uprated to 2014 values.

32. We assume a zero salvage value for sale of this equipment.

**Installation of alternative compliant measures**

33. As firms are not allowed to use UV treatment in the production of spring water, we believe they will do a combination of the following:

a) Increased actions on hygiene;
b) A reassessment of positive release system; and
c) Additional microbiological sampling.

**Increased actions on hygiene**

34. The European Commission has sanctioned industry developed guidance on the hygienic production of bottled water covering spring water. The guidance stipulates the following control measures for a microbiological contamination incident: “increased hygiene training for staff, increased levels of maintenance of equipment and increased hygienic practices”. The British Soft Drinks Association (BSDA) has advised that there would be a one-off cost of £30k per business for such measures (2013 prices). For the six businesses affected, this equates to £183k in 2015 (2014 prices, 2014 NPV).

**The use of a ‘Positive Release’ system**

35. Naturally sourced water enters the bottling plant direct from a spring through stainless steel pipes in a closed system. Bottling takes place under hygienic conditions to protect the water from any contamination. The bottled are sealed, labelled and packed for distribution. As part of the process and in addition to the legal requirements for analysis and checks by local authority trading standard officials, various checks are performed on the bottled water. Microbiological analysis from source to the finished product is undertaken, as well as physical and chemical checks to ensure that no surreptitious pollution has taken place and that the inherent composition of the water is stable. The bottled water is then ‘positively released’, having been held until such time that these checks have been performed and all results are satisfactory.

36. The use of a ‘positive release’ system is common practice in the industry as confirmed by the BSDA, and required by members of the British Water Coolers Association and Natural Hydration Council. Survey results seem to indicate that some firms do not operate on such a system. Positive release can assure that a particular batch / lot of water is indeed free from contamination before it is released onto the market. However, it has been advised that positive release does not guarantee safe product as there may be slow growing organisms present that would not necessarily manifest during the time put aside for positive release, this would all be looked at in a risk analysis and be part of the Hazard and Critical Control Points (HACCP) plan. During the time set aside for positive release, any results which are of concern on a particular batch / lot means that the bottled water would not be released and

the batch / lot would be quarantined until the source of pollution was found and eradicated (a
legal requirement).

37. We have not been able to find data on the additional cost of an extended positive release
system, and therefore the costs of this system are not monetised in this impact assessment. However industry has informed that this additional measure will not be significant.

Additional microbiological sampling

38. The British Soft Drinks Association has advised us that additional microbiological testing
would be necessary for a defined amount of time (estimated at three months). Depending
on the water source, industry could test for a longer period of time such as six months upon
changing manufacturing methods such as removal of a UV installation. However industry
have informed us that it is unlikely that additional testing would go beyond three months.
The British Soft Drinks Association has advised that this additional testing is likely to be a
one of cost for each business per month of around £500 (2013 prices). Using a best
estimate of a three month period of additional testing for six businesses, this equates to a
one of cost of £9,154 (2014 prices, 2014 NPV).

39. In summary we believe that affected FBOs will do a combination of the above three
scenarios. It is hoped that information from FBOs will be provided during the consultation
period, so that true costs can be established.

Re-labelling as a ‘bottled drinking water’

Labelling Costs

40. We consider here whether firms that wish to continue with the use of UV treatment would re-
label their products as bottled drinking water. Re-labelling may become a significant
consideration to firms in the instance that if it is not possible for a business to continue to
market spring water because the source requires disinfection for potability (i.e. suitability for
human consumption). Industry has advised that this is an unlikely scenario (British Soft
Drinks Association Bottled Water Group, 2013). Therefore we do not include the impacts of
such action in this end cost and benefit analysis calculations for this impact assessment.
However, it is worth considering these costs, as re-labelling may be required if it becomes
subsequently apparent upon assessment of source quality in the absence of UV disinfection
treatment, that this is necessary.

41. Research indicates that the average cost of implementing a minor label change for bottled
water is £1,810 in 2010 prices (‘Developing a framework for assessing the costs of labelling
changes on the UK’18) equivalent to £1,556 in 2014 prices and 2014 NPV. Removal of the
term ‘spring water’ would go across all stock keeping units (SKUs). The British Soft Drinks
Association have advised that there are around 20 SKUs which highlight ‘spring water’ as an
ingredient, for any one of their members covering different pack sizes, types and potentially
flavoured ranges. Therefore, the average one-off label change cost for all businesses is
estimated at £31,121. However, this estimate relates to the whole of the UK and is therefore
an overestimate for the respective value for Wales.

42. In addition to just re-labelling, there are other associated costs around rebranding such as
the need for new marketing materials such as leaflets and advertising campaigns. The
BSDA have estimated that this would add between £50k-£100k additional cost per business
(2013 prices) in 2015. For the six businesses, this would be equivalent to central estimate of

£0.46m (2014 prices, 2014 present value) with a low and high estimate of £0.31m to £0.61m respectively.

Brand Value

43. The British Soft Drinks Association stated that brand value and referenced bottled water category are highly significant to their members’ clients, who do focus on the category of water supplied. As previously mentioned, there are 9 spring water brands in Wales. In the UK, a spring water brand is not necessarily the same as a spring water source, as a spring water FBO is likely to package spring water for a number of different retailers and businesses and the same spring water source can be sold under different brand names of major retailers.

44. Typically we would expect a reduction in profits if FBOs re-categorise products currently labelled as spring water as bottled drinking water. Internal research from Defra suggests that the average medium own brand spring water costs £0.28 per 100 litres while the average medium own brand bottled drinking water costs £0.22 per 100 litres (data sourced from price comparison website). This implies that the term spring water commands an average price premium of 27% which could have impacts on firm revenues. However, there are cases where imported bottled drinking water is sold at a premium because of associated marketing campaigns. We have not monetised this cost as industry has informed us that members are unlikely to take such action.

45. As well as a loss in price premium and hence revenue, the British Soft Drinks Association have indicated that re-labelling this would lead to losses in manufacturing and associated jobs in warehousing and distribution jobs losses. The British Soft Drinks Association has not provided figures for this situation therefore this is currently a non-monetised cost. An additional concern is that if UV treatment could not be used, there could be a microbial contamination leading to a product recall. A product recall could damage a brand significantly, leading to loss sales and profits for a firm. However other EU MSs do not use UV treatment and there are no specific unique reasons as to why UV is required by UK firms in spring water production. As long as EU requirements for exploitation are met, it should be possible to prevent microbial contamination. It is important to note that bottled drinking water is subject to the same risks as other food items which are mass produced. However there have been no product recalls for bottled drinking water based on microbial contamination for a decade and to date\textsuperscript{19}. Therefore product recall and brand value are currently non-monetised costs.

On-going Benefits to businesses

46. Firms will be prohibited from using UV treatment. Subsequently, they will not be spending money on electricity. Therefore their costs in this area will reduce. We have been advised by a supplier of UV equipment that electricity consumption may vary according to the rate of the water flow being treated and that realistically most sites will have a small UV system. Electricity costs for a small UV system are estimated to be approximately £300 per annum. Large UV systems are assumed to have electricity costs of £4k per annum (2013 prices); but uprated to 2014 prices in cost-benefit analysis modelling. We assume a central scenario where £300 per annum forms the basis of our low scenario, £4k the basis of our high scenario and we take the mid-point to calculate a central estimate (£2,150). We still assume that six businesses in Wales will be affected by the proposed intervention. This equates to a

\textsuperscript{19} \url{http://www.food.gov.uk/search/?site=enforcement-alerts&client=fsa_topical&output=xml_no_dtd&oe=UTF-8&ie=UTF-8&proxystylesheet=fsa_topical&q=water}
central estimate of £113k with a low scenario of £16k and a high scenario of £210k (2014 prices, 2014 NPV).

47. The British Soft Drinks Association have indicated that incremental cost savings for not using UV would be for new lamps, safe disposal of spent lamps and preventative maintenance plans. This is estimated at between £300 to £3k per annum depending on the size of the business (2013 prices) and we take a central estimate as the mid-point of the range at £1,650 per business. For the six businesses, this is equivalent to a central estimate of £87k over 2015-2024 with a low scenario of £16k and a high scenario of £158k (2014 prices, 2014 NPV).

Costs to Consumers

48. It is quite possible that any costs borne by the industry could be passed onto consumers by higher prices for bottled water products. We currently do not have information on whether this would happen so this impact assessment assumes no pass-through to consumers.

Benefits to Consumers

49. Rectifying the market failure is of ultimate benefit to the UK consumer who will be better informed about the category of bottled water product they choose to purchase, regardless of which EU MS it was produced in. We currently do not have data on how much consumers actually value this increased information therefore it has not been possible to monetise this benefit to consumers. Gathering this data would be a costly exercise which would not be an appropriate or proportionate use of resources, given that the under-implementation of EU law must be addressed regardless of the market failure and only a minority of consumers use such information in their purchasing decision making processes. However it should be noted that the consumers who use bottled water information in their purchasing decisions will have increased information and will benefit from Policy Option 2. Therefore this impact assessment underestimates the net benefit to the UK of Policy Option 2.

Costs to Government

50. Local authority trading standard officers will also need to become familiar with the new regulation. It is estimated that it would take one trading standards officer 2 hours to read the regulations and disseminate information to key staff (1.5 hours to read and 0.5 hours to disseminate information). The median hourly pay rate for a trading standards officer is around £19.37 (ASHE Provisional 2014 Estimates in 2014 prices20, with a 30% overhead uplift in accordance with the UK standard cost model)21. There are 22 local authorities in Wales. The total one-off familiarisation cost to enforcement bodies in Wales of £852, which translates to an equivalent annual cost of £99 (2014 prices, 2014 NPV).

51. We assume that there are no costs to Government from monitoring compliance with the EU legislation due to be implemented. Time spent to check compliance with this EU law cannot be separated from other checks. Therefore verification control costs arising solely due to addressing the under-implementation of EU law have not been monetised. Any monitoring costs of compliance with this EU law would also likely to be marginal as enforcers must continue to monitor businesses to ensure compliance with other regulations.

Summary Table

52. A summary table of the costs and benefits is provided below:

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<table>
<thead>
<tr>
<th>Costs</th>
<th>Low Scenario</th>
<th>Central Scenario</th>
<th>High Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning and dissemination costs for</td>
<td>0.001</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>businesses and government</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Removal of UV Equipment</td>
<td>0.018</td>
<td>0.024</td>
<td>0.031</td>
</tr>
<tr>
<td>Write off cost of UV equipment</td>
<td>0.024</td>
<td>0.049</td>
<td>0.073</td>
</tr>
<tr>
<td>Additional hygiene action</td>
<td>0.183</td>
<td>0.183</td>
<td>0.183</td>
</tr>
<tr>
<td>Additional microbial sampling over 3 months</td>
<td>0.009</td>
<td>0.009</td>
<td>0.009</td>
</tr>
<tr>
<td><strong>TOTAL COSTS</strong></td>
<td><strong>0.235</strong></td>
<td><strong>0.266</strong></td>
<td><strong>0.296</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricity cost savings from not running</td>
<td>0.016</td>
<td>0.113</td>
<td>0.210</td>
</tr>
<tr>
<td>UV systems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL BENEFITS</strong></td>
<td><strong>0.032</strong></td>
<td><strong>0.200</strong></td>
<td><strong>0.368</strong></td>
</tr>
</tbody>
</table>

| NET BENEFIT                                | -0.266       | -0.067           | 0.132         |

53. This section discusses 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.

54. As discussed above, the FSA and Defra conducted a formal bottled drinking water survey in 2013 with manufacturers of bottled water. Survey results demonstrated that only six spring water producers in Wales still use UV treatment. Of these three businesses, there were no micro or small businesses.

55. Therefore, we do not propose to seek derogation for small and micro businesses as our evidence suggests that none are affected. Additionally small and micro businesses are not exempt from the EU requirements for use of the marketing term spring water.
Annex F: List of interested Parties

ADAS
Alderwicks
Brecon Carreg
Calypso Soft Drinks
Childrens Commission Wales
Decantae Mineral Water Ltd
Dwr Cerist Cyf
Hafod Spring Water
Iceland Foods Ltd
Llanllyr Water
Minton Trehearne Davis
Montgomeryshire Natural Spring Water
National Health Service Wales
National Public Health Service Wales
Natural Resources Wales
Pembrokeshire Spring Water Co
Princes Gate Spring Water
Prysg Natural Spring Water
Radnor Hills Mineral Water Company
Royal Welsh Agricultural Society
Snowdon Water
The Beacons
Three Wells Water Co Ltd
Trederwen Springs Ltd Wales
Ty Nant Spring Water
Wales Social Partners Unit
Welsh Government
Y Ffynnon