

Title: The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017

CONSULTATION SUMMARY PAGE

Date launched:	12 APRIL 2017	Closing date:	05 JULY 2017		
<p>Who will this consultation be of most interest to? Producers of Natural Mineral Water, Spring Water and Bottled Drinking Water. Enforcement Authorities responsible for the enforcement of the Regulations in this sector.</p>					
<p>What is the subject of this consultation? In 2015 all regulation on bottled water of any description was consolidated into the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 (“the 2015 Regulations”). A subsequent EU instrument and enquiries into the application of the 2015 Regulations necessitate amending the 2015 Regulations. The FSA has also drafted guidance on the 2015 Regulations (as to be amended by the proposed Regulations) for comment.</p>					
<p>What is the purpose of this consultation? To seek the views of stakeholders on the proposed amendments to the 2015 Regulations, including:</p> <ul style="list-style-type: none"> • Transposition of Commission Directive 2015/1787 removing the requirement for check and audit monitoring for spring water and bottled drinking water • Amendment of regulation 2 on definitions of “fluoride removal treatment” and “ozone-enriched air treatment” • Amendment of regulation 13 on sale of natural mineral water • Clarification of regulation 15 on the disinfection of spring water • Amendment of regulation 17 on the advertising of spring water • Amendment of regulation 18 on the sale of spring water • Amendment of Schedule 3 to meet the requirements of Directive 2009/54 • Amendment of parameters in Schedule 7 to match Directive 98/83 • Amendment of Schedule 9 to clarify period of exemption <p>To seek comments on draft guidance on the 2015 Regulations as to be amended by the proposed Regulations.</p>					
<p>Responses to this consultation should be sent to:</p> <table border="0"> <tr> <td>John Hirst Regulatory Policy Team Food Standards Agency Wales Tel: 02920 678940 Email: Food.Policy.Wales@foodstandards.gsi.gov.uk</td> <td>Postal address Food Standards Agency 11th Floor, Southgate House Wood Street Cardiff CF10 1EW</td> </tr> </table>				John Hirst Regulatory Policy Team Food Standards Agency Wales Tel: 02920 678940 Email: Food.Policy.Wales@foodstandards.gsi.gov.uk	Postal address Food Standards Agency 11 th Floor, Southgate House Wood Street Cardiff CF10 1EW
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Impact Assessment included?	No				

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017

DETAIL OF CONSULTATION

Introduction

In 2015, all regulation on bottled water was consolidated into a single Statutory Instrument, the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Wales) 2015 (“the 2015 Regulations”). A new European Directive namely Commission Directive (EU) 2015/1787 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption has subsequently been published that alters the monitoring requirements for spring water and bottled drinking water and requires amendment of the 2015 Regulations. The FSA is proposing to also take the opportunity to amend the 2015 Regulations in response to a number of enquiries received so that any ambiguities in the 2015 Regulations can be removed.

Proposals

Commission Directive 2015/1787

Commission Directive 2015/1787 has amended Annexes II and III to Directive 98/83/EC, which lay down the minimum requirements of the monitoring programmes for all water intended for human consumption and the specifications for the method of analysis of different parameters.

The amendment to Annex II to Directive 98/83 removes the need for “check monitoring” and “audit monitoring” for bottled drinking water which is marketed as spring water or bottled drinking water.

Check monitoring is the regular monitoring by food authorities that ensures the water complies with certain parameters specified in the Regulations at a frequency determined by volume of production. Audit monitoring is an annual check on all the chemical and microbiological parameters set out in the regulations, and parameters already being sampled under check monitoring do not have to be included again in this annual sampling.

The EU law requirements for check monitoring and audit monitoring have been removed because it was considered that existing requirements in other food safety regulations were sufficient:

(i) The General Food Regulations 2004 prohibit a Food Business Operator (FBO) from producing food that is unsafe. This includes foods that contain certain ingredients or contaminants above safe levels. These Regulations enforce Regulation (EU) 178/2002.

(ii) FBOs are required, under the Food Hygiene (Wales) Regulations 2006 (as amended) to produce a Hazard and Critical Control Plan (HACCP). This plan should show how the FBO proposes to mitigate all identified hazards. These Regulations enforce Regulation (EU) 852/2004

It is therefore proposed to amend regulation 24(2)(a) and Schedule 8 of the 2015 Regulations, to remove the requirement for check monitoring and audit monitoring for spring water and bottled drinking water.

The monitoring of radiation in spring water and bottled drinking water is covered separately under Council Directive 2013/51/Euratom.

Regulation 2 of the 2015 Regulations

The FSA proposes to amend the definitions of “fluoride removal treatment” and “ozone-enriched air treatment” to make clear that any such treatment applied to Natural Mineral Water or Spring Water from outside Wales must be authorised by the competent authority in another part of the UK, another EEA state or a non-EEA state if it is to be sold in Wales. In relation to water from a non-EEA state, the Welsh Ministers, or equivalent authority in another part of the UK, will need to be satisfied that an authorisation in that state is equivalent to an authorisation under EU law.

Regulation 13 of the 2015 Regulations

The FSA proposes to amend regulation 13 to make clear that natural mineral water produced outside Wales is required to comply with the requirements as described in regulations 8, 9, 10, 11 and 12 of the 2015 Regulations if it is to be sold in Wales.

Regulation 15 of the 2015 Regulations

The FSA also proposes to use the opportunity to enhance the clarity of regulation 15 of the 2015 Regulations to make clear that the prohibition on disinfecting spring water and on adding any substance to spring water does not prevent the use of spring water in the manufacture of soft drinks. Equivalent provision is already made in relation to natural mineral water in regulation 9 (2) of the 2015 Regulations.

Regulation 17 of the 2015 Regulations

Article 9 of Directive 2009/54 requires that

(1) It shall be prohibited, both on packaging or labels and in advertising in any form whatsoever, to use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, which...

(b) In the case of drinking water packaged in containers, which does not satisfy the provisions of Annex I, Section I, are liable to cause confusion with a natural mineral water, in particular the description ‘mineral water’

Annex I, Section I to the Directive provides a definition for natural mineral water

Regulations 20 and 21 of the 2015 Regulations transpose this requirement for bottled drinking water. It is proposed to amend Regulation 17 of the 2015 Regulations to provide clarity that this is also the case for spring water – to make clear that it is prohibited to market spring water in such a way so as to potentially cause confusion between that spring water and natural mineral water.

Regulation 18 of the 2015 Regulations

The FSA proposes to amend regulation 18 to make clear that spring water produced outside Wales is required to comply with the requirements as described in regulations 14, 15, 16 and 17 of the 2015 Regulations if it to be sold in Wales.

Schedule 3 to the 2015 Regulations

Schedule 3 to the 2015 Regulations provides that no person may carry out ozone-enriched air treatment unless, prior to treatment, the water satisfies the requirements of paragraphs 3, 4 and 5 of Schedule 4. The references to paragraphs 3, 4 and 5

should, in fact, be references to paragraphs 6, 7 and 8. It is proposed to amend Schedule 3 to the 2015 Regulations to correct these cross-references.

Schedule 7 to the 2015 Regulations

Annex 1, Part C of Directive 98/83 sets out indicator parameters, including for 'colour' 'odour' and 'taste'

Part 3 of Schedule 7 to the 2015 Regulations currently sets out indicator parameters that are not precisely the same as in the Directive

Discussions within the FSA have been inconclusive as to whether the wording in the 2015 Regulations is equivalent to (or more stringent than) the wording of the Directive. Nevertheless, it is considered that amending the wording of the 2015 Regulations to match the wording of the Directive is the most appropriate measure.

Schedule 9 to the 2015 Regulations

The FSA proposes amending Schedule 9 to the 2015 Regulations to clarify that if an exemption is granted from food authority monitoring of radon and/or Tritium and/or Indicative Dose as detailed in the 2015 Regulations, this exemption lapses after a period of 5 years, beginning on the date the food authority notifies its decision to the Agency. However, the exemption period will lapse immediately if the level of radon, tritium or indicative dose exceeds the relevant parametric value.

Key proposal(s):

- **Transposition of Commission Directive 2015/1787 removing the requirement for check and audit monitoring for spring water and bottled drinking water**
- **Amendment of regulation 2 on definitions of “fluoride removal treatment” and “ozone-enriched air treatment”**
- **Amendment of regulation 13 on sale of natural mineral water**
- **Clarification of regulation 15 on the disinfection of spring water**
- **Amendment of regulation 17 on the advertising of spring water**
- **Amendment of regulation 18 on the sale of spring water**
- **Amendment of Schedule 3 to meet the requirements of Directive 2009/54**
- **Amendment of parameters in Schedule 7 to match Directive 98/83**
- **Amendment of Schedule 9 to clarify period of exemption**

Costs

Commission Directive 2015/1787 will remove the requirement for enforcement authorities to provide check monitoring and audit monitoring for spring water and bottled drinking water under Annex II to Directive 98/83. However, monitoring requirements under Regulations (EU) 178/2002 and 852/2004 will remain, so interventions by food authorities will continue to be required. It is not considered that the difference in resources expended to ensure compliance with the appropriate legislation will be significantly altered.

Similarly, it is not considered that the responsibility of FBOs will change, as their existing HACCP plan should provide verification that they have validated systems in place to ensure that they provide safe food under Regulation 178/2002 and have controls in place to mitigate against any hazards under Regulation 852/2004. This

would need to include demonstrating that the product meets the parameters in Schedule 4 and/or 7 of the 2015 Regulations as appropriate to the category of water.

It is not felt that the other proposed amendments will incur any costs to industry or enforcement authorities, and therefore there will be no costs to pass on to consumers.

The draft guidance provided as a part of this consultation will provide clarity on the application of the 2015 Regulations (as to be amended by the proposed Regulations). While these will require some familiarisation on the part of industry and enforcement authorities, it is felt that the clarity that this guidance provides will mitigate any costs of that familiarisation in terms of time spent pursuing enquiries into the interpretation of the Regulations. In addition consultees will have had the opportunity to examine the guidance as part of this consultation exercise and will therefore already be largely familiar with it.

It is therefore considered that the measures in this consultation are cost-neutral and, as such, we have not prepared an impact assessment. We would welcome comments on any costs or benefits we have not considered or challenges to the assumptions made in this section.

Engagement and Consultation Process

We consider that these are minor amendments to give absolute clarity on the intention of the 2015 Regulations, as well as implementing an EU Directive, without placing unnecessary burdens on food businesses or enforcement authorities. It is not envisaged that any of these measures will have a significant impact on food businesses, and will remove a responsibility from enforcement authorities. This consultation seeks stakeholders' views on these considerations.

Once the consultation has been closed, all responses will be considered and a summary of responses and the FSA's comments on those responses will be provided on the FSA website. If changes are required to the policy or intended legislation as a result of comments received, this will also take place after the consultation has closed.

Questions asked in this consultation:

- Q1: Do you agree with the proposal to transpose Commission Directive 2015/1787, which would remove the requirement for check and audit monitoring for spring water and bottled drinking water from the 2015 Regulations?**
- Q2: Do you agree that clarity on the use of spring water as an ingredient in production of soft drinks is desirable?**
- Q3: Do you agree that the Regulations should clarify that no person may sell spring water in Wales if it has been labelled with anything that may cause it to be confused with a natural mineral water?**
- Q4: Do you agree that water produced elsewhere should comply with the requirements described in the Wales Regulations if it is to be sold in Wales?**
- Q5: Do you agree with the proposal to amend Schedule 3 to the 2015 Regulations reflect the requirements of the relevant EU Directive?**
- Q6: Do you agree with the proposal to amend Schedule 7 to the 2015 Regulations reflect the requirements of the relevant EU Directive?**
- Q7: Do you agree with the proposal to amend Schedule 9 to the 2015 Regulations to make clear that there is a 5-year limit on exemptions?**
- Q8: Do you agree with the assessment of the proposals as cost-neutral? Please provide evidence of any costs or benefits that may arise from the implementation of the proposals.**
- Q9: Do you have any comments on the draft guidance?**
- Q10: Do you consider that the policy/proposed Regulations will have an effect on opportunities for use of the Welsh language?**
- Q11: We would like to know your views on the effects that the proposed Regulations would have on the Welsh language, specifically on:**
- i) opportunities for people to use Welsh and**
 - ii) on treating the Welsh language no less favourably than English.**
- Q12: What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?**

Responses

Responses are required by close **05July 2017**. 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).

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

Yours,

John Hirst
Regulatory

Enclosed

Annex A: Standard Consultation Information

Annex B: List of interested parties

Annex C: Draft Statutory Instrument

Annex D: Draft Regulatory Guidance

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.
2. 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.
3. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

4. A list of interested parties to whom this letter is being sent appears in Annex B. 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.
5. A Welsh version of the consultation package can be found at www.food.gov.uk
6. Please contact us if you require this consultation in an alternative format such as Braille or large print.
7. This consultation has been prepared in accordance with HM Government consultation principles¹.

¹ <http://www.bis.gov.uk/policies/bre/consultation-guidance>

Annex B: Interested Parties List

Brecon Water
Calypso Soft Drinks
Dŵr Cerist
Decantae
Highland Spring
Montgomery Spring
Pembrokeshire Spring
Pant Du
Princes Gate
Radnor Hills
Trederwen Springs
Tŷ Nant

British Bottled Water Producers
British Soft Drinks Association
British Water Coolers Association
Natural Hydration Council

Welsh Government
Welsh local authorities

W E L S H S T A T U T O R Y
I N S T R U M E N T S

2017 No. (W.)

FOOD, WALES

The Natural Mineral Water, Spring
Water and Bottled Drinking Water
(Wales) (Amendment) Regulations
2017

EXPLANATORY NOTE

(This note is not part of the Regulations)

2017 No. (W.)

FOOD, WALES

**The Natural Mineral Water, Spring
Water and Bottled Drinking Water
(Wales) (Amendment) Regulations
2017**

Made ***

Laid before the National Assembly for Wales

Coming into force ***

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

In accordance with section 48(4A)(2) of the Food Safety Act 1990, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency before making these Regulations.

There has been open and transparent public consultation during the preparation and evaluation of

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- (1) 1990 c. 16. 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. Section 16(1) was amended by section 40(1) of, and paragraphs 7 and 8 of Schedule 5 to, the 1999 Act. Section 17(1) was amended by paragraphs 8 and 12(a) of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 31 was amended by section 40(1) of, and paragraph 8 of Schedule 5 to, the 1999 Act. Section 48 was amended by section 40(1) of, and paragraph 8 of Schedule 5 to, the 1999 Act. Functions formerly exercisable by the “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 paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
- (2) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.

these 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⁽¹⁾.

Title, application and commencement

1.—(1) The title of these Regulations is the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017.

(2) These Regulations apply in relation to Wales.

(3) These Regulations come into force on XX.

Amendment of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

2. The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015⁽²⁾ are amended in accordance with regulations 3 to 12.

3. In regulation 2 (interpretation), in paragraph (1)—

(a) in the definition of “fluoride removal treatment”, for sub-paragraph (b) substitute—

“(b) in the case of natural mineral water or water intended to be bottled and labelled as “spring water”, “dŵr ffynnon”, or its equivalent in any other language, brought into Wales from another part of the United Kingdom or from another EEA State, a treatment which has been authorised by the responsible authority in the area in which the water is extracted as complying with the requirements of Articles 1 to 3 of Regulation 115/2010 and which does not have a disinfectant action; or

(c) in the case of natural mineral water or water intended to be bottled and labelled as “spring water”, “dŵr ffynnon”, or its equivalent in any other language, brought into Wales from a country other than an EEA State, a treatment that has been authorised by the responsible authority in that country in accordance with procedures for authorising fluoride removal treatment in that country which have

(1) OJ No L 31, 1.2.2002, p 1, last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council (OJ No L 189, 27.6.2014, p 1).

(2) S.I. 2015/1867 (W. 274).

been determined by the Agency or responsible authority in another part of the UK or in another EEA State to be equivalent to the requirements of Articles 1 to 3 of Regulation 115/2010 and which does not have a disinfectant action;”;

(b) in the definition of “ozone-enriched air treatment”, for sub-paragraph (b) substitute—

“(b) in the case of natural mineral water or water intended to be bottled and labelled as “spring water”, “dŵr ffynnon”, or its equivalent in any other language, brought into Wales from another part of the United Kingdom or from another EEA State, a treatment which has been authorised by the responsible authority in the area in which the water is extracted as complying with Article 5 of Directive 2003/40, as read with Article 7 of that Directive in respect of its application to spring water, as implemented in that part of the UK or that EEA State, and which does not have a disinfectant action; or

(c) in the case of natural mineral water or water intended to be bottled and labelled as “spring water”, “dŵr ffynnon”, or its equivalent in any other language, brought into Wales from a country other than an EEA State, a treatment that has been authorised by the responsible authority in that country in accordance with procedures for authorising ozone-enriched air treatment in that country which have been determined by the Agency or responsible authority in another part of the UK or in another EEA State to be equivalent to the requirements of Article 5 of Directive 2003/40, as read with Article 7 of that Directive in respect of its application to spring water, and which does not have a disinfectant action;”.

4. In regulation 13 (sale of natural mineral water), for sub-paragraphs (a) to (d) of paragraph (2) substitute—

“(a) has been extracted from a spring—

(i) in Wales, which has been exploited in contravention of regulation 8; or

(ii) otherwise than in Wales, which has been exploited otherwise than

in compliance with the requirements as described at regulation 8(1)(a) and (c) and regulation 8(2), or if the responsible authority of the area in which the spring is exploited has not given permission for the spring to be so exploited;

- (b) has been subjected—
 - (i) in Wales, to any treatment or addition in contravention of regulation 9; or
 - (ii) otherwise than in Wales, to—
 - (aa) a treatment which is not described at regulation 9(1)(a)(i), 9(1)(a)(ii), a fluoride removal treatment, or an ozone-enriched air oxidation treatment;
 - (bb) any addition other than an addition described in regulation 9(1)(b); or
 - (cc) any disinfection treatment, the addition of bacteriostatic elements, or any other treatment likely to change the viable colony count of the natural mineral water;
- (c) is bottled—
 - (i) in Wales, in contravention of regulation 10; or
 - (ii) otherwise than in Wales, in contravention of the requirements as described in regulation 10;
- (d) is labelled—
 - (i) in Wales, in contravention of regulation 11; or
 - (ii) otherwise than in Wales, in contravention of the requirements as described in regulation 11;”.

5.—(1) Regulation 15 (treatments and additions for water intended to be labelled and sold as “spring water” or “dŵr ffynnon”) is renumbered as paragraph (1) of that regulation.

(2) After paragraph (1) as so renumbered, insert—

“(2) Paragraph (1) does not prevent the use of water labelled and sold as “spring water”, “dŵr ffynnon”, or its equivalent in any language in the manufacture of soft drinks.”.

6. In regulation 17 (advertising of water as “spring water” or “dŵr ffynnon”), after paragraph (2), insert—

“(3) No person may advertise water intended to be labelled and sold as “spring water”, “dŵr ffynnon”, or its equivalent in any language 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.”.

7. In regulation 18 (sale of water as “spring water” or “dŵr ffynnon”) for sub-paragraphs (a) to (c) of paragraph (1) substitute—

“(a) is bottled—

- (i) in Wales, in contravention of regulation 14(1); or
- (ii) otherwise than in Wales, in contravention of the requirements as described in regulation 14(1).

(b) has been subjected—

- (i) in Wales, to any treatment or addition in contravention of regulation 15; or
- (ii) otherwise than in Wales, to—
 - (aa) treatment which is not described at regulation 15(1)(a)(i), 15(1)(a)(ii), a fluoride removal treatment, or an ozone-enriched air oxidation treatment;
 - (bb) any addition other than an addition described in regulation 15(1)(b); or
 - (cc) any disinfection treatment, the addition of bacteriostatic elements, or any other treatment likely to change the viable colony count of the natural mineral water;

(c) is labelled—

- (i) in Wales, in contravention of regulation 16; or
- (ii) otherwise than in Wales, in contravention of the requirements as described in regulation 16;”.

8. In regulation 24 (monitoring of water bottled and labelled as “spring water” or “dŵr ffynnon” and bottled drinking water), omit paragraph (2)(a).

9. In Schedule 3 (ozone-enriched air treatment), in sub-paragraph (b) of paragraph (1), for “3, 4 and 5” substitute “6, 7 and 8”.

10. In Schedule 7 (requirements for water bottled and labelled as “spring water” or “dŵr ffynnon” and bottled drinking water including prescribed concentrations or values of parameters), in Part 3 (parametric values for indicator parameters), in Table C (indicator parameters), in the row relating to—

- (a) item 5, parameter “Colour”—
 - (i) in column 3 (units of measurement), for “Mg/l Pt/Co scale” substitute “Acceptable to consumers and no abnormal change”; and
 - (ii) in column 4 (maximum concentration or value), omit “20”;
- (b) item 10, parameter “Odour”—
 - (i) in column 3 (units of measurement), for “Dilution number” substitute “Acceptable to consumers and no abnormal change”; and
 - (ii) in column 4 (maximum concentration or value), omit “3 at 25°C”;
- (c) item 14, parameter “Taste”—
 - (i) in column 3 (units of measurement), for “Dilution number” substitute “Acceptable to consumers and no abnormal change”; and
 - (ii) in column 4 (maximum concentration or value), omit “3 at 25°C”.

11. Omit Schedule 8 (monitoring for parameters other than radioactive substances in water bottled and labelled as “spring water” or “dŵr ffynnon” and bottled drinking water).

12.—(1) In Schedule 9 (monitoring for radioactive substances in water bottled and labelled as “spring water”, “dŵr ffynnon” and bottled drinking water), paragraph 13 (exemption from monitoring) is renumbered as sub-paragraph (1) of that paragraph.

(2) After sub-paragraph (1) so renumbered, insert—

“(2) Subject to sub-paragraph (3), the exemption from monitoring under sub-paragraph (1) lapses after a period of 5 years, beginning on the date the food authority notifies its decision to the Agency in accordance with sub-paragraph (1)(b).

(3) The exemption from monitoring under sub-paragraph (1) lapses immediately if the

level of radon, tritium or indicative dose exceeds the relevant parametric value specified in Part 4 of Schedule 7.”

Name

Minister for Social Services and Public Health under authority of the Cabinet Secretary for Health, Well-being and Sport, one of the Welsh Ministers

Date



**Food Standards Agency Guidance on
the Natural Mineral Water, Spring
Water and Bottled Drinking Water
Regulations in Wales and Northern
Ireland**

Draft for consultation

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Definitions

The definitions specified below apply for the purposes of this guidance.

The 2015 regulations

Where the words “the 2015 regulations” are used, they refer to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 and the Natural Mineral Water, Spring Water and Bottled Drinking Water (Northern Ireland) Regulations 2015 as amended by subsequent regulations. The details of the 2015 regulations and all amending regulations are included at Appendix 2.

Natural Mineral Water

Natural mineral water is water originating in an underground water table or deposit, which emerges or is extracted from a spring tapped at one or more natural or bore exits. It must be microbiologically wholesome and have been protected from all risk of pollution¹. It can be clearly distinguished from ordinary drinking water by its nature, including its mineral content and its constituents, and by its original purity.

In relation to water extracted from a spring in Wales or Northern Ireland, permission to use the spring for the extraction of natural mineral water must be obtained from the food authority in whose area the spring is located. The water must also be recognised according to the process in the 2015 regulations².

Water that has been recognized as natural mineral water must be sold using “natural mineral water” as its sales description. It cannot be sold under any other sales description. This means that it cannot be sold as “spring water” or as ordinary bottled drinking water.³

Spring Water

The term “spring water” is not defined in the 2015 regulations, but in this guidance, it shall be taken to mean “water to be bottled and/or labelled and/or sold as spring water”.

Water can only be bottled and/or labelled and/or sold with the description “spring water” if it originates in an underground water source, is intended for human

¹ Regulation 2

² Regulation 4 and Annex 1

³ Regulation 11(2)

consumption and is bottled at source⁴. Unlike natural mineral water, water that is labelled as spring water does not have to be officially recognised. The water must meet the requirements Schedules 4 and 7 to the 2015 Regulations

Water from a spring from which water sold as spring water is extracted may also be sold as bottled drinking water.

Bottled Drinking Water

Bottled drinking water means drinking water which is bottled, and is neither labelled nor sold as “spring water” or as natural mineral water. It can come from a variety of sources, including municipal supplies. The water must meet the requirements Schedule 7 to the 2015 Regulations

Food Authority

In this guidance, “food authority” means, in relation to Wales, each county or county borough council, and in relation to Northern Ireland, each district council.

Spring

The definition of spring is taken from the European Court ruling on case C-207/14⁵ on the definition of “one and the same spring”.

The notion of ‘natural mineral water from one and the same spring’ contained in Article 8(2) of Directive 2009/54/EC⁶ of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters must be interpreted as referring to a natural mineral water that is drawn from one or more natural or bore exits, and which originates in one and the same underground water table or in one and the same underground deposit, where, at all those natural or bore exits, that water has identical characteristics, pursuant to the criteria specified in Annex I to Directive 2009/54, which remain stable within the limits of natural fluctuation.

While this judgement refers specifically to a natural mineral water, the FSA considers that the same approach is also likely to apply in the case of spring water.

⁴ Regulation 14

⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62014CJ0207>

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0045:0058:EN:PDF>

Regulation across the UK

Q: Why does this guidance only apply in Wales and Northern Ireland?

The FSA is only responsible for the regulation of this sector in Wales and Northern Ireland. Defra holds responsibility in England and Food Standards Scotland is responsible for regulations in Scotland.

The consolidated Regulations in Wales and Northern Ireland (as amended) reflect the requirements of all Directives and Regulations in this area. A list of these can be found at Appendix 2.

Q: Are there differences between the 2015 regulations in Wales and Northern Ireland and the rest of the UK?

A: Yes. These are laid out for the different categories of water below.

Natural Mineral Water:

There are no differences in requirements for this category.

Spring Water:

Water that is bottled, supplied, advertised or sold as spring water in Wales and Northern Ireland may not undergo any treatment other than those specified in the 2015 regulations.

This specifically includes any treatment intended to disinfect the water i.e. to lower the “viable colony count” (the number of bacteria)⁷.

There is no regulatory prohibition on such treatments in England and Scotland.

This means that water may not be advertised or sold as spring water in Wales and Northern Ireland if it has been disinfected, even if the disinfection process is permissible in the country where the water is produced.

Spring Water and Bottled Drinking Water:

The requirement that the calcium content for any water which has been softened or desalinated was not below 60mg/l was removed in the 2015 Regulations in Wales and Northern Ireland. Forthcoming 2017 regulations in England will also remove this requirement. The requirement remains in Scottish legislation.

⁷ Regulation 15

Production of Natural Mineral Water

Q: How do I get a natural mineral water recognised?

A: If you are seeking recognition of a natural mineral water extracted from the ground in Wales or Northern Ireland, you must apply to the food authority within whose area the water is extracted and supply the required evidence that the water source meets the standards in the 2015 regulations⁸. The food authority will assess the application and, if it is compliant, grant “recognition” of the natural mineral water⁹. You must also apply for the food authority’s permission to exploit the spring.¹⁰

Q: What happens once the water is recognised as natural mineral water?

A: The European Commission will be informed of the water’s recognition. The list of registered natural mineral water in the EU Official Journal will be updated. A notification will appear in the London Gazette (Wales) or the Belfast Gazette (Northern Ireland). Details of the natural mineral water recognition will also be published on Gov.UK website.

Q: What if the food authority doesn’t agree that the water can be sold as natural mineral water?

A: If you disagree with their decision, you will have 6 months to apply to the Food Standards Agency for a review of that decision (if the application is made to a food authority in Wales or Northern Ireland)¹¹. A person will then be appointed by the FSA to review the decision.

Q: What do I do if things change?

A: If you wish to withdraw recognition, you must apply to the food authority that granted recognition.

In practice, if you are aware of any material changes to the composition of the water, or there is any change in the trade description of the water, the food authority that granted recognition will wish to know.

If you no longer wish to exploit the water, but still intend keeping the recognition status, you will need to be able to show that the water is safe for human

⁸ Regulation 4(2) and Schedule 1 of the 2015 regulations

⁹ The process for applying for, changing and appealing a decision is similar in England and Scotland. However, you should seek advice from your food authority for further guidance.

¹⁰ Regulation 8 (1) (b)

¹¹ Regulation 5 (2)

consumption before production begins again¹². You may meet this requirement by carrying out routine checks to ensure that the water meets the requirements of the regulation or carrying out a full suite of testing in advance of resuming production.

Q: Can I treat the water before I bottle it?

A: There are four treatments that are allowed for natural mineral water

- filtration or decanting to separate unstable elements
- physical elimination of free carbon dioxide;
- fluoride removal
- ozone-enriched air oxidation

Details of these treatments and the circumstances under which they are allowed to be carried out and the authorisations needed are contained in the 2015 regulations¹³.

You may introduce carbon dioxide to produce effervescent (sparkling) Natural Mineral Water so long as it is labelled appropriately¹⁴

No other treatments are permitted for Natural Mineral Water. In particular, no process that reduces the viable colony count (the amount of bacteria in the water) is permitted¹⁵.

Q: Can Natural Mineral Water be used as an ingredient in soft drinks?

A: You can use natural mineral water in soft drinks.¹⁶ You can use the term natural mineral water in the ingredients list as long as the water complies with the 2015 regulations before the stage it is added to the soft drink. There is no obligation to include the name of the source, but this is permitted if you wish.

¹² Article 14 of EU Regulation 178/2002 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

¹³ Regulation 9 (1) (a) and Schedules 2 and 3

¹⁴ Regulation 9 (1) (b)

¹⁵ Regulation 9 (1) (c)

¹⁶ Regulation 9 (2)

Production of Spring Water

Q: Does all water extracted from a spring need to comply with the spring water rules?

A: The rules for spring water apply to any water that is bottled, labelled or intended to be sold, as spring water. Spring water must comply with chemical and microbiological limits laid down in the 2015 regulations¹⁷. There is no restriction on using water from a spring to produce bottled drinking water provided it fulfils the requirements for bottled water.

Q: Do I need to ask for spring water to be granted recognition in the same way as natural mineral water?

A: There is no legal requirement for spring water to be 'recognised' but it must comply with the 2015 regulations if it is intended to bottle and sell the water as spring water.

Q: Do I have to bottle the water at the source?

Spring water must be bottled at source.¹⁸ It cannot be transported in tankers to the bottling plant unless this was the practice on or before 13 December 1996. The right to tanker is linked to the spring, not the bottler.

Q: Can I treat the water before I bottle it?

There are four treatments that are allowed for spring water.

- filtration or decanting to separate unstable elements
- physical elimination of free carbon dioxide;
- fluoride removal
- ozone-enriched air oxidation

Details of these treatments and the circumstances under which they are allowed to be carried out and the authorisations needed are contained in the 2015 regulations¹⁹.

You may introduce (or re-introduce) carbon dioxide to the water²⁰.

¹⁷ Schedule 7

¹⁸ Regulation 14 (1) (a)

¹⁹ Regulation 15 (a) and Schedules 2 and 3

²⁰ Regulation 15 (b)

No other treatments are permitted if you want to sell the water as spring water in Wales or Northern Ireland. In particular, no process that reduces the viable colony count (the amount of bacteria in the water) is permitted²¹.

Q: I am using a UV treatment to ensure that no contamination gets into the water after its extraction. Is that allowed?

A: In Wales and Northern Ireland, the use of any treatment that “reduces the viable colony count” is prohibited. This includes the use of UV treatment. A UV unit is designed to decontaminate the water by deactivating the bacteria within it. This means that even if the water coming out of the spring is within the compositional requirements in terms of the 2015 regulations, you must not use UV treatment at any point in the production process.

Q: Can I use UV treatment for any bottled water?

A: You can use UV treatment for any water that is to be labelled as bottled drinking water. You should ensure that any UV unit is working correctly. An independent test of the equipment is recommended for this.

Q: Can spring water produced elsewhere be sold in Wales and Northern Ireland?

A: So long as the spring water complies with the 2015 regulations in Wales and Northern Ireland it can be sold anywhere in the UK. If the water has been subject to UV treatment, or any other prohibited process, then it may not be sold or supplied in Wales or Northern Ireland, unless it is relabelled as bottled drinking water, even if it remains legal to sell it in the country of production.

Q: How do I know if the water I am selling is compliant with the Regulation?

A: You should check with your supplier or discuss with your food authority.

Q: Can Spring Water from outside the UK be treated with UV?

A: Spring Water produced in the EU should already comply with the 2015 regulations in Wales and Northern Ireland as the rules on allowed treatments are based on the EU Directive. Spring Water from outside the EU must comply with EU requirements if it is sold anywhere within the EU.

²¹ Regulation 15 (c)

Q: Can Spring Water be used as an ingredient in soft drinks?

A: You can use spring water in the manufacture of soft drinks. You can use the term spring water in the ingredients list. The spring water must comply with the 2015 regulations until the point of introduction of the first additional ingredient. For example, UV disinfection is allowed for the composite product (the soft drink) but the spring water must not have undergone this treatment before it is added.

Production of Bottled Drinking Water

Q: Are there any rules specifically for bottled drinking water?

A: Any water sold as bottled drinking water must still comply with chemical and microbiological requirements in the 2015 regulations²².

Q: Can I use UV treatment for bottled drinking water?

A: You can use UV treatment for any water that is to be labelled as bottled drinking water.

²² Regulation 19 and Schedule 7

Labelling, advertising and sale of water in bottles

Q: What information do I have to put on the label for natural mineral water?

A: There are detailed rules on labelling of Natural Mineral Water in the 2015 regulations²³. For example, you must indicate where it comes from, you must not put anything on the label that suggests the water comes from anywhere else and you may not make certain claims about the water's properties.

In addition you must declare the composition of the water and give information about any of the permitted treatments the water has undergone.

These requirements also apply to advertising and sale of the water.

Q: What information do I have to put on the label of a spring water bottle?

A: There are detailed rules on labelling "Spring Water" in the 2015 regulations²⁴. For example, you must indicate the name of the place and of the spring from which the water is extracted and you must not put anything on the label that suggests it comes from anywhere else.

In addition you must give information about any of the permitted treatments the water has undergone.

These rules also apply to advertising and sale of spring water.

Q: What do I have to put on the label of a bottled drinking water bottle?

A: You may not put anything on the label that is misleading, and in particular you may not include the words "mineral water" on the label²⁵ or suggest that it is "spring water"²⁶. This extends to the use of these phrases in other languages.

Q: My company name includes the word "spring". Can I put this on the label of a bottled drinking water?

A: You are not allowed to put anything on any food label that may mislead the consumer. If you put the word "spring" in a prominent way on the label of a bottled drinking water, for instance in prominent branding, there is a strong possibility that a

²³ Regulation 11 and Schedule 6

²⁴ Regulation 16

²⁵ Regulation 20

²⁶ Article 7 of Regulation 1169/2011 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN>

court would view this as misleading the consumer into believing they were purchasing spring water.

Trade description and sales description

Q: What is meant by “trade description”, and “sales description”?

A: A “trade description” is the name you give to the water for the purposes of sale. A “sales description” is a description of the category of product, such as “natural mineral water” or “spring water”.

Q: What can I use as the trade description?

This trade description must not refer to a location other than where the water is extracted. No person may sell natural mineral water from the same spring under more than one trade description. No person may sell spring water from the same spring under more than one trade description.

Q: Are the rules the same for natural mineral water and spring water?

A: Yes, although the way they are recorded is slightly different in practice.

You will be requested to confirm the “trade description” you intend to use when you have a natural mineral water recognised as this will be included in a listing of all UK recognised natural mineral waters on Gov.uk²⁷.

There is no requirement for recognition of spring water, and a central register of trade descriptions and sources is not kept.

Q: Do I have to include the trade description on the label?

A: There is no requirement to include the trade description on the label. If a “sales description” is used it may only be “natural mineral water”²⁸ or “spring water” or the permitted variants of this to indicate the source of carbon dioxide gas for sparkling water²⁹. This wording may also be included in another language³⁰.

²⁷ <https://www.gov.uk/guidance/food-standards-labelling-durability-and-composition#table-showing-natural-mineral-waters-recognised-in-the-uk>

²⁸ Regulation 11 (2)

²⁹ Regulation 11 (2) (b)

³⁰ If it is included in Welsh, the wording must be “dŵr mwynol naturiol” (for natural mineral water) or “dŵr ffynnon” (for spring water) or a permitted variant of either.

Q: What if the trade description does not include the source of the water?

For Natural Mineral Water³¹ and Spring Water³² you must include either the name of the spring or the place of exploitation using letters at least one and a half times the height and width of the largest of the letters used for that trade description

Q: Are there rules on trade description for bottled drinking water?

A: There are no restrictions on what trade description or sales description you may use other than in connection with use of the terms “natural mineral water” or “spring water”, which may only be used according to the rules above.

Q: Can I supply natural mineral water or spring water to a third party for onward sale, such as a supermarket or venue caterer?

A: Not all branding on the bottle of natural mineral water will constitute the trade description. The third party branding may be placed on the label including, where appropriate, a description of a product range, such as “value/economy” or “best /superior”. This branding should be distinct from the name of the product (for instance in a different font or graphically separated in some way).

A table of examples is provided on the next page of this guidance.

³¹ Regulation 11 (1) (b)

³² Regulation 16 (2) (b)

Examples of trade and sales descriptions³³

Retailer: ABC Supermarket

Trade description “Glen Valley”

Sales Description “Natural Mineral Water”

Example	Description	Satisfactory/unsatisfactory ³⁴
<i>ABC Supermarket best quality range</i> Natural Mineral Water	Supermarket “own branding” including the product range is separate from the sales description – no trade description included.	Satisfactory
<i>ABC Supermarket best quality range</i> Natural Mineral Water Dŵr Mwynol Naturiol	Supermarket “own branding” is separate from the sales description – sales description supplied in another language	Satisfactory
<i>ABC Supermarket best quality range</i> Glen Valley Natural Mineral Water	Supermarket “own branding” is separate from the trade description that matches the description in the register	Satisfactory
<i>ABC Supermarket best quality range</i> Naturally carbonated Natural Mineral Water	Supermarket “own branding” is separate from the sales description – permitted variant of sales description used	Satisfactory
ABC Supermarket Natural Mineral Water	No separation of own-brand from sales description – this would constitute a “trade description”	Not satisfactory
<i>ABC Supermarket</i> Valley Glen Natural Mineral Water	Trade description is different from the recognised trade description which is “Glen Valley”.	Not satisfactory

³³ These names are for illustrative purposes only. Any similarity to any existing organisation or product is entirely coincidental. The rules would also apply to water supplied by all suppliers in addition to retailers, such as a caterer or events venue. This is not an exhaustive list of possible combinations.

³⁴ Only the courts can ultimately decide whether a product is compliant with the 2015 regulations

Monitoring of Natural Mineral Water

Q: Who is responsible for monitoring the water?

A: Under general food law³⁵, it is the responsibility of the Food Business Operator to ensure that food (which includes water bottled for human consumption) is safe. You are required to maintain records to verify that you have taken the appropriate steps to ensure that food is safe. In addition to the requirements of the 2015 regulations, as a food business, you will need a Hazard Analysis Critical Control Point (HACCP) plan to document how you will deal with any hazards that could affect the safety of your product³⁶.

Q: As a producer, what monitoring/sampling do I need to carry out?

A: For a water source that is exploited

Your HACCP Plan will document how you will ensure that the water meets the requirements of the 2015 regulations³⁷. You will need to carry out operational checks to ensure the water remains microbiologically and chemically stable.

A: For a water source that is recognised but not exploited

As a food business, you will need to conduct routine analysis as part of your due diligence/HACCP to ensure that the water source remains protected. Alternatively, at the point you decide to go back into production you will need to carry out a full suite of testing to demonstrate the product is safe and marketable in line with food safety and compositional requirements for natural mineral water

Q: What checks will the food authority carry out?

A: For a water source which is exploited

The food authority is responsible for periodic monitoring to check that the water meets all the regulatory requirements.

A: For a water source that is recognised but not exploited

Before it is exploited again for the purpose of marketing as a natural mineral water, a new programme of monitoring must demonstrate that the water continues to meet

³⁵ Regulation (EC) 178/2002 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF>

³⁶ Regulation (EC) 852/2004 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0852-20090420&from=EN>

³⁷ Schedule 4

the conditions as set out in original recognition documents. If the water has changed at all, it would be for the food authority to determine the time-scales for whether the source could be exploited straightaway or whether the source is de-recognised with a view to providing recognition after a further period of assessment.

Monitoring of Spring Water and Bottled Drinking Water

Q: Who is responsible for monitoring?

A: Under general food law³⁸, it is the responsibility of the Food Business Operator to ensure that food (which includes water bottled for human consumption) is safe. You are required to maintain records to verify that you have taken the appropriate steps to ensure that food is safe. In addition to the requirements of the 2015 regulations, as a food business, you will need a Hazard Analysis Critical Control Point (HACCP) plan to document how you will deal with any hazards that could affect the safety of your product³⁹.

Q: What monitoring is required for spring water and bottled drinking water?

A: Spring water and bottled drinking water must not contain anything which would be a danger to human health. The parameters, both chemical and microbiological, by which food is deemed safe are detailed in the 2015 regulations. As a food business, you must make sure that the microbiological and chemical parameters set out in the 2015 regulations are met⁴⁰.

Q: What will the food authority monitor?

A: The food authority is responsible for monitoring the compliance of all FBOs to ensure that products are safe and comply with all relevant regulations. This may include inspection of your premises and examination of your HACCP documents including the verification records you keep that show continuing compliance. The food authority may take samples, but these samples will be tested to check for compliance with the 2015 regulations and do not replace the need for a food business operator to meet the requirements of general food law.

Q: The food authority used to monitor the water, which was my assurance that the water was safe. Why can't I rely on that?

A: From 27 October 2017⁴¹ the requirement to carry out specific check and audit monitoring has been removed from the responsibilities of the food authority. This is

³⁸ Regulation (EC) 178/2002 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF>

³⁹ Regulation (EC) 852/2004 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0852-20090420&from=EN>

⁴⁰ Schedule 7

⁴¹ Transposing Commission Directive (EU) 2015/1787 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L1787&from=EN> amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption.

because the law already requires FBOs to follow HACCP and ensure that unsafe food is not placed on the market. The duty of the food authority is not to carry out validation of FBOs' systems, but to ensure compliance with the 2015 regulations.

Q: What happens if I do not comply with any one or some of the parameters?

A: The food authority will advise you whether the non-compliance poses any risk to human health and what type of remedial action is necessary to restore the quality of the water with the emphasis on rectifying the problem at source. If any product presents a risk to human health it may be seized by the food authority. You may also be asked to recall or withdraw from sale such products.

Radiological Monitoring of Spring Water and Bottled Drinking Water

Q: Who has to carry out radiological monitoring?

A: The food authority is required to carry out radiological monitoring of spring water and bottled drinking water

Q: What does the food authority have to monitor?

A: The Food Authority must monitor radon, tritium and Indicative Dose at the point of bottling unless it is established that an exemption can be granted (see below)⁴².

Q: Has radioactivity been a historic issue for bottled water?

The FSA has published a fact sheet which outlines results of a survey conducted in 2014⁴³. While radiological monitoring has not shown significant problems in the past, it is important that assurance is maintained that there are no changes to this situation.

Q: Why does the food authority have to keep on doing radiological monitoring if there is no problem?

A: If evidence can be found, to the satisfaction of the food authority, that for a period of at least five years the parameter in question (e.g. radon) will remain below the value specified, then the food authority may apply an exemption from radiological monitoring. This means that the food authority would not carry out radiological monitoring of the water for the period of the exemption.

Q: What evidence would need to be provided for an exemption to be granted?

This evidence will include the following:

- Radon – Evidence, such as a representative survey, must show that there is no exceedance of the maximum permitted level of radon
- Tritium - There must be no man made sources of tritium present within the catchment area. Evidence for this may include providing information on surveillance programmes or investigations. Information from the public register⁴⁴ may be useful.

⁴² Reg 24(2)(b) and Schedule 9

⁴³ <https://www.food.gov.uk/sites/default/files/fsis-01-14-radioactivity-in-bottled-water.pdf>

⁴⁴ <http://epr.environment-agency.gov.uk/ePRInternet/SearchRegisters.aspx>

- Indicative Dose – Representative monitoring data or other reliable information must demonstrate that there is no elevated natural or artificial radioactivity

Q: What additional information would provide evidence for an exemption from food authority monitoring?

A: For representative surveys for radon the following information may provide evidence, including historical data:

- 1) geology of the area (what are the main rock-bearing formations in the aquifer, do these formations have radioactive elements in them such as uranium etc)
- 2) hydrology of the area (what are the routes of transfer of environmental contaminant in the rock or manmade (industry produced) radiation and what type of radiation)
- 3) radioactivity of the rock type
- 4) radioactivity of the soil type
- 5) radioactivity of the well type

For Indicative Dose, sampling results must be below the parametric value

For tritium, sampling must demonstrate that there are no artificial sources of tritium or other artificial radionuclides in the catchment area

Q: Does Radon monitoring need to happen even if previous results show that there is no problem?

A: If previous radon monitoring of a water source has not shown high concentrations, there is no need for further monitoring unless there has been some relevant material change in the source. If other monitoring (for example gross alpha) has been carried out, this will not provide reliable information about possible radon concentrations. The main reason is that some water sources may have significantly higher concentrations of radon than its radioactive parent (radium).

Q: Can I be exempted from food authority monitoring for tritium?

A: Yes, as long as the Food Authority is satisfied on the basis of representative surveys, monitoring data or other reliable information that tritium will remain below 100Bq/l.

Q: Can I be exempted from food authority monitoring Indicative Dose?

A: Yes, if gross alpha activity is less than 0.1Bq/l and gross beta activity is less than 1.0Bq/l, the Food Authority can assume that the Indicative Dose is less than 0.1mSv.

Monitoring is only necessary where there is a source of artificial or elevated natural radioactivity present and it cannot be shown on the basis of other representative surveys or investigation that the level will remain below 0.1mSv.

Q: What will an exemption mean in practice?

The food authority will not be required to monitor the water for a period of 5 years. At the end of the 5 year exemption period, a further 5 year exemption period may be granted if the food authority is satisfied that the parameters will remain below the relevant parametric values for a minimum of 5 years.

In practice, the FBO's HACCP plan may include measures to provide evidence that no material change to the risk has taken place to the food authority at the end of this five-year period to allow the food authority to determine whether a further exemption may be granted.

There are currently no formal administrative procedures in place for exemptions. The process of granting exemptions will be kept under review. In the meantime, Competent Authorities throughout the UK will be gathering and looking at existing data on radioactivity and considering undertaking further surveys with a view to obtaining sufficient evidence to justify initial five year UK wide exemptions.

Q: Why does the exemption only last for 5 years?

A: A five year period for applying the exemption is considered long enough to reduce the burdens on both food authorities and food businesses of monitoring where risk is deemed unlikely or where the risk of breaching a parametric value is low, but not so long that there is a possibility that levels of radioactive substances could change during this time. There could also be potential problems with record keeping if exemptions lasted for more than five years.

Q: Do I have to submit the same level of data at the end of the 5 year period?

A: You will need to be able to show, to the satisfaction of the food authority, that there has been no change in risk. In some circumstances, this may involve further monitoring of the parameters in the 2015 regulations; in others it may be sufficient to show a lack of any activity that carries the possibility of changing the risk, such as seismic activity or other underground disturbance.

Q: What if things change during the period of the exemption?

A: The exemption from monitoring will not apply following any significant local geological event or incident which could affect radiation levels, e.g. disruption due to unconventional shale gas extraction activity.

The British Geological Survey has advised that a link between seismic events and radon release is inconclusive, and it would be difficult to define a seismic threshold above which monitoring needs to change. Nevertheless, any seismic activity would need to be taken into account when considering the renewal of an exemption.

Monitoring would be required to establish baseline data which would confirm whether a further exemption could be granted for a period of time, or whether formal monitoring for radiological parameters is required.

The exemption will lapse immediately if there is any significant change in parametric values observed at source and bottling.

Q: Is there an official procedure in place for notifying the FSA about an exemption?

A: There is no official procedure in place yet, a pro-forma has been prepared and can be used by the food authority when submitting information to the Competent Authority. It is attached at Appendix 1.

Q: What if I do have to test for radon? I have no experience of testing for radon, what should I do?

A. Radon monitoring is a new requirement, and so the FSA recommend a simple and stepped approach:

Step 1: The Food Business Operator should complete a desk based study - undertake the initial screening of radon hazard by assessing publically available data such as the hazard maps in a Drinking Water Inspectorate-commissioned report on Radon in water⁴⁵, or their local authority, who may hold information about previous monitoring for radon in local water supplies. Additional information about radon is available from the UK reference site on radon from Public Health England⁴⁶.

Step 2: If screening demonstrates that there is no risk of radon exceeding 100Bq/l because, for example, radon in air levels are low, and the underlying rock type is not uranium bearing, this information should be appended to the representative survey data and submitted to the food authority, which will then confirm whether you qualify for a five year exemption from monitoring by the food authority for radon and the date at which the exemption begins.

Step 3: If Step 1 demonstrates that there may be a risk of radon exceeding 100Bq/l , or there is insufficient publically available information on which to base a judgement, a water sample should be taken by the food business operator at the point of bottling and analysed for radon. Radon sampling and testing must be carried out carefully and quickly to ensure that a representative analysis is obtained. With a half-life of

⁴⁵ <http://www.dwi.gov.uk/research/completed-research/reports/DWI70-2-301.pdf>

⁴⁶ <http://www.ukradon.org/information/ukmaps>

only 3.8 days the radon activity will decrease rapidly. The sampling technique should be specified by the laboratory accredited to conduct the analysis.

Laboratories should be accredited to carry radio-analytical methods fully accredited by the United Kingdom Accreditation Service (UKAS) against ISO 170253. Public Health England laboratories can undertake testing for radon in water.

Step 4 If monitoring results from Step 3 demonstrate that there is no risk of radon exceeding 100Bq/l at the source; this information should be appended to the representative survey data and submitted to the food authority.

Step 5: If monitoring results at the point of bottling exceed 100Bq/l, but remain below 1000Bq/l then monitoring by the food business operator must continue at the sampling frequencies required by the 2015 regulations, which are dependent on production volume. The water is considered safe to drink and no remedial action is required.

Q: What happens if monitoring results exceed 1000Bq/l for radon?

A: Where levels of radon above 1000Bq/l are detected, treatment is required immediately. The Drinking Water Inspectorate has published guidance on treatment of small water supplies - section 7.1 – Radon Removal. A sample result of under 1000Bq/l must follow any remedial action before the product is allowed back on the market.

Q: What happens if I exceed a particular parameter for Indicative Dose or tritium?

A: The 2015 regulations stipulate that if a parametric value is exceeded in a sample of spring water or bottled drinking water further sampling must be carried out by the food authority to ensure that the measured values are representative of an average activity concentration for a full year

Appendix 1 – Proforma for exemption for radiological monitoring



Department
for Environment
Food & Rural Affairs

EXEMPTION PROFORMA

Complete a new form each time any changes are observed

Exemption for monitoring: Radon / Tritium / Indicative Dose (delete as applicable)

Food Authority Details

Food Authority:

Country:

Authorised Office Name:

Authorised Officer Contact Details:

Email:

Food Business Operator Details

Name of Food Business Operator:

Abstraction licence Number:

Address of Food Business Operator:

Email:

*Sample data (representative of the quality of water concerned through the year
in which the sample is taken)*

Radon:

Tritium:

Indicative Dose:

Evidence seen:

Radon:

Tritium:

Indicative Dose:

Date at which 5 year exemption has been granted:

Radon:

Tritium:

Indicative Dose:

Additional Information

Confirmation

I undertake to inform the Competent Authority of any changes that may affect the basis under which I granted exemption from monitoring of radiological parameters

_____ **Date** _____

Submit this form electronically to: FSA/Defra when completed

Appendix 2 – List of Regulations

List of European Directives and Regulations that specifically apply to Natural Mineral Water, Spring Water and Bottled Drinking Water

1. Council Directive 2009/54/EC⁴⁷ on the exploitation and marketing of natural mineral water
2. Council Directive 98/83/EC⁴⁸ on the quality of water intended for human consumption (known colloquially as “The Drinking Water Directive”)
3. Council Directive 2013/51/ EURATOM⁴⁹ laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption
4. Commission Regulation (EU) 115/2010⁵⁰ laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters
5. Commission Directive 2003/40/EC⁵¹ 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
6. Commission Directive 2015/1787⁵² - Amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

⁴⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0054&from=EN>

⁴⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF>

⁴⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0051&from=EN>

⁵⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0013:0015:EN:PDF>

⁵¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0040&from=EN>

⁵² <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L1787&from=EN>

List of Regulations that apply to Natural Mineral Water, Spring Water and Bottled Drinking Water in Wales and Northern Ireland

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015⁵³

The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015⁵⁴

(amending regulations to be added once made in 2017)

⁵³ <http://www.legislation.gov.uk/wsi/2015/1867/made>

⁵⁴ <http://www.legislation.gov.uk/nisr/2015/365/contents/made>