
Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations in Wales and Northern Ireland

27 October 2017

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Summary

Please put your answers in the box and stick to the options in the lists given. This is to make sure the guidance is found by the right audience on the website.

Intended audience:	Producers of natural mineral water, spring water and bottled drinking water
Which UK nations does this cover?	Wales and Northern Ireland
Purpose:	This guidance is intended to give producers the information required to comply with the Regulations.
Legal status:	This guidance is regulatory guidance (Information specifying what food business operators need to do to comply with domestic or EU legislation). Where advice is on best practice, this will be made clear.
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Revision history

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please let us know by emailing betterregulation@foodstandards.gsi.gov.uk. If you have any comments on the guidance itself, please call us using the contact number on page 2

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
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Introduction

1. In 2015 all regulations on natural mineral water, spring water and bottled drinking water was consolidated in Wales and Northern Ireland into a single set of Regulations for each country. In 2017 the first amending regulations were made. This guidance covers the up-to-date legislative position after the 2017 Regulations came into force.

Intended audience

2. This guidance is for food business operators.

Purpose of guidance

3. The guidance has been produced to help food businesses comply with the Regulations.

Legal status of guidance

4. These guidance notes have been produced to provide advice on:
 - the legal requirements of the Regulations at [Appendix 3](#) and
 - best practice in this area.
5. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you follow the guidance notes they will help you to comply with the law. You are **not** required by law to follow best practice advice. **To distinguish between the two types of information, all advice on best practice is in shaded boxes, with a heading of Best Practice.**

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.

The 2017 Regulations

Where the words “the 2017 regulations” are used, they refer specifically to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2017 and the Natural Mineral Water, Spring Water and Bottled Drinking Water (Northern Ireland) (Amendment) Regulations 2017.

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. It must come from a source that has a stable composition.

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.

¹ Regulation 2

² Regulation 4 and Annex 1

Water that has been recognised 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 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 consumption and is bottled at source⁴. Unlike natural mineral water, water that is labelled as spring water does not have to be officially recognised nor have a stable composition. The water must meet the requirements outlined in 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 of 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.

³ Regulation 11(2)

⁴ Regulation 14

Spring

For natural mineral water and spring water, a spring is a continuous body of underground water that emerges at some point. It can be tapped at one or more natural or bore exits. You should note the very specific definition of “one and the same spring” in relation to Trade Description.

Source

“Source” is not defined within these regulations but can be considered as being both the body of ground water and the point of emergence.

Borehole

A borehole is an artificially produced exit for water emerging from a source originating in an underground water table or deposit.

Regulation across the UK

Q01: Why does this guidance only apply in Wales and Northern Ireland?

A: 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.

Q02: Are there differences between the 2015 regulations in Wales and Northern Ireland and the rest of the UK?

A: Yes. The main differences are laid out for the different categories of water below.

Natural Mineral Water:

There are no significant differences in requirements for this category. Some procedural changes exist, for instance in how to appeal against decisions on recognition.

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)⁵.

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.

⁵ Regulation 15

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. Currently this requirement is still in force in England and Scotland.

The requirement to monitor spring water and bottled drinking water for Radon was brought in to the 2015 Regulations. These have also been adopted in Scotland.

The removal of check and audit monitoring in the 2017 amending regulations has also been adopted in Scotland.

Future amendments in England are likely to address these discrepancies in the Regulations. This will be reflected in future amendments to this document.

Production of Natural Mineral Water

Q03: 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 regulations⁶. The food authority will assess the application and, if it is compliant, grant “recognition” of the natural mineral water⁷. You must also apply for the food authority’s permission to exploit the spring.⁸

Q04: 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.

Q05: 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)⁹. A person will then be appointed by the FSA to review the decision.

⁶ Regulation 4(2) and Schedule 1 of the 2015 regulations

⁷ 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.

⁸ Regulation 8 (1) (b)

⁹ Regulation 5 (2)

Q06: What do I do if things change?

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

Best 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, recommended good practice would be to inform the food authority that granted the recognition

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 consumption before production begins again¹⁰. 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.

Q07: 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 can be carried out and the authorisations needed are contained in the 2015 regulations¹¹.

¹⁰ Article 14 of EU Regulation 178/2002 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

¹¹ Regulation 9 (1) (a) and Schedules 2 and 3

You may introduce carbon dioxide to produce effervescent (sparkling) Natural Mineral Water so long as it is labelled appropriately¹².

No process, including permitted treatments, may reduce the viable colony count (the number of bacteria in the water).

No other treatments are permitted if you want to sell the water as natural mineral water in Wales or Northern Ireland.

Q08: Can Natural Mineral Water be used as an ingredient in soft drinks?

A: You can use natural mineral water in soft drinks.¹³ You can use the term natural mineral water in the ingredients list if the water complies 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 natural mineral water must not have undergone this treatment before it is added. There is no obligation to include the name of the source, but this is permitted if you wish.

¹² Regulation 9 (1) (b)

¹³ Regulation 9 (2)

Production of Spring Water

Q09: 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 regulations¹⁴. There is no restriction on using water from a spring to produce bottled drinking water provided it fulfils the requirements for bottled water.

Q10: 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.

Q11: Do I have to bottle the water at the source?

A: Spring water must be bottled at source.¹⁵ 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.

Q12: Can I treat the water before I bottle it?

A: 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.

¹⁴ Schedule 7

¹⁵ Regulation 14 (1) (a)

Details of these treatments and the circumstances under which they can be carried out and the authorisations needed are contained in the 2015 regulations¹⁶.

You may introduce (or re-introduce) carbon dioxide to the water¹⁷.

No process, including permitted treatments, may reduce the viable colony count (the number of bacteria in the water)¹⁸.

No other treatments are permitted if you want to sell the water as spring water in Wales or Northern Ireland.

Q13: I am using an ultra violet (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.

Q14: Can I use UV treatment for any spring water?

A: You can use UV treatment for any water that comes from a source from which you also draw water intended to be sold as spring water. However, any water that has undergone such a treatment may only be labelled and sold as bottled drinking water. You should ensure that any UV unit is working correctly. An independent test of the equipment is recommended for this.

Q15: 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,

¹⁶ Regulation 15 (a) and Schedules 2 and 3

¹⁷ Regulation 15 (b)

¹⁸ Regulation 15(c)

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.

Q16: 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.

Q17: 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.

Q18: Can Spring Water be used as an ingredient in soft drinks?

A: You can use spring water in the manufacture of soft drinks¹⁹. 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.

There is no obligation to include the name of the source, but this is permitted if you wish.

Production of Bottled Drinking Water

Q19: 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 regulations²⁰.

¹⁹ Regulation 15(2)

²⁰ Regulation 19 and Schedule 7

Q20: 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.

Labelling, advertising and sale of water in bottles

Q21: 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 regulations²¹. 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.

Q22: 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 regulations²². 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.

²¹ Regulation 11 and Schedule 6

²² Regulation 16

Q23: 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 label²³ or suggest that it is “spring water”²⁴. This extends to the use of these phrases in other languages.

Q24: 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 court would view this as misleading the consumer into believing they were purchasing spring water.

Q25: Can I call my product “natural spring water”

A: The 2017 amending Regulations prohibit the use of any term “which is liable to cause confusion of the water with a natural mineral water”²⁵.

However, while there is a specific prohibition on the use of the word “mineral” in relation to spring water, there is no such specific regulatory prohibition on the word “natural”.

Whether the use of the term “natural spring water” would cause confusion with natural mineral water, would be a matter for courts to decide, on a case by case basis.

²³ Regulation 20

²⁴ Article 7 of Regulation 1169/2011 <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN>

²⁵ Regulation 6 of the 2017 Regulations

Trade description and sales description

Q26: What is meant by “trade description”, and “sales description”?

A. The trade description is the name that normally identifies the product. For example, the trade description may be a ‘brand’ name or a description of the provenance of the water.

The sales description is the category of the product, such as ‘natural mineral water’ or ‘spring water’.

Q27: 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.uk²⁶.

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

Q28: Do I have to include a trade description on the label?

A: There is no requirement to include a trade description on the label. If a “sales description” is used it may only be “natural mineral water”²⁷ or “spring water” or the permitted variants of this to indicate the source of carbon dioxide gas for sparkling water²⁸. This wording may also be included in another language²⁹.

²⁶ <https://www.gov.uk/guidance/food-standards-labelling-durability-and-composition#table-showing-natural-mineral-waters-recognised-in-the-uk>

²⁷ Regulation 11 (2)

²⁸ Regulation 11 (2) (b)

²⁹ 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.

Q29: What can I use as the trade description?

A: For natural mineral water, the trade description is the name in which the product is registered. For water sold as spring water, you may choose any trade description, but it must comply with the rules for trade descriptions.

Q30: What are the rules for a trade description?

A: If the trade description refers to a location, it must only indicate the locality/hamlet/place where the water is extracted. No other location can be referred to on the label.

For Natural Mineral Water³⁰ and Spring Water³¹, if the trade description does not include the name of the source of the water 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.

You may not sell natural mineral water from one and the same spring under more than one trade description. You may not sell spring water from one and the same spring under more than one trade description.

Q31: What is meant by “one and the same spring”

A: The definition of “one and the same spring” (for the purposes of trade descriptions) is taken from the European Court ruling on case C-207/14³².

The notion of ‘natural mineral water from one and the same spring’ contained in Article 8(2) of Directive 2009/54/EC³³ 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

³⁰ Regulation 11 (1) (b)

³¹ Regulation 16 (2) (b)

³² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62014CJ0207>

³³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0045:0058:EN:PDF>

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 specific case of a trade description for spring water. While spring water does not need to have a stable composition over time, the judgement is nevertheless indicative of many other of the

Q32: 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 the use of the terms “natural mineral water” or “spring water”, which may only be used according to the rules above.

Q33: Can I supply natural mineral water or spring water to a third party for onward sale, such as a supermarket or venue caterer?

A: Yes. 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 trade or sales description (for instance in a different font or graphically separated in some way)

The name of the source must be included on the label, whether a trade description or a sales description is used.

If a trade description is used which does not include the name of the source, this name must be included on the label using letters at least one and a half times the height and width of the largest letters used for the trade description.

For natural mineral waters the appropriate mineral analysis must appear on the label.

Q34: Can I supply natural mineral water or spring water to more than one third party for onward sale, such as a supermarket or venue caterer?

A: Yes, there is nothing in the Regulations that prevents this. However, only one trade description may be used for natural mineral water from one and the same spring. The same rule applies to spring water from one and the same spring.

Examples of trade and sales descriptions³⁴

- Retailer: ABC Supermarket
- Trade description “Glen Valley”
- Sales Description “Natural Mineral Water”

Monitoring of Natural Mineral Water

Q35: 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.

Q36: 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.

³⁴ 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.

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

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

Q37: What checks will the food authority carry out?

A: For a water source that 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 marketing as a natural mineral water, a new programme of monitoring must demonstrate that the water continues to meet 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

Q38: 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.

Q39: 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.

Q40: 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, nor to ensure that the product is compliant with the parameters in the 2015 Regulations.

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

Q41: 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 because the law already requires FBOs to follow HACCP procedures 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 (as amended).

Q42: 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.

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.

Radiological Monitoring of Spring Water and Bottled Drinking Water

Q43: Who must carry out radiological monitoring?

A: The FBO is required to carry out radiological monitoring of spring water and bottled drinking water. This is part of the responsibility of the Food Business Operator to ensure that food (which includes water bottled for human consumption) is safe. (see Q38 above)

Q44: What must the food authority monitor?

A: The Food Authority must carry out representative surveys for radon, tritium and Indicative Dose⁴². Unless an exemption (see below) is applied, this must be at the frequencies contained in the 2015 Regulations⁴³. The food authority is also required to carry out further monitoring, as appropriate, if the FBO's monitoring shows that any of the parametric values in the Regulations is exceeded.

Q45: Has radioactivity been a historic issue for bottled water?

A: The FSA has published a fact sheet which outlines results of a survey conducted in 2014⁴⁴. 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.

Q46: Must the food authority 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

⁴² Reg 24(2)(b) and Schedule 9 (Part 1)

⁴³ Schedule 9 (Part 2)

⁴⁴ <https://www.food.gov.uk/sites/default/files/fsis-01-14-radioactivity-in-bottled-water.pdf>

for the period of the exemption. The food authority is required to notify the FSA if an exemption is applied.

Note: The exemption applies to the food authority and not the food business.

Q47: Is there an official procedure in place for notifying the FSA about an exemption?

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

Q48: What evidence would need to be provided for an exemption to be applied?

A: This evidence will include the following:

- Radon – Evidence, such as a representative survey, must show that there is no exceedance of the parametric value for radon of 100 bq/l.
- Tritium – If there are man-made sources of tritium present within the catchment area, evidence must be provided showing no exceedance of the parametric value of 100 Bq/l. This may include evidence from surveillance programmes or investigations or information from the public register⁴⁵.
- Indicative Dose – Representative monitoring data or other reliable information must demonstrate that natural or artificial radioactivity does not exceed the parametric value of 0.1 mSv.

Q49: What additional information would provide evidence for an exemption?

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 contaminants in the rock or manmade (industry produced) radiation and what type of radiation)
- 3) radioactivity of the rock type

⁴⁵ <https://www.gov.uk/guidance/access-the-public-register-for-environmental-information>

- 4) radioactivity of the soil type
- 5) radioactivity of the well type

Q50: Can the food authority exemption apply to monitoring for radon, tritium AND Indicative Dose?

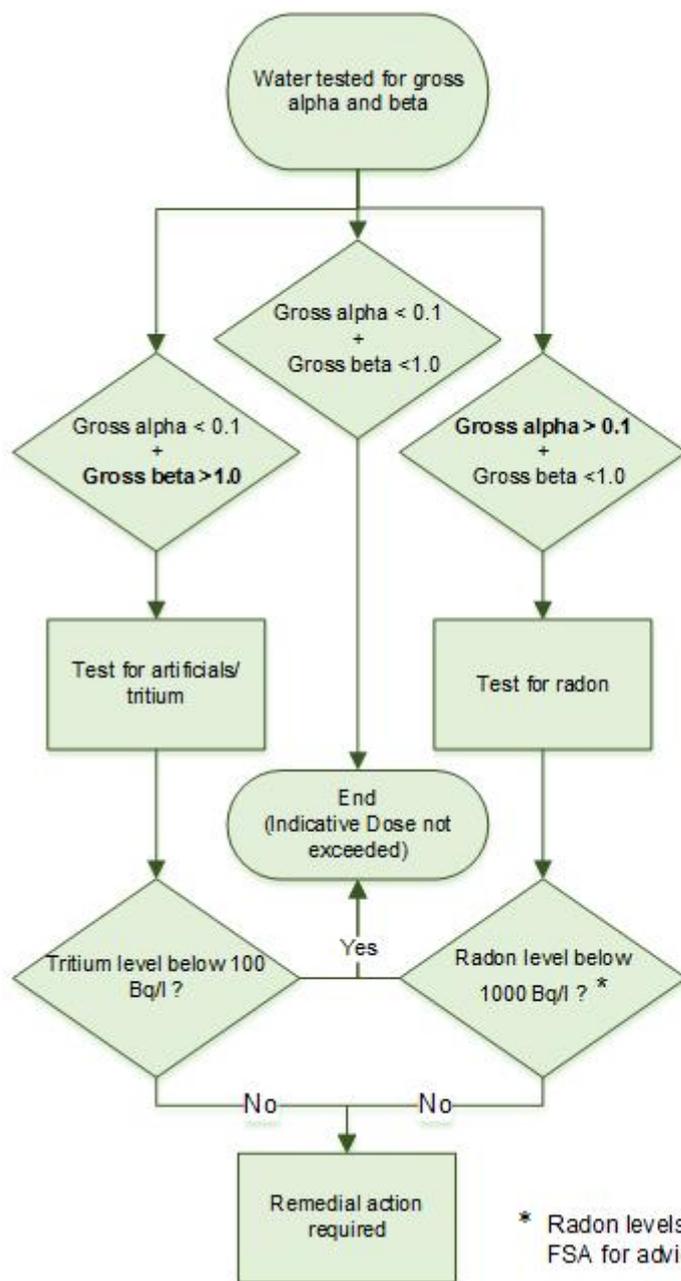
A: Yes. If gross alpha and gross beta activities are less than 0.1 and 1.0 Bq/l respectively then the ID can be assumed to be less than the parametric value of 0.1 mSv and no further analysis is needed for tritium or radon.

If the Food Authority is satisfied, on the basis of representative surveys, monitoring data or other reliable information that tritium and radon will remain below 100Bq/l no further analysis is required.

Further monitoring for tritium and other man-made radionuclides is only necessary where there is a source of artificial radioactivity present in the catchment area and it cannot be shown on the basis of other representative surveys or investigation that the level will remain below 100Bq/l.

Further monitoring for radon is only necessary where it cannot be shown on the basis of other representative surveys or investigation that the level will remain below 100Bq/l.

A flow chart to help decide whether further testing is required is provided below



* Radon levels ≥ 100 - < 1000 Bq/l should be reported to the FSA for advice.

Q51: What will an exemption mean in practice?

A: The food authority will not be required to carry out radiological monitoring of 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, your 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 exemption. Thereafter, the FBO would have to demonstrate to the Food Authority that parametric values were not being exceeded

Q52: Why does the exemption only last for 5 years?

A: A 5-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.

Q53: 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 levels remain within the parametric values. 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 increasing the risk, such as seismic activity or other underground disturbance.

Q54: What if things change during the period of the exemption?

A: The exemption from monitoring may not apply following any significant local geological event or incident which could increase 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 considered when renewing an exemption.

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

The exemption will lapse immediately if any of the parametric values observed at the point of bottling are exceeded.

Q55: 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 publicly available data such as the hazard maps in a Drinking Water Inspectorate-commissioned report on Radon in water⁴⁶, 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 England⁴⁷.

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

⁴⁶ <http://www.dwi.gov.uk/research/completed-research/reports/DWI70-2-301.pdf>

⁴⁷ <http://www.ukradon.org/information/ukmaps>

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 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 or ISO 13164-4-2015. [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 for radon at the point of bottling exceed 100Bq/l, but remain below 1000Bq/l then monitoring by the food authority 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.

Q56: What happens if monitoring results exceed 1000Bq/l for radon?

A: Where levels of radon above 1000Bq/l are detected, remedial 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. If the water is already placed on the market this should be reported to your food authority

Q57: What happens if I exceed a 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. If this demonstrates that parametric values are being exceeded, then further sampling must be carried out at the frequencies specified in the 2015 Regulations⁴⁸.

⁴⁸ Schedule 9 Part 2

Appendix 1 – Proforma for exemption for radiological monitoring



Department
for Environment
Food & Rural Affairs

EXEMPTION PROFORMA

Complete a new form every five years if it can be demonstrated that parametric values are not exceeded

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

Food Authority Details

Food Authority:

Country:

Authorised Officer 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 which must be below parametric values

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 _____

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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/EC⁴⁹ on the exploitation and marketing of natural mineral water
2. Council Directive 98/83/EC⁵⁰ on the quality of water intended for human consumption (known colloquially as “The Drinking Water Directive”)
3. Council Directive 2013/51/ EURATOM⁵¹ 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) 115/2010⁵² 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/EC⁵³ 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 2015/1787⁵⁴ - Amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

⁴⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0054&from=EN>

⁵⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF>

⁵¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0051&from=EN>

⁵² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0013:0015:EN:PDF>

⁵³ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0040&from=EN>

⁵⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L1787&from=EN>

Appendix 3 - 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 2015⁵⁵

The Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2015⁵⁶

The Natural Mineral Water, Spring Water and Bottled Drinking Water (amendment) (Wales) Regulations 2017⁵⁷

The Natural Mineral Water, Spring Water and Bottled Drinking Water (amendment) (Northern Ireland) Regulations 2017⁵⁸

⁵⁵ <http://www.legislation.gov.uk/wsi/2015/1867/made>

⁵⁶ <http://www.legislation.gov.uk/nisr/2015/365/contents/made>

⁵⁷ <http://www.legislation.gov.uk/wsi/2017/935/made>

⁵⁸ <http://www.legislation.gov.uk/nisr/2017/201/contents/made>