Údarás Sábháilteachta Bia na hÉireann
Food Safety Authority of Ireland

25

GUIDANCE NOTE

Guidance for the assessment of compliance of legislation applicable to natural mineral waters, spring waters and other water (Revision 4) (2025)

Guidance Note No. 25: Guidance for the assessment of compliance of legislation applicable to natural mineral waters, spring waters and other water (Revision 4) (2025)

This is not a legal document. Guidance notes from the Food Safety Authority of Ireland is intended to help food businesses to comply with their legal obligations.

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(Revision 4) (2025)

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INTRODUCTION

For regulatory purposes there are three classes of bottled water: natural mineral water, spring water and 'other water'.

Natural mineral water is derived from a natural spring extracted from the ground and is packaged at source; it meets the legal requirements for natural mineral water and is recognised as natural mineral water by the responsible authority. In Ireland, the Food Safety Authority of Ireland (FSAI) has nominated the National Standards Authority of Ireland (NSAI) as the responsible authority. The FSAI has national responsibility for coordinating the enforcement of food safety legislation in Ireland. The Health Service Executive (HSE) National Environmental Health Service (NEHS) enforces bottled water legislation under a service contract with the FSAI.

Spring water is intended for human consumption in its natural state; it meets the legal requirements for spring water and is packaged at source.

'Other water' is water intended for human consumption; it is not a natural mineral water or spring water.

The treatments permitted for natural mineral water and spring water are very limited. Therefore, the source water is required to be of very good quality in its natural state. To maintain the quality of the source of natural mineral water or spring water, the food business operator (FBO) must take suitable precautions to protect the source from any contamination. 'Other water' may be treated as necessary, using normal water treatment technologies, to ensure that the product is suitable for human consumption.

Scope of the guidance on legislation applicable to bottled water

The 2025 update of Guidance Note 25 takes into account S.I. No. 204 of 2025. The Guidance Note was previously revised in 2024 to take account of the recast Drinking Water Directive (EU) 2020/2184.

Although this Guidance Note is primarily aimed at environmental health officer (EHOs), the guidance provides useful information that can also be referred to by FBOs.

GUIDANCE OUTLINE

Section 1 addresses the production of natural mineral water. Guidance is provided for the interpretation of Directive 2009/54/EC, Commission Directive 2003/40/EC, and Commission Regulation (EU) No 115/2010.

Section 2 deals with the production of spring water. Guidance is provided for the interpretation of Directive 2009/54/EC, Commission Directive 2003/40/EC, and Commission Regulation (EU) No 115/2010.

Section 3 covers the production of other water. Guidance is provided for the interpretation of Directive (EU) 2020/2184.

Section 4 provides guidance on Council Directive 2013/51/Euratom in relation to radioactive substances in water intended for human consumption. It is applicable to spring water and 'other waters'.

Appendix I provides examples of labels for natural mineral water, spring water and 'other water'.

Appendix II provides information on the protection of the wellhead/borehole.

Appendix III outlines information for risk assessment and risk management.

Appendix IV provides information on disinfection and cleaning of the well.

Appendix V provides guidance on the definition of original purity for natural mineral water. Appendix VI provides guidance on storage tanks.

Table 1 provides a summary of EU and national legislation applicable to natural mineral water, spring water and 'other water'.

Table 2 provides a summary of the differing provisions for natural mineral water, spring water and 'other water'.

Table 3 provides an overview of the legislation applicable to natural mineral water, spring water and 'other water'.

Table 4 lists the category of bottled water, criteria, and legislation applicable for each sampling point.

Scope of legislation

This Guidance Note provides information on the following pieces of legislation:

- Directive 2009/54/EC on the exploitation and marketing of natural mineral waters
- Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.
- Commission Regulation (EU) 115/2010/EC laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters with respect to the legislative requirements for natural mineral waters and spring waters.
- Directive (EU) 2020/2184 of the European Parliament and of the council on the quality of water intended for human consumption.
- Council Directive 2013/51/Euratom laying down requirements for the protection of the health of the public regarding radioactive substances in water intended for human consumption.
- Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Table 1 Summary of EU and national legislation applicable to natural mineral water, spring water and 'other water'

EU legislation	Natural mineral water	Spring water	Other water
Directive 2009/54/EC	All	Article 4, 5(1, 2 and 3), Article 7(2 (b) and (c)), Article 9(4) and Article 9(5)	n/a
Commission Directive 2003/40/EC	All	Article 5 and Article 6	n/a
Commission Regulation (EU) No 115/2010	All	All	n/a
Directive (EU) 2020/2184	n/a	All	All
Council Regulation (Euratom) 2016/52*	All	All	All
Regulation (EC) No 178/2002 (S.I. No. 747 of 2007) (as amended)	All	All	All
Regulation (EC) No 852/2004 (S.I. No. 369 of 2006)	All	All	All
Council Directive 2013/51/Euratom	n/a	All	All
Commission Regulation (EC) No 2073/2005[1]	All	All	All

[1] As per Commission Regulation (EC) No 2073/2005, as amended, bottled waters fall into Food Safety Criteria category 1.3, ready-to-eat foods unable to support the growth of *L. monocytogenes*. Bottled waters must comply with the limit set out for *L. monocytogenes* in the regulation. As per footnote 4, regular testing against the criterion is not required in normal circumstances for bottled waters.

National legislation			
S.I. No. 282 of 2016 **Amended by** S.I. No. 55 of 2020, S.I. No. 691 of 2022, S.I. No. 204 of 2025	All	All	All

* Council Regulation (Euratom) 2016/52 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident, or any other case of radiological emergency is only applicable following a nuclear accident or any other case of radiological emergency and falls outside the scope of this Guidance Note.

The NSAI standard, I.S. 432:2010 Packaged groundwater, can be used as a guide to the interpretation of the requirements of Directive 2009/54/EC, Directive (EU) 2020/2184 and Regulation (EC) No 852/2004. In addition, the following is the list of references which are used as a guide to the interpretation of the requirements of Regulation (EC) No 852/2004:

- I.S. 340:2007 Hygiene in the catering sector
- I.S. 341:2007 Hygiene in food retailing and wholesaling.

The following categories of products are not considered natural mineral waters, spring waters or 'other waters':

- Waters with medicinal claims, as no medicinal claims are permitted on foods
- Waters used for curative purposes in thermal or hydrothermal establishments
- Waters not intended for human consumption
- Packaged ice
- Flavoured natural mineral water drinks, flavoured spring water drinks, and flavoured other water drinks.

Drinks containing natural mineral water or spring water as an ingredient, fall outside the scope of Guidance Note 25, but must comply with all relevant legislation relating to natural mineral waters and spring waters.

Table 2 Summary of the differing provisions for natural mineral water, spring water and 'other water'

Bottled water – the differences in requirements	Natural mineral water	Spring water	Other water
Recognised by responsible authority	Yes	No	No
Hydrogeologist report required by the NSAI	Yes	No	No
Hydrogeologist report recommended[2]	n/a	Yes	Yes
Bottled at source	Yes	Yes	No
Information on where the spring is exploited and the name of the spring	Yes	Yes	No
Include a statement of analytical composition on the label	Yes	No	No
Constant mineral composition	Yes	No	No
Treatment permitted[2]	No	No	Yes

Table 3 Summary of the legislation applicable to natural mineral water, spring water and 'other water'

EU legislation	Natural mineral water	Spring water	'Other water'
Directive 2009/54/EC	All	Article 5(1, 2 and 3), Article 9(4) and Article 9(5)	n/a
Commission Directive 2003/40/EC	All	Article 5 and Article 6	n/a
Commission Regulation (EU) No 115/2010	All	All	n/a
Directive (EU) 2020/2184	n/a	Applicable sections outlined in this Guidance Note	Applicable sections outlined in this Guidance Note
Council Directive 2013/51/ Euratom	n/a	All	All

[2] A hydrogeologist report is recommended, as it provides further information on the chemical and microbiological hazards.

[2] Ozone-enriched air treatment is permitted once Commission Directive 2003/40/EC is complied with.

Table 4 The category of bottled water, criteria, and legislation for each sampling point

Category of bottled water	Criteria	Legislation	Sampling point
Natural mineral water	Microbiological criteria	Article 5 of Directive 2009/54/EC	Source and during marketing
	Chemical criteria	Annex I, Commission Directive 2003/40/EC	
	Natural mineral water treated with ozone (residues of bromoforms, bromates, dissolved ozone)	Commission Directive 2003/40/EC	At point of bottling
Spring water	Microbiological criteria (as per NMW)	Article 5 of Directive 2009/54/EC	Source and during marketing
	Microbiological and chemical criteria	Annex I, Part A & Part B, of Directive (EU) 2020/2184	At point of bottling
	Radioactive substances	Article 5 of Council Directive 2013/51/Euratom	At point of bottling
	Spring water treated with ozone (residues of bromoforms, bromates, dissolved ozone)	Commission Directive 2003/40/EC	At point of bottling
'Other water'	Microbiological and chemical criteria	Annex 1, Part A & B of Directive (EU) 2020/2184	At point of bottling
	Radioactive substances	Article 5 of Council Directive 2013/51/Euratom	At point of bottling

It is recommended that microbiological and chemical samples are taken at the same time; however, this may not be the case in exceptional circumstances.

In addition, all food businesses producing natural mineral waters, spring waters or other waters are subject to the general requirements of food law, including:

- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs. This Regulation sets out the rules which apply to all food, from the farm to the point of sale to the consumer. It places the responsibility for the safety of food, on food producers.

Point of compliance

It is important to clearly identify the sample source because the legislation is explicit in relation to where the legal requirements apply. Environmental Health Officers must clearly state where the sample has been collected from on the National Sample Submission Form (NSSF). The following outlines the definition of 'sample source'.

At source means the well/borehole from which the water will be exploited. Samples taken at source should be collected in a suitable sample container (sterile container for microbiological samples).

Note: Where an EHO is dealing with a closed system at source, the establishment should have a sampling point at which the sample can be taken. The sampling point should be before any filtration etc. of the source water occurs.

During marketing is any point after the sealed bottle has come off the production line. Samples of the manufacturer's bottled water can be used when taking samples at the 'during marketing' stage.

Point of bottling means the point at which the water is put into the bottle. The sample can be taken, using a suitable sampling container (such as a sterile container for microbiological samples or laboratory-cleaned glass bottles for PAHs and pesticides), as water is being put into bottles or containers on the production line. Alternatively, a bottle/container of the manufacturer's bottled water, at the point of bottling from the production line, is sufficient. In this instance, it is important that the bottle/container has not been stored in a warehouse for a period of time.

Note: Due to the automated and enclosed nature of the bottling process, point of bottling samples are most often taken in the form of the manufacturer's bottled water. In this way, 'point of bottling' and 'during marketing' samples may be taken at the same point. Therefore, it is important that the sample taken is labelled appropriately for the type of water and the relevant point of compliance that is set out in legislation (i.e. natural mineral water for microbiological analysis taken at this point should be labelled as a "during marketing" sample). Information on the point of compliance set out in the relevant bottled water legislation can be found in Table 4 above.

Regulation (EC) No 178/2002 on general food law

Regulation (EC) No 178/2002 (as amended) is applicable to all food businesses, and it sets down the general principles of food law that must be followed, e.g. labelling, food safety requirements, product withdrawal, recall and traceability.

The definition of 'food' in Regulation (EC) No 178/2002 on general food law is "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans", and it includes water.

The Regulation requires that FBOs (producing bottled water) must ensure that unsafe bottled water is not placed on the market. Unsafe water is water that is injurious to health or unfit for people to drink. Where any unsafe water has been placed on the market, it must be withdrawn. Where any unsafe water has reached the consumer, the consumer must be informed of the reason for the withdrawal and the product must be recalled from them. The NEHS or the FSAI must also be informed.

General hygiene requirements for all bottled water establishments – Regulation (EC) No 852/2004

The operators of bottled water establishments must have procedures in place based on hazard analysis and critical control point (HACCP) principles. The FBO must know the hazards associated with the business from catchment through to distribution. The hazard analysis must take into consideration microbiological, physical, and chemical hazards, and demonstrate how the FBO is controlling them and how it will remedy any problems that are identified. Documents and monitoring records may be required to support this. These should demonstrate to environmental health officer (EHOs) that the bottled water establishment is complying with Article 5 of Regulation (EC) No 852/2004, which requires FBOs to put in place, implement and maintain a permanent procedure(s) based on HACCP principles. The Regulation allows for a degree of flexibility in the application of these principles and in the complexity of the procedure(s)/system developed.

The hazard analysis should provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, hazards in the production of safe natural mineral waters, spring waters and 'other water'.

Labelling requirements – Regulation (EU) No 1169/2011

The requirements of Regulation (EU) No 1169/2011 on the provision of food information to consumers for pre-packed foods on sale in Ireland apply to bottled water. Appendix I of this Guidance Note outlines the mandatory information required and provides examples of labels for natural mineral water, spring water and other water products.

In addition to the Regulation (EU) No 1169/2011 requirements, Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs requires that foodstuffs must be accompanied by an indication which allows identification of the lot to which a foodstuff belongs, i.e. a lot/batch number.

All relevant European Union (EU) and Irish legislation can be found on the FSAI website at *Legislation | Food Safety Authority of Ireland (fsai.ie)*

Official Controls – Regulation (EU) No 2017/625

This regulation lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States. Official controls should be thorough and effective and should ensure that Union legislation is applied correctly.

Regarding Food Fraud, all general rules on official controls can be reviewed under Article 9 of Regulation (EU) No 2017/625. Article 9 (2) states that Competent authorities shall perform official controls regularly, with appropriate frequencies determined on a risk basis, to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, and taking into account information regarding such violations shared through the mechanisms of administrative assistance provided for in Articles 102 to 108 and any other information pointing to the possibility of such violations.

TERMS AND DEFINITIONS

aggressive water: water actively seeking to gain minerals and metals, resulting in the corrosion of iron and copper surfaces, and dissolving of concrete and stone surfaces.

aquifer: an underground layer of permeable rock, sediment (usually sand or gravel) or soil that yields water. The pore spaces in aquifers are filled with water and are interconnected so that water flows through them.

biofilm: a layer of microorganisms adhering to the surface of a structure, which may be organic or inorganic, together with the substances that they secrete.

borehole: a deep, narrow hole made in the ground, especially to locate water or oil.

ct (value): concentration of a disinfectant (mg/L) × its exposure time (minutes). disinfect: to clean something, especially with a chemical, in order to destroy bacteria.

disinfection: a treatment, chemical or physical, which destroys, eliminates, or inactivates pathogenic microorganisms.

food business: any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing, and distribution of food.

groundwater: the water present beneath the Earth's surface in soil pore spaces and in the fractures of rock formations.

groundwater catchment area: the surface area within which rainfall can either directly or indirectly enter the groundwater system into which the well is tapped, and which can contribute to the yield of the well. hamlet: a small village.

hazard: a biological, chemical, or physical agent or treatment capable of causing adverse health effects (harm).

indicative dose (ID): the committed effective dose for one year of ingestion resulting from all the radionuclides whose presence has been detected in a supply of water intended for human consumption, of natural and artificial origin, but excluding tritium, potassium-40, radon, and radon decay products.

karst: a type of landscape consisting of rock that is solid but chemically soluble (dissolves), such as limestone.

karst aquifer: a body of chemically soluble rock that allows liquid or gases to pass through it.

monitoring: includes auditing, inspection, measurement, sampling, or analysis, whether periodic or continuous.

natural mineral water (NMW): microbiologically wholesome water, located in an aquifer and emerging from a spring(s) or bore(s) tapping the aquifer and packaged at source. NMW is characterised by its natural mineral and trace element content that remains within the background fluctuation levels in its original state. The NSAI is the authority responsible for the recognition of NMW.

oligotrophic: an environment where the nutrients required for phytoplankton growth (e.g. nitrate, phosphate, silicic acid) are heavily depleted all year round and oxygen is abundant.

overburden: rock or soil overlying a mineral deposit, archaeological site, or other underground feature.

parametric value: the value of substances in water intended for human consumption above which it must be assessed whether the presence of such substances poses a risk to human health, requiring action to improve the quality of water to a level which complies with the requirements for the protection of human health. phytoplankton: a diverse collection of organisms consisting of microscopic plants.

polyanionic extracellular surface polymeric substances (EPS): substances excreted by microorganisms primarily composed of polysaccharides as well as other microbially derived compounds such as proteins, phospholipids, teichoic acid, and nucleic acid. They contribute to cell adaptability and resilience, and they perform functional roles in the environment, such as the formation of biofilms.

radioactive substance: any substance that contains one or more radionuclides, the activity or concentration of which cannot be disregarded as far as radiation protection is concerned.

recall: the removal of an unsafe food from the market when it may have reached the consumer, and the notification of the consumer.

receptor: the area surrounding a borehole that is receiving groundwater. recharge zone: the

primary area through which water enters an aquifer.

risk: the product of a probability/likelihood (P) of occurrence × the severity (S) of the consequential adverse effect.

risk assessment: the overall process of risk identification, risk analysis and risk evaluation. source: the location

of an aquifer spring.

spring: the point at which groundwater issues from an aquifer or a groundwater store, usually at or near ground level. A spring may consist of a natural outlet at one or more topographical locations or may comprise free-flowing boreholes.

spring water: microbiologically wholesome water, originating in an aquifer or a subsurface porous deposit and emerging from a spring tapped at its natural outlet by means of a borehole and packaged at source.

time of travel (TOT): the time required for a contaminant to move in the saturated zone from a specific point to a well. It is the average linear velocity of flowing groundwater using Darcy's law.

topographical: the detailed mapping or charting of the features of a relatively small area, district, or locality.

unsafe food: food that is injurious to health or unfit for human consumption as detailed in Article 14 of Regulation (EC) No 178/2002 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. water table: the level below which the ground is saturated with water. withdrawal: the removal of an unsafe food from the market before it has reached the consumer.

zone of contribution (ZOC): the area surrounding a spring that includes all areas that supply groundwater recharge to the supply.

Point of compliance: see page 7 for more detail.

SECTION 1: NATURAL MINERAL WATER

Natural mineral water must be bottled at source. Recognition of natural mineral water is a legal requirement and, in Ireland, the NSAI is the authority responsible for this recognition. The HSE National Environmental Health Service (NEHS) is the authority responsible for the enforcement of all other requirements for natural mineral water establishments. If, during inspections or otherwise, either the NSAI or the HSE NEHS has information which is of relevance to the other agency, this information should be shared with the agency, either by direct contact with the relevant personnel or via the FSAI (www.fsai.ie).

Directive 2009/54/EC and the labelling and compositional criteria specified in Commission Directive 2003/40/EC apply to all natural mineral water producers. In addition, if natural mineral water is treated with ozone-enriched air, the conditions of use of this treatment, as outlined in Commission Directive 2003/40/EC, must be complied with. Commission Regulation (EU) No 115/2010 applies to natural mineral waters which are treated for the removal of fluoride. The following table provides information on Directive 2009/54/EC.

1.1 Directive 2009/54/EC on the exploitation and marketing of natural mineral waters

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 1(1)	This Directive concerns waters extracted from the ground of a Member State and recognised by the responsible authority of that Member State as natural mineral waters satisfying the provisions of Annex I, Section I. The waters referred to above may be so recognised only if the responsible authority in the country of abstraction has certified that they satisfy the provisions of Annex I, Section I and that regular checks are made on the application of the provisions of Annex II, point 2. The validity of the certification referred to above may not exceed a period of five years. It shall not be necessary to repeat the recognition procedure if the certification is renewed before the end of that period.	In Ireland, the NSAI (www.nsai.ie) is the responsible authority for the official recognition of natural mineral water. The NSAI reviews the data submitted by the FBO which provides information on: • Geological/topographical/hydrogeological data • Microbiological, physical, and chemical (hydrochemical, physico-chemical) data. The NSAI reviews microbiological and chemical data submitted by the FBO from the previous two years. A complete chemical analysis audit (as described in Directive (EU) 2020/2184) is also carried out by the NSAI. Following an inspection and review of data, the NSAI issues a 'Certificate of Recognition' and 'Conditions of Exploitation' to natural mineral water establishments which have met the recognition criteria of this Directive. Each natural mineral water source recognised by the NSAI will have a unique chemical fingerprint.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		The 'Conditions of Exploitation' will include: i. Tolerances for each chemical constituent. The chemical composition should not be outside the specified tolerance limits. ii. The specific boreholes which the recognition by the NSAI applies to. The chemical composition of natural mineral water is usually stable. However, in some circumstances, the composition may change; e.g. over a period of time (decades), the hardness of the water may change. This is a natural change in the water. In this case, the NSAI reviews the data and amends the 'Conditions of Exploitation'. Generally, one aquifer provides one source of natural mineral water. However, a number of boreholes can be sourcing natural mineral water from a single aquifer. If an additional aquifer is used, the FBO must demonstrate that the natural mineral water from the additional aquifer has the same chemical fingerprint as the natural mineral water already recognised by the NSAI. If the chemical fingerprint is different, a separate recognition process for this aquifer is required. A copy of the 'Certificate of Recognition' and 'Conditions of Exploitation' can be obtained from the FBO. Copies of these documents should be obtained by the HSE NEHS in advance of the FBO's inspection. NSAI certification is valid for a period not exceeding five years. It is not necessary to repeat the recognition procedure if the certification is renewed before the end of that period.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 1(2)	This Directive also concerns water extracted from the ground of third countries, imported into the community and recognised as a natural mineral water by the responsible authority of a Member State. The validity of the certification of natural mineral water from third countries may not exceed a period of five years.	**Verification of imported natural mineral waters** A HSE environmental health officer (EHO) must verify whether imported natural mineral water products from other Member States or from third countries are from a recognised source. Similarly, if imported natural mineral water is used as an ingredient in a product, the natural mineral water must be from a source recognised in the EU. This can be verified by checking the list of recognised natural mineral waters sourced within the EU and from third countries, which is published on the EU website at: ec4fbcc0-7185-4dce-820a-27f7e2653dad_en (europa.eu) The validity of the certification of natural mineral water from third countries may not exceed a period of five years.
Article 1(3)	This Directive shall not apply to: **(a)** Waters which are medicinal products within the meaning of Directive 2001/83/EC relating to medicinal products for human use. **(b)** Natural mineral waters used at source for curative purposes in thermal or hydromineral establishments.	This legislation does not apply to waters sourced for curative purposes in thermal or hydromineral establishments. These products are considered medicinal products and are not governed by food legislation.
Article 1(4)	The grounds for granting the recognition referred to in paragraphs 1 and 2 shall be stated in due form by the responsible authority of the Member State and shall be officially published.	The NSAI issues a 'Certificate of Recognition' and 'Conditions of Exploitation' to all natural mineral water establishments which have met the recognition criteria of this Directive. The list of Irish natural mineral waters recognised by Ireland is published on the EU website at: ec4fbcc0-7185-4dce-820a-27f7e2653dad_en (europa.eu)
Article 1(5)	Each Member State shall inform the Commission of the cases where the recognition referred to in paragraphs 1 and 2 has been granted or withdrawn. The list of natural mineral waters so recognised shall be published in the *Official Journal of the European Union*.	The list of Irish natural mineral waters recognised by Ireland is published on the EU website at: http://ec.europa.eu/food/safety/labelling_nutrition/mineral_waters_en.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 2	Member States shall take the measures necessary to ensure that only the waters referred to in Article 1 which comply with the provisions of this Directive may be marketed as natural mineral waters.	Only natural mineral waters that are officially recognised in the EU and comply with the Directive may be marketed as natural mineral waters.
Article 3	Natural mineral water springs may be exploited, and their waters bottled only in accordance with Annex II.	Natural mineral water springs may only be exploited, and their water bottled if they meet the conditions for the exploitation and marketing of natural mineral water in Annex II of the Directive.
Article 4(1)	Natural mineral water, in its state at source, may not be the subject of any treatment other than: (a) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties;	The following treatments are permitted, provided that they do not alter the essential chemical composition which gives the water its properties or the microbiological composition of the water: FBOs must demonstrate that microfiltration or decanting does not alter the essential chemical composition or microbiological composition of the water.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	(b) the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that: **(i)** the treatment complies with the conditions for use to be laid down by the Commission following consultation with the European Food Safety Authority **(ii)** the treatment is notified to, and specifically controlled by, the competent authorities;	The use of ozone-enriched air in natural mineral water by establishments for the separation of iron, manganese and sulphur compounds and arsenic must comply with the requirements of this Directive. FBOs must apply to the NEHS for authorisation to use this treatment. Such treatment must only commence following receipt of written approval from the HSE. Records of ozone use should be retained by the FBO. The FBO must receive written approval from the NEHS before it is authorised to use this treatment. In addition, see Article 5 of Commission Directive 2003/40/EC.
	(c) The separation of undesirable constituents other than those specified in points (a) or (b), in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that: **(i)** the treatment complies with the conditions for use to be laid down by the Commission following consultation with the European Food Safety Authority **(ii)** the treatment is notified to, and specifically controlled by, the competent authorities;	The use of any other treatments for the separation of undesirable constituents from natural mineral water other than iron compounds, sulphur compounds, manganese compounds and arsenic are not permitted, as they alter the composition of the water. FBOs must apply to the NEHS for the authorisation to use such treatment(s). Treatments must only commence following receipt of written approval from the NEHS. The FBO must receive written approval from the NEHS before it is authorised to use this treatment.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	(d) the total or partial elimination of free carbon dioxide by exclusively physical methods.	Carbon dioxide may be removed from natural mineral water prior to packaging by physical methods only. The sales description of natural mineral water which has undergone the total or partial elimination of free carbon dioxide by exclusively physical methods must indicate as appropriate on the label: **(a)** 'Fully de-carbonated natural mineral water' or **(b)** 'Partially de-carbonated natural mineral water'. As outlined in Regulation (EU) No 1169/2011, the name of the food and net quantity must appear in the same field of vision. Note: Natural mineral water may also be treated with activated alumina in order to remove fluoride. The fluoride removal treatment must be in accordance with Commission Regulation (EU) No 115/2010.
	The first subparagraph shall not constitute a bar to the utilisation of natural mineral waters and spring waters in the manufacture of soft drinks.	Once natural mineral water is mixed with other ingredients, it is no longer classified as a natural mineral water. This product is now categorised as a soft drink and may be labelled 'natural mineral water drink'. Natural mineral water may be used as an ingredient in soft drinks and other flavoured water products. In this case, Directive 2009/54/EC does not apply, as the final product is outside the scope of this particular legislation. However, if natural mineral water is used as an ingredient and listed in the ingredients list, the water must meet all the requirements of Directive 2009/54/EC (except the specific labelling requirements for NMW). There is no requirement to declare the name of the natural mineral water source on the packaging.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 4(2)	Natural mineral water, in its state at source, may not be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in Annex I, Section III. Annex I, Section III: Supplementary qualifications relating to effervescent natural mineral waters at source or after bottling, effervescent natural mineral waters give off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure. They fall into three categories to which the following descriptions respectively shall apply: **(a)** 'Naturally carbonated natural mineral water' means water the carbon dioxide content of which from the spring after decanting, if any, and bottling is the same as at source, taking into account where appropriate the reintroduction of a quantity of carbon dioxide from the same water table or deposit equivalent to that released in the course of those operations and subject to the usual technical tolerances; **(b)** 'Natural mineral water fortified with gas from the spring' means water the carbon dioxide content of which from the same water table or the same deposit after decanting, if any, and bottling is greater than that established at source;	**Addition of carbon dioxide** Nothing may be added to natural mineral water, with the exception of carbon dioxide (as outlined in the conditions laid down in Annex I, Section III). It is recommended that the carbon dioxide used is certified by the supplier as being suitable for food use, and the FBO must ensure that the carbon dioxide does not give rise to contaminants in the water. In the case of effervescent natural mineral water, the sales descriptions on the label may be: **(a)** 'Naturally carbonated mineral water' **(b)** 'Natural mineral water fortified with gas from the spring' or **(c)** 'Carbonated natural mineral water'. As outlined in Regulation (EU) No 1169/2011, the name of the food and net quantity must appear in the same field of vision. **Flavoured water products** Natural mineral water to which flavourings are added cannot be sold as a flavoured natural mineral water. However, natural mineral water may be used as an ingredient in soft drinks and other flavoured water drinks. Drinks containing natural mineral water as an ingredient, fall outside the scope of Guidance Note 25, but must comply with all relevant legislation relating to natural mineral waters and spring waters.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	(c) 'carbonated natural mineral water' means water to which has been added carbon dioxide of an origin other than the water table or deposit from which the water comes.	
Article 4(3)	Any disinfection treatment by whatever means and, subject to paragraph 2, the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water, shall be prohibited.	Disinfection treatments, e.g. ultraviolet (UV) treatments, or the addition of bacteriostatic elements are prohibited for use on natural mineral water. Comparison of the microbiological composition pre- and post-permitted treatment for natural mineral water will indicate if disinfection is taking place. For more information on disinfection and cleaning of the well, see Appendix IV.
Article 5(1)	The revivable total colony count of a natural mineral water at source shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. This total colony count shall be determined under the conditions laid down in Annex I, Section II, point 1.3.3.	The production of microbiologically safe bottled natural mineral water is dependent on maintaining a high level of hygienic controls, including the protection of the source against all contamination, and also during the abstraction and bottling and capping processes. Table 5 provides a summary of the microbiological limits which apply to natural mineral water at source and in the package. Data analysis of microbiological results of at-source water over a period of time provides an indication of typical total viable count (TVC) levels. These TVC levels should remain stable and thus act as an indicator that the source has adequate protection against microbiological contamination. **Annex I, Section II, point 1.3.3** The TVC must be determined under the following conditions (Annex I, Section II, point 1.3.3): Determination of the revivable TVC per millilitre of water: **(a)** at 20 °C to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture **(b)** at 37 °C in 24 hours on agar-agar.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	After bottling, the total colony count at source may not exceed 100 per millilitre at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37 °C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4 °C ± 1 °C during this 12-hour period.	After bottling, the TVC must not exceed: • 100 colony-forming units (cfu)/mL at 20 °C to 22 °C in 72 hours • 20 cfu/mL at 37 °C in 24 hours. The TVC is only valid if it is determined within 12 hours of bottling (the water being maintained at 4 °C ± 1 °C during this 12-hour period) *, as water in its natural environment contains microorganisms. On storage, the number of microorganisms will initially increase until all the naturally available nutrients in the water are utilised. The number will then decrease due to lack of nutrients, and after a period will increase again. Therefore, EHOs responsible for the supervision of natural mineral water establishments should sample for all relevant microorganisms, including TVCs, bearing in mind that the analysis has to commence within 12 hours of bottling. Microbiological sampling at the marketing stage (distribution and retail stage) should not include TVC, as the time post-bottling is unknown and therefore the results of such analysis cannot be interpreted. If the TVC (within 12 hours of bottling) exceeds the legislative limits, then the bottled water is in breach of the legislation. Product which has not left the control of the FBO must not be released on to the market. If product has reached the consumer, the FBO must consult with the competent authority (the NEHS or the FSAI) regarding appropriate control actions. EHOs are advised to review the source protection and the various stages of production for hygiene practices which may establish the cause of the breach in the legislative limits. ***Clarification from the European Commission** According to ISO 6222:1999 (or an equivalent method), the analysis should be started within 12 hours after bottling, and samples have to be kept at 5 °C ± 3 °C during this period. This does not mean that the sample temperature has to be at 5 °C ± 3 °C; rather, the samples have to be stored in a refrigerator/ cool box regulated at 5 °C ± 3 °C. ISO 6222 on Enumeration of culturable micro-organisms was last reviewed in 2021 and continues to state 5 °C

Reference	Requirements of Directive 2009/54/EC	Interpretation
		+/- 3 °C. Two other relevant and recently reviewed ISO methods also state 5° C +/- 3° C namely, ISO 19458 on Sampling for microbiological analysis, which was reviewed in 2020 and ISO 5667-3 on Part 3: Preservation and handling of water samples, which was reviewed in 2024.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	At source, those values must not normally exceed 20 per millilitre at 20 to 22 °C in 72 hours and 5 per millilitre at 37 °C in 24 hours respectively, on the understanding that they shall be considered as guide figures and not as maximum permitted concentrations.	At source, the TVC should not normally exceed: • 20 cfu/ml at 20 °C to 22 °C in 72 hours • 5 cfu/ml at 37 °C in 24 hours. These are guide figures and not maximum permitted concentrations. EHOs are advised to review the source protection and the various stages of production for hygiene practices which may establish the cause of breaches in the legislative limits. See above for action to take if TVC levels in the bottle are above the legislative limits.
Article 5(2)	At source and during its marketing, a natural mineral water shall be free from: **(a)** parasites and pathogenic microorganisms; **(b)** *Escherichia coli* and other coliforms and faecal streptococci in any 250 ml sample examined; **(c)** sporulated sulphite-reducing anaerobes in any 50 ml sample examined; **(d)** *Pseudomonas aeruginosa* in any 250 ml sample examined.	Where the packaged water is deemed to be unsafe by reason that it may be injurious to health or unfit for human consumption, the FBO must initiate the procedure to withdraw or recall the batch of product in question. Where the product in question has reached the consumer, the FBO must accurately and effectively inform consumers of the reason for the withdrawal of the product and, if necessary, recall product that has already been released for purchase. Where the packaged water product does not comply with the legal requirements for microbiological criteria, the FBO must: • Take action to ensure that the water is not consumed • Where necessary, recall the product and notify consumers. ***Escherichia coli*** The presence of *E. coli* in natural mineral water is considered an index of faecal contamination of the water. As such, the water is considered injurious to health and, therefore, unsafe as defined in Regulation (EC) No 178/2002. Natural mineral water containing *E. coli* must be withdrawn from the market and, where it has reached the consumer, consumers must be notified and EHOs should ensure that the FBO takes the necessary measures to remove the product from consumers, such as:

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• Notifying trade customers • Notifying consumers • Removing the affected batch of bottled water from the food chain • Removing the affected batch of bottled water from consumers. See the *FSAI's Guidance Note No. 10, Product Recall and Traceability (Revision 3).* Enterococci (faecal streptococci) The presence of enterococci in natural mineral water is considered an index of faecal contamination of the water. As such, the water is considered injurious to health, and therefore unsafe. In accordance with Article 19 of Regulation (EC) No 178/2002, natural mineral water containing enterococci must be withdrawn from the market and, where it has reached the consumer, consumers must be notified and EHOs should ensure that the FBO takes the necessary measures to remove the product from consumers, such as: • Notifying trade customers • Notifying consumers • Removing the affected batch of bottled water from the food chain • Removing the affected batch of bottled water from consumers. See the *FSAI's Guidance Note No. 10, Product Recall and Traceability (Revision 3).* **Coliforms** The presence of coliforms (in the absence of *E. coli* or enterococci) in natural mineral water is not a strong indication of the potential presence of enteric pathogens. Such bottled water should not be considered unsafe for consumption. However, the presence of coliforms should prompt investigation by the EHO and the FBO. The FSAI should be informed of each case of coliforms detected in bottled water, and each result must be dealt with on a case-by-case basis (email: foodincidents@fsai.ie).

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Pseudomonas aeruginosa The presence of *Pseudomonas aeruginosa (P. aeruginosa)* (in the absence of *E. coli* or enterococci) in natural mineral water is not a significant health risk for the general population. The presence of *P. aeruginosa* should prompt investigation by the EHO and the FBO as to the cause of the contamination. *P. aeruginosa* is, however, a risk for the severely immunocompromised, such as those in hospitals and care units. The FSAI should therefore be informed of each case of *P. aeruginosa* detected in bottled water (email: foodincidents@fsai.ie). The FSAI will then advise the Health Protection Surveillance Centre (HPSC) of such findings. Each result must be dealt with on a case-by-case basis. ***Giardia*, helminths, and *Cryptosporidium*** The legal limit for *Giardia*, helminths and *Cryptosporidium* contamination in both natural mineral water and spring water is zero at source and during marketing. It is not recommended to sample for helminths, *Cryptosporidium* or *Giardia* due to the logistical challenges of sampling for and isolating this organism. Instead, it is recommended to sample for *E. coli* and enterococci which are indexes of faecal contamination. If *E. coli* or enterococci are detected, then it should be assumed that parasites could also be present, and steps should be taken to ensure their removal. For information on completing a risk assessment for *Cryptosporidium* that also applies to *Giardia*, please see page 19, Appendix 1 of Section 10 of *European Communities (Drinking Water) (No. 2) Regulations 2007: A Handbook on the Implementation of the Regulations for Water Services Authorities for Private Water Supplies*. The Water Services Training Group also runs courses on how to perform this risk assessment.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		ISO 15553:2006 is the internationally recognised standard method for the detection and identification of *Cryptosporidium* and *Giardia* in water. A sample volume of between 10 L and 1000 L can be taken for testing in accordance with ISO 15553:2006. A list of laboratories accredited to carry out testing in accordance with ISO 15553:2006 can be found on the Irish National Accreditation Board (INAB) website. https://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory-Accreditation/Testing/ **Frequency of *Cryptosporidium* and *Giardia* testing** It is not recommended to sample for *Cryptosporidium* or *Giardia* due to the logistical challenges of sampling for and isolating this organism. Instead, it is recommended to sample for *E. coli* and enterococci which are indexes of faecal contamination. If *E. coli* or enterococci are detected, then it should be assumed that parasites could also be present, and steps should be taken to ensure their removal. *Cryptosporidium* and *Giardia* will not be eliminated by most disinfection processes; therefore, if indicator organisms suggest that the well has become contaminated with faecal material, the FBO may need to test that the well is free of parasites after taking appropriate action to remove them. In all cases of contamination, EHOs are also advised to investigate immediately in order to identify the cause of contamination, e.g. review the microbiological status of the source water and the level of hygiene controls in the abstraction and bottling processes. This may indicate the cause of the breach in the legislative limits.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 5(3)	Without prejudice to paragraphs 1 and 2 and the conditions of exploitation laid down in Annex II, at the marketing stage: **(a)** the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacterial count which it had at source; **(b)** the natural mineral water may not contain any organoleptic defects.	TVCs for natural mineral water are generally very low but can vary from source to source. Microbiological data for the previous two years are reviewed by the NSAI prior to recognition. The normal viable counts are determined from these data.
Article 6	Any containers used for packaging natural mineral waters shall be fitted with closures designed to avoid any possibility of adulteration or contamination.	The possibility of adulteration or contamination can be reduced with the use of tamper-proof or tamper evident closures on the packaged water containers. Material used for wrapping and packaging should not be a source of contamination. Wrapping materials should be stored in such a manner that they are not exposed to a risk of contamination. Wrapping and packaging operations should be carried out so as to avoid contamination of the products. Where appropriate, and particularly in the case of cans and glass jars, the integrity of the container's construction and its cleanliness should be ensured (Chapter X of Annex II of Regulation (EC) No 852/2004). All food contact materials must comply with Regulation (EC) No 1935/2004, S.I. No. 49 of 2017 and Regulation (EC) No 2023/2006 on good manufacturing practice. Additionally, the packaging must comply with any material-specific requirements. For example, plastics must comply with Commission Regulation (EU) No 10/2011 and must be supplied with Declarations of Compliance to this effect. Recycled plastics must comply with Regulation (EC) No 282/2008. At present (2019), there are no specific additional requirements for glass. However, Commission Regulation (EC) No 372/2007 outlines restrictions on the gaskets used in lids for glass containers.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 7(1)	The sales description of natural mineral waters shall be 'natural mineral water' or, in the case of an effervescent natural mineral water as defined in Annex I, Section III, as appropriate, 'naturally carbonated natural mineral water', 'natural mineral water fortified with gas from the spring' or 'carbonated natural mineral water'.	**Sales description** (this is not the trade description) The sales description on the label of natural mineral waters must be 'natural mineral water'. This is the legal name that must be provided in order to ensure sufficient information for consumers. In addition, a trade name may also be used (see Article 8(2) below). The sales description of natural mineral water which contains added carbon dioxide must be one of the following options: • 'Naturally carbonated natural mineral water' • 'Natural mineral water fortified with gas from the spring' • 'Carbonated natural mineral water'. As outlined in Regulation (EU) No 1169/2011, the name of the food and net quantity must appear in the same field of vision. Article 29 of Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC) states that the nutrition declaration requirement does not apply to Directive 2009/54/EC on the exploitation and marketing of natural mineral waters. Therefore, natural mineral waters do not have to provide the nutrition information in the format outlined in Regulation (EU) No 1169/2011.
	The sales description of natural mineral waters which have undergone any of the treatments referred to in point (d) of the first subparagraph of Article 4(1) shall have added to it, as appropriate, the indication 'fully de-carbonated' or 'partially de-carbonated'.	See Appendix I for examples of labels. The sales description of natural mineral water which has undergone the total or partial elimination of free carbon dioxide by exclusively physical methods must have added to it, as appropriate, the indication on the label: **(a)** 'Fully de-carbonated natural mineral water' or **(b)** 'Partially de-carbonated natural mineral water'. As outlined in Regulation (EU) No 1169/2011, the name of the food and net quantity must appear in the same field of vision.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 7(2)	Labels on natural mineral waters shall also give the following mandatory information: **(a)** a statement of the analytical composition, giving its characteristic constituents; **(b)** the place where the spring is exploited and the name of the spring; **(c)** Information on any treatments referred to in points (b) and (c) of the first subparagraph of Article 4(1).	Labels on natural mineral waters must also give the following mandatory information: (a) Analytical composition The label on natural mineral water must give a statement of the analytical composition, describing its characteristic constituents. In order to comply with this requirement, the average composition of the water must be declared on the label. The average composition on the label should reflect the composition of the well water. Examples of ions which may appear in the statement of analytical composition are listed below. Such ions must be declared in units of milligrams per litre (mg/L). The chemical name or symbol must be used to define the ions listed. Examples include: • Calcium or Ca • Magnesium or Mg • Sodium or Na • Potassium or K • Other cations • Bicarbonate or HCO_3 • Chloride or Cl • Sulphate or SO_4 • Nitrate or NO_3 Commission Directive 2003/40/EC states that the fluoride content must be provided in the analytical composition for all natural mineral waters with a fluoride concentration exceeding 1.5 mg/L. Nutrition and health claims under Regulation (EC) No 1924/2006, as amended, may also be made on natural mineral water, e.g. 'source of calcium'. If these claims are made, they must comply with the requirements of Regulation (EC) No 1924/2006, as amended. The content of the specified ion which the claim relates to must be provided in the analytical composition on the label.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Authorised health claims and the conditions applying to them are listed on the Community Register. A list of rejected health claims and the reasons for their rejection are also listed on the Community Register, which can be accessed at Nutrition and Health Claims - European Commission (europa.eu) **(b)** The place where the spring is exploited and the name of the spring The label must state the place where the spring is exploited and the name of the spring. The location of the source of the water should be readily identifiable and distinguishable from the information provided on the product label. **(c)** Permitted treatments requiring additional labelling • Ozone-enriched air: where the natural mineral water has been treated with ozone-enriched air, the label must include the following information: 'water subjected to an authorised ozone-enriched air oxidation technique'. This information must be printed in the same field as the information on the analytical composition. • Other permitted treatments: where the natural mineral water has undergone a separation process which is controlled by the NEHS the label must provide information on the treatment. • The removal of fluoride with activated alumina in accordance with Commission Regulation (EU) No 115/2010: the label must state 'water subjected to an authorised adsorption treatment' in proximity to the statement of the analytical composition. Commission Directive 2003/40/EC states that natural mineral waters with a fluoride concentration exceeding 1.5 mg/L must bear on the label the words 'contains more than 1.5 mg/L of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. This information must be placed in immediate proximity to the trade name and in clearly visible characters. The fluoride content must be stated in the analytical composition table.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 7(3)	In the absence of Community provisions on information on any treatments referred to in paragraph 2(c), Member States may maintain their national provisions.	There are no national provisions.
Note: Labelling of natural mineral water must also comply with the requirements of Regulation (EU) No 1169/2011 on the provision of food information to consumers, as amended, and S.I. No. 556 of 2014.		
Article 8(1)	The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring.	A spring is a body of groundwater that emerges at some point. A spring may have more than one natural bore exit. All natural mineral water from these boreholes is considered to be from the one spring source. If a FBO advises that natural mineral water packed in its establishment is from more than one spring, the FBO must be able to demonstrate that there are two separate sources of natural mineral waters, e.g. compositional differences of natural mineral water from each spring. In this case, each source of natural mineral water requires a separate recognition process by the NSAI. **Trade description:** The name of the locality, hamlet or place may occur in the wording of a trade description, provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring. When the labels or inscriptions on the containers in which the mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, this place or the name of the spring must be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 8(2)	It shall be prohibited to market natural mineral water from one and the same spring under more than one trade description.	**Trade description** According to Regulation (EU) No 1169/2011, a trademark/trade description/brand name is permitted in addition to the name of the food, i.e. natural mineral water. However, a trade description cannot appear instead of the legal or customary name, as it does not provide sufficient information for consumers. Note: • It is not permitted to market natural mineral water from the same spring under more than one trade description. If a natural mineral water is bottled under one trade description, all other natural mineral water products from the same source must carry the same trade description. • Water recognised as natural mineral water may also be sold as spring water, provided that it meets the requirements for spring water. Similarly, such spring water must only be marketed under one trade description. This trade description can be different from the trade description used on the natural mineral water product. • Water recognised as natural mineral water may also be sold as 'other water' provided that it meets the requirements for other water. 'Other water' may be sold under more than one trade description.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 8(3)	When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, that place of exploitation or the name of the spring shall be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description. The first subparagraph shall apply, *mutatis mutanxdis* and with the same intention as regards the importance attributed to the name of the spring or the place of its exploitation, with regard to the trade description used in advertising, in whatsoever form, relating to natural mineral waters.	Note: When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, the place or the name of the spring must be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description. See Appendix I for examples of labels. Article 8(3) also applies to all types of advertising of natural mineral water, e.g. posters, TV advertisements, websites, etc.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 9(1)	It shall be prohibited, both on packaging or labels and in advertising in any form whatsoever, to use indications, designations, trademarks, brand names, pictures, or other signs, whether figurative or not, which: **(a)** in the case of a natural mineral water, suggest a characteristic which the water does not possess, in particular as regards its origin, the date of the authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity; **(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'.	The labelling or advertising of the products must not mislead the consumer. The use of the term 'mineral water' is not permitted on spring water or 'other waters'. A statement of the analytical composition is required for natural mineral water. Although not required, it is permitted to provide a statement of the analytical composition on the label of spring water and other packaged waters. If analytical composition is provided on the label of a spring water, it does not trigger the requirement to provide nutrition information as set out in Chapter IV, Section 3 of Regulation (EU) No 1169/2011 on the provision of food information to consumers, as spring water falls within the scope of Directive 2009/54/ EC. If 'other waters' provide analytical composition information on the label, they have to provide nutrition information as set out in Chapter IV, Section 3 of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

<table>
<tr><th>Reference</th><th>Requirements of Directive 2009/54/EC</th><th>Interpretation</th></tr>
<tr><td>Article 9(2)</td><td>All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited.

However, the indications listed in Annex III shall be authorised if they meet the relevant criteria laid down in that Annex or, in the absence thereof, criteria laid down in national provisions and provided that they have been drawn up on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognised scientific methods, in accordance with Annex I, Section I, point 2.</td><td>Medicinal claims on foods are prohibited. All indications attributing to natural mineral water properties relating to the prevention, treatment or cure of a human illness are prohibited.

Annex II: Indications and Criteria laid down in Article 9(2)

The label of natural mineral water may indicate the following properties, provided that the specific criteria are met. If an indication/claim is made on the natural mineral water, the content of the specified ion must be provided in the compositional panel.
<table>
<tr><th colspan="2">Indications and criteria laid down in Article 9(2)</th></tr>
<tr><th>Indications</th><th>Criteria</th></tr>
<tr><td>Low mineral content</td><td>Mineral salt content, calculated as a fixed residue, not greater than 500 mg/L</td></tr>
<tr><td>Very low mineral content</td><td>Mineral salt content, calculated as a fixed residue, not greater than 50 mg/L</td></tr>
<tr><td>Rich in mineral salts</td><td>Mineral salt content, calculated as a fixed residue, greater than 1500 mg/L</td></tr>
<tr><td>Contains bicarbonate</td><td>Bicarbonate content greater than 600 mg/L</td></tr>
<tr><td>Contains sulphate</td><td>Sulphate content greater than 200 mg/L</td></tr>
<tr><td>Contains chloride</td><td>Chloride content greater than 200 mg/L</td></tr>
<tr><td>Contains calcium</td><td>Calcium content greater than 150 mg/L</td></tr>
<tr><td>Contains magnesium</td><td>Magnesium content greater than 50 mg/L</td></tr>
<tr><td>Contains fluoride</td><td>Fluoride content greater than 1 mg/L</td></tr>
<tr><td>Contains iron</td><td>Bivalent iron content greater than 1 mg/L</td></tr>
<tr><td>Acidic</td><td>Free carbon dioxide content greater than 250 mg/L</td></tr>
<tr><td>Contains sodium</td><td>Sodium content greater than 200 mg/L</td></tr>
<tr><td>Suitable for the preparation of infant food</td><td>n/a</td></tr>
<tr><td>May be laxative</td><td>n/a</td></tr>
<tr><td>May be diuretic</td><td>n/a</td></tr>
</table>
</td></tr>
</table>

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Criteria are not specified for the following indications: • Suitable for the preparation of infant food: • as recommended in the FSAI Scientific Recommendations for a National Infant Feeding Policy, 2nd Edition, natural mineral water should not be used either to reconstitute infant formula or as an infant drink. Boiled tap water should be used to prepare powdered infant formula. If this is not available, boiled bottled water should be used. If water is used to mix foods for infants, the water (not being natural mineral water) should be cooled boiled water. Milk (breast milk or formula) and cooled boiled water should be the only drinks given up to, approximately, age of four months and should constitute the great majority of the drinks given during infancy. • May be laxative: this claim has not been authorised. • May be diuretic: this claim has not been authorised. Nutrition and health claims under Regulation (EC) No 1924/2006, as amended, may also be made on natural mineral water, e.g. 'source of', 'high in'. If these claims are made, they must comply with the requirements of Regulation (EC) No 1924/2006, as amended. The content of the specified ion must be provided in the compositional panel. Authorised health claims and the conditions applying to them are listed in the Community Register. A list of rejected health claims and the reasons for their rejection are also listed in the Community Register, which can be accessed at Nutrition and Health Claims - European Commission (europa.eu)

Reference	Requirements of Directive 2009/54/EC	Interpretation
	Member States may authorise the indications 'stimulates digestion', 'may facilitate the hepato-biliary functions' or similar indications. They may also authorise the inclusion of other indications, provided that the latter do not conflict with the principles provided for in the first subparagraph and are compatible with those provided for in the second subparagraph.	Only indications outlined in Annex II are authorised in Ireland. Such indications on imported products should be verified with the competent authority of the country of origin.
Article 9(3)	Member States may adopt special provisions regarding indications – both on packaging or labels and in advertising – concerning the suitability of a natural mineral water for the feeding of infants. Such provisions may also concern the properties of the water which determine the use of those indications. Member States which intend taking such measures shall inform the other Member States and the Commission of them beforehand.	As recommended in FSAI Scientific Recommendations for a National Infant Feeding Policy, 2nd Edition, natural mineral water should not be used either to reconstitute formula or as an infant drink. If water is used to mix foods for infants, the water (not being natural mineral water) should be cooled boiled water. Milk (breast milk or formula) and cooled boiled water should be the only drinks given up to, approximately, age of four months and should constitute the great majority of the drinks given during infancy.
Note: Article 9(4) and Article 9(5) do not apply to natural mineral water.		
Article 10	Member States shall adopt the measures necessary to ensure that trade in natural mineral waters which comply with the definitions and rules laid down in this Directive cannot be impeded by the application of non-harmonised national provisions governing the properties, composition, conditions of exploitation, packaging, labelling, or advertising of natural mineral waters or foodstuffs in general.	*This section is intentionally left blank*

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 11(1)	Where a Member State has detailed grounds for considering that a natural mineral water does not comply with the provisions laid down in this Directive, or endangers public health, albeit freely circulating in one or more Member States, that Member State may temporarily restrict or suspend trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.	*This section is intentionally left blank*
Article 11(2)	At the request of any Member State or the Commission, the Member State which has recognised that water shall provide all relevant information concerning recognition of that water, together with the results of the regular checks.	*This section is intentionally left blank*
Article 11(3)	The Commission shall examine as soon as possible the grounds adduced by the Member State referred to in paragraph 1 within the Standing Committee referred to in Article 14(1) and shall deliver its opinion forthwith and take appropriate measures.	*This section is intentionally left blank*

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 11(4)	If the Commission considers that amendments to this Directive are necessary in order to ensure the protection of public health, it shall adopt those amendments. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 14(3). The Member State which has adopted safeguard measures may, in that event, retain them until the amendments have been adopted.	*This section is intentionally left blank*
Article 12	The following measures shall be adopted by the Commission: **(a)** limits for the concentrations of constituents of natural mineral waters; **(b)** any necessary provisions for the indication on the labelling of high levels of certain constituents; **(c)** the conditions of use of ozone-enriched air referred to in point (b) of the first subparagraph of Article 4(1); **(d)** the information on the treatments referred to in Article 7(2)(c); **(e)** methods of analysis, including limits of detection, to verify the absence of pollution of natural mineral waters;	*This section is intentionally left blank*

Reference	Requirements of Directive 2009/54/EC	Interpretation
	(f) the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).	
Article 13	Any decision likely to have an effect on public health shall be adopted by the Commission following consultation of the European Food Safety Authority.	To date, no decisions have been adopted by the European Commission.
Article 14	**1.** The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002. **2.** Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. **3.** Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	This Article relates to European Commission procedures and is not applicable to natural mineral water producers.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 15	This Directive shall not apply to natural mineral waters intended for export to third countries.	The requirements of the Directive do not apply to natural mineral water products intended for export outside the EU. EHOs should check where the product will be marketed, i.e. within or outside the EU, prior to inspection. All exported products must comply with the specific legislation of the importing country.
Article 16	Directive 80/777/EEC, as amended by the acts listed in Annex IV, Part A, is hereby repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.	In 2009, Directive 2009/54/EC was published, which is a recast of Council Directive 80/777/EEC and its amendments. However, since Directive 2009/54/EC is a recast of Council Directive 80/777/EEC with no material modification, S.I. No. 282 of 2016 (as amended) remains applicable as the Statutory Instrument for Directive 2009/54/EC.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Annex I of Directive 2009/54/EC		
Section I of Annex I		
Definition 1	1. 'Natural mineral water' means microbiologically wholesome water, within the meaning of Article 5, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits. Natural mineral water can be clearly distinguished from ordinary drinking water: **(a)** by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects; **(b)** by its original purity, both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.	Annex I relates to the recognition of natural mineral water. In Ireland, the NSAI is the responsible authority for the recognition of natural mineral water. Following an inspection, the NSAI issues a 'Certificate of Recognition' and 'Conditions of Exploitation' to all natural mineral water establishments which have met the recognition criteria of this Directive. Guidance on the recognition requirements is available in the NSAI's I.S. 432:2010 Packaged groundwater. Information obtained during an inspection by either the NSAI or the NEHS which may be of relevance to the other agency should be passed on to that agency either directly or via the FSAI. Each natural mineral water source recognised by the NSAI will have a unique chemical fingerprint. The 'Conditions of Exploitation' will include the following: **i.** Tolerances for each chemical constituent: the chemical composition should not be outside of the specified tolerance limits. **ii.** The specific borehole for which the recognition by the NSAI applies to natural mineral water must retain its original purity. Only limited treatments are permitted, as outlined under Article 4 above. The water source must be protected from all risks of pollution. Methods to protect the source against risk are outlined in Annex II below. See **Appendix V** for more information on the definition of 'original purity' for natural mineral water.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Definition 2	The characteristics referred to in point 1, which may give natural mineral water properties favourable to health, shall have been assessed: **(a)** from the following points of view: **(i)** geological and hydrological; **(ii)** physical, chemical and physico-chemical; **(iii)** microbiological; **(iv)** if necessary, pharmacological, physiological, and clinical; **(b)** according to the criteria listed in Section II; **(c)** according to scientific methods approved by the responsible authority. The analyses referred to in point (a)(iv) of the first subparagraph may be optional where the water presents the compositional characteristics on the strength of which it was considered a natural mineral water in the Member State of origin prior to 17 July 1980. This is the case in particular when the water in question contains, per kg, both at source and after bottling, a minimum of 1000 mg of total solids in solution or a minimum of 250 mg of free carbon dioxide.	The FBO must submit data on the following areas, which is for review by the NSAI: • Geological and hydrogeological data • Microbiological, physical, and chemical (hydrochemical and physico-chemical) data • If necessary, pharmacological, physiological, and clinical data. The NSAI reviews microbiological and chemical data submitted by the FBO from the previous two years. A complete chemical analysis audit (as described in Directive (EU) 2020/2184) is also carried out by the NSAI. Following an inspection and review of the data, the NSAI issues a 'Certificate of Recognition' and 'Conditions of Exploitation' to natural mineral water establishments which have met the legislative criteria for recognition.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Definition 3	The composition, temperature and other essential characteristics of natural mineral water shall remain stable within the limits of natural fluctuation; in particular, they shall not be affected by possible variations in the rate of flow. Within the meaning of Article 5(1), the normal viable colony count of natural mineral water means the reasonably constant total colony count at source before any treatment, the qualitative and quantitative composition of which, as taken into account in the recognition of that water, is checked by periodic analysis.	The 'Conditions of Exploitation' will include tolerances for each chemical constituent. The chemical composition should not be outside of these tolerance limits. The chemical composition of natural mineral water is usually stable. However, in some circumstances, the composition may change. For example, over a period of time (decades), the hardness of the water may change. This is a natural change in the water. In this case, the NSAI reviews the data and amends the 'Conditions of Exploitation'. TVCs for natural mineral water are generally very low but can vary from source to source. Microbiological data for the previous two years are reviewed by the NSAI prior to recognition. The normal viable counts are determined from these data.
Section II of Annex I: Requirements and criteria for applying the definition		
1.1 Requirements for geological and hydrological surveys		
1.1 1.1.1	There shall be a requirement to supply the following particulars: The exact site of the catchment with indications of its altitude, on a map with a scale of not more than 1:1000;	FBOs must have a hydrological and geological survey carried out by a qualified professional in this area. A copy of the survey should be maintained for inspection as long as the well is in production. The survey should include: • Approximate size and location of the groundwater catchment area by a line on an appropriate map • Origin and nature of the terrain in and adjacent to the groundwater catchment area • Geology of the groundwater catchment area • Hydrogeology of the groundwater system feeding the water source • Geotechnical properties of the construction site • Identification of other abstraction points and water features (boreholes, wells, and springs) within the catchment area
1.1.2	A detailed geological report on the origin and nature of the terrain;	
1.1.3	The stratigraphy of the hydrogeological layer;	
1.1.4	A description of the catchment operations;	
1.1.5	The demarcation of the area or details of other measures protecting the spring against pollution.	

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• Identification of activities being carried out in the groundwater catchment area • Assessment of the risk of these activities contaminating the groundwater. FBOs must define the control measures in place for each risk identified. Where appropriate, the location of sites from which there is a risk of contamination to the groundwater should be shown on a map of the area. During the groundwater catchment area study, the following should be defined where practicable and, where necessary, should be quantified: • Recharge zone • Response of the water table to meteorological events during the different seasons, e.g. rainfall or drought • Correlation of the groundwater chemistry and microbiology to meteorological events and seasonal land use activities • Effect of abstracting groundwater from the production well on the other abstraction points and on surface water flow (streams and rivers) • Geotechnical characteristics of the ground conditions at the well construction site, in order to assist in design specifications for the foundations and source protection. The progression of well construction and development should include the following steps: • Identify the project area • Study the catchment area • Establish the nature of the hydrogeological system • Drill and test exploration boreholes • Drill and test production boreholes • Test the source to establish suitability.

Reference	Requirements of Directive 2009/54/EC	Interpretation
1.2 Requirements for physical, chemical, and physio-chemical surveys		
1.2.1	These surveys shall establish: The rate of flow of the spring;	The survey should also include the following information: • Rate of flow of the spring and sustainable yield of the borehole • Relationship between the nature of the terrain and the nature and types of minerals in the water. A chemical analysis of the water must be carried out in order to establish the following: • Dry residues at 180 °C and 260 °C • Electrical conductivity or resistivity, with the measurement temperature having to be specified • Hydrogen ion concentration (pH) • Anions and cations • Non-ionised elements • Trace elements • Radio-actinological properties at source (the NSAI requires FBOs to send samples for α and ß radiation analysis every four years) • Toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.
1.2.2	The temperature of the water at source and the ambient temperature;	
1.2.3	The relationship between the nature of the terrain and the nature and type of minerals in the water;	
1.2.4	The dry residues at 180 °C and 260 °C;	
1.2.5	The electrical conductivity or resistivity, with the measurement temperature having to be specified;	
1.2.6	The hydrogen ion concentration (pH);	
1.2.7	The anions and cations;	
1.2.8	The non-ionised elements;	
1.2.9	The trace elements;	
1.2.10	The radio-actinological properties at source;	
1.2.11	Where appropriate, the relative isotope levels of the constituent elements of water, oxygen (16 O — 18 O) and hydrogen (protium, deuterium, tritium);	
1.2.12	The toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.	

Reference	Requirements of Directive 2009/54/EC	Interpretation
1.3 Criteria for microbiological analyses at source		
1.3.1	**These analyses shall include** A demonstration of the absence of parasites and pathogenic micro-organisms;	A microbiological analysis of the water must demonstrate that the water meets the specified microbiological criteria (see Article 5 above). As part of the recognition process, each natural mineral water establishment is required to carry out the following microbiological sampling and analysis programme: • Annual samples from authorised boreholes (source) and packed product, for a range of micro parameters • Monthly samples of source water analysed for a range of microanalyses • Annual samples of source water analysed for pathogens and indicator organisms • Daily samples of source water analysed for a range of micro parameters • Samples of each batch of packaged product analysed for a range of micro parameters.
1.3.2	A quantitative determination of the revivable colony count indicative of faecal contamination: **(a)** absence of *Escherichia coli* and other coliforms in 250 ml at 37 °C and 44,5 °C; **(b)** absence of faecal streptococci in 250 ml; **(c)** absence of sporulated sulphite-reducing anaerobes in 50 ml; **(d)** absence of *Pseudomonas aeruginosa* in 250 ml;	
1.3.3	Determination of the revivable total colony count per ml of water: **(a)** at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture; **(b)** at 37 °C in 24 hours on agar.	
1.4 Requirements for clinical and pharmacological analyses		
1.4.1	The analyses, which shall be carried out in accordance with scientifically recognised methods, shall be suited to the particular characteristics of the natural mineral water and its effects on the human organism, such as diuresis, gastric and intestinal functions, compensation for mineral deficiencies.	*This section is intentionally left blank*

Reference	Requirements of Directive 2009/54/EC	Interpretation
1.4.2	The establishment of the consistency and concordance of a substantial number of clinical observations may, if appropriate, take the place of the analyses referred to in point 1.4.1. Clinical analyses may, in appropriate cases, take the place of the analyses referred to in point 1.4.1 provided that the consistency and concordance of a substantial number of observations enable the same results to be obtained.	*This section is intentionally left blank*
Section III of Annex I: Supplementary qualifications relating to effervescent natural mineral waters		
	This section is outlined in Article 4(2) above.	

Reference	Requirements of Directive 2009/54/EC	Interpretation
Annex II Conditions for exploitation and marketing of natural mineral water		
Exploitation and marketing 1	Exploitation of a natural mineral water spring shall be subject to permission from the responsible authority of the country where the water has been extracted, after it has been established that the water in question complies with the provisions laid down in Annex I, Section I.	The NSAI is the responsible authority in Ireland for the exploitation and recognition of natural mineral water.
Exploitation and marketing 2	Equipment for exploiting the water shall be so installed as to avoid any possibility of contamination and to preserve the properties, corresponding to those ascribed to it, which the water possesses at source. To that end, in particular: (a) the spring or outlet shall be protected against the risks of pollution;	The catchment area is the surface area within which rainfall can either directly or indirectly enter the groundwater system within which the well is trapped, and which can contribute to the yield of the well. The catchment area should be included in the NEHS food safety inspections of the establishment. As the groundwater is not treated, protection and management of the well and groundwater catchment area should be a critical control point in the HACCP plan of the establishment. Protection of the source must be managed effectively. The production well and groundwater catchment areas must be protected from hazards. The FBO must manage the groundwater source to avoid contamination. **Site location** Consideration should be given to the following areas in relation to site location: • The potential risk of contamination from other activities in the vicinity and the necessary controls implemented to minimise the risk of contamination • Protection and maintenance of the grounds of the establishment in order to avoid the establishment of breeding sites for rodents and insects • Procedures in place for the management of all waste generated on site • Site maintenance and cleanliness • Site design and layout, in order to facilitate the operation of good hygiene practices.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Site security/site access The site should be adequately secured to prevent unauthorised access. The FBO should have security measures in place to ensure that only authorised staff have access to water source, production, and storage areas. **Areas for identification and protection on the groundwater production site** The FBO must identify the groundwater protection zones, identify both permitted and unacceptable activities in protection zones, and put in place a well field management programme. This can be done under the guidance of a hydrogeologist. Examples of protection zones: • **Wellhead protection measures:** an intruder alarm system should be installed on the production borehole, with access to the borehole head limited to authorised personnel. Boreholes should have sampling valves for sampling at source. The pipework entering the establishment should be reviewed, and storage silos and pipework must also be protected. • **Inner protection zone:** the area is defined by a 100-day time of travel (TOT) from any point below the water table to the source. In karst areas it will not usually be feasible to delineate 100-day TOT boundaries, as there are large variations in permeability, high flow velocities and a low level of predictability. If it is necessary to use the arbitrary fixed-radius method, a distance of 300 m is normally used. A semicircular area is used for springs. The distance may be increased for sources in karst aquifers and reduced in granular aquifers and around low-yield sources.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• **Outer protection zone:** this area covers the remainder of the zone of contribution (ZOC) (or complete catchment area) of the groundwater source. It is defined as the area needed to support an abstraction from groundwater recharge, i.e. the proportion of effective rainfall that infiltrates to the water table. If the arbitrary fixed-radius method is used, a distance of 1000 m is recommended in some instances, with variations in karst aquifers and around springs and low-yield wells. The FBO should liaise with the county council on activities on the surrounding land, review ongoing planning applications and annual land use surveys, etc. **Contamination sources** The FBO must ensure that the boreholes and groundwater are protected from sources of contamination. Possible contamination sources include the following: • Connections between the ground surface and the underlying aquifer from surface activity can be a source of contamination and should be controlled. • All fuel and liquid storage tanks should be located above ground, rest on impervious bases and be bunded. Tanks for petrol, diesel or other liquid hydrocarbons should not be located within 100 m of the well or observation boreholes. • The ground underlying any storage tank in the construction area must be investigated and categorised with regard to permeability and potential hydraulic contact with the aquifer. • The drilling or excavation of new abstraction points within the ZOC must be avoided, as it could seriously impact on the performance and quality of the source used for packaging.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• The use of land in the ZOC should be monitored at defined intervals in order to detect changes in activities, and a risk assessment of these activities should be undertaken in order to identify potential contamination of the source. For more information on risk assessment, please see Appendix III. **i. Planning applications** for developments in the groundwater catchment area must be critically assessed for potential contamination of the groundwater system during the development and following completion of the development. FBOs should have evidence that they reviewed planning applications on the local area for developments in the specified protection zones which may impact on the protection of the aquifer. A log of this review and each outcome should be maintained on file. **ii. Agricultural activity** on the land should be limited. Pesticides and herbicides must not be used in the area of the well. Controlled use of rodenticide is acceptable. Agreements should be in place between the FBO and the county council or the owner of the land regarding restricted agricultural activities within the protection zone. See **Appendix II, Table 14** for a list of pesticides used in Ireland. The following measures should also be considered in order to prevent contamination of the well: • All pipes, valve arrays and power cables to and from the well and packaging establishment must be adequately secured and protected. • Chemicals should be segregated and stored in a bunded area or over suitable drip trays. Where the bunds provided have drains, the drains must be locked at all times. The bunds on the site should be integrity tested every three years. The volume of bunds should exceed the volume of the largest unit in the bund by 10%.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• All wastewater from the site must be discharged to an appropriate wastewater collection system. • Waste compactors should be located in a bunded area. • In the event of a contamination incident involving the aquifer or surface water, the FBO should seek advice from the NEHS on what action to take. • Agricultural contamination sources include: – Storage and use of fertilisers, pesticides, and weedkillers – Run-off from silage pits – Spreading of manure – Septic and slurry tanks – Fuel storage tanks – Burial of offal – Disposal of other farm wastes – Animal access. • Commercial contamination sources include: – Petrol and service stations – Underground storage tanks – Cemeteries – Construction sites – Railway lines (due to the use of weedkiller) and roads – Waste from hospitals – Dry cleaners and laundries – Junk yards. • Industrial contamination sources include: – Storage of chemicals above or below ground – Chemical spillages – Disposal of solvents and waste products – Effluent establishments and settlement lagoons – Disposal of effluent sludge – Leaks from pipelines – Inadequately protected wells (operating/ abandoned) – Use of weedkillers, pesticides.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• Residential contamination sources include: – Storage of heating oil – Septic tanks and sewer lines – Use of garden chemicals – Disposal of hazardous household products. • Other contamination sources include: – Municipal dumps – Storm drains and sewer lines – Road maintenance depots – Incinerators. **Natural protection** The thickness and type of overburden present affects the level of natural protection provided.
Food contact materials Annex II, point 2	(b) the catchment, pipes and reservoirs shall be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water;	**Requirements for food contact materials** All material, from the point of abstraction through to bottling, which comes into contact with natural mineral water must comply with food contact material legislation. All processing equipment which comes into direct contact with the water must be manufactured in compliance with good manufacturing practice so that, under normal conditions of use, it will not transfer its constituents to the water in quantities that could endanger human health and/or impart odours or taint to the product. All product contact piping must be made from materials that are supplied labelled 'for food contact' and that comply with food contact material legislation. The surfaces in contact with the water must be resistant to corrosion when cleaned with food-grade cleaning and sanitising agents.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Hygiene requirements Annex II, point 2	(c) the conditions of exploitation, particularly the washing and bottling equipment, shall meet hygiene requirements; in particular, the containers shall be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the spring water;	**Hygiene requirements** All processing equipment which comes into direct contact with natural mineral water must be manufactured in compliance with good manufacturing practice so that, under normal conditions of use, it has no adverse effect on the microbiological or chemical composition of the water. Equipment must be installed so that there is adequate access under, around and inside the equipment to enable effective cleaning. Equipment must be maintained at defined intervals and procedures must be in place to ensure that the maintenance activity does not result in product or equipment contamination. Product contact surfaces must be non-toxic and easy to clean and maintain. Hygiene requirements of Regulation (EC) No 852/2004 are applicable throughout production. Plastic bottles may be blow-moulded on site. An extensive certificate of compliance should accompany the delivery of all plastic material for use with food. Sterilisation of bottles and caps is permitted. The sterilised material should be free from residues following this process. If a different water supply is used for cleaning, this water must be potable. This water supply must be strictly controlled.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Transport Annex II, point 2	(d) the transport of spring water in containers other than those authorised for distribution to the ultimate consumer shall be prohibited. However, point (d) need not be applied to spring waters extracted, exploited, and marketed in the territory of a Member State if, in that Member State on 17 July 1980, transport of the spring water in tanks from the spring to the bottling plant was authorised. Similarly, point (d) need not be applied to spring waters extracted, exploited, and marketed in the territory of a Member State if, in that Member State on 13 December 1996, transport of the spring water in tanks from the spring to the bottling plant was authorised.	**Transport of spring waters** Transport of natural mineral waters: Natural mineral water must be packaged in containers for the final consumer on site (typically in 0.5 L, 1 L or 10 L containers). The derogation mentioned does not apply to Ireland. **Reservoirs/storage tanks** Natural mineral water sourced from one or more boreholes from a single aquifer can be stored in the same storage tanks. Natural mineral water sourced from a different aquifer should be stored in a separate storage tank. See **Appendix VI** for Guidance on storage tanks.
Exploitation and marketing 3	Where it is found during exploitation that the natural mineral water is polluted and no longer presents the microbiological characteristics laid down in Article 5, the person exploiting the spring shall forthwith suspend all exploitation, particularly the bottling process, until the cause of pollution is eradicated, and the water complies with the provisions of Article 5.	If in-house or official control testing results indicate that the water is polluted, production must stop immediately. The problem must be rectified prior to recommencement of production. If the natural mineral water from a particular borehole becomes contaminated, the FBO must inform the NSAI, the NEHS and the FSAI. The NSAI will then suspend permission for the exploitation of natural mineral water from these boreholes. The FBO may continue to exploit natural mineral water from additional recognised boreholes, provided that they are not contaminated.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Boreholes can be disinfected in order to rectify the contamination problem. For example, hypochlorite is permitted as a disinfectant. FBOs must be able to demonstrate that there is no carryover of disinfectant into the natural mineral water, e.g. residue analysis sampling. See Appendix IV for more information on disinfection and cleaning of the well. Contamination of boreholes may be caused by the development of a biofilm on the inside casing or piping down the borehole. FBOs generally monitor for biofilm development by sampling for the presence of TVCs and coliform. As a control measure, FBOs may replace the borehole casing/piping to prevent contamination. **Other causes of contamination include the following:** • Piping into the establishment • Equipment used • Poor hygiene practices of staff.
Exploitation and marketing 4	The responsible authority in the country of origin shall carry out periodic checks to see whether: **(a)** the natural mineral water in respect of which exploitation of the spring has been authorised complies with the provisions of Annex I, Section I; **(b)** the provisions of points 2 and 3 are being applied by the person exploiting the spring.	The NSAI is the authority in Ireland responsible for the recognition of natural mineral water. HSE EHOs are responsible for official control inspections in such establishments. Official control inspections must be carried out in accordance with the FSAI's Guidance Note No. 1, *Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 2).*

1.2 Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 1(1)	This Directive establishes the list of constituents of natural mineral waters which may present a risk to public health, the limits for admissible levels of these constituents, the deadlines for application of these limits and the labelling requirements for certain constituents. These constituents must be present in the water naturally and may not result from contamination at source. It also defines the conditions for using ozone-enriched air for separating compounds of iron, manganese, sulphur and arsenic from natural mineral waters or spring waters, and the labelling requirements for waters which have undergone such treatment.	All natural mineral water, at the time of packaging, must comply with the maximum concentration limits set out in Table 6 for the constituents listed. If checks are carried out on the final product and the results are non-compliant, then testing at the time of packaging should be carried out. Analysis of official control samples of natural mineral water for the parameters from Annex I of Commission Directive 2003/40/EC must be in accordance with Table 7.

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 2	**1.** By 1 January 2006 at the latest, natural mineral waters shall, at the time of packaging, comply with the maximum concentration limits set out in Annex I for the constituents listed in that Annex. **2.** However, in the case of fluorides and nickel, the deadline referred to above is extended until 1 January 2008. **3.** By way of derogation from paragraph 1, during the procedure for official recognition of natural mineral waters collected within their territory, the competent authorities of the Member States may take a lower reference value for nitrates and nitrites, provided that the same reference value is applied to all applications made to them.	*This section is intentionally left blank*
Article 3	For the purposes of official controls, the Member States shall comply with the specifications listed in Annex II for analysing the constituents listed in Annex I.	*This section is intentionally left blank*

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 4	**1.** Natural mineral waters with a fluoride concentration exceeding 1,5 mg/l shall bear on the label the words 'contains more than 1,5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. **2.** The label information laid down in paragraph 1 of this Article shall be placed in immediate proximity to the trade name and in clearly visible characters. **3.** Natural mineral waters which, under the terms of paragraph 1 of this Article, bear label information, shall indicate the actual fluoride content in relation to the physico-chemical composition in terms of essential constituents, as laid down in Article 7(2)(a) of Directive 80/777/EEC.	Natural mineral waters with a fluoride concentration exceeding 1.5 mg/L must bear on the label the words 'contains more than 1.5 mg/L of fluoride: not for regular consumption by infants and children under 7 years of age'. This information must be placed in immediate proximity to the trade name and in clearly visible characters. The fluoride content must be stated in the analytical composition table. Article 7(2)(a) of Council Directive 80/777/EEC is now replaced with Article 7(2)(a) of Directive 2009/54/EC.
Article 5	1. Without prejudice to the provisions of Article 4(1)(b) of Directive 80/777/EEC, application of the treatment of natural mineral waters with ozone-enriched air must be notified in advance to the competent authorities, who shall ensure that: (a) use of such treatment is justified by the composition of the water in terms of compounds of iron, manganese, sulphur, and arsenic;	**Treatment of natural mineral water with ozone-enriched air** Council Directive 80/777/EEC is repealed and has been replaced with Article 5 of Directive 2009/54/EC. 1. FBOs must apply to their local HSE NEHS for authorisation for the use of this treatment. Such treatment must only commence following receipt of written approval from the HSE NEHS. Records of ozone use should be retained by the FBO. The HSE NEHS must specifically control the use of this treatment in the food business authorised to use this treatment.

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
	(b) the operator takes all measures necessary to guarantee that the treatment is effective and safe and to allow it to be checked by the competent authorities.	**(a)** The HSE must ensure that the use of this treatment is justified by the composition of the water in terms of compounds of iron, manganese, sulphur, and arsenic. The FBO must demonstrate that the untreated water contains the specific compounds (iron, manganese, sulphur, and arsenic) which may be removed using this treatment. **(b)** The FBO must be able to demonstrate the effectiveness of this treatment to the NEHS when requested. Comparisons of chemical composition pre- and post-treatment should demonstrate the effectiveness of the treatment.
	2. Ozone-enriched air treatment of natural mineral waters must comply with all the following conditions: **(a)** the physico-chemical composition of the natural mineral waters in terms of essential constituents shall not be modified by the treatment; **(b)** the natural mineral water before treatment must comply with the microbiological criteria laid down in Article 5(1) and (2) of Directive 80/777/EEC; **(c)** the treatment shall not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Annex III or residues which could pose a risk to public health.	**(a)** The physico-chemical composition of the natural mineral waters in terms of essential constituents must not be modified by the treatment. The FBO must demonstrate, e.g. via comparison of chemical analysis data pre- and post-treatment, that the essential chemical composition of the natural mineral water (as determined by the FBO) is not altered by this treatment. **(b)** The use of this treatment is likely to reduce the microbiological composition of the natural mineral water. Therefore, the natural mineral water must comply with the microbiological criteria specified in Article 5(1) and 5(2) of Directive 2009/54/EC for natural mineral water prior to this treatment. **(c)** The treatment must not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Annex III below or residues which could pose a risk to public health. The NEHS must monitor treated natural mineral water for compliance with the residue criteria outlined in Annex III. Sampling should take place at the point of bottling (see Table 4).

<table>
<tr><th>Reference</th><th>Requirements of Commission Directive 2003/40/EC</th><th>Interpretation</th></tr>
<tr><td></td><td></td><td>Annex III: Maximum limits for residues from treatment of natural mineral water by ozone-enriched air
<table>
<tr><th>Treatment residue</th><th>Maximum limit* (µg/L)</th></tr>
<tr><td>Dissolved ozone</td><td>50</td></tr>
<tr><td>Bromates</td><td>3</td></tr>
<tr><td>Bromoforms</td><td>1</td></tr>
</table>
* Compliance with the maximum limits is monitored by the competent authorities in the Member States at the time of bottling or other form of packaging intended for the final consumer.</td></tr>
<tr><td>Article 6</td><td>Pursuant to Article 7(2)(c) of Directive 80/777/EEC, the labelling of natural mineral waters which have been treated with ozone-enriched air shall bear, in proximity to the analytical composition of characteristic constituents, the words ‘water subjected to an authorised ozone-enriched air oxidation technique’.</td><td>Additional labelling requirements
Where the natural mineral water has been treated with ozone-enriched air, the label must include the following information: ‘water subjected to an authorised ozone-enriched air oxidation technique’. This information must be printed in proximity to the information on the analytical composition.

Article 7(2)(a) of Council Directive 80/777/EEC is now replaced with Article 7(2)(a) of Directive 2009/54/EC.</td></tr>
<tr><td>Article 7</td><td>Without prejudice to the provisions of Article 9(4)(b) of Directive 80/777/EEC, the provisions of Articles 5 and 6 of this Directive shall apply to spring waters.</td><td>Articles 5 and 6 of Directive 2009/54/EC also apply to spring waters.</td></tr>
</table>

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 8	1. The Member States shall take the necessary measures to permit the marketing of products complying with the present Directive by 1 January 2004 at the latest. 2. Without prejudice to the deadlines set out in Article 2(1) and (2), the Member States shall prohibit the marketing of products not complying with the present Directive from 1 July 2004. However, products packaged and labelled prior to 1 July 2004 may be sold until stocks are exhausted.	*This section is intentionally left blank*
Article 9	The Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with this Directive by 31 December 2003 at the latest. They shall forthwith inform the Commission thereof. The provisions adopted pursuant to this paragraph shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. Member States shall determine how such reference is to be made.	*This section is intentionally left blank*

1.3 Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Reference	Requirements of Commission Regulation (EU) No 115/2010	Interpretation
Article 1(1)	The treatment of natural mineral waters and spring waters with activated alumina in order to remove fluoride, hereinafter 'the fluoride removal treatment', shall be allowed. Natural mineral waters and spring waters together are referred to hereinafter as 'water'.	Natural mineral water may be treated with activated alumina in order to remove fluoride.
Article 1(2)	The fluoride removal treatment shall be performed in accordance with the technical requirements as set out in the Annex.	The removal of fluoride with activated alumina must be in accordance with this Regulation.
Article 2	The release of residues into the water as a result of the fluoride removal treatment shall be as low as technically feasible according to the best practices and shall not pose a risk to public health. To ensure this, the operator shall implement and monitor the critical processing steps set in the Annex.	The FBO must implement and monitor the critical processing steps set out in the Annex.
Article 3(1)	The application of a fluoride removal treatment shall be notified to the competent authorities at least three months prior to use.	The application of a fluoride removal treatment must be notified to the HSE at least three months prior to use.
Article 3(2)	With the notification the operator shall communicate to the competent authorities relevant information, documentation and analytical results on the treatment which show that it complies with the Annex.	The FBO must submit relevant information, documentation, and analytical results on the treatment to the HSE which demonstrate compliance with the Annex.

Reference	Requirements of Commission Regulation (EU) No 115/2010	Interpretation
Article 4	The label on water which has been the subject of a fluoride removal treatment shall include, in proximity to the statement of the analytical composition, the indication 'water subjected to an authorised adsorption technique'.	Natural mineral water which has undergone this treatment for the removal of fluoride must have the following indication on the label: 'Water subjected to an authorised adsorption technique'. This indication must be in proximity to the statement of the analytical composition.
Article 5	Products which were placed on the market by 10 August 2010, and which do not comply with Article 4, may continue to be marketed until 10 August 2011.	No such products were on the market in Ireland prior to 10 August 2010.

Reference	Requirements of Commission Regulation (EU) No 115/2010	Interpretation
Annex: Technical requirements for the use of activated alumina for the removal of fluoride from natural mineral waters and spring waters The following critical processing steps must be implemented and monitored appropriately:		
1.	Before the activated alumina is used for the treatment of water it shall be subjected to an initialisation procedure which includes the use of acidic or alkaline chemicals to remove any residues and a backwash treatment to remove fine particles.	
2.	A regeneration procedure shall be applied at intervals ranging from one to four weeks depending on the water quality and throughput. It shall include the use of appropriate chemicals to remove the adsorbed ions in order to restore the adsorption capacity of the activated alumina, and to remove any possibly formed biofilms. This procedure shall be done in the following three stages: – Treatment with sodium hydroxide to remove fluoride ions and replace them with hydroxide ions – Treatment with an acid to remove residual sodium hydroxide and activate the medium – Rinsing with drinking or demineralised water and conditioning with the water as the final step in order to ensure that the filter has no impact on the overall mineral content of the treated water.	The minimum filter pore size used for natural mineral water and spring water should be no smaller than 0.8 µm (micrometres). This is to allow for the removal of iron and manganese.

Reference	Requirements of Commission Regulation (EU) No 115/2010	Interpretation
3.	The chemicals and reagents used for the initialisation and regeneration procedures shall comply with the relevant European standards (European Standards developed by the European Committee for Standardisation (CEN)) or applicable national standards relating to the purity of the chemical reagents used for treatment of water intended for human consumption.	*This section is intentionally left blank*
4.	The chemicals and reagents used for the initialisation and regeneration procedures shall comply with the relevant European standards (European Standard EN 12902 (2004): Products used for treatment of water intended for human consumption. Inorganic supporting and filtering materials) or applicable national standards relating to the purity of the chemical reagents used for treatment of water intended for human consumption.	*This section is intentionally left blank*
5.	The processing steps shall be subject to good manufacturing practices and HACCP principles set out in Regulation (EC) No 852/2004 of the European Parliament and of the Council on food hygiene (OJ L 139, 30.4.2004, p.1).	*This section is intentionally left blank*
6.	The operator shall establish a monitoring programme in order to ensure the proper functioning of the processing steps in particular as regards the maintenance of the essential characteristics of the water and its fluoride content.	*This section is intentionally left blank*

1.4 Sampling and analysis of natural mineral waters by the official agency (HSE)

Minimum frequencies of sampling and analysis for the purpose of monitoring by the official agency are not specified in Directive 2009/54/EC for natural mineral water. The following frequency of sampling at the establishment is recommended:

- Quarterly microbiological sampling
- Biannual chemical sampling.

The volume of product produced in the establishment must be considered when sampling. See Table 4 for a list of sampling points.

Frequencies may vary depending on production periods. The frequencies can be adjusted accordingly when statistical trends on the microbiological/chemical qualities are established.

In order to establish a profile of the microbiological and chemical composition of the water during production, it is suggested that samples should be taken at various locations, e.g. at source, during marketing and at the point of bottling.

Ice produced from natural mineral water

Ice produced from natural mineral water is not covered by Directive 2009/54/EC. However, if it is claimed that the ice cubes are produced using natural mineral water, then that water must meet the requirements of legislation applicable to natural mineral water (except labelling requirements).

1.5 NSAI Recognition and Certification Process for Natural Mineral Water

Recognition of natural mineral water is a legal requirement and, in Ireland, the NSAI is the authority responsible for this recognition.

To facilitate NMW recognition and certification, a full hydrogeological survey must be performed by the FBO and submitted to the NSAI for independent validation. The NSAI reviews the data submitted by the FBO which provides information on:

•Geological/topographical/hydrogeological data

•Microbiological, physical, and chemical (hydrochemical, physico-chemical) data

The NSAI will also perform inspections of the FBO, and samples are taken for analysis. The results of the samples and historical data are used to assess the stability and profile of the water to establish label declarations. Where the water source is found to be suitable, the NSAI issues a 'Certificate of Recognition' and 'Conditions of Exploitation' to natural mineral water establishments which have met the recognition criteria of this Directive. Each natural mineral water source recognised by the NSAI will have a unique chemical fingerprint.

The FBO should be able to show the NEHS that they have been inspected (by provision of the NSAI report). They should also be able to demonstrate that they have responded to any non-compliances raised by the NSAI. Under normal circumstances a certificate would be issued in a matter of weeks once a suitable response has been received from the FBO.

NSAI recognition is valid for a period not exceeding five years. It is not necessary to repeat the recognition procedure if the certification is renewed before the end of that period.

The list of Irish natural mineral waters recognised by Ireland is published on the EU website at: http://ec.europa.eu/food/safety/labelling_nutrition/mineral_waters_en.

Table 5 Summary of microbiological limits for natural mineral water

Microbiological parameter	Limit at source	Limit during marketing	Reference	Recommended frequency of analysis of in-house testing by the FBO***
TVC @ 20–22 °C for 72 hours	≤20 cfu/mL*	≤100 cfu/mL**	Article 5(1) of Directive 2009/54/EC	Daily
TVC @ 37 °C for 24 hours	≤5 cfu/mL*	≤20 cfu/mL**	Article 5(1) of Directive 2009/54/EC	Daily
Coliforms	0 in 250 mL	0 in 250 mL	Article 5(2b) of Directive 2009/54/EC	Daily
Escherichia coli	0 in 250 mL	0 in 250 mL	Article 5(2b) of Directive 2009/54/EC	Daily
Sporulated sulphite-reducing anaerobes	0 in 50 mL	0 in 50 mL	Article 5(2c) of Directive 2009/54/EC	Monthly
Enterococci (faecal streptococci)	0 in 250 mL	0 in 250 mL	Article 5(2b) of Directive 2009/54/EC	Daily
Pseudomonas aeruginosa	0 in 250 mL	0 in 250 mL	Article 5(2d) of Directive 2009/54/EC	Monthly
Parasites and pathogenic microorganisms	Absent	Absent	Article 5(2a) of Directive 2009/54/EC	Annually

* Figures are legislative guide figures.

** Note: Directive 2009/54/EC states that the water must be being maintained at 4 °C ± 1 °C during this 12-hour period; however, the FSAI received clarification from the European Commission that according to ISO 6222 (or an equivalent method), the analysis should be started within 12 hours after bottling and samples have to be kept at 5 °C ± 3 °C during this period. This does not mean that the sample temperature has to be at 5 °C ± 3 °C, but that the samples have to be stored in a refrigerator regulated at 5 °C ± 3 °C. ISO 6222 on Enumeration of culturable micro-organisms was last reviewed in 2021 and continues to state 5'C +/- 3'C. Two other relevant and recently reviewed ISO methods also state 5'C +/- 3'C namely, ISO 19458 on Sampling for microbiological analysis, which was reviewed in 2020 and ISO 5667-3 on Part 3: Preservation and handling of water samples, which was reviewed in 2024.

*** Sourced from I.S. 432:2010

Table 6 Criteria for chemical constituents naturally present in natural mineral water

Constituent	Maximum limit (mg/L)
Antimony	0.0050
Arsenic	0.010 (as total)
Barium	1.0
Boron	For the record*
Cadmium	0.003
Chromium	0.050
Copper	1.0
Cyanide[10]	0.070
Fluoride	5.0
Lead	0.010
Manganese	0.50
Mercury	0.0010
Nickel	0.020
Nitrates	50
Nitrites	0.1
Selenium	0.010

* The maximum limit for boron will be fixed, where necessary, following an opinion of the European Food Safety Authority, and based on a proposal from the European Commission by 1 January 2006. Update February 2024: There is no maximum limit for boron.

If the constituents listed above are present in natural mineral water above the specified limits, the natural mineral water may pose a risk to public health.

Table 7 Performance characteristics* for analysing the chemical constituents of natural mineral water

Constituents	Accuracy of parametric value (in %) **	Precision of parametric value (in %) ***	Detection limit (in %) of parametric value****
Antimony	25	25	25
Arsenic	10	10	10
Barium	25	25	25
Boron (See note below Table 6)			
Cadmium	10	10	10
Chromium	10	10	10
Copper	10	10	10
Cyanide[3]	10	10	10
Fluoride	10	10	10
Lead	10	10	10
Manganese	10	10	10
Mercury	20	10	20
Nickel	10	10	10
Nitrates	10	10	10
Nitrites	10	10	10
Selenium	10	10	10

* Analytical methods for measuring concentrations of the constituents listed in Table 6 must be able to measure, as a minimum, concentrations equal to the parametric value with a specified accuracy, precision, and detection limit. Whatever the sensitivity of the method of analysis used, the result will be expressed using at least the same number of decimal places as for the maximum limit laid down in Table 6.

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

*** Precision is the random error and is expressed in general as the standard deviation (within a batch and between batches) of a sample of results from the average. Acceptable precision is equal to twice the relative standard deviation.

**** The detection limit is either:

– Three times the relative standard deviation within a batch of a natural sample containing a low concentration of the parameter, or

– Five times the relative standard deviation within a batch of a virgin sample.

[3] The method should make it possible to determine total cyanide in all its forms.

SECTION 2: SPRING WATER

The HSE National Environmental Health Service (NEHS) is the authority responsible for the enforcement of all food legislation in spring water establishments. Unlike natural mineral water, there is no legal requirement for recognition of spring water.

Articles 4, 5, 7(2 (b) and (c)), 8 and 9(4 and 5) of Directive 2009/54/EC apply to spring water. The provisions of Directive (EU) 2020/2184 on the quality of water intended for human consumption also apply to spring water. In addition, the provisions of Articles 5 and 6 of Commission Directive 2003/40/EC apply to spring water which is treated with ozone-enriched air. All requirements of Commission Regulation EU No 115/2010 apply to spring water which is treated with activated alumina for the removal of fluoride, and Council Directive 2013/51/Euratom lays down requirements for the protection of the health of the public regarding radioactive substances.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 4(1(a))	Natural mineral water, in its state at source, may not be the subject of any treatment other than: (a) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties;	Article 9(4) of Directive 2009/54/EC states that the term 'spring water' shall be reserved for water which has not undergone any treatment other than those referred to in Article 4 of Directive 2009/54/EC, meaning that Article 4 of Directive 2009/54/EC is applicable to spring water. Spring water, in its natural state at source, may not be the subject of any treatment other than those listed in Article 4. The following treatments are permitted, if this does not alter the essential chemical composition which gives the water its properties or the microbiological composition of the water: (a) FBOs must demonstrate that microfiltration or decanting does not alter the essential chemical composition or microbiological composition of the water. This can be demonstrated by comparison of water composition before and after microfiltration or decanting. Microfiltration could take place at any point between the wellhead and bottling. The minimum filter pore size used for natural mineral water and spring water should be no smaller than 0.8 µm (micrometres). This is to allow for the removal of iron and manganese.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 4(1(b))	(b) The separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that: **(i)** the treatment complies with the conditions for use to be laid down by the Commission following consultation of the European Food Safety Authority, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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); **(ii)** the treatment is notified to, and specifically controlled by, the competent authorities;	**(b)** Treatment with ozone-enriched air must be notified to and controlled by the NEHS. **(c)** Any treatment to separate undesirable constituents, other than those described in (a) and (b) above, must be notified to the NEHS. Information on the treatment described in (b): The use of ozone-enriched air in spring water establishments for the separation of iron, manganese, sulphur compounds and arsenic must comply with the requirements of this Directive. FBOs must apply to their local NEHS for authorisation for the use of this treatment. Such treatment must only commence following receipt of written approval from the HSE. Records of ozone use must be retained by the FBO. The NEHS will monitor the use of the authorised treatment.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 4(1(c))	(c) the separation of undesirable constituents other than those specified in points (a) or (b), in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that: **(i)** the treatment complies with the conditions for use to be laid down by the Commission following consultation of the European Food Safety Authority; **(ii)** the treatment is notified to, and specifically controlled by, the competent authorities;	Information on the treatment described in (c): For the use of any other treatments for the separation of undesirable constituents from spring water other than iron compounds, sulphur compounds, manganese compounds or arsenic. FBOs must apply to the NEHS for the authorisation to use such treatment(s). Treatments must only commence following receipt of written approval from the HSE. The NEHS will monitor the use of the authorised treatment.
Article 4(1(d))	(d) the total or partial elimination of free carbon dioxide by exclusively physical methods. The measures referred to in points (b)(i) and (c)(i), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2). The first subparagraph shall not constitute a bar to the utilisation of natural mineral waters and spring waters in the manufacture of soft drinks.	Information on the treatment described in (d): Carbon dioxide may be removed from spring water prior to packaging by physical methods only. The sales description of spring water which has undergone the total or partial elimination of free carbon dioxide by exclusively physical methods must have added to it, as appropriate, the indication on the label: **(a)** 'Fully de-carbonated spring water' or **(b)** 'Partially de-carbonated spring water'. Once spring water is mixed with other ingredients, it is no longer classified as spring water. The product is now categorised as a soft drink and may be labelled as a spring water drink. Spring water may be used as an ingredient in soft drinks and other flavoured water products. In this case, Directive 2009/54/EC does not apply, as the final product is outside the scope of this particular legislation. However, if spring water is used as an ingredient and listed in the ingredients list, the water must meet all the requirements of Directive 2009/54/EC. There is no requirement to declare the name of the spring water source on the packaging.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Spring water may be used as an ingredient in soft drinks and other flavoured water products. In this case, Directive 2009/54/EC does not apply, as the final product is outside the scope of this particular legislation. However, if spring water is used as an ingredient and listed in the ingredients as spring water, the water must meet all the requirements of Directive 2009/54/EC (except certain labelling requirements). If spring water is used as an ingredient, there is no requirement to declare the name of the spring water source on the packaging of the product. Note: Spring water may also be treated with activated alumina in order to remove fluoride. The fluoride removal treatment must be in accordance with Commission Regulation 115/2010/EC.
Article 4(2)	Natural mineral water, in its state at source, may not be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in Annex I, Section III.	Nothing may be added to spring water, with the exception of carbon dioxide (as outlined in the conditions laid down in Annex I, Section III). It is recommended that the carbon dioxide used is certified by the supplier as being suitable for food use, and the FBO must ensure that the carbon dioxide does not give rise to contaminants in the water.
Article 4(3)	Any disinfection treatment by whatever means and, subject to paragraph 2, the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water, shall be prohibited.	Disinfection treatments, e.g. ultraviolet (UV) treatments, or the addition of bacteriostatic elements are prohibited for use on spring water. Comparison of the microbiological composition pre- and post-permitted treatment for spring water will indicate whether disinfection is taking place.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 5 of Directive 2009/54/EC: The following microbiological criteria are applicable to spring water at source and during marketing.		
Article 5(1)	The revivable total colony count of a natural mineral water at source shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. This total colony count shall be determined under the conditions laid down in Annex I, Section II, point 1.3.3. After bottling, the total colony count at source may not exceed 100 per millilitre at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37 °C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4 °C ± 1 °C during this 12-hour period.	The term 'spring water' must be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which satisfies the microbiological requirements laid down in Article 5 of Directive 2009/54/EC. Table 8 provides a summary of the microbiological criteria of Directive 2009/54/EC which apply to spring water at source and in the package. Data analysis of microbiological results of at-source water over a period of time provides an indication of typical TVC levels. These TVC levels should remain stable and thus act as an indicator that the source has adequate protection against microbiological contamination. **Annex I, Section II, point 1.3.3** The TVC must be determined under the following conditions (Annex I, Section II, point 1.3.3): Determination of the revivable TVC per millilitre of water: **(a)** at 20 °C to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture **(b)** at 37 °C in 24 hours on agar-agar. After bottling, the TVC must not exceed: • 100 cfu/mL at 20 °C to 22 °C in 72 hours • 20 cfu/mL at 37 °C in 24 hours.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		TVC is only valid if it is determined within 12 hours of bottling, as water in its natural environment contains microorganisms (Directive 2009/54/EC states that the water must be maintained at 4 °C ± 1 °C during this 12-hour period; however, the FSAI received clarification from the European Commission that according to ISO 6222 (or an equivalent method), the analysis should be started within 12 hours after bottling and samples have to be kept at 5 °C ± 3 °C during this period. This does not mean that the sample temperature has to be at 5 °C ± 3 °C, but that the samples have to be stored in a refrigerator regulated at 5 °C ± 3 °C). ISO 6222 on Enumeration of culturable micro-organisms was last reviewed in 2021 and continues to state 5 °C +/- 3 °C. Two other relevant and recently reviewed ISO methods also state 5 °C +/- 3 °C namely, ISO 19458 on Sampling for microbiological analysis, which was reviewed in 2020 and ISO 5667-3 on Part 3: Preservation and handling of water samples, which was reviewed in 2024. On storage, the number of microorganisms will initially increase until all the naturally available nutrients in the water are utilised. The number of microorganisms will then decrease due to a lack of nutrients and, after a period, will increase again. Therefore, EHOs responsible for the supervision of spring water establishments should sample for all relevant microorganisms, including sampling for TVCs within 12 hours of bottling. Microbiological sampling at the marketing stage (distribution and retail stage) should not include TVCs, as the time post-bottling is unknown, and therefore the results of such analysis cannot be interpreted.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	At source, those values must not normally exceed 20 per millilitre at 20 to 22 °C in 72 hours and 5 per millilitre at 37 °C in 24 hours respectively, on the understanding that they shall be considered as guide figures and not as maximum permitted concentrations.	If TVCs (within 12 hours of bottling) exceed the legislative limits, then the bottled water is in breach of the legislation. Product which has not left the control of the FBO must not be released on to the market. If product has reached the consumer, the FBO must consult with the competent authority regarding appropriate control actions. EHOs are advised to review the source protection and the various stages of production for hygiene practices, which may establish the cause of the breach in the legislative limits. Please see the *FSAI's Guidance Note No. 10, Product Recall and Traceability (Revision 3).*

Reference	Requirements of Directive 2009/54/EC	Interpretation
		At source, the TVC should not normally exceed: • 20 cfu/mL at 20 °C to 22 °C in 72 hours • 5 cfu/mL at 37 °C in 24 hours These are guide figures and not maximum permitted concentrations. EHOs are advised to review the source protection and the various stages of production for hygiene practices, which may establish the cause of the breaches in the legislative limits.
Article 5(2)	At source and during its marketing, a natural mineral water shall be free from: **(a)** parasites and pathogenic microorganisms; **(b)** *Escherichia coli* and other coliforms and faecal streptococci in any 250 ml sample examined; **(c)** sporulated sulphite-reducing anaerobes in any 50 ml sample examined; **(d)** *Pseudomonas aeruginosa* in any 250 ml sample examined.	Where the packaged water is deemed to be unsafe by reason that it may be injurious to health or unfit for human consumption, the FBO must initiate the procedure to withdraw or recall the batch of product in question. Where the product in question has reached the consumer, the FBO must accurately and effectively inform consumers of the reason for the withdrawal of the product and, if necessary, recall product that has already been released for purchase. Where the packaged water product does not comply with the legal requirements for microbiological criteria, the packaged water business operator must: • Take action to ensure that the water is not consumed • Where necessary, recall the product and notify consumers. ***Escherichia coli*** The presence of *E. coli* in spring water is considered an index of faecal contamination of the water. As such, the water is considered injurious to health, and therefore unsafe as defined in Regulation (EC) No 178/2002. Spring water containing *E. coli* must be withdrawn from the market and, where it has reached consumers, the consumers must be notified and EHOs should ensure that the FBO takes the necessary measures to remove the product from consumers, including:

Reference	Requirements of Directive 2009/54/EC	Interpretation
		• Notifying trade customers • Notifying consumers • Removing the affected batch of bottled water from the food chain • Removing the affected batch of bottled water from consumers. ***Enterococci (faecal streptococci)*** The presence of enterococci in spring water is considered an index of faecal contamination of the water. As such, the water is considered injurious to health, and therefore unsafe. In accordance with Article 19 of Regulation (EC) No 178/2002, spring water containing enterococci must be withdrawn from the market and, where it has reached consumers, the consumers must be notified and EHOs should ensure that the FBO takes the necessary measures to remove the product from consumers, including: • Notifying trade customers • Notifying consumers • Removing the affected batch of bottled water from the food chain • Removing the affected batch of bottled water from consumers. ***Coliforms*** The presence of coliforms (in the absence of *E. coli* or enterococci) in spring water is not a strong indication of the potential presence of enteric pathogens. Such bottled water should not be considered unsafe for consumption. However, the presence of coliforms should prompt investigation by the EHO and the FBO. The FSAI should be informed of each case of coliforms detected in bottled water, and each result must be dealt with on a case-by-case basis (email: foodincidents@fsai.ie).

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Pseudomonas aeruginosa The presence of *P. aeruginosa* (in the absence of E. coli or enterococci) in spring water is not a significant health risk for the general population. The presence of *P. aeruginosa* should prompt investigation by the EHO and the FBO as to the cause of the contamination. *P. aeruginosa* is, however, a risk for the severely immunocompromised subpopulation found in certain areas of hospitals, such as intensive care units. The FSAI should therefore be informed of each case of *P. aeruginosa* detected in bottled water (email: foodincidents@fsai.ie). The FSAI will then advise the HPSC of such findings. Each result must be dealt with on a case-by-case basis. In all cases of contamination, EHOs are also advised to investigate immediately to identify the cause of contamination, e.g. review the microbiological status of the source water, as well as the level of hygiene controls in the abstraction and bottling processes. This may indicate the cause of the breach in the legislative limits. For more information, please see the *FSAI's Guidance Note No. 10, Product Recall and Traceability (Revision 3).*
Article 5(3)	Without prejudice to paragraphs 1 and 2 and the conditions of exploitation laid down in Annex II, at the marketing stage: **(a)** the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacterial count which it had at source; **(b)** the natural mineral water may not contain any organoleptic defects.	TVCs for spring water are generally very low but can vary from source to source. A review of microbiological data for the previous years should provide an indication of the normal viable counts for the spring water.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 7(2(b))	Labels on natural mineral waters shall also give the following mandatory information: (b) the place where the spring is exploited and the name of the spring.	Article 9(4) of Directive 2009/54/EC states that the term 'spring water' must be reserved for water which satisfies the labelling requirements of Article 7(2), points (b) and (c). Labels on spring water must give the following mandatory information: – the place where the spring is exploited and the name of the spring;
Article 7(2(c))	(c) information on any treatments referred to in points (b) and (c) of the first subparagraph of Article 4(1).	– information on any treatments referred to in points (b) and (c) of the first subparagraph of Article 4(1).
Article 8(1)	The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring.	The name of the place may appear in the wording of a trade description, provided that it refers to the spring which is exploited at the place indicated by that description, and provided that it is not misleading as regards the place of exploitation of the spring.
Microbiological criteria of Annex I of Directive (EU) 2020/2184 The microbiological criteria in **Annex I** of Directive (EU) 2020/2184 are applicable to spring water at the point of bottling.		

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 8(2)	It shall be prohibited to market natural mineral water from one and the same spring under more than one trade description.	***Trade description*** According to Regulation (EU) No 1169/2011 on the provision of food information to consumers, a trademark/trade description/brand name is permitted in addition to the name of the food, i.e. spring water. However, trade descriptions cannot appear instead of the legal or customary name, as they do not provide sufficient information for consumers. Note: It is not permitted to market spring water from one and the same spring under more than one trade description. If a spring water is bottled under one trade description, all other spring water products from the same source must carry the same trade description. Spring water may also be sold as 'other water', provided that it meets the requirements for other water. 'Other water' may be sold under more than one trade description.
Article 8(3)	When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, that place of exploitation or the name of the spring shall be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description. The first subparagraph shall apply, *mutatis mutandis* and with the same intention as regards the importance attributed to the name of the spring or the place of its exploitation, with regard to the trade description used in advertising, in whatsoever form, relating to natural mineral waters.	When the label or inscriptions on the containers in which the spring water is offered for sale include a trade description different from the name of the spring or the place of its exploitation, this place or the name of the spring must be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 9(4)	The term 'spring water' shall be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which: **(a)** satisfies the conditions of exploitation laid down in Annex II, points 2 and 3, which shall be fully applicable to spring waters; **(b)** satisfies the microbiological requirements laid down in Article 5; **(c)** satisfies the labelling requirements of Article 7(2), points (b) and (c), and Article 8; **(d)** has not undergone any treatment other than those referred to in Article 4. Other treatments may be authorised by the Commission. The measures referred to in point (d), designed to amend nonessential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2). In addition, spring waters shall comply with the provisions of Directive (EU) 2020/2184 on the quality of water intended for human consumption.	The description 'spring waters' should not be used in the marketing of any products which are not spring waters as defined. Unlike natural mineral water, spring water does not have a unique chemical fingerprint. Spring water must be bottled at source in its natural state and only limited treatments are permitted by Annex II, points 2 and 3 outlined below. The legal limits for *Giardia*, helminths and *Cryptosporidium* contamination in both natural mineral water and spring water is zero, both at source and during marketing. It is not recommended to sample for helminths, *Cryptosporidium* or *Giardia* due to the logistical challenges of sampling for and isolating this organism. Instead, it is recommended to sample for *E. coli* and enterococci which are indexes of faecal contamination. If *E. coli* or enterococci are detected, then it should be assumed that parasites could also be present, and steps should be taken to ensure their removal. For information on completing a risk assessment for *Cryptosporidium* that also applies to *Giardia*, please see page 19 of Section 10 of *European Communities (Drinking Water) (No. 2) Regulations 2007: A Handbook on the Implementation of the Regulations for Water Services Authorities for Private Water Supplies*. The Water Services Training Group also runs courses on how to perform this risk assessment. ISO 15553:2006 is the internationally recognised standard method for the detection and identification of *Cryptosporidium* and *Giardia* in water. A sample volume of between 10 L and 1000 L can be taken for testing in accordance with ISO 15553:2006. A list of laboratories accredited to carry out testing in accordance with ISO 15553:2006 can be found on the INAB website.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Frequency of *Cryptosporidium* and *Giardia* testing It is not recommended to sample for *Cryptosporidium* or *Giardia* due to the logistical challenges of sampling for and isolating this organism. Instead, it is recommended to sample for *E. coli* and enterococci which are indexes of faecal contamination. If *E. coli* or enterococci are detected, then it should be assumed that parasites could also be present, and steps should be taken to ensure their removal. *Cryptosporidium* and *Giardia* will not be eliminated by most disinfection processes; therefore, if indicator organisms suggest that the well has become contaminated with faecal material, the FBO may need to test that the well is free of parasites after taking appropriate action to remove them.
Source protection Annex II, point 2	Equipment for exploiting the water shall be so installed as to avoid any possibility of contamination and to preserve the properties, corresponding to those ascribed to it, which the water possesses at source. To that end, in particular: (a) the spring or outlet shall be protected against the risks of pollution;	A spring is a body of groundwater that emerges at some point. A spring may have more than one natural or bore exit. All spring water from these boreholes is considered to be from the one source. **(a) Protection against the risk of pollution** The catchment area is the surface area within which rainfall can either directly or indirectly enter the groundwater system within which the well is trapped, and which can contribute to the yield of the well. The catchment area, or as much of the catchment area that is under the direct control of the bottled water producer, should be included in the HSE food safety inspections of the establishment. As the groundwater is not treated, it is essential that the catchment area is protected and managed effectively. The production well and groundwater catchment areas must be protected from hazards. The FBO must manage the groundwater source to avoid contamination. See **Appendix II**, Protection of the wellhead/ borehole, for more information on protection of the catchment area.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Site location Consideration should be given to the following areas in relation to site location: • The potential risk of contamination from other activities in the vicinity and the necessary controls implemented to minimise the risk of contamination • Protection and maintenance of the grounds of the development in order to avoid the establishment of breeding sites for rodents and insects • Procedures in place for the management of all waste generated on site • Site maintenance and cleanliness • Site design and layout to facilitate the operation of good hygiene practices. **Site security/site access** The site should be adequately secured to prevent unauthorised access. The FBO must have security measures in place, e.g. fencing and intruder alarms, to ensure that only authorised staff have access to water source, production, and storage areas.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Areas for identification and protection on the groundwater production site To protect the source, the FBO should identify the groundwater protection zones, including both the inner protection zone and the outer protection zone; identify permitted and unacceptable activities in protection zones; and put in place a well field management programme. Examples of protection zones include: • Wellhead protection measures: an intruder alarm system should be installed on the production borehole, with access to the borehole head limited to authorised personnel. Boreholes should have sampling valves for sampling at source. The pipework entering the establishment should be reviewed. Storage silos and pipework must also be protected. • Outer protection zone: for the production well, e.g. fields surrounding the well. FBOs should liaise with local authorities on activities on the surrounding land, review ongoing planning applications and annual land use surveys, etc.
Food contact materials Annex II, point 2	(b) the catchment, pipes and reservoirs shall be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water;	**(b) Requirements for food contact materials** All material which comes into contact with spring water must comply with food contact material legislation. All processing equipment which comes into direct contact with the water must be manufactured in compliance with good manufacturing practice so that, under normal conditions of use, it will not transfer its constituents to the water in quantities that could endanger human health and/or impart odours or taint the product. All food contact materials, including piping, must be made from materials that are supplied and labelled 'for food contact' and comply with food packaging legislation. The surfaces in contact with the water must be resistant to corrosion when cleaned with food-grade cleaning and sanitising agents.

Reference	Requirements of Directive 2009/54/EC	Interpretation
		Plastic bottles may be blow-moulded on site. An extensive certificate of compliance should accompany the delivery of all plastic material for use with food. Sterilisation of bottles and caps is permitted. The sterilised material should be free from residues following this process.
Hygiene requirements Annex II, point 2	(c) the conditions of exploitation, particularly the washing and bottling equipment, shall meet hygiene requirements; in particular, the containers shall be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the spring water;	**(c) Hygiene requirements** All processing equipment which comes into direct contact with spring water must be manufactured in compliance with good manufacturing practice so that, under normal conditions of use, it does not have an adverse effect on the microbiological or chemical composition of the spring water. Equipment must be installed so that there is adequate access under, around and inside the equipment to enable effective cleaning. Equipment must be maintained at defined intervals and procedures must be in place to ensure that the maintenance activity does not result in product or equipment contamination. Product contact surfaces must be non-toxic and easy to clean and maintain. Hygiene requirements of Regulation (EC) No 852/2004 are applicable throughout production. If a different water supply is used for cleaning, this water must be potable. This water supply must be strictly controlled. Separate pipes are required to be used for the supply of this cleaning water.
Transport, Annex II, point 2	(d) the transport of spring water in containers other than those authorised for distribution to the ultimate consumer shall be prohibited. However, point (d) need not be applied to spring waters extracted, exploited, and marketed in the territory of a Member State if, in that Member State on 17 July 1980, transport of the spring water in tanks from the spring to the bottling plant was authorised.	**(d) Transport of spring water** Spring water must be packaged in containers for the final consumer on site. The derogation mentioned in point (d) across does not apply to Ireland, as no Irish establishment was authorised to transport spring water from its source to the bottling establishment on 17 July 1980.

Reference	Requirements of Directive 2009/54/EC	Interpretation
	Similarly, point (d) need not be applied to spring waters extracted, exploited, and marketed in the territory of a Member State if, in that Member State on 13 December 1996, transport of the spring water in tanks from the spring to the bottling plant was authorised.	
Contamination Annex II, point 3	Where it is found during exploitation that the spring water is polluted and no longer presents the microbiological characteristics laid down in Article 5, the person exploiting the spring shall forthwith suspend all exploitation, particularly the bottling process, until the cause of pollution is eradicated, and the water complies with the provisions of Article 5.	If the spring water source is polluted, the FBO must suspend the exploitation of the spring water until the cause of pollution is eradicated. Exploitation of the spring water can recommence when the water complies with the microbiological criteria outlined for spring water.
Article 9(4(b))	(b) satisfies the microbiological requirements laid down in Article 5.	See Section 2.5 for guidance on microbiological criteria for spring water.

Reference	Requirements of Directive 2009/54/EC	Interpretation
Article 9(4(c))	(c) satisfies the labelling requirements of Article 7(2), points (b) and (c), and Article 8;	The label of spring water must bear the following mandatory information: **Spring name** The label must state the place where the spring is exploited and the name of the spring. The location of the source of the water should be readily identifiable from the information provided on the label. **Information requirements of Article 4(1), points (b) and (c): permitted treatments requiring additional labelling:** • **Ozone-enriched air:** where the spring water has been treated with ozone-enriched air, the label must include the following information: 'water subjected to an authorised ozone-enriched air oxidation technique'. This information must be printed in proximity to the information on the analytical composition. • **Other permitted treatments:** where the spring water has undergone a separation process which is authorised by the HSE, the label must provide information on such a treatment. The removal of fluoride with activated alumina, as outlined below in Commission Regulation 115/2010/EC: the label 'water subjected to an authorised adsorption treatment' should be printed in proximity to the statement of the analytical composition.
Article 9(5)	In the absence of Community provisions on the treatment for spring waters referred to in point (d) of the first subparagraph of paragraph 4, Member States may maintain their national provisions on the treatments.	*This section is intentionally left blank*

Table 8 Summary of microbiological limits for spring waters at source and during marketing for FBOs (Article 5 of Directive 2009/54/EC)[4]

Microbiological parameter	Limit at source	Limit during marketing	Recommended frequency of analysis of in-house testing by FBO***	Reference to legislation
Note: Legislative limits are specified for the parameters which are subject to full monitoring by the official agency. Indicator values are specified for the parameters which may be subject to partial monitoring by the official agency. Exceeded indicator values are used as a prompt to investigate further.				
TVC @ 20–22 °C for 72 hours	≤20 cfu/mL*	≤100 cfu/mL**	Daily	Article 5(1) of Directive 2009/54/EC
TVC @ 37 °C for 24 hours	≤5 cfu/mL*	<20 cfu/mL**	Daily	Article 5(1) of Directive 2009/54/EC
Coliforms	0 in 250 mL	0 in 250 mL	Daily	Article 5(2b) of Directive 2009/54/EC
Escherichia coli	0 in 250 mL	0 in 250 mL	Daily	Article 5(2b) of Directive 2009/54/EC
Sporulated sulphite-reducing anaerobes	0 in 50 mL	0 in 50 mL	Monthly	Article 5(2c) of Directive 2009/54/EC
Enterococci (faecal streptococci)	0 in 250 mL	0 in 250 mL	Daily	Article 5(2b) of Directive 2009/54/EC
Pseudomonas aeruginosa	0 in 250 mL	0 in 250 mL	Monthly	Article 5(2d) of Directive 2009/54/EC
Parasites and pathogenic microorganisms	Absent	Absent	Annually	Article 5(2a) of Directive 2009/54/EC

* Figures are guide figures and not maximum permitted concentrations'

** Directive 2009/54/EC states that the water must be being maintained at 4 °C ± 1 °C during this 12-hour period; however, the FSAI received clarification from the European Commission that according to ISO 6222 (or an equivalent method), the analysis should be started within 12 hours after bottling and samples have to be kept at 5 °C ± 3 °C during this period. This does not mean that the sample temperature has to be at 5 °C ± 3 °C, but that the samples must be stored in a refrigerator regulated at 5 °C ± 3 °C. ISO 6222 on Enumeration of culturable micro-organisms was last reviewed in 2021 and continues to state 5 °C +/- 3 °C. Two other relevant and recently reviewed ISO methods also state 5 °C +/- 3 °C namely, ISO 19458 on Sampling for microbiological analysis, which was reviewed in 2020 and ISO 5667-3 on Part 3: Preservation and handling of water samples, which was reviewed in 2024.

*** Sourced from I.S. 432: 2010.

[4] Directive 2009/54/EC only applies to packaged spring water at source and during marketing and not at the point of compliance (i.e. point of bottling) where it must comply with Directive (EU) 2020/2184 instead

2.1 Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters

Note: Only the provisions of Articles 5 and 6 of Commission Directive 2003/40/EC apply to spring water which is treated with ozone-enriched air.

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 5(1) (a)	Without prejudice to the provisions of Article 4(1)(b) of Directive 80/777/EEC, application of the treatment of natural mineral waters with ozone-enriched air must be notified in advance to the competent authorities, who shall ensure that: (a) use of such treatment is justified by the composition of the water in terms of compounds of iron, manganese, sulphur, and arsenic;	Treatment of spring water with ozone enriched air FBOs must apply to their local NEHS for authorisation for the use of this treatment. Such treatment must only commence following receipt of written approval from the HSE. Records of ozone-enriched air use should be retained by the FBO. The NEHS will monitor the use of this treatment in the food business operation authorised to use this treatment. (a) The HSE must ensure that the use of this treatment is justified by the composition of the water in terms of compounds of iron, manganese, sulphur, and arsenic. The FBO must demonstrate that the untreated water contains the specific compounds (iron, manganese, sulphur, and arsenic) which may be removed using this treatment.
Article 5(1) (b)	(b) the operator takes all measures necessary to guarantee that the treatment is effective and safe and to allow it to be checked by the competent authorities.	(b) The FBO must be able to demonstrate the effectiveness of this treatment to the NEHS when requested. Comparisons of chemical composition pre- and posttreatment should demonstrate the effectiveness of the treatment.

Reference	Requirements of Commission Directive 2003/40/EC	Interpretation
Article 5(2)	Ozone-enriched air treatment of natural mineral waters must comply with all the following conditions: **(a)** the physico-chemical composition of the natural mineral waters in terms of essential constituents shall not be modified by the treatment; **(b)** the natural mineral water before treatment must comply with the microbiological criteria laid down in Article 5(1) and (2) of Directive 80/777/EEC; **(c)** the treatment shall not lead to the formation of residues exceeding the maximum limits laid down in Annex III or residues which could pose a risk to public health.	**(a)** The physico-chemical composition of the spring waters in terms of essential constituents must not be modified by the treatment. The FBO must demonstrate, e.g. via comparison of chemical analysis data pre- and post-treatment, that the essential chemical composition of the spring water (as determined by the FBO) is not altered by this treatment. **(b)** The use of this treatment is likely to reduce the microbiological composition of the spring water. Therefore, spring water must comply with the microbiological criteria specified in Article 5(1) and 5(2) of Directive 2009/54/EC for spring water prior to this treatment. **(c)** The treatment must not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Annex III or residues which could pose a risk to public health. The NEHS must monitor treated spring water for compliance with the residue criteria outlined in Annex III. Sampling should take place at the point of bottling.
		Summary of microbiological criteria specified in Article 5(1) and 5(2) of Directive 2009/54/EC: Spring water must be free from parasites, pathogenic microorganisms, *Escherichia coli*, coliforms, enterococci (faecal streptococci), sporulated sulphite-reducing anaerobes and *Pseudomonas aeruginosa*. TVCs after bottling of spring water must not exceed: • 100 cfu/ml at 20 °C to 22 °C in 72 hours • 20 cfu/ml at 37 °C in 24 hours.

<table>
<tr><th>Reference</th><th>Requirements of Commission Directive 2003/40/EC</th><th>Interpretation</th></tr>
<tr><td></td><td></td><td>TVCs at source of spring water should not normally exceed:
20 cfu/ml at 20 °C to 22 °C in 72 hours
5 cfu/ml at 37 °C in 24 hours.
Annex III: Maximum limits for residues from treatment of spring waters by ozone-enriched air<table><tr><th>Treatment residue</th><th>Maximum limit (*) (µg/L)</th></tr><tr><td>Dissolved ozone</td><td>50</td></tr><tr><td>Bromates</td><td>3</td></tr><tr><td>Bromoforms</td><td>1</td></tr></table>(*) Compliance with the maximum limits is monitored by the competent authorities in the Member States at the time of bottling or other form of packaging intended for the final consumer.</td></tr>
<tr><td>Article 6</td><td>Pursuant to Article 7(2)(c) of Directive 80/777/EEC, the labelling of natural mineral waters which have been treated with ozone-enriched air shall bear, in proximity to the analytical composition of characteristic constituents, the words ‘water subjected to an authorised ozone-enriched air oxidation technique’.</td><td>Additional labelling requirements:
Where the spring water has been treated with ozone-enriched air, the label must include the following information: ‘water subjected to an authorised ozone-enriched air oxidation technique’. This information must be printed in proximity to the information on the analytical composition.

Note: Article 7(2)(a) of Directive 80/777/EEC is now replaced with Article 7(2)(a) of Directive 2009/54/EC.</td></tr>
<tr><td>Article 7</td><td>Without prejudice to the provisions of Article 9(4)(b) of Directive 80/777/EEC, the provisions of Articles 5 and 6 of this Directive shall apply to spring waters.</td><td>Articles 5 and 6 of Commission Directive 2003/40/EC apply to spring waters without prejudice to the microbiological requirements provisions of Article 9(4)(b) of Directive 2009/54/EC.</td></tr>
</table>

2.2 Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Commission Regulation (EU) No 115/2010 lays down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters. All requirements of Commission Regulation (EU) No 115/2010 apply to spring water which is treated with activated alumina for the removal of fluoride.

Reference	Requirements of Commission Regulation 115/2010/EC	Interpretation
Article 1(1)	The treatment of natural mineral waters and spring waters with activated alumina to remove fluoride, hereinafter 'the fluoride removal treatment', shall be allowed. Natural mineral waters and spring waters together are referred to hereinafter as 'water'.	Spring water may be treated with activated alumina to remove fluoride.
Article 1(2)	The fluoride removal treatment shall be performed in accordance with the technical requirements as set out in the Annex.	The removal of fluoride with activated alumina must be in accordance with this Regulation.
Article 2	The release of residues into the water as a result of the fluoride removal treatment shall be as low as technically feasible according to the best practices and shall not pose a risk to public health. To ensure this, the operator shall implement and monitor the critical processing steps set in the Annex.	The FBO must implement and monitor the critical processing steps set out in the Annex.
Article 3(1)	The application of a fluoride removal treatment shall be notified to the competent authorities at least three months prior to use.	The application of a fluoride removal treatment must be notified to the HSE at least three months prior to use.

Reference	Requirements of Commission Regulation 115/2010/EC	Interpretation
Article 3(2)	With the notification, the operator shall communicate to the competent authorities relevant information, documentation and analytical results on the treatment which show that it complies with the Annex.	The FBO must submit relevant information, documentation, and analytical results on the treatment to the HSE which demonstrate compliance with the Annex.
Article 4	The label on water which has been the subject of a fluoride removal treatment shall include, in proximity to the statement of the analytical composition, the indication 'water subjected to an authorised adsorption technique'.	Spring water which has undergone this treatment for the removal of fluoride must have the following indication on the label: • 'Water subjected to an authorised adsorption technique'. This indication must be in proximity to the statement of the analytical composition.
Article 5	Products which were placed on the market by 10 August 2010, and which do not comply with Article 4, may continue to be marketed until 10 August 2011.	No such products were on the market in Ireland prior to 10 August 2010.
Annex: Technical requirements for the use of activated alumina for the removal of fluoride from natural mineral waters and spring waters The following critical processing steps must be implemented and monitored appropriately:		
1.	Before the activated alumina is used for the treatment of water it shall be subjected to an initialisation procedure which includes the use of acidic or alkaline chemicals to remove any residues and a backwash treatment to remove fine particles.	*This section is intentionally left blank*

Reference	Requirements of Commission Regulation 115/2010/EC	Interpretation
2.	A regeneration procedure shall be applied at intervals ranging from one to four weeks depending on the water quality and throughput. It shall include the use of appropriate chemicals to remove the adsorbed ions in order to restore the adsorption capacity of the activated alumina, and to remove any possibly formed biofilms. This procedure shall be done in the following three stages: – Treatment with sodium hydroxide to remove fluoride ions and replace them with hydroxide ions. – Treatment with an acid to remove residual sodium hydroxide and activate the medium. – Rinsing with drinking or demineralised water and conditioning with the water as the final step in order to ensure that the filter has no impact on the overall mineral content of the treated water.	The minimum filter pore size used for natural mineral water and spring water should be no smaller than 0.8 µm (micrometres). This is to allow for the removal of iron and manganese.
3.	The chemicals and reagents used for the initialisation and regeneration procedures shall comply with the relevant European standards (European Standards developed by the European Committee for Standardisation (CEN)) or applicable national standards relating to the purity of the chemical reagents used for treatment of water intended for human consumption.	*This section is intentionally left blank*

Reference	Requirements of Commission Regulation 115/2010/EC	Interpretation
4.	The activated alumina shall comply with the European standard for leaching tests (EN 12902) (2) to ensure that no residues are released into the water resulting in concentrations exceeding the limits set in Directive 2003/40/EC or in the absence of limits in that Directive, the limits set in Directive 98/83/EC or in applicable national legislation. The total amount of aluminium ions in the treated water as it results after the release of aluminium, the main component of activated alumina, shall not exceed 200 microg/L, as established in Directive 98/83/EC. This amount shall be checked regularly in accordance with the Council Directive.	*This section is intentionally left blank*
5.	The processing steps shall be subject to good manufacturing practices and HACCP principles set out in Regulation (EC) No 852/2004 of the European Parliament and of the Council on food hygiene (OJ L 139, 30.4.2004, p.1).	*This section is intentionally left blank*
6.	The operator shall establish a monitoring programme in order to ensure the proper functioning of the processing steps in particular as regards the maintenance of the essential characteristics of the water and its fluoride content.	*This section is intentionally left blank*

2.3 Ice produced from spring water

Ice produced from spring water is not covered by Directive 2009/54/EC. However, if it is claimed that the ice cubes are produced using spring water, then that water must meet the requirements of Directive 2009/54/EC (except labelling requirements).

2.4 Directive (EU) 2020/2184 on the quality of water intended for human consumption

The provisions of Directive (EU) 2020/2184 on the quality of water intended for human consumption apply to spring water at the point of compliance i.e. point of bottling. Guidance on the requirements of this Directive is provided in Section 3. Guidance on the microbiological criteria and chemical criteria of Directive (EU) 2020/2184 is provided in Sections 2.5 and 2.6, respectively.

2.5 Microbiological criteria for spring water

The microbiological criteria outlined in Article 5 of Directive 2009/54/EC and Annex I, Part A of Directive (EU) 2020/2184 apply to spring water. The FBO must be able to demonstrate that the spring water produced meets the microbiological criteria of Article 5 of Directive 2009/54/EC at source and during marketing and the microbiological criteria of Annex I, Part A of Directive (EU) 2020/2184 at the point of bottling. Table 8 provides a summary of the microbiological limits for spring water at source, and during marketing. Table 13 outlines the list of microbiological parameters in Annex III, Part A, of Directive (EU) 2020/2184 for which methods of analysis are specified. Directive (EU) 2020/2184 states that samples should be taken at the point of compliance; in the case of water put into bottles or containers intended for sale, this is at the point at which the water is put into the bottles or containers, i.e. at the point of bottling only.

2.6 Chemical and physical criteria for spring water

The chemical and physical criteria outlined in Annex I of Directive (EU) 2020/2184 apply to spring water. The FBO must be able to demonstrate that the spring water produced meets the chemical criteria of Annex I, part B of Directive (EU) 2020/2184 at the point of bottling. In addition, if spring water is treated with ozone-enriched air, the spring water must meet the criteria for maximum residues specified in Annex III of Commission Directive 2003/40/EC. Directive (EU) 2020/2184 states that samples should be taken at the point of compliance; in the case of water put into bottles or containers intended for sale i.e. at the point of bottling only.

Table 11 provides a summary of the chemical and physical criteria applicable for spring water at the point of bottling. Table 12 outlines the list of chemical parameters for which performance characteristics are specified for the analysis of spring water. All breaches in the chemical criteria should be notified to the FSAI for a risk assessment. Appropriate follow-up action will be decided following a risk assessment.

Table 9 Guidelines for the frequency of routine official control sampling and analysis

Volume of water produced for offering for sale in bottles or containers each day* (m^3)	Partial monitoring – number of samples per year	Full monitoring – number of samples per year
≤10	1	1
>10	12	1

* The volumes are calculated as averages taken over a calendar year.

Note: Frequencies may vary depending on production periods. The frequencies can be adjusted accordingly when statistical trends on the chemical qualities are established.

Note: As required by Directive (EU) 2020/2184 the frequency of routine official control sampling and analysis should be based on risk. As a minimum, one partial and one full monitoring sample should be taken per year. The frequency should be reviewed annually and revised (either reduced or increased) based on risk, considering factors such as:

- Confidence in management
- Borehole construction
- Age of borehole
- Protection of the source
- History of sample results
- Change in land use
- Suspicion of, or known, pollution events
- Changes to abstraction rate
- Change of activities in the local area

2.7 Sampling and analysis of spring water by official agency (HSE)

Frequency of microbiological sampling

The microbiological criteria applicable to spring water are provided in Article 5 of Directive 2009/54/EC.

Directive 2009/54/EC does not specify minimum frequencies for the sampling and analysis of spring water by the official agency. The frequencies should be based on risk and can be adjusted accordingly when statistical trends on the microbiological qualities are established. To establish a profile of the microbiological composition of the water during production, it is suggested that samples should be taken at various locations, e.g. at source, during marketing and at the point of bottling.

Directive (EU) 2020/2184 does not provide minimum frequencies for the sampling and analysis for monitoring purposes of spring water by the official agency. Guidelines for the frequency of sampling and analysis for monitoring purposes for spring water and other water are provided in Table 9. EHOs can choose to increase or decrease the frequencies of sampling and analysis based on risk assessment.

Frequency of chemical sampling

The chemical criteria applicable to spring water are provided in Annex I of Directive (EU) 2020/2184. In addition, if spring water is treated with ozone-enriched air, the spring water must meet the criteria for maximum residues specified in Commission Directive 2003/40/EC.

Commission Directive 2003/40/EC does not specify minimum frequencies for the sampling and analysis of spring water by the official agency. Biannual sampling by the official agency at the spring water establishment is recommended for sampling against the criteria in Commission Directive 2003/40/EC.

Table 9 provides guidelines for the frequency of routine official control sampling and analysis at point of bottling for monitoring purposes of spring water by the official agency against the criteria in Annex I of Directive (EU) 2020/2184. Frequencies are specified for both partial monitoring and full monitoring. The microbiological, chemical, and physical criteria for spring water which require partial monitoring by the official agency are provided in Table 10. The microbiological, chemical, and physical criteria for spring water which require full monitoring by the official agency are provided in Table 11.

Frequency of radiological sampling

The European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016[1], 2020[2], 2022[3] and 2025 [4] fully implement Member States' obligations to define sampling frequencies for radioactivity in bottled water. Annual sampling is performed on the eight highest producing manufacturers, beginning in 2024. Sampling from all other bottled water manufacturers will take place in subsequent years until 2028, as agreed between the EPA, the NEHS and the FSAI. Data collated from this period will be analysed by the EPA, the NEHS and the FSAI, to decide on how the sampling frequencies should continue.

SECTION 3: OTHER WATER

3.1 Directive (EU) 2020/2184 on the quality of water intended for human consumption.

The HSE National Environmental Health Service (NEHS) is the responsible authority for the enforcement of all food legislation in 'other water' establishments. Unlike natural mineral water, there is no legal requirement for recognition of 'other water'. The provisions of Directive (EU) 2020/2184 on the quality of water (sold in bottles or containers) intended for human consumption apply to 'other water'. 'Other water' means drinking water which is bottled and is neither described as spring water or a recognised natural mineral water. 'Other water' can come from a variety of sources, e.g. groundwater and public water supplies.

Reference	Requirements of directive (EU) 2020/2184	Interpretation
Article 1	1. This Directive concerns the quality of water intended for human consumption for all in the Union. 2. The objectives of this Directive are to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean, and to improve access to water intended for human consumption.	The consumer must be protected from the adverse effects of any contamination of water intended for human consumption by the FBO ensuring that the water is wholesome and clean. Compliance with Directive (EU) 2020/2184 should ensure this.

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
Article 2(1a)	For the purposes of this Directive, the following definitions apply: 1. 'water intended for human consumption' means: (a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes in both public and private premises, regardless of its origin and whether it is supplied from a distribution network, supplied from a tanker, or put into bottles or containers, including spring waters	This section of the Guidance Note provides interpretation of the requirements of 'other water' sold in bottles or containers.
Article 2(1b) and Article 2(2) do not apply to 'other water' sold in bottles or containers.		
Article 3 provides for exemptions. Ireland has no exemptions from the requirements outlined in Directive (EU) 2020/2184 for 'other water' sold in bottles or containers.		

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
Article 4(1)	Without prejudice to their obligations under other Union law, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if all the following requirements are met: **(a)** that water is free from any microorganisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health, and **(b)** that water meets the minimum requirements set out in Parts A, B and D of Annex I (c) Member States have taken all other measures necessary to comply with Articles 5 to 14.	In order to be considered wholesome and clean, the water, at the point of bottling, must at a minimum meet the chemical, physical and microbiological criteria outlined in Annex I, Parts A, and B of Directive (EU) 2020/2184 These parameters and the legislative criteria are summarised in Table 11. In addition, the bottled water should be free from parasites; for example, *Cryptosporidium* spp. and *Giardia* spp. and other substances which, either in terms of numbers or concentrations, are considered potentially dangerous to public health. For information on completing a risk assessment for *Cryptosporidium* that also applies to *Giardia*, please see page 19 of Appendix 1 of Section 10 of *European Communities (Drinking Water) (No. 2) Regulations 2007: A Handbook on the Implementation of the Regulations for Water Services Authorities for Private Water Supplies*. ISO 15553:2006 is the internationally recognised standard method for the detection and identification of *Cryptosporidium* and *Giardia* in water. A sample volume of between 10 L and 1000 L can be taken for testing in accordance with ISO 15553:2006. A list of laboratories accredited to carry out testing in accordance with ISO 15553:2006 can be found on the INAB website. **Frequency of *Cryptosporidium* and *Giardia* testing** It is not recommended to sample for *Cryptosporidium* or *Giardia* due to the logistical challenges of sampling for and isolating this organism. Instead, it is recommended to sample for *E. coli* and enterococci which are indexes of faecal contamination. If *E. coli* or enterococci are detected, then it should be assumed that parasites could also be present, and steps should be taken to ensure their removal.

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
		Cryptosporidium and *Giardia* will not be eliminated by most disinfection processes; therefore, if indicator organisms suggest that the well has become contaminated with faecal material, the FBO may need to test that the well is free of parasites after taking appropriate action to remove them. For all groundwater, the potential contaminants in the water will depend on geological factors and on the activities being carried out in the water catchment area. Hence, in part, the type of monitoring required will be site specific. For example, if there were a chemical factory in the catchment area, the water would need to be tested for the presence of the potential chemical contaminants from this source. It is worth noting that changes in the level of ammonia and potassium in water samples from a particular well is usually an indication of pollution. FBOs should be able to demonstrate that any process, e.g. disinfection of boreholes or rinsing of bottles, does not contaminate the water. Sampling of the water for residues following these processes should indicate if there is contamination.
Quality Standards Article 5(1, 2, 3)	1. Member States shall set values applicable to water intended for human consumption for the parameters set out in Annex I. 2. The parametric values set pursuant to paragraph 1 of this Article shall not be less stringent than those set out in Parts A, B, C and D of Annex I. As regards the parameters set out in Part C of Annex I, the values shall be set only for monitoring purposes and for the sake of ensuring that the requirements set out in Article 14 are met.	(1) The microbiological, physical, and chemical criteria in Annex I of Directive (EU) 2020/2184 apply to 'other waters' produced in Ireland (see Table 11). In addition, Table 11 provides a list of indicator parameters which can be used to provide information on the organoleptic and microbiological quality of the water, as well as information on the effectiveness of drinking water treatment (particularly disinfection, and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Directive.

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	3. A Member State shall set values for additional parameters not included in Annex I where the protection of human health within its national territory or part of it so requires. The values set shall, as a minimum, satisfy the requirements of point (a) of Article 4(1).	.
Point of compliance: Articles 6(1a, b and d), 6(2) and 6(3) do not apply to water put into bottles or containers.		
Point of compliance Article 6(1c)	The parametric values set in accordance with Article 5 for the parameters listed in Parts A and B of Annex I shall be complied with, in the case of water intended for human consumption put into bottles or containers, at the point at which the water is put into the bottles or containers;	In the case of water put into bottles or containers intended for human consumption, the point of compliance with the criteria listed in Table 10 is at the point at which the water is put into the bottles or containers.
Articles 7 to 10 do not apply to 'other waters' put into bottles or containers intended for human consumption.		

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
Minimum hygiene requirements for materials that come in contact with water intended for human consumption Article 11(1)	For the purposes of Article 4, Member States shall ensure that materials that are intended to be used in new installations or, in the case of repair works or reconstruction, in existing installations for the abstraction, treatment, storage or distribution of water intended for human consumption and that come into contact with such water do not: (a) directly or indirectly compromise the protection of human health as provided for by this Directive; (b) adversely affect the colour, odour, or taste of the water; (c) enhance microbial growth; (d) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose of the material.	*This section is intentionally left blank*
Article 11 (2)	For the purpose of ensuring the uniform application of paragraph 1, the Commission shall adopt implementing acts to establish the specific minimum hygiene requirements for materials that come into contact with water intended for human consumption on the basis of the principles set out in Annex V. Those implementing acts shall establish: (a) by 12 January 2024, methodologies for testing and accepting starting substances, compositions, and constituents to be included in European positive lists of starting substances, compositions, or constituents, including specific migration limits and scientific pre-conditions related to substances or materials;	Please see Annex V in Directive (EU) 2020/2184 for further information.

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	(b) by 12 January 2025, on the basis of lists including expiry dates compiled by ECHA, European positive lists of starting substances, compositions or constituents for each group of materials, namely organic, cementitious, metallic, enamels and ceramic or other inorganic materials, which are authorised for use in the manufacture of materials or products in contact with water intended for human consumption, including, where appropriate, conditions for their use and migration limits, which are to be determined on the basis of the methodologies adopted pursuant to point (a) of this subparagraph, and taking into account paragraphs 3 and 4; (c) by 12 January 2024, procedures and methods for testing and accepting final materials as used in a product made from materials or combinations of starting substances, compositions, or constituents on the European positive lists, including: (i) the identification of relevant substances and other parameters, such as turbidity, flavour, odour, colour, total organic carbon, the release of unexpected substances and enhancement of microbial growth, to be tested in migration water; (ii) methods for testing the effects on water quality, having regard to any relevant European standards; (iii) pass/fail criteria for the test results, which take into account, inter alia, conversion factors for substance migration into estimated levels at the tap, and conditions of	

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	application or use, where appropriate. The implementing acts provided for in this paragraph shall be adopted in accordance with the examination procedure referred to in Article 22.	
Article 11 (3)	The first European positive lists to be adopted in accordance with point (b) of the first subparagraph of paragraph 2 shall be based, inter alia, on existing national positive lists, other existing national provisions and on the risk assessments that led to the establishment of such national lists. For this purpose, Member States shall notify ECHA of any existing national positive lists, other provisions, and available assessment documents by 12 July 2021. The European positive list of starting substances for organic materials shall take into account the list established by the Commission pursuant to Article 5 of Regulation (EC) No 1935/2004.	*This section is intentionally left blank*
Article 11 (4)	The European positive lists shall contain the only starting substances, compositions or constituents that are authorised for use as referred to in point (b) of the first subparagraph of paragraph 2. The European positive lists shall contain expiry dates set on the basis of a recommendation from ECHA. The expiry dates shall be set in particular on the basis of the hazardous properties of the substances, the quality of the underlying risk assessments, and the extent to which those risk assessments are up to date. The European positive lists may also contain transitional provisions.	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	On the basis of opinions from ECHA as referred to in paragraph 6, the Commission shall regularly review and update, where necessary, the implementing acts referred to in point (b) of the first subparagraph of paragraph 2, in line with the latest scientific and technological developments. The first review shall be completed by 15 years after the adoption of the first European positive list. The Commission shall ensure that any relevant acts, or standardisation mandates, which it adopts pursuant to other Union legislation are consistent with this Directive.	
Article 11 (5)	For the purpose of inclusion in or removal from the European positive lists of starting substances, compositions or constituents, economic operators or relevant authorities shall submit applications to ECHA. The Commission shall adopt delegated acts in accordance with Article 21, in order to supplement this Directive, by laying down a procedure, including information requirements, on the application process. The procedure shall ensure that applications are accompanied by risk assessments and that economic operators or relevant authorities deliver the necessary information for the risk assessment in a specific format.	*This section is intentionally left blank*
Article 11 (6)	The Committee for Risk Assessment of ECHA set up pursuant to point (c) of Article 76(1) of Regulation (EC) No 1907/2006 shall issue an opinion on any application submitted pursuant to paragraph 5 within a time limit to be set out in the delegated acts referred to in that paragraph. Further procedural provisions on the application process and on the issuing of	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	opinions by the Committee for Risk Assessment of ECHA may also be included in those delegated acts.	
Article 11 (7)	Member States shall consider that products approved in accordance with specific minimum hygiene requirements provided for in paragraph 2 satisfy the requirements set out in paragraph 1. Member States shall ensure that only such products in contact with water intended for human consumption that use final materials approved in accordance with this Directive can be placed on the market for the purposes of this Directive. This shall not prevent Member States, in particular when specific local raw water quality so requires, from adopting more stringent protective measures for the use of final materials in specific or duly justified circumstances, in accordance with Article 193 TFEU. Such measures shall be notified to the Commission. Regulation (EU) 2019/1020 shall apply to products covered by this Article.	*This section is intentionally left blank*
Article 11 (8)	The Commission shall adopt delegated acts in accordance with Article 21, in order to supplement this Directive, by determining the appropriate conformity assessment procedure applicable to products covered by this Article on the basis of the modules in Annex II to Decision No 768/2008/EC of the European Parliament and of the Council[5] . In determining which conformity assessment procedure is to be used, the Commission shall ensure that the objectives referred to in	*This section is intentionally left blank*

[5] Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	Article 1(2) of this Directive are complied with, whilst taking into account the principle of proportionality. For this purpose, the Commission shall take as a starting point the System 1+ of assessment and verification of constancy of performance set out in Annex V to Regulation (EU) No 305/2011, or a broadly equivalent procedure, except where it would be disproportionate. The delegated acts referred to in this paragraph shall also contain rules for the designation of conformity assessment bodies, where such are involved in the respective conformity assessment procedures.	
Article 11 (9)	Pending the adoption of the implementing acts referred to in paragraph 2, Member States shall be entitled to maintain or adopt national measures on specific minimum hygiene requirements for the materials referred to in paragraph 1, provided that those measures comply with the rules of the TFEU.	*This section is intentionally left blank*
Article 11 (10)	The Commission shall request one or several European standardisation organisations to draft a European standard for uniform testing and assessment of products in contact with water intended for human consumption in accordance with Article 10 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council[6] , in order to facilitate compliance with this Article.	*This section is intentionally left blank*
Article 11 (11)	The Commission shall adopt delegated acts in accordance with Article 21 in order to supplement this Directive by establishing harmonised specifications for a	*This section is intentionally left blank*

[6] Regulation (EU) No. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	conspicuous, clearly legible, and indelible marking to be used to indicate that products in contact with water intended for human consumption are in conformity with this Article.	
Article 11 (12)	No later than 12 January 2032, the Commission shall review the functioning of the system as set out in this Article and present a report to the European Parliament and the Council, based in particular on experience gained through the application of Regulations (EC) No 1935/2004 and (EU) No 305/2011, assessing whether: (a) human health as regards the matters covered by this Article is adequately protected throughout the Union; (b) the internal market for products in contact with water intended for human consumption is functioning properly; (c) there is a need for any further legislative proposal on the matters covered by this Article.	*This section is intentionally left blank*
Minimum requirements for treatment chemicals and filter media Article 12(1)	For the purposes of Article 4, Member States shall ensure that treatment chemicals and filter media that come into contact with water intended for human consumption do not: (a) directly or indirectly compromise the protection of human health as provided for by this Directive (b) adversely affect the colour, odour, or taste of the water; (c) unintentionally enhance microbial growth;	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	(d) contaminate the water at levels that are higher than necessary in view of the intended purpose	
Article 12(2)	For the national implementation of the requirements of this Article, Article 4(2) shall apply accordingly.	*This section is intentionally left blank*
Article 12(3)	Pursuant to paragraph 1 of this Article, and without prejudice to Regulation (EU) No 528/2012 and by using relevant European standards for specific treatment chemicals or filter media, Member States shall ensure that the purity of treatment chemicals and filter media is assessed and the quality of such chemicals and filter media is guaranteed.	*This section is intentionally left blank*
Article 13(2)	To meet the obligations imposed in paragraph 1, appropriate monitoring programmes shall be established in accordance with Part A of Annex II for all water intended for human consumption. Those monitoring programmes shall be supply-specific, taking into account the outcomes of the risk assessment of the catchment areas for abstraction points and of the supply systems, and shall consist of the following elements: (a) monitoring of the parameters listed in Parts A, B and C of Annex I, and of the parameters set in accordance with Article 5(3), in accordance with Annex II, and, where a risk assessment of the supply system is carried out, in accordance with Article 9 and Part C of Annex II, unless a Member State decides that one of those parameters can be removed, in accordance with point (b) of the second subparagraph of Article 8(5) or point (a) of Article 9(4), from the list of parameters to be monitored; (c) monitoring of the substances and compounds included in the watch	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	list, in accordance with the fifth subparagraph of paragraph 8 of this Article; (d) monitoring, for the purposes of the identification of hazards and hazardous events, as provided for in point (c) of the first subparagraph of Article 8(2); (e) operational monitoring conducted in accordance with point three of Part A of Annex II.	
Article 13(3)	The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Part D of Annex II.	*This section is intentionally left blank*
Article 13(4)	Member States shall comply with the specifications for the analysis of parameters set out in Annex III, in accordance with the following principles: (a) methods of analysis other than those specified in Part A of Annex III may be used, provided that it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified in Part A of Annex III, by providing the Commission with all relevant information concerning such methods and their equivalence; (b) for the parameters listed in Part B of Annex III, any method of analysis may be used provided that it meets the requirements set out therein.	*This section is intentionally left blank*
Article 13(5)	Member States shall ensure that additional monitoring is carried out on a case-by-case basis of substances and microorganisms for which no parametric value has been set in accordance with Article 5, if there is reason to suspect that they may be present	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	in numbers or concentrations which constitute a potential danger to human health.	
Article 13(6)	By 12 January 2024, the Commission shall adopt delegated acts in accordance with Article 21 in order to supplement this Directive by adopting a methodology to measure microplastics with a view to including them on the watch list referred to in paragraph 8 of this Article once the conditions set out under that paragraph are fulfilled.	*This section is intentionally left blank*
Article 13(7)	By 12 January 2024, the Commission shall establish technical guidelines regarding methods of analysis for monitoring of per- and polyfluoroalkyl substances under the parameters 'PFAS Total' and 'Sum of PFAS', including detection limits, parametric values, and frequency of sampling.	*This section is intentionally left blank*
Article 13(8)	The Commission shall adopt implementing acts to establish and update a watch list addressing substances or compounds of concern to the public or the scientific community on health grounds ('the watch list'), such as pharmaceuticals, endocrine-disrupting compounds and microplastics. Substances and compounds shall be added to the watch list where they are likely to be present in water intended for human consumption and could pose a potential risk to human health. To that end, the Commission shall make use, in particular, of scientific research of the WHO. The addition of any new substance or compound shall be duly justified under Articles 1 and 4. Beta-estradiol and Nonylphenol shall be included in the first watch list in	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	view of their endocrine-disrupting properties and the risk they pose to human health. The first watch list shall be established by 12 January 2022. The watch list shall indicate a guidance value for each substance or compound and where necessary a possible method of analysis that does not entail excessive costs. Member States shall put in place monitoring requirements with regard to the potential presence of the substances or compounds which are included in the watch list, at relevant points of the supply chain for water intended for human consumption. For this purpose, Member States may take into account the information collected under Article 8(1), (2) and (3) of this Directive and may use the monitoring data collected in accordance with Directives 2000/60/EC and 2008/105/EC or other relevant Union legislation, in order to avoid overlapping of monitoring requirements. The monitoring results shall be included in the data sets, set up in accordance with point (b) of Article 18(1), together with the results of the monitoring performed under point (c) of the first subparagraph of Article 8(2). Where a substance or compound included in the watch list is detected, under Article 8(2) or under the fifth subparagraph of this paragraph, in concentrations exceeding the guidance values set out in the watch list, Member States shall ensure that the following measures are	

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	considered and that those measures considered relevant are taken: (a) preventive measures, mitigation measures or appropriate monitoring in the catchment areas for abstraction points or in raw water as set out in points (a), (b) and (c) of the first subparagraph of Article 8(4); (b) requiring water suppliers to carry out monitoring of those substances or compounds, in accordance with point (a) of the second subparagraph of Article 8(5); (c) requiring water suppliers to check whether treatment is adequate to reach the guidance value and, where necessary, to optimise the treatment; and (d) remedial actions in accordance with Article 14(6) where Member States consider it necessary to protect human health. The implementing acts provided for in this paragraph shall be adopted in accordance with the examination procedure referred to in Article 22.	
Article 14(1)	Member States shall ensure that any failure to meet the parametric values set in accordance with Article 5 is immediately investigated in order to identify the cause.	The FBO must investigate the cause of chemical or microbiological contamination. Appropriate enforcement measures must be taken to ensure that the microbiological and chemical criteria are met. If a bottled water sample fails to comply with the provisions of Annex I, Part A or B of Directive (EU) 2020/2184, the EHO may seize, remove, detain, or direct the withdrawal from the market of the bottled water. For water which is non-compliant with the indicator parameters set out in Annex I, Part C, Member States must consider whether that non-compliance poses any risk to human health. Member States must take remedial action to restore the quality of the water where that is necessary to protect human health.

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
Article 14(2)	If, despite the measures taken to meet the obligations imposed in Article 4(1), water intended for human consumption does not meet the parametric values set in accordance with Article 5, and without prejudice to Article 6(2), the Member State concerned shall ensure that the necessary remedial action is taken as soon as possible to restore the quality of the water and shall give priority to its enforcement, having regard to, *inter alia,* the extent to which the relevant parametric value has been exceeded and the associated potential danger to human health. In the event of non-compliance with the parametric values set out in Part D of Annex I, remedial action shall include the measures set out in Article 10(3).	*This section is intentionally left blank*
Article 14(3)	Regardless of whether any failure to comply with the parametric values has occurred, Member States shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or the use of such water restricted and that any other remedial action that is necessary to protect human health is taken. Member States shall consider a failure to meet the minimum requirements for parametric values set out in Parts A and B of Annex I as a potential danger to human health, except where the competent authority considers the non-compliance with the parametric value to be trivial.	In the case of non-compliances, FBOs should contact the FSAI Food Incidents team by emailing foodincidents@fsai.ie for a risk assessment. **If the product is determined to be unsafe, the FBO must issue a suspension of production or recall of the batch in question in accordance with Article 14 of Regulation (EC) No 178/2002, as amended.**
Article 14(4)	In the cases described in paragraphs 2 and 3, where the non-compliance with the parametric values is considered to be a potential danger to human health, Member States	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	shall as soon as possible take all of the following measures: (a) notify all affected consumers of the potential danger to human health and its cause, of the exceedance of a parametric value and of the remedial actions taken, including prohibition or restriction of use or other action; (b) give, and regularly update, the necessary advice to consumers on conditions of consumption and use of the water, taking particular account of population groups with increased water-related health risks; and (c) inform consumers once it has been established that there is no longer a potential danger to human health and inform them that the service has returned to normal.	
Article 14(5)	The competent authorities or other relevant bodies shall decide what action under paragraph 3 is to be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.	*This section is intentionally left blank*
Article 14(6)	In the event of non-compliance with the parametric values or with the specifications set out in Part C of Annex I, Member States shall consider whether that non-compliance poses any risk to human health. They shall take remedial action to restore the quality of the water intended for human consumption where that is necessary to protect human health.	*This section is intentionally left blank*
Article 15 relates to derogations, none of which apply to Ireland.		

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
Articles 16 to 23 do not apply to 'other waters' in bottles or containers intended for human consumption.		
Transposition Article 24	Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with Articles 1 to 18, Article 23, and Annexes I to V by 12 January 2023. They shall immediately communicate the text of those measures to the Commission. When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference when their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated. 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	S.I. No. 282 of 2016 **Amended by** S.I. No. 55 of 2020, S.I. No. 691 of 2022, S.I. No. 204 of 2025
Transitional Period Article 25	1. By 12 January 2026, Member States shall take the measures necessary to ensure that water intended for human consumption complies with the parametric values set out in Part B of Annex I for Bisphenol A, Chlorate, Chlorite, Haloacetic Acids, Microcystin-LR, PFAS Total, Sum of PFAS and Uranium. 2. Until 12 January 2026, water suppliers shall not be obliged to monitor water intended for human consumption in accordance with	*This section is intentionally left blank*

Reference	Requirements of Directive (EU) 2020/2184	Interpretation
	Article 13 for the parameters listed in paragraph 1 of this Article.	
Repeal Article 26	1. Directive 98/83/EC, as amended by the acts listed in Part A of Annex VI, is repealed with effect from 13 January 2023, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of the Directives set out in Part B of Annex VI. L 435/32 EN Official Journal of the European Union 23.12.2020 References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VII.	*This section is intentionally left blank*
Entry into Force Article 27	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	*This section is intentionally left blank*
Addresses Article 28	This Directive is addressed to the Member States.	*This section is intentionally left blank*

3.2 Treatment of 'other waters'

Unlike natural mineral water and spring water, there are no restrictions on the treatments permitted for use on 'other water'. Bacteriostatic treatments, e.g. the use of a UV lamp, are permitted to reduce the microbial composition of water to the specified criteria. Unlike natural mineral water and spring water, there are no additional labelling requirements if 'other waters' have undergone any treatment. Treatment of 'other waters' should be carefully controlled by the FBO in order to ensure the treatment's effectiveness.

Where disinfection forms part of the preparation or distribution of 'other waters', the efficiency of the disinfection treatment applied should be verified and any contamination from disinfection by-products is kept as low as possible without compromising the disinfection.

The FBO must verify the efficiency of the disinfection treatment applied through the implementation of HACCP principles and appropriate sampling.

To ensure the elimination of *Cryptosporidium* spores using ultraviolet -C disinfection, a critical control point of 40 millijoules per cm^2 (mJ/cm^2) will result in a 4-log inactivation of *Cryptosporidium spores.* This critical control point of 40 millijoules per cm^2 (mJ/cm^2) will ensure a high level of public health protection as concentrations of *Cryptosporidium* typically do not exceed 3-log in raw sewage.

3.3 Labelling of 'other waters'

Labelling of 'other water' must comply with the requirements of the general labelling legislation (Regulation (EU) No 1169/2011 and S.I. No. 556 of 2014 (as amended). There is no restriction on the use of trade names on 'other waters', and the source of the water is not mandatory. There are no additional labelling requirements if 'other waters' have undergone any treatment. Nutrition and health claims under Regulation (EC) No 1924/2006, as amended, may also be made on 'other water', e.g. that it is a source of calcium. If these claims are made, they must comply with the requirements of Regulation (EC) No 1924/2006, as amended. Authorised health claims and the conditions applying to them are listed in the European Union Register, along with a list of rejected health claims and the reasons for their rejection. The European Union Register can be accessed here: Nutrition and health claims – EU labelling rules - Your Europe (europa.eu)

See Appendix I, Figure 7 for an example of a label used for 'other water'.

3.4 Chemical and physical criteria for 'other waters'

The FBO must be able to demonstrate that the 'other water' produced meets the chemical and physical legislative criteria outlined in Table 11 at the point of bottling. Tables 10 and 11 also list indicator parameters for 'other waters' which can be used to provide information on the organoleptic and microbiological quality of the water and the effectiveness of drinking water treatment. Breaches in the chemical criteria should be notified to the FSAI for a risk assessment.
Appropriate follow-up action will be decided following a risk assessment.

3.5 Microbiological criteria for 'other waters'

The FBO must be able to demonstrate that the 'other water' produced meets the microbiological legislative criteria outlined in Table 11 at the point of bottling. Table 10 and Table 11 also list indicator parameters for 'other waters' which can be used to provide information on the organoleptic and microbiological quality of the water and the effectiveness of drinking water treatment.

Regulation (EC) No 178/2002, as amended (Article 14), states that food shall not be placed on the market if it is unsafe, i.e. injurious to health or unfit for human consumption. Therefore, *E. coli* and/or enterococci must be absent from 'other water' sampled at the point of bottling and during marketing.

Action to take in the event of non-compliance with the microbiological criteria

Where the 'other water' is deemed to be unsafe by reason that it may be injurious to health or unfit for human consumption, the FBO must initiate the procedure to withdraw or recall the batch of product in question.

Where the product in question has reached the consumer, the FBO must accurately and effectively inform consumers of the reason for the recall of the product.

Where the 'other water' product does not comply with the legal requirements for microbiological criteria, the packaged water business operator must:

- Take action to ensure that the water is not consumed
- Where necessary, recall the product and notify consumers.

Escherichia coli and enterococci (faecal streptococci)

The presence of *E. coli* and/or enterococci in 'other water' is considered an index of faecal contamination of the water. As such, the water is considered injurious to health and therefore unsafe. In accordance with Article 19 of Regulation (EC) No 178/2002, 'other water' containing *E. coli* or enterococci must be withdrawn from the market and, where it has reached the consumer, the consumers must be notified of the reason for its withdrawal. EHOs should ensure that the FBO takes the necessary measures to remove the product from consumers by:

- Notifying trade customers
- Notifying consumers
- Removing the affected batch of bottled water from the food chain
- Removing the affected batch of bottled water from consumers.

See the FSAI's Guidance Note No. 10, Product Recall and Traceability (Revision 3).

Coliforms

The presence of coliforms (in the absence of *E. coli* or enterococci) in 'other water' is not a strong indication of the potential presence of enteric pathogens. Such bottled water must not be considered unsafe for consumption. The presence of coliforms should prompt investigation by the EHO and the FBO as to the source of the contamination. The FSAI should be informed of each case of coliforms detected in bottled water, and each result must be dealt with on a case-by-case basis (email: foodincidents@fsai.ie).

3.6 Sampling and analysis by the HSE National Environmental Health Service

Recommended frequencies of sampling and analysis for other water sold in bottles or containers are provided in Directive (EU) 2020/2184. The microbiological, chemical, and physical parametric values provided in Directive (EU) 2020/2184 apply at the point at which the water is put into bottles or containers. Therefore, the sampling of 'other water' produced in Ireland against the criteria of Directive (EU) 2020/2184 should take place at the point of bottling in the food business.

'Other waters' which are sampled at retail level can be analysed for the chemical and microbiological parameters outlined in Directive (EU) 2020/2184. However, environmental health officers should be aware that these criteria apply at the point of bottling. Regulation (EC) No 178/2002, as amended (Article 14), states that food shall not be placed on the market if it is unsafe, i.e. injurious to health or unfit for human consumption. Therefore, 'other water' sampled at the retail stage/during marketing should be absent from contamination which is considered injurious to health or unfit for human consumption, e.g. *E. coli* or enterococci.

Guidelines on the frequencies of sampling and analysis for monitoring purposes of other water are provided in Table 9. EHOs can choose to increase or decrease the frequencies of sampling and analysis based on risk assessment.

Partial monitoring: the purpose of partial monitoring is to provide information on the organoleptic and microbiological quality of the water supplied for human consumption, as well as information on the effectiveness of drinking water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in Directive (EU) 2020/2184, as amended. Table 10 lists the indicator parameters which can be subject to partial monitoring by the official agency

Full monitoring: the purpose of full monitoring is to provide the information necessary to determine whether or not all of the parametric values of Directive (EU) 2020/2184 (Annex I, Parts A and B and the indicator parameters in Part C) are being complied with. Table 11 lists the parameters which may be subject to full monitoring and the legislative criteria for each.

Table 12 outlines the list of parameters for which performance characteristics are specified.
Analysis of official control samples should be in accordance with this table.

Table 10 Chemical, physical and microbiological indicator parameters which can be subject to partial monitoring by the official agency (applicable to spring water and 'other waters')

Chemical indicator parameters
Aluminium (necessary only if used as water treatment chemical; in all other cases, the parameter is in the list for audit monitoring)
Ammonium (necessary only if chloramination is used; in all other cases, the parameter is in the list for audit monitoring)
Conductivity
Hydrogen ion concentration
Iron (necessary only if used as water treatment chemical; in all other cases, the parameter is in the list for audit monitoring)
Nitrite (necessary only if chloramination is used; in all other cases, the parameter is in the list for audit monitoring)
Physical indicator parameters
Taste
Colour
Odour
Turbidity
Microbiological indicator parameters
TVC @ 22°C and 37°C[7]
Coliform bacteria
Clostridium perfringens (including spores) (necessary only if the water originates from or is influenced by surface water)
Escherichia coli (E. coli)
Pseudomonas aeruginosa[8]
Sporulated sulphite-reducing anaerobes[9]
Intestinal enterococci

[7] As per Directive (EU) 2020/2184, Colony count at 22°C applies to both spring water and 'other waters'. Colony count at 37°C is applicable to spring water under Directive 2009/54/EC, and to 'other waters' under S.I. No 204 of 2025.

[8] *Pseudomonas aeruginosa* as a microbiological indicator parameter is applicable to spring water, as per Directive 2009/54/EC. Testing for *Pseudomonas aeruginosa* is required for 'other waters' as per S.I. No. 204 of 2025.

[9] As per Directive 2009/54/EC, sporulated sulphite-reducing anaerobes shall be absent in 50 mL. This is applicable to spring water only.

Table 11 Chemical, physical and microbiological parameters subject to full monitoring by the official agency (applicable to spring water and 'other waters', including recommended frequency of analysis for FBOs)[10]

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Chemical parameters				
Acrylamide	0.10 µg/L		The parametric value of 0.10 µg/L refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.	Every 4 years
Aluminium		200 µg/L		Annually
Ammonium		0.50 mg/L		Monthly
Antimony	10 µg/L			Annually
Arsenic	10µg/L			Annually
Benzene	1.0 µg/L			Annually
Benzo(a)pyrene	0.010 µg/L			Annually
Bisphenol A[10]	2.5 µg/L			
Boron	1.5 mg/L		A parametric value of 2.4 mg/L shall be applied when desalinated water is the predominant water source of the supply system concerned or in regions where geological conditions could lead to high levels of boron in groundwater.	Annually
Bromate	10µg/L		Only applicable to Spring Water	Annually

[10] By 12 January 2026, Member States shall take the measures necessary to ensure that water intended for human consumption complies with the parametric values set out in Part B of Annex I for Bisphenol A, Chlorate, Chlorite, Haloacetic Acids, Microcystin-LR, PFAS Total, Sum of PFAS and Uranium.

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Residues: dissolved ozone	50 µg/L		Apply only to spring water which is treated with ozone-enriched air. Criterion applies at the time of bottling or other form of packaging intended for the final consumer.	
Residues: bromates	3 µg/L		Apply to natural mineral water and spring water which is treated with ozone-enriched air. Criterion applies at the time of bottling or other form of packaging intended for the final consumer.	Yearly
Residues: bromoforms	1 µg/L		Apply only to spring water which is treated with ozone-enriched air. Criterion applies at the time of bottling or other form of packaging intended for the final consumer.	
Cadmium	5.0 µg/L			Annually
Chloride		250 mg/L	The water should not be corrosive.	Quarterly
Chromium	25 µg/L		The parametric value of 25 µg/L shall be met, at the latest, by 12 January 2036. The parametric value for chromium until that date shall be 50 µg/L.	Annually

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Chlorate[10]	0.25 mg/L		A parametric value of 0.70 mg/L shall be applied where a disinfection method that generates chlorate, in particular chlorine dioxide, is used for disinfection of water intended for human consumption. Where possible, without compromising disinfection, Member States shall strive for a lower value. This parameter shall be measured only if such disinfection methods are used.	
Chlorite[10]	0.25 mg/L		A parametric value of 0.70 mg/L shall be applied where a disinfection method that generates chlorite, in particular chlorine dioxide, is used for disinfection of water intended for human consumption. Where possible, without compromising disinfection, Member States shall strive for a lower value. This parameter shall be measured only if such disinfection methods are used.	
Copper	2.0 mg/L			Annually

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Cyanide[11]	50 µg/L			Annually
1,2-Dichloroethane	3.0 µg/L			Every 4 years
Epichlorohydrin	0.10 µg/L		The parametric value of 0.10 µg/L refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.	Every 4 years
Fluoride(s)	1.5 mg/L			Annually
Haloacetic acids (HAAs)[10]	60 µg/L		This parameter shall be measured only when disinfection methods that can generate HAAs are used for the disinfection of water intended for human consumption. It is the sum of the following five representative substances monochloro-, dichloro-, and trichloro-acetic acid, and mono- and dibromo-acetic acid.	
Iron		200 µg/L		Annually

[11] Annual analysis of cyanide is not feasible until method development is completed for this parameter.

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Lead	5 µg/L		The parametric value of 5 µg/L shall be met, at the latest, by 12 January 2036. The parametric value for lead until that date shall be 10 µg/L. After that date, the parametric value of 5 g/L shall be met at least at the point of supply. For the purposes of point (b) of the first subparagraph of Article 11(2), the parametric values of 5 µg/L at the tap shall apply.	Annually
Manganese		50 µg/L		Annually
Mercury	1.0 µg/L			Annually
Microcystin-LR[10]	1.0 µg/L		This parameter shall be measured only in the event of potential blooms in source water (increasing cyanobacterial cell density or bloom forming potential)	
Nickel	20 µg/L			Annually
Nitrate	50 mg/L		Member States shall ensure that the condition that [nitrate]/50 + [nitrite]/3 ≤1, where the square brackets signify the concentrations in mg/L for nitrate (NO_3^-) and nitrite (NO_2^-), is complied with and that the value of 0.10 mg/L for nitrites is complied with ex water treatment works.	Annually

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Nitrite	0.50 mg/L		Member States shall ensure that the condition that [nitrate]/50 + [nitrite]/3 ≤1,where the square brackets signify the concentrations in mg/L for nitrate (NO3 −) and nitrite (NO2 −), is complied with and that the value of 0.10 mg/L for nitrites is complied with ex water treatment works.	Annually
Oxidisability		5.0 mg/L O_2	This parameter need not be measured if the parameter total organic carbon (TOC) is analysed.	Quarterly
Pesticides	0.10 µg/L		'Pesticides' means organic insecticides, organic herbicides, organic fungicides, organic nematocides, organic acaricides, organic algicides, organic rodenticides, organic slimicides, related products (*inter alia*, growth regulators) and their metabolites, as defined in point (32) of Article 3 of Regulation (EC) No 1107/2009 of the European Parliament and the council[12] that are considered relevant for water intended for human consumption. A pesticide metabolite shall be deemed relevant for water intended for human consumption if there is reason to consider that it has	Every 4 years Please see Table 14 for a list of pesticides used in Ireland.

[12] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
			intrinsic properties comparable to those of the parent substance in terms of its pesticide target activity or that either itself or its transformation products generate a health risk for consumers. The parametric value of 0,10 µg/l shall apply to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide, the parametric value shall be 0,030 µg/l. Member States shall define a guidance value to manage the presence of non-relevant metabolites of pesticides in water intended for human consumption. Only pesticides which are likely to be present in a given supply need to be monitored. Based on the data reported by Member States, the Commission may establish a database of pesticides and their relevant metabolites taking into account their possible presence in water intended for human consumption.	
Pesticides – Total	0.50 µg/L		'Pesticides – Total' means the sum of all individual pesticides, as defined in the previous row, detected, and quantified in the monitoring procedure.	Every 4 years

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
PFAS Total[10]	0.50 µg/L		'PFAS Total' means the totality of per- and polyfluoroalkyl substances. This parametric value shall only apply once technical guidelines for monitoring this parameter are developed in accordance with Article 13(7). Member States may then decide to use either one or both of the parameters 'PFAS Total' or 'Sum of PFAS'.	
Sum of PFAS[10]	0.10 µg/L		'Sum of PFAS' means the sum of per- and polyfluoroalkyl substances considered a concern as regards water intended for human consumption listed in point 3 of Part B of Annex III. This is a subset of 'pfas Total' substances that contain a perfluoroalkyl moiety with three or more carbons (i.e. –CnF2n–, n ≥ 3) or a perfluoroalkyl ether moiety with two or more carbons s (i.e. –CnF2nOCmF2m–, n and m ≥ 1).	

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Polycyclic aromatic hydrocarbons	0.10 µg/L		Sum of concentrations of the following specified compounds: benzo(b)-fluoranthene, benzo(k)-fluoranthene, benzo(ghi)perylene and indeno(1,2,3-cd) pyrene.	Every 4 years
Selenium	20 µg/L		A parametric value of 30 µg/L shall be applied for regions where geological conditions could lead to high levels of selenium in groundwater	Annually
Sodium		200 mg/L		Quarterly
Sulphate		250 mg/L	The water should not be corrosive.	Quarterly
Tetrachloroethene and trichloroethene	10 µg/L		The sum of concentrations of these two parameters	Every 4 years
Total organic carbon		No abnormal change	This parameter need not be measured for supplies of less than 10000 m^3 a day.	Quarterly
Uranium[10]	30 µg/L			

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Trihalomethanes – Total	100 µg/L		Where possible, without compromising disinfection, Member States shall strive for a lower parametric value. It is the sum of concentrations of the following specified compounds: chloroform, bromoform, dibromochloromethane and bromodichloromethane.	Every 4 years
Vinyl chloride	0.50 µg/L		The parametric value of 0.50 µg/L refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.	Every 4 years
Radioactivity – Total dose		0.10 mSv/year for indicative dose (ID)	0.1 mSv/year for ID is Ireland's parametric value.	No monitoring of a specific parameter must be required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
				water intended for human consumption in concentrations which could exceed the corresponding parametric value.

Parameter	Parametric value Ref: Directive (EU) 2020/2184	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Radioactivity – tritium		100 Bq/l for tritium	See Section 4: Radioactive substances in water intended for human consumption, for more information.	No monitoring of a specific parameter is required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of water intended for human consumption in concentrations which could exceed the corresponding parametric value.
Microbiological parameters				
Escherichia coli (E. coli)	0/250 mL			
Enterococci	0/250 mL			
Pseudomonas aeruginosa[13]	0/250 mL			
Colony count @ 22 °C[14]	100/mL	No abnormal change		
Colony count @ 37 °C[15]	20/mL			
Coliforms	0/250 mL			

[13] *Pseudomonas aeruginosa* as a microbiological indicator parameter is applicable to spring water, as per Directive 2009/54/EC. Testing for *Pseudomonas aeruginosa* is required for 'other waters' as per S.I. No. 204 of 2025.

[14] As per Directive (EU) 2020/2184, Colony count at 22°C applies to both spring water and 'other waters'.

[15] Colony count at 37°C is applicable to spring water under Directive 2009/54/EC, and to 'other waters' under S.I. No 204 of 2025.

Sporulated sulphite-reducing anaerobes		0/50 mL	Applicable to Spring Water only.	
Parameter	**Parametric value Ref: Directive (EU) 2020/2184**	**Indicator parametric value/unit**	**Note**	**Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010**
Clostridium perfringens (including spores)		0/100 mL	This parameter need not be measured unless the water originates from, or is influenced by, surface water. In the event of non-compliance with this parametric value, the Member State concerned must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic microorganisms, e.g. *Cryptosporidium*. Member States must include the results of all such investigations in the reports they must submit under Article 13(2).	
Physical parameters				
Colour		Acceptable to consumers and no abnormal change		Daily
Conductivity		2500 uS cm^{-1} at 20 °C	Water should not be aggressive.	Daily

Parameter	Parametric value	Indicator parametric value/unit	Note	Recommended frequency of analysis (by FBO) Ref: I.S. 432:2010
Hydrogen ion concentration		≥6.5 and ≤9.5 pH units	The water should not be aggressive. For still water put into bottles or containers, the minimum value may be reduced to 4.5 pH units. For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.	Daily
Odour		Acceptable to consumers and no abnormal change		Daily
Turbidity	Acceptable to consumers and no abnormal change			Daily

3.7 Specific methods of analysis

As per Directive (EU) 2020/2184, Member States shall ensure that the methods of analysis used for the purposes of monitoring and demonstrating compliance with this Directive, with the exception of turbidity, are validated and documented in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level. Member States shall ensure that laboratories or parties contracted by laboratories apply quality management system practices in accordance with EN ISO/IEC 17025 or other equivalent standards accepted at international level.

For the purposes of assessing the equivalence of alternative methods with the methods laid down in this Annex, Member States may use standard EN ISO 17994, established as the standard on the equivalence of microbiological methods, or standard EN ISO 16140 or any other similar internationally accepted protocols, to establish the equivalence of methods based on principles other than culturing, which are beyond the scope of EN ISO 17994.

In the absence of an analytical method meeting the minimum performance criteria set out in Part B, Member States shall ensure that monitoring is carried out using the best available techniques not entailing excessive costs.

Table 12 outlines the chemical and indicator parameters for which performance characteristics are specified. For the parameters set out in Table 12, the method of analysis used shall, as a minimum, be capable of measuring concentrations equal to the parametric value with a limit of quantification, as defined in point (2) of Article 2 of Commission Directive 2009/90/EC(1), of 30 % or less of the relevant parametric value and an uncertainty of measurement as specified in Table 12. The result shall be expressed using at least the same number of significant figures as for the parametric value listed in Table 11. The uncertainty of measurement laid down in Table 12 shall not be used as an additional tolerance to the parametric values set out in Table 12.

Table 12 Minimum performance characteristic 'Uncertainty of measurement'

Parameter	Uncertainty of measurement (See Note 1) % of the parametric value (except for pH)	Notes
Aluminium	25	
Ammonium	40	
Acrylamide	30	
Antimony	40	
Arsenic	30	
Benzo(a)pyrene	50	Note 2
Benzene	40	
Bisphenol A	50	
Boron	25	
Bromate	40	
Cadmium	25	
Chloride	15	
Chlorate	40	
Chlorite	40	
Chromium	30	
Copper	25	
Cyanide[11]	30	Note 3
1,2-dichloroethane	40	
Epichlorohydrin	30	
Fluoride	20	
HAAs	50	
Hydrogen ion concentration pH	0.2	Note 4
Iron	30	

Parameter	Uncertainty of measurement (See Note 1) % of the parametric value (except for pH)	Notes
Lead	30	
Manganese	30	
Mercury	30	
Microcystin-LR	30	
Nickel	25	
Nitrate	15	
Nitrite	20	
Oxidisability	50	Note 5
Pesticides	30	Note 6
PFAS	50	
Polycyclic aromatic hydrocarbons	40	Note 7
Selenium	40	
Sodium	15	
Sulphate	15	
Tetrachloroethene	40	Note 8
Trichloroethene	40	Note 8
Trihalomethanes – Total	40	Note 7
Total organic carbon (TOC)	30	Note 9
Turbidity	30	Note 10
Uranium	30	
Vinyl Chloride	50	

Notes to Table 12

Note 1: Uncertainty of measurement is a non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used. The performance criterion for measurement uncertainty (k = 2) is the percentage of the parametric value stated in the table or any stricter value. The uncertainty of measurement shall be estimated at the level of the parametric value, unless otherwise specified.

Note 2: If the value of uncertainty of measurement cannot be met, the best available technique should be selected (up to 60 %).

Note 3: The method determines total cyanide in all forms.

Note 4: The value for the uncertainty of measurement is expressed in pH units.

Note 5: Reference method: EN ISO 8467.

Note 6: The performance characteristics for individual pesticides are given as an indication. Values for the uncertainty of measurement as low as 30 % can be achieved for several pesticides, while higher values up to 80 % may be allowed for a number of pesticides.

Note 7: The performance characteristics apply to individual substances, specified at 25 % of the parametric value in Part B of Annex I.

Note 8: The performance characteristics apply to individual substances, specified at 50 % of the parametric value in Part B of Annex I.

Note 9: The uncertainty of measurement should be estimated at the level of 3 mg/l of the total organic carbon (TOC). EN 1484 Guidelines for the determination of TOC and dissolved organic carbon (DOC) shall be used for the specification of the uncertainty of the test method.

Note 10: The uncertainty of measurement should be estimated at the level of 1,0 NTU (nephelometric turbidity units), in accordance with EN ISO 7027 or another equivalent standard method.

Sum of PFAS

The following substances shall be analysed based on the technical guidelines developed in accordance with Article 13(7):

— Perfluorobutanoic acid (PFBA)

— Perfluoropentanoic acid (PFPA)

— Perfluorohexanoic acid (PFHxA)

— Perfluoroheptanoic acid (PFHpA)

— Perfluorooctanoic acid (PFOA)

— Perfluorononanoic acid (PFNA)

— Perfluorodecanoic acid (PFDA)

— Perfluoroundecanoic acid (PFUnDA)

— Perfluorododecanoic acid (PFDoDA)

— Perfluorotridecanoic acid (PFTrDA)

— Perfluorobutane sulfonic acid (PFBS)

— Perfluoropentane sulfonic acid (PFPS)

— Perfluorohexane sulfonic acid (PFHxS)

— Perfluoroheptane sulfonic acid (PFHpS)

— Perfluorooctane sulfonic acid (PFOS)

— Perfluorononane sulfonic acid (PFNS)

— Perfluorodecane sulfonic acid (PFDS)

— Perfluoroundecane sulfonic acid

— Perfluorododecane sulfonic acid

Those substances shall be monitored when the risk assessment and risk management of the catchment areas for abstraction points carried out in accordance with Article 8 conclude that those substances are likely to be present in a given water supply.

Table 13 outlines the list of microbiological parameters for which methods of analysis are specified in Annex III of Directive (EU) 2020/2184

Table 13 Microbiological parameters for which methods of analysis are specified

Parameter	Standard method
Escherichia coli (E. coli)	EN ISO 9308-1:2014 /AMD.1:2016 or EN ISO 9308-2:2012
Enterococci	EN ISO 7899-2:2000
Pseudomonas aeruginosa	EN ISO 16266:2008
Enumeration of culturable microorganisms – colony count 22 °C	EN ISO 6222:1999
Enumeration of culturable microorganisms – colony count 37 °C	EN ISO 6222:1999
Coliform bacteria	ISO 9308-1:2014/AMD.1:2016
Clostridium perfringens (including spores)	EN ISO 14189:2016

Alternative methods may be used providing that it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified. Based on the results of the risk assessment, additional testing may be required where there is reason to suspect that microorganisms may be present.

SECTION 4: RADIOACTIVE SUBSTANCES IN WATER INTENDED FOR HUMAN CONSUMPTION

Council Directive 2013/51/Euratom

Council Directive 2013/51/Euratom supersedes Directive (EU) 2020/2184 as regards the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. The Directive is applicable to spring water and 'other water'; it is not applicable to natural mineral waters. Natural mineral waters are excluded from the scope of this Directive, as Directive 2009/54/EC. covers them

The Directive sets out minimum rules for spring water and 'other waters'; Member States can adopt more stringent measures.

Each Member State should establish monitoring programmes to check that water intended for human consumption meets the requirements of this Directive. However, no monitoring of a specific parameter must be required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of water intended for human consumption in concentrations which could exceed the corresponding parametric value.

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Subject matter		
Article 1	This Directive lays down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. It lays down parametric values and frequencies and methods for monitoring radioactive substances.	*This section is intentionally left blank*

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Definitions		
Article 2(1)	(1) 'water intended for human consumption' means: **(a)** all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, a tanker, or in bottles or containers; **(b)** all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form;	Water intended for human consumption includes spring waters and 'other waters'. Natural mineral waters (NMWs) are exempt. The Directive also includes water used in any food production unless it can be shown that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form; however, this is outside the scope of this Guidance Note.
Article 2(2)	'Radioactive substance' means any substance that contains one or more radionuclides the activity or concentration of which cannot be disregarded as far as radiation protection is concerned;	*This section is intentionally left blank*

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Article 2(3)	'Indicative dose' or 'ID' means the committed effective dose for one year of ingestion resulting from all the radionuclides whose presence has been detected in a supply of water intended for human consumption, of natural and artificial origin, but excluding tritium, potassium-40, radon, and short-lived radon decay products;	*This section is intentionally left blank*
Article 2(4)	(4) 'parametric value' means the value of radioactive substances in water intended for human consumption above which Member States shall assess whether the presence of radioactive substances in water intended for human consumption poses a risk to human health which requires action and, where necessary, shall take remedial action to improve the quality of water to a level which complies with the requirements for the protection of human health from a radiation protection point of view.	*This section is intentionally left blank*
Scope and exemptions		
Article 3(1)	This Directive applies to water intended for human consumption.	The Directive applies to water intended for human consumption; this includes spring waters and 'other waters'. Natural mineral waters and waters which are medicinal products are exempt.
Article 3(2)	This Directive does not apply to: **(a)** natural mineral waters recognised as such by the competent national authorities, in accordance with Directive 2009/54/EC; **(b)** waters which are medicinal products within the meaning of Directive 2001/83/EC.	

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Article 3(3)	Member States may exempt from this Directive: **(a)** water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the general public concerned; **(b)** water intended for human consumption from an individual supply providing on average less than 10 m^3 a day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.	There are no exemptions in Ireland.
Article 3(4)	Member States that have recourse to the exemptions provided for in paragraph 3(b) shall ensure that: **(a)** the general public concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption; **(b)** when a potential danger to human health arising from the quality of such water is apparent, the general public concerned promptly be given appropriate advice.	*This section is intentionally left blank*

SECTION 4: RADIOACTIVE SUBSTANCES IN WATER INTENDED FOR HUMAN CONSUMPTION (CONTINUED)

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
General obligations		
Article 4	Without prejudice to the provisions laid down in point a of Article 6(3) of Directive 96/29/Euratom, Member States shall take all measures necessary to establish an appropriate monitoring programme for water intended for human consumption, to ensure that in the event of non-compliance with the parametric values laid down pursuant to this Directive: **(a)** it shall be assessed whether that poses a risk to human health which requires action and, **(b)** remedial action shall be taken, where necessary, to improve the quality of water to a level which complies with requirements for the protection of human health from a radiation protection point of view.	The Environmental Protection Agency (EPA) used a risk-based approach to conduct a national surveillance monitoring programme of radioactivity in all regulated water supplies serving more than 50 people or with a production volume greater than 10 m^3 per day. This was carried out over a six-year period (2017–2023).
Parametric values and points of compliance		
Article 5(1)	Member States shall set parametric values applicable for the monitoring of radioactive substances in water intended for human consumption in accordance with Annex I.	For Ireland, the parametric values are: • 0.1 mSv/year for ID • 500 Bq/l for radon

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Article 5(2)	Where monitoring of water intended for human consumption is undertaken in accordance with the requirements of Annex II of this Directive the point of compliance shall be: **(a)** in the case of water supplied from a distribution network, the point at which it emerges from the taps where the water is normally taken; **(b)** in the case of water supplied from a tanker, the point at which it emerges from the tanker; **(c)** in the case of water put into bottles or containers intended for sale, the point at which the water is put into the bottles or containers; **(d)** in the case of water used in a food-production undertaking, the point where the water is used in the undertaking.	When monitoring bottled water in accordance with the requirements of Annex II of the Directive, the point of compliance must be the point at which the water is put into the bottles or containers.
Article 5(3)	The definition of points of compliance in paragraph (2)(a) is without prejudice to the choice of a sampling point, which may be any point within the supply zone or at the treatment works provided there is no adverse change in the concentration value between the sampling point and the point of compliance.	*This section is intentionally left blank*

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Monitoring and analysis		
Article 6(1)	Member States shall take all measures necessary to ensure that monitoring for radioactive substances in water intended for human consumption is undertaken in accordance with the monitoring strategies and frequencies set out in Annex II, in order to check whether the values of radioactive substances comply with the parametric values laid down pursuant to Article 5(1). Member States shall ensure that monitoring is undertaken so as to ensure that the measured values obtained are representative of the quality of the water consumed throughout the year. For water intended for human consumption that is put into bottles or containers intended for sale, this shall be without prejudice to the principles of HACCP as required by Regulation (EC) No 852/2004 and to the principles of official controls as laid down in Regulation (EC) No 882/2004.	No monitoring of a specific parameter is required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of water intended for human consumption in concentrations which could exceed the corresponding parametric value.
Article 6(2)	Monitoring for the ID shall be carried out, and analytical performance characteristics shall be in accordance with the requirements set out in Annex III.	*This section is intentionally left blank*
Article 6(3)	Member States shall ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject to checking by an external organisation approved by the competent authority for that purpose.	Laboratories should be accredited to ISO 17025:2017 for the test and the test method.

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Remedial action and notification of the general public		
Article 7(1)	Member States shall ensure that any failure to comply with a parametric value laid down pursuant to Article 5(1) is immediately investigated in order to identify the cause.	The FSAI and the EPA should be contacted if there is a failure to comply with a parametric value. The details should be notified by email to: foodincidents@fsai.ie
Article 7(2)	Where a failure to comply with a parametric value occurs, the Member State shall assess whether the failure poses a risk to human health which requires action.	
Article 7(3)	In the event that such a risk referred to under paragraph 2 exists, the Member State shall: **(a)** take remedial action in order to comply with requirements for the protection of human health from a radiation protection point of view; and **(b)** ensure that the general public concerned is: **(i)** notified of the risk and the remedial action taken; and **(ii)** advised on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.	

Reference	Requirements of Council Directive 2013/51/Euratom	Interpretation
Transposition into national law		
Article 8(1)	Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with this Directive by 28 November 2015 at the latest. They shall forthwith communicate to the Commission the text of those provisions. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.	Not relevant for Guidance Note No. 25.
Article 8(2)	The Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.	Not relevant for Guidance Note No. 25.
Entry into force		
Article 9	This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	Not relevant for Guidance Note No. 25.

ANNEX I – PARAMETRIC VALUES FOR RADON, AND ID OF WATER INTENTED FOR HUMAN CONSUMPTION

Figure 1 Parametric values for radon and ID for water intended for human consumption

Parameter	Parametric value	Unit	Notes
Radon	100	Bq/l	(Note 1)
ID	0,10	mSv	

Note 1:

(a) Member States may set a level for radon which is judged inappropriate to be exceeded and below which optimisation of protection should be continued, without compromising water supply on a national or regional scale. The level set by a Member State may be higher than 100 Bq/l but lower than 1 000 Bq/l. In order to simplify national legislation, Member States may choose to adjust the parametric value to this level.

(b) Remedial action is deemed to be justified on radiological protection grounds, without further consideration, where radon concentrations exceed 1 000 Bq/l.

ANNEX II – MONITORING OF RADIOACTIVE SUBSTANCES

1. General principles and monitoring frequencies	Interpretation
All parameters for which parametric values must be set pursuant with Article 5(1) shall be subject to monitoring. However, no monitoring of a specific parameter shall be required where a competent authority can establish that, for a period of time to be determined by them, that parameter is not likely to be present in a given supply of water intended for human consumption in concentrations which could exceed the corresponding parametric value. In case of naturally occurring radionuclides, where previous results have shown that the concentration of radionuclides is stable, the frequency, in derogation from the minimum sampling requirements set out in point 6, is to be decided by the Member State, taking into consideration the risk to human health. A Member State is not required to monitor water intended for human consumption for radon or tritium or to establish the ID where it is satisfied on the basis of representative surveys, monitoring data or other reliable information that, for a period of time to be determined by them, the levels of radon, tritium or of the calculated ID will remain below the respective parametric values listed in Annex I. In that case, it shall communicate the grounds for its decision to the Commission and provide the Commission with the necessary documentation supporting that decision, including the findings of any surveys, monitoring or investigations carried out. In this context, the provisions with regard to the minimum sampling and analysis requirements set out in point 6 of this Annex do not apply.	*This section is intentionally left blank*

2. Radon	Interpretation
Member States shall ensure that representative surveys are undertaken to determine the scale and nature of likely exposures to radon in water intended for human consumption originating from different types of groundwater sources and wells in different geological areas. The surveys shall be designed in such a way that underlying parameters, and especially the geology and hydrology of the area, radioactivity of rock or soil, and well type, can be identified and used to direct further action to areas of likely high exposure. Monitoring of radon concentrations shall be undertaken where there is reason to believe, on the basis of the results of the representative surveys or other reliable information, that the parametric value laid down pursuant to Article 5(1) might be exceeded.	The EPA last conducted a representative survey in 2021. Annual sampling is now performed on the eight highest producing manufacturers, beginning in 2024. Sampling from all other bottled water manufacturers will take place in subsequent years until 2028, as agreed between the EPA, NEHS and FSAI. Data collated from this period will be analysed by the EPA, NEHS and FSAI, to decide on how the sampling frequencies should continue. .

3. Tritium	Interpretation
Member States shall ensure that monitoring of tritium in water intended for human consumption is carried out where an anthropogenic source of tritium or other artificial radionuclides is present within the catchment area, and it cannot be shown on the basis of other surveillance programmes or investigations that the level of tritium is below the parametric value listed in Annex I. Where monitoring for tritium is required, it shall be carried out at the frequencies indicated in the table appearing in point 6 of this Annex. If the concentration of tritium exceeds its parametric value, an investigation of the presence of other artificial radionuclides shall be required.	The EPA does not routinely monitor for tritium, as there are no significant sources of artificial tritium in water catchments in Ireland.
4. Indicative dose	**Interpretation**
Monitoring of water intended for human consumption for the ID shall be carried out where a source of artificial or elevated natural radioactivity is present and it cannot be shown on the basis of other representative monitoring programmes or other investigations that the level of ID is below the parametric value listed in Annex I. Where monitoring for artificial radionuclide levels is required, it shall be carried out at the frequency indicated in the table appearing in point 6 of this Annex. Where monitoring for natural radionuclide levels is required, each Member State shall define the frequency of the monitoring of either gross alpha activity, gross beta activity or individual natural radionuclides depending on the screening strategy adopted by it (according to Annex III). The monitoring frequency may vary from a single check measurement to the frequencies indicated in the table appearing in point 6 of this Annex. Where only a single check for natural radioactivity is required, a recheck shall be required at least where any change occurs in relation to the supply likely to influence the concentrations of radionuclides in water intended for human consumption.	Monitoring of drinking water supplies for tritium or artificially occurring radionuclides in supplies is not required at this time as there are currently no significant sources of tritium or artificial radioactivity in the catchments of Irish drinking water supplies.
5. Water treatment	**Interpretation**
Where treatment to reduce the level of radionuclides in water intended for human consumption has been taken, monitoring shall be carried out at the frequencies indicated in the table appearing in point 6 to ensure the continued efficacy of that treatment.	This would be valid for water supplies with a radon problem.

6. Minimum sampling and analysis frequencies	
The minimum sampling and analysis frequency for the monitoring of water intended for human consumption supplied from a distribution network or from a tanker or used in a food production undertaking shall be as set out in Figure 2.	*This section is intentionally left blank*

Figure 2 Minimum sampling and analysis frequencies for monitoring of water intended for human consumption supplied from a distribution network or from a tanker or used in a food production undertaking

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m^3	Number of samples per year (Notes 3 and 4)
volume ≤ 100	(Note 5)
100 < volume ≤ 1 000	1
1 000 < volume ≤ 10 000	1 +1 for each 3 300 m^3/d and part thereof of the total volume
10 000 < volume ≤ 100 000	3 +1 for each 10 000 m^3/d and part thereof of the total volume
volume > 100 000	10 +1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200l/ day/capita.

Note 3: As far as possible, the number of samples should be distributed equally in time and location.

Note 4: In the event of intermittent short-term supply, the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned.

Note 5: The frequency is to be decided by the Member State concerned.

Member States shall define sampling frequencies for water intended for human consumption put into bottles or containers intended for sale. In so doing Member States may take into consideration the volume of water produced.

7. Averaging	
Where a parametric value is exceeded in a particular sample, Member States shall define the extent of resampling necessary to ensure that the measured values are representative of an average activity concentration for a full year.	*This section is intentionally left blank*

ANNEX III – MONITORING FOR INDICATIVE DOSE AND ANALYTICAL PERFORMANCE CHARACTERISTICS

1. Monitoring is for compliance with the ID	Interpretation
Member States may use various reliable screening strategies to indicate the presence of radioactivity in water intended for human consumption. These strategies may include screening for certain radionuclides, or screening for an individual radionuclide, or gross alpha activity or gross beta activity screening. **(a)** screening for certain radionuclides, or screening for an individual radionuclide If one of the activity concentrations exceeds 20% of the corresponding derived value or the tritium concentration exceeds its parametric value listed in Annex I, an analysis of additional radionuclides shall be required. The radionuclides to be measured shall be defined by Member States taking into account all relevant information about likely sources of radioactivity. **(b)** screening strategies for gross alpha activity and gross beta activity Member States may use screening strategies for gross alpha activity and gross beta activity (2) where appropriate gross beta activity may be replaced by residual beta activity after subtraction of the K-40 activity concentration. to monitor for the parametric indicator value for ID. For this purpose, gross alpha activity or gross beta activity screening levels shall be set. The recommended screening level for gross alpha activity is 0,1 Bq/l. The recommended screening level for gross beta activity is 1,0 Bq/l. If the gross alpha activity and gross beta activity are less than 0,1 Bq/l and 1,0 Bq/l respectively, the Member State may assume that the ID is less than the parametric value of 0,1 mSv and radiological investigation is not needed unless it is known from other sources of information that specific radionuclides are present in the water that are liable to cause an ID in excess of 0,1 mSv. If the gross alpha activity exceeds 0,1 Bq/l or the gross beta activity exceeds 1,0 Bq/l, analysis for specific radionuclides shall be required. Member States may set alternative screening levels for gross alpha activity and gross beta activity where they can demonstrate that the alternative levels are in compliance with an ID of 0,1 mSv. The radionuclides to be measured shall be defined by Member States taking into account all relevant information about likely sources of radioactivity. Since elevated levels of tritium may indicate the presence of other artificial radionuclides, tritium, gross alpha activity, and gross beta activity should be measured in the same sample. (1) Where appropriate gross beta activity may be replaced by residual beta activity after subtraction of the K-40 activity concentration.	This is valid for monitoring for compliance, but only for naturally occurring radioactivity.

2. Calculation of the ID	
The ID shall be calculated from the measured radionuclide concentrations and the dose coefficients laid down in Annex III, Table A of Directive 96/29/Euratom or more recent information recognised by the competent authorities in the Member State, on the basis of the annual intake of water (730 l for adults). Where the following formula is satisfied, Member States may assume that the ID is less than the parametric value of 0,1 mSv and no further investigation shall be required: $\sum_{i=1}^{n} \frac{C_i\,(obs)}{Ci\,(der)} \leq 1$ where $C_i\,(obs)$ = observed concentration of radionuclide i $C_i\,(der)$ = derived concentration of radionuclide i n = number of radionuclides detected.	

Figure 3 Derived concentrations for radioactivity in water intended for human consumption ([1])

Origin	Nuclide	Derived concentration
Natural	U-238 ([2])	3,0 Bq/l
	U-234 ([2])	2,8 Bq/l
	Ra-226	0,5 Bq/l
	Ra-228	0,2 Bq/l
	Pb-210	0,2 Bq/l
	Po-210	0,1 Bq/l
Artificial	C-14	240 Bq/l
	Sr-90	4,9 Bq/l
	Pu-239/Pu-240	0,6 Bq/l
	Am-241	0,7 Bq/l
	Co-60	40 Bq/l
	Cs-134	7,2 Bq/l
	Cs-137	11 Bq/l
	I-131	6,2 Bq/l

([1]) This table includes values for the most common natural and artificial radionuclides; these are precise values, calculated for a dose of 0,1 mSv, an annual intake of 730 litre and using the dose coefficients laid down in Annex III, Table A of Directive 96/29/Euratom; derived concentrations for other radionuclides can be calculated on the same basis, and values can be updated on the basis of more recent information recognised by the competent authorities in the Member State.

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

Figure 4 Performance characteristics and methods of analysis

For the following parameters and radionuclides, the method of analysis used must, as a minimum, be capable of measuring activity concentrations with a limit of detection specified below:

	Parameters and radionuclides	Limit of detection (Notes 1, 2)	Notes
	Radon	10Bq/l	Note 3
	Gross alpha activity Gross beta activity	0,04 Bq/l 0,4 Bq/l	Note 4 Note 4
	U-238	0,02 Bq/l	
	U-234	0,02 Bq/l	

	Parameters and radionuclides	Limit of detection (Notes 1, 2)	Notes
	Ra-226	0.04 Bq/l	
	Ra-228	0.02 Bq/l	Note 5
	Pb-210	0.02 Bq/l	
	Po-210	0.01 Bq/l	
	C-14	20 Bq/l	
	Sr-90	0,4 Bq/l	
	Pu-239/Pu-240	0,04 Bq/l	
	Am-241	0,06 Bq/l	
	Co-60	0,5 Bq/l	
	Cs-134	0,5 Bq/l	
	Cs-137	0,5 Bq/l	
	I-131	0,5 Bq/l	

Note 1: The limit of detection shall be calculated according to the ISO standard 11929: Determination of the characteristic limits (decision threshold, detection limit and limits of the confidence interval) for measurements of ionising radiation – Fundamentals and application, with probabilities of errors of 1st and 2nd kind of 0,05 each.

Note 2: Measurement uncertainties shall be calculated and reported as complete standard uncertainties, or as expanded standard uncertainties with an expansion factor of 1,96, according to the ISO Guide for the Expression of Uncertainty in Measurement. Note 3: The limit of detection for radon is 10% of its parametric value of 500 Bq/l.

Note 4: The limit if detection for gross alpha activity and gross beta activities are 40% of the screening values of 0,1 and 1,0 Bq/l respectively.

Note 5: This limit of detection applies only to initial screening for ID for a new water source; if initial checking indicates that it is not plausible that Ra-228 exceeds 20% of the derived concentration, the limit of detection may be increased to 0,08 Bq/l for routine Ra-228 nuclide specific measurements, until a subsequent re-check is required.

APPENDIX I: LABELLING OF BOTTLED WATER AND EXAMPLES OF LABELS FOR NATURAL MINERAL WATER, SPRING WATER AND OTHER WATER

Mandatory labelling information

Bottled waters must comply with the requirements set out in Regulation (EU) No 1169/2011 on the provision of food information to consumers for pre-packed foods on sale in Ireland. The following mandatory information must appear directly on the package or on an attached label:

1. The name of the food*
2. The list of ingredients (not applicable)
3. Any ingredient or processing aid listed in Annex II of food information to consumers or derived from a substance or product listed in Annex II of Regulation (EU) No 1169/2011 causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form (not applicable)
4. The quantity of certain ingredients or categories of ingredients
5. The net quantity of the food*
6. The date of minimum durability
7. Any special storage conditions and/or conditions of use
8. The name or business name and address of the FBO
9. The country of origin or place of provenance where its absence may mislead the consumer as to the true origin or provenance of the food or where the country of origin is specifically required under legislation
10. Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions (not applicable)
11. With respect to beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume (not applicable)
12. A nutrition declaration (see details below).

*Must appear in the same field of vision

Nutrition declarations for bottled waters

Article 29 of Regulation (EU) No 1169/2011 on the provision of food information to consumers states that the nutrition declaration requirement does not apply to Directive 2009/54/EC on the exploitation and marketing of natural mineral waters. Annex V of Regulation (EU) No 1169/2011 lists foods which are exempted from the requirement of the mandatory nutrition declaration, and included in this list are waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings.

APPENDIX I: LABELLING OF BOTTLED WATER AND EXAMPLES OF LABELS FOR NATURAL MINERAL WATER, SPRING WATER AND OTHER WATER PRODUCTS (CONTINUED)

As per Annex I of Regulation (EU) No 1169/2011, 'nutrition declaration' or 'nutrition labelling' means information stating the:

(a) Energy value; or

(b) Energy value and one or more of the following nutrients only:

- fat (saturates, monounsaturates, polyunsaturates),
- carbohydrate (sugars, polyols, starch),
- salt,
- fibre,
- protein,
- any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII.

'Other waters' which are not covered by Directive 2009/54/EC are exempt from mandatory nutrition labelling under Annex V of Regulation (EU) No 1169/2011. However, if a company voluntarily provides information on the presence of minerals on these products, then the products are subject to mandatory nutrition labelling and must comply with Section 3 of Regulation (EU) No 1169/2011.

As stated in Annex I, vitamins and minerals defined in point 2 of Part A of Annex XIII must be present in significant amounts before they can be included in the nutrition declaration. Significant amounts are defined as follows in Annex XIII:

Significant number of vitamins and minerals

As a rule, the following values should be taken into consideration in deciding what constitutes a significant amount:

- 15% of the nutrient reference values specified in point 1 supplied by 100 g or 100 ml in the case of products other than beverages,
- 7.5% of the nutrient reference values specified in point 1 supplied by 100 ml in the case of beverages, or,
- 15% of the nutrient reference values specified in point 1 per portion if the package contains only a single portion.

If a company chooses to provide information on minerals for 'other water' labels, it can only do this if the minerals are present in significant amounts. A full nutrition declaration per 100 ml will be required in the following order to meet mandatory requirements:

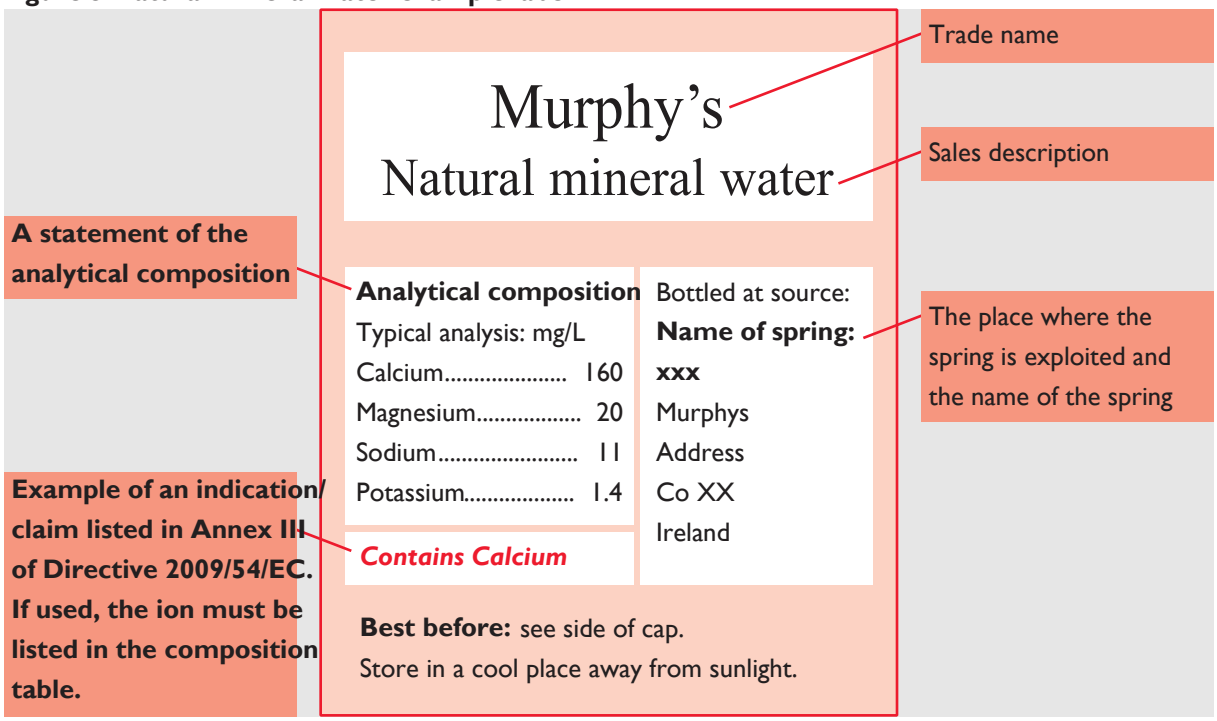
- Energy (kJ/kcal)
- Fat (g)
- Saturates (g)
- Carbohydrate (g)
- Sugars (g)
- Protein (g)

- Salt (g)
- Vitamins and minerals (units specified in Annex XIII).

In cases where the energy value or the amount of nutrient(s) in a product is negligible, the information on those elements may be replaced by a statement such as 'Contains negligible amounts of…' and must be indicated in close proximity to the nutrition declaration when present. This could be applied to the main nutrients if present in negligible amounts (energy, fat, saturates, carbohydrate, sugars, protein, salt).

In summary, if a company wishes to provide information on the label of bottled waters (other than natural mineral waters) about the mineral content, then it will have to comply with Regulation (EU) No 1169/2011 and provide full nutrition information. Figures 5, 6 and 7 provide examples of natural mineral water, spring water and other water labels.

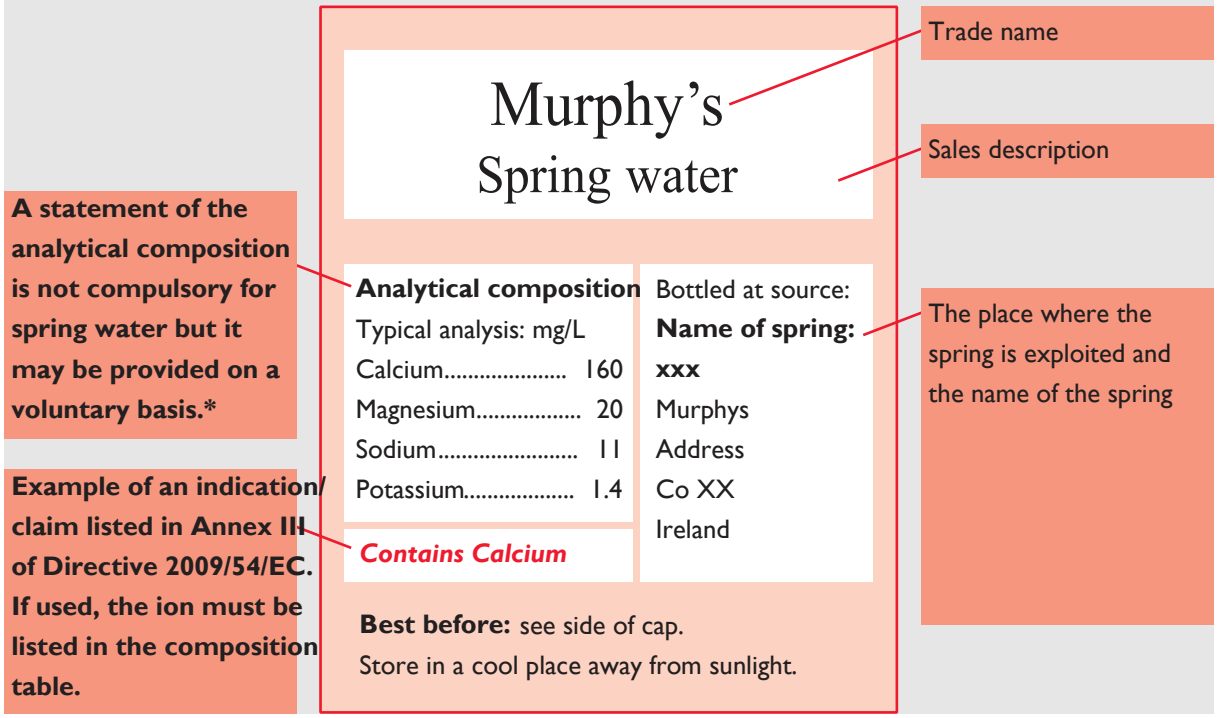
Figure 5 Natural mineral water example label



Additional information that may be required on the label:

- Natural mineral waters with a **fluoride concentration exceeding 1.5 mg/l** must bear on the label the words 'contains more than 1.5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. This information must be placed in immediate proximity to the trade name and in clearly visible characters. If the water fluoride concentration exceeds 1.5 mg/l, then the actual fluoride content should be indicated on the label.
- Natural mineral waters treated with **ozone-enriched air** must bear, in proximity to the analytical composition of characteristic constituents, the words **'water subjected to an authorised ozone-enriched air oxidation technique'.**
- The label on water which has been the subject of a fluoride removal treatment must include, in proximity to the statement of the analytical composition, the indication **'water subjected to an authorised adsorption technique'.**
- When the labels or inscriptions on the containers in which the natural mineral water is offered for sale include a trade description different from the name of the spring or the place of its exploitation, that place of exploitation or the name of the spring must be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.
- All indications attributing to a natural mineral waters properties relating to the prevention, treatment or cure of a human illness must be prohibited.

Figure 6 Spring water example label

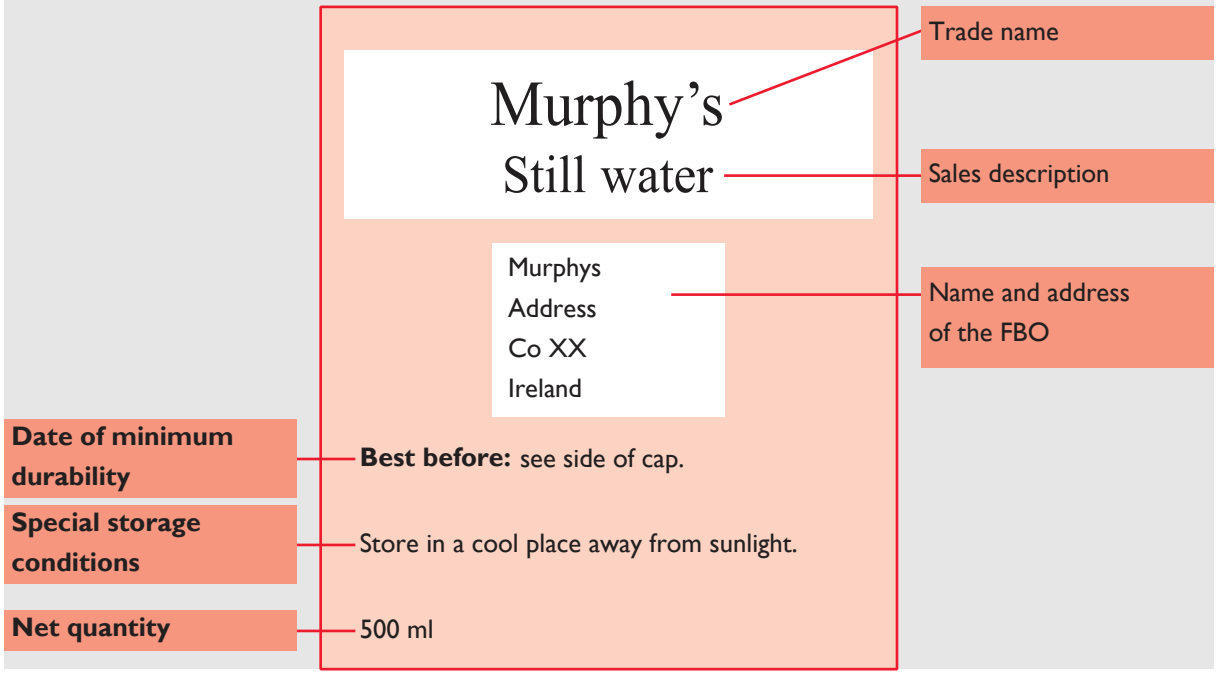


* It is permitted to provide an analytical composition table on the label of spring water. FBOs that choose to provide an analytical composition table for spring waters do not have to provide additional nutrition information (Article 29 of Regulation (EU) No 1169/2011 on the provision of food information to consumers), as they fall within the scope of Directive 2009/54/EC. **Additional information that may be required on the label:**

- Spring waters with a **fluoride concentration exceeding 1.5 mg/L** must bear on the label the words 'contains more than 1.5 mg/L of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. This information must be placed in immediate proximity to the trade name and in clearly visible characters. If the water fluoride concentration exceeds 1.5 mg/L, then the actual fluoride content should be indicated on the label.
- The labelling of spring waters which have been treated with **ozone-enriched air** must bear, in proximity to the analytical composition of characteristic constituents, the words 'water subjected to an authorised ozone-enriched air oxidation technique'. The use of a fluoride removal treatment should be indicated on the label of treated water. The label on water which has been the subject of a fluoride removal treatment must include, in proximity to the statement of the analytical composition, the indication **'water subjected to an authorised adsorption technique'.**

- Natural mineral waters, spring waters and 'other waters' are covered by Regulation (EC) No 1924/2006. The Regulation applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation, or advertising of foods to be delivered as such to the final consumer. If a FBO makes a nutrition claim, then it is subject to Regulation (EC) No 1924/2006 and must be able to substantiate the claim being made.
- If a nutrition claim is made, it is mandatory to provide nutrition information in the prescribed format set out in Regulation (EU) No 1169/2011 on the provision of food information to consumers.

Figure 7 'Other water' example label



The source of the water is not mandatory for other waters and there are no additional labelling requirements if 'other waters' have undergone any treatment.

Annex V of Regulation (EU) No 1169/2011 states that "waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings" are exempt from the requirement to provide a nutrition declaration. If a FBO wishes to voluntarily provide nutrition information on the label of 'other waters', then it must appear in the prescribed format set out in Regulation (EU) No 1169/2011.

Nutrition and health claims may also be made on 'other waters', where they comply with the requirements of Regulation (EC) No 1924/2006 and provided that the general conditions on fair information practices set out in Regulation (EU) No 1169/2011 are complied with. In particular, food information should not be misleading by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, e.g. a claim that a water is fat free would not be permitted. When a nutrition or health claim is made, a nutrition declaration set out in the Regulation (EU) No 1169/2011 is mandatory.

APPENDIX II: PROTECTION OF THE WELLHEAD/BOREHOLE

Wellhead and borehole protection

The wellhead is the part of the borehole that is visible at the surface. Adequate protection is required in order to prevent against possible contamination of the source. Section 4 of the EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection outlines the recommendations for wellhead design. The same information is applicable for boreholes used for spring water or natural mineral waters.

As a general rule, a well should be located upslope and as far away as possible from potential sources of pollution. The safe distance depends on a number of interrelated factors, including the nature of the subsoil, the depth to the water table, the slope of the land, the rate of pumping, the size of the pollution source and its distance from the well. The guidance document Water Well Construction is available from the Institute of Geologists of Ireland (IGI); Section 1, Table 1 of the document sets out the recommended distance of a private well from likely pollution sources. Examples of likely pollution sources are provided and include farmyards, silage pits, public or animal access points, septic tank systems, public sewer pipes, railway tracks and oil tanks.

The wellhead should contain a weather and vermin proof, detachable prefabricated metal shed or kiosk that is bolted onto a concrete slab. The shed should be detachable if unbolted in order to provide unrestricted access to the wellhead. Alternatively, if a block shed is to be constructed it must also be vermin proof, but it is advisable to ensure that unrestricted access to the wellhead can be gained for maintenance purposes. Information on what should be checked in relation to wellhead and borehole construction can be found in Section 5 and Appendix 1 of the EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection.

Construction of the borehole

The borehole should be designed by a competent hydrogeologist/groundwater engineer, based on the encountered hydrogeological conditions, in accordance with the EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection and the IGI's Water Well Construction guidelines.

A hydrogeologist/groundwater engineer should supervise the construction of the borehole. The borehole construction details should be recorded (borehole logs/drilling records) and kept on file.

A water well-grade PVC pump chamber casing is required to extend from the surface to a sufficient depth in order to seal off shallow groundwater in the subsoil and upper bedrock in accordance with Section 3 of the EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection. This prevents shallower groundwater, which is more susceptible to pollution, from being pulled into the borehole.

The construction of an adequate wellhead and annular seal is critical to the protection of the borehole.

The gap between the casing and the inside of the bored well should be completely sealed with the injection of cement grout (in accordance with Section 3.1.2 of EPA Advice Note No. 14) from the bottom up in order to reduce the potential for contamination by shallow groundwater. This is known as the annular seal. Details on the depth and location of the annular seal should be recorded on the borehole log.

The pump should be installed with the pump intake located above the bottom of the pump chamber casing.

A concrete pad a minimum of 150 mm thick should be installed around the top of the casing and extend for a distance of 500 mm in all directions from the casing. The top of the pump chamber casing should be sealed and extend at least 500 mm above the top of the concrete pad surrounding the casing.

Any exploration boreholes drilled on site during the investigation phase should be backfilled and grouted up or completed with appropriate wellhead protection if they are being retained for possible future use or monitoring purposes. This is required in order to prevent any inadequately protected boreholes from acting as conduits for entry of contaminants into the groundwater.

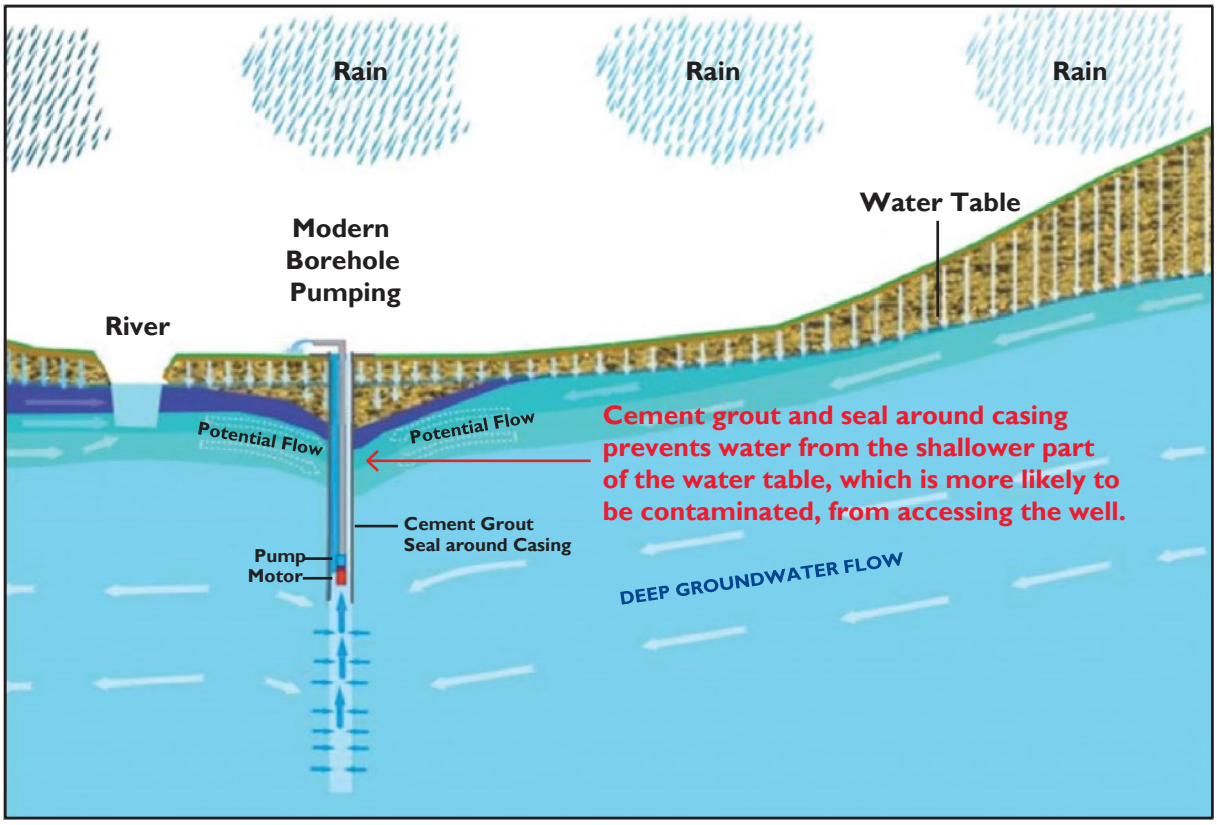
A tap should be provided at the wellhead for monitoring of the raw water quality.

Further information on proper borehole construction and well lining specifications can be found in the following documents:

1. EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection.
2. IGI's Water Well Construction guidelines

Figure 8 illustrates a modern borehole pumping system.

Figure 8 Image adapted from EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection, courtesy of the Irish Environmental Protection Agency



Protection of the water source through effective catchment management

The EPA Drinking Water Advice Note No. 7: Source Protection and Catchment Management to Protect Groundwater Supplies summarises six steps that should be undertaken for effective catchment management:

1. Define the source protection zones

(a) The spring or outlet must be protected against the risks of pollution.

There are a number of ways of protecting the spring or outlet against the risks of pollution, such as improved well location, design, construction, and management of potential contamination sources.

It is important to emphasise that it is not just the outlet from the spring that needs to be protected from pollution, but all of the land area supplying groundwater to the well. This area is known as the catchment area or the zone of contribution (ZOC). The ZOC itself is made up of both an inner and outer protection zone. The first thing a FBO should do is identify, define, and map out these areas. For more information on how to do this, see Geological Survey Ireland: Geological Mapping. As much of the catchment area/ZOC that is possible to access should be included in the HSE food safety inspection of the establishment.

The ZOC/catchment area must be defined in order to identify the source protection zone for the water supply. The FSAI recommends that both the inner and outer zones of the ZOC be defined by a competent hydrogeologist, taking into account the site-specific conditions.

The following data will usually be required to establish source protection zones:

- Water levels and groundwater gradients near the sources
- Pumping test data for wells and/or flow measurements for springs
- Vulnerability maps for the ZOC.

The inner protection zone

The inner protection zone is the immediate area surrounding the well/source. The purpose of managing this area is to protect against the risks associated with direct contamination of the well from human, animal, industrial and agricultural sources and in particular against microbial pollution. The area is defined by a 100 day travel time from any point below the water table to the abstraction source. Factors which may affect the size of the inner protection zone are as follows:

- Bedrock/aquifer permeability
- Direction of groundwater flow
- Groundwater velocity
- Other factors identified during a risk analysis (e.g. karst features).

Wells placed in vulnerable geological areas such as karst aquifers, where surface water may more readily access the zone, may require larger inner protection zones.

The outer protection zone

The outer protection zone covers the rest of the area outside the inner protection zone that contributes to the supply of the well (also referred to as the ZOC). It is defined as the total area which resupplies the well abstraction point with water.

In order to define the outer protection zone, a FBO will need information on the following:

- The rate at which groundwater is abstracted from the well (including a margin of safety)
- The rate at which the groundwater to the well is recharged
- The direction in which the groundwater flows.

2. Hazard mapping

After defining the ZOC, a FBO should perform a hazard analysis in order to identify potential threats within the ZOC. Examples of potential threats include:

- Farmyards (e.g. run-off)
- Wastewater treatment systems (e.g. domestic/industrial septic tanks)
- Land spreading (e.g. slurry)
- Fuel storage tanks
- Municipal dumps
- Dry cleaners and laundries
- Cemeteries

- Pharmaceutical plants (e.g. discharges containing residual hormones/chemicals)
- Landfills (e.g. seeping into groundwater)
- Waste products (crushed waste, building materials, etc.)
- Storm drains
- Hospitals
- Fuel/oil from vehicles
- The use of herbicides and pesticides in the ZOC
- Additional exploration of boreholes within catchment areas
- Increased flooding due to climate change, particularly for shallow wells.

Note: Copies of the hazard analysis should be maintained as long as the well is in production.

3. Identify the pathways

Soil permeability and recharge type can also contribute to well vulnerability. Technical specifications for the assessment of pathway factors can be found in Geological Survey Ireland's Groundwater Protection Schemes, published by the Department of the Environment and Local Government, the Environmental Protection Agency, and Geological Survey Ireland, and should be followed where relevant. In order to take into account, the vertical movement of potential contaminants from the land surface to the water table, an assessment of the groundwater's potential vulnerability to contamination should be undertaken. The inner and outer protection zones are then overlain on the vulnerability maps in accordance with the methodology outlined in the Department of the Environment and Local Government, the Environmental Protection Agency, and Geological Survey Ireland publication, Groundwater Protection Schemes. This will assist the FBO in the monitoring of potentially polluting activities within the ZOC by identifying areas where the groundwater is at a greater risk of being affected by potentially polluting activities.

If the borehole and wellhead have not been constructed in accordance with best practice as outlined in the EPA Drinking Water Advice Note No. 14: Borehole Construction and Wellhead Protection, then there is the potential for direct surface water access to the groundwater in the immediate vicinity of the borehole.

4. Identify the vulnerability of the receptor

The receptor is defined as the area around the borehole that is receiving groundwater. The following factors should be taken into consideration when assessing the vulnerability of the receptor:

- Whether the borehole's open section is located in the shallower or deeper regions of the water table
- Details on how the water is extracted from the source
- Existing relevant water quality data
- Details on borehole construction, logs, and wellhead protection.

5. Risk assessment

The above steps should be combined into a risk assessment. Any hazards identified should be recorded along with details of how likely they are to occur and the severity of the consequences. The assessment should determine whether a source is suitable for water abstraction and bottling or conclude whether

suitability could be achieved if certain control measures were put in place. For more information, see Appendix III on risk assessment and management.

6. Control measures

Any hazards identified should be given a relative risk score based on estimating the likelihood of an occurrence of the hazard and the severity of the outcome. The FBO should then introduce control measures on a prioritised basis for any hazards identified during the risk assessment and mapping. Records should be kept on site for as long as the well is in production.

Further advice on measures to protect well sources and their catchment areas from contamination can be found in the EPA Drinking Water Advice Note No. 7: Source Protection and Catchment Management to Protect Groundwater Supplies.

Module 4 in the World Health Organization's Water Safety Plan Manual outlines how to implement control measures in order to minimise the risk from identified hazards.

7. Pesticides

Using pesticides or fertilisers near wells or vulnerable zones

The use of pesticides must only be carried out by person(s) registered according to the conditions outlined in S.I. No. 155 of 2012 – European Communities (Sustainable Use of Pesticides) Regulations 2012, as amended. S.I. No. 155 of 2012, as amended, sets out minimum safe distances for the usage of pesticides near water abstraction points intended for human consumption. Minimum safe distances are set out based on production volume and the number of people the well is supplying. The S.I. also prohibits the usage of any pesticides within 50 m of a landscape feature that is known to be a groundwater-vulnerable area, including karst areas, sinkholes, and collapse features.

The S.I. sets out a minimum distance of 200m for usage of pesticides near the abstraction point of any surface water, borehole, spring or well used for the abstraction of water for human consumption in a water scheme supplying 100m^3 or more per day or serving 500 or more persons.

S.I. No. 113 of 2022- European Union (Good Agricultural Practice for the Protection of Waters) Regulations 2022, as amended, sets out minimum safe distances for the usage of organic fertiliser near water abstraction points intended for human consumption. Minimum safe distances are set out based on production volume and the number of people the well is supplying. The S.I. also prohibits the usage of any organic fertiliser within 15 m of a landscape feature that is known to be a groundwater-vulnerable area, including karst areas, sinkholes, and collapse features. Article 17(1) states that chemical fertilisers must not be applied to land within 2 m of any surface waters.

For example, the S.I. sets out a minimum distance of 200 m for usage of organic fertilisers near the abstraction point of any surface water, borehole, spring or well used for the abstraction of water for human consumption in a water scheme supplying 100 m^3 or more per day or serving 500 or more persons.

Pesticide monitoring

Each FBO should risk-assess its own source, checking for the use of pesticides in the ZOC, paying particular attention to any activities in areas of extreme vulnerability, for example, in areas of exposed bedrock or features such as swallow holes.

Any pesticide compounds found to be in use in the ZOC should be analysed using a screening/baseline monitoring programme undertaken during the season of use of the pesticide in question.

It is recommended that monitoring of the baseline suite of parameters is undertaken at least annually, within the season/period of use. The FBO should seek up-to-date advice from the Department of Agriculture,

Food, and the Marine (DAFM) as to the most appropriate screening suite in light of current land use practices within the ZOC.

The FBO should have a plan in place for escalated monitoring in the event that any levels are measured above the limit of detection.

Pesticides used in Ireland

Uisce Éireann, in consultation with the Department of Agriculture, Food and the Marine, has identified 21 pesticides commonly used in Ireland, which are listed in Table 14.

Table 14 List of Pesticides commonly used in Ireland

1	2,4-D	Herbicide
2	Atrazine	Herbicide
3	Bentazone	Herbicide
4	Chlorfenvinphos	Acaricide Insecticide
5	Clopyralid	Herbicide
6	Cypermethrin	Agaricide Insecticide
7	Dichlobenil	Herbicide
8	Dichlorprop	Herbicide
9	Diflufenican	Herbicide
10	Diuron	Algicide Herbicide
11	Glyphosate	Herbicide
12	Isoproturon	Algicide Herbicide
13	Linuron	Herbicide
14	MCPA	Herbicide
15	MCPP (Mecoprop)	Herbicide
16	Metaldehyde	Molluscicide
17	Pendimethalin	Herbicide
18	Propyzamide	Herbicide
19	Simazine	Algicide Herbicide
20	2,3,6-Trichlorobenzoic acid	Herbicide
21	Triclopyr	Herbicide

Uisce Éireann, also monitor for an additional 12 active substances which are listed below

1	2,4-DB
2	Boscalid
3	Chlorotoluron
4	Chlorpropham
5	Diazinon
6	Dicamba
7	Dieldrin
8	Epoxiconazole
9	Fluroxypyr
10	Metazachlor
11	Pentachlorophenol (PCP)
12	Picloram

8. Biofilms

Formation of biofilms

Biofilms are composed of viable and non-viable microorganisms which become embedded together and stick to surfaces by producing polyanionic extracellular polymeric substances (EPS). These EPSs are primarily composed of polysaccharides, as well as other microbially derived compounds such as proteins and nucleic acids. Biofilms can attach and develop on any surface; however, they typically prefer rough or jagged surfaces, as these protect the bacteria from removal via shear force. The rate at which biofilms develop can vary between different material and surface types, for example, iron or plastic, and smooth or rough surfaces. While seasonal changes such as temperature can affect biofilm growth, these changes more often affect the dominant species found in the biofilm rather than inhibiting/ encouraging its growth.

Biofilms grow slowly, but once formed they can be a persistent cause of contamination in drinking water systems. For example, in drinking water systems, only 5% of bacteria are in the 'water phase'; the other 95% are attached to the surrounding surfaces. Biofilms are problematic in drinking water systems, as they can harbour pathogens and the EPS they produce can lead to protection against disinfectants such as chlorine.

Groundwater systems, particularly those found in pristine natural mineral water and spring water systems, are oligotrophic, i.e. these are areas that have high oxygen concentrations and low concentrations of nutrients required for microscopic plant growth. Biofilms grow particularly slowly under these conditions, given the low availability of food sources for bacteria. However, a contamination event may introduce nutrient compounds (e.g. nitrogen) that can accelerate the growth of biofilms.

Indicators of a biofilm build-up

The presence of a biofilm can be indicated by deteriorations in overall water quality. This includes deteriorations in the taste, appearance, odour, and chemical composition of the water. The presence of a slime coating on the pump surfaces and reductions in pump yield or efficiency are also indicators of biofilm development.

Food safety issues with biofilms

Bacteria, viruses, and parasites such as *Cryptosporidium* can become trapped in biofilms. While viruses and *Cryptosporidium* cannot grow in biofilms, they can attach to biofilms after a contamination event and then be released regularly into the water supply. Therefore, it is important that a well is cleaned in the event of a biofilm build-up. *Pseudomonas aeruginosa* is an opportunistic pathogen and is associated with hospital-acquired infections in individuals that are profoundly immunocompromised. *P. aeruginosa* is commonly found in soil and water and has adapted to live in oligotrophic environments. *P. aeruginosa* is also capable of forming biofilms with other microorganisms. Groundwater temperatures (approximately 15 °C) in Ireland are typically too low for *P. aeruginosa* growth (the growth range is 25–42 °C; optimum growth temperature is 37 °C); however, the organism can survive in temperatures as low as 4 °C, particularly when in a biofilm.

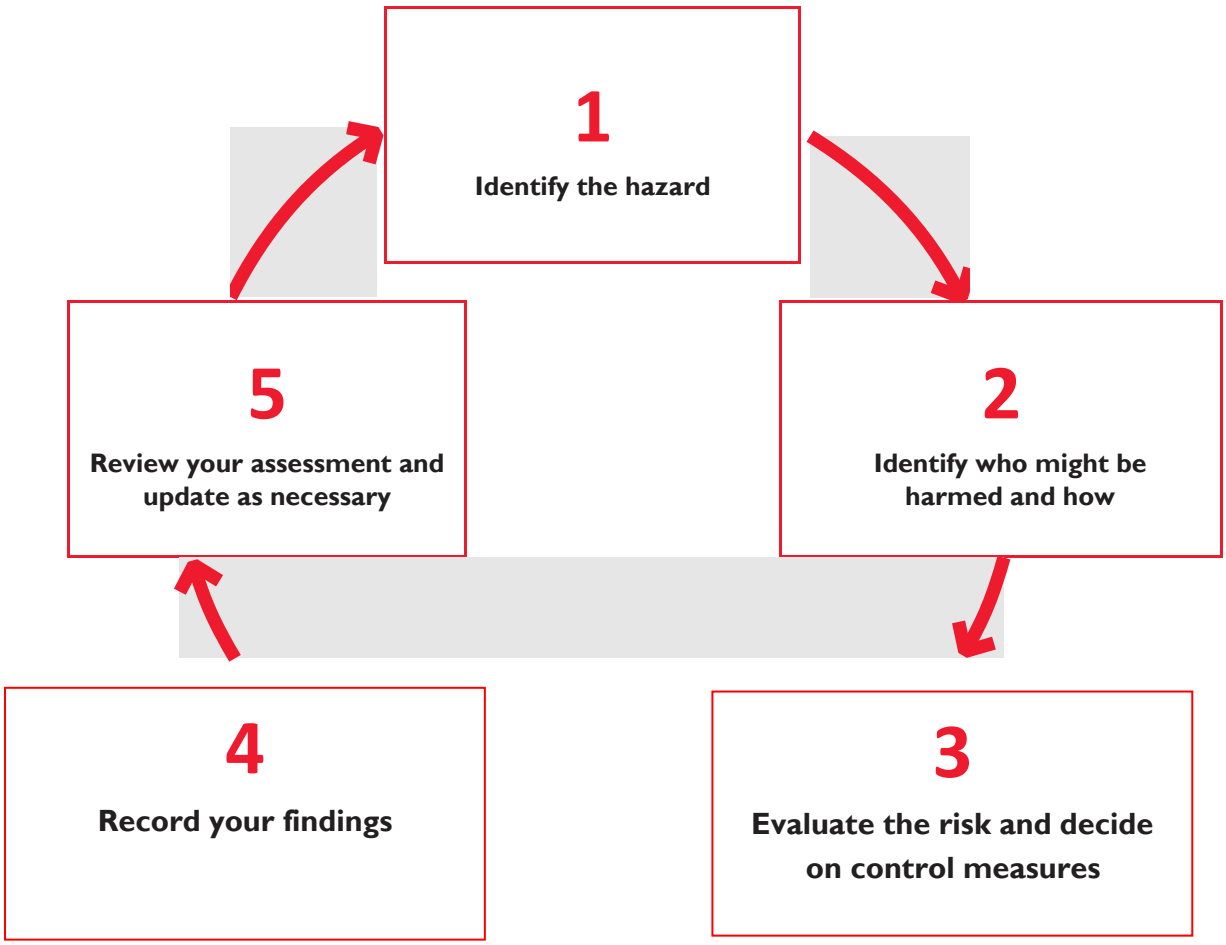
9. Heavy Metals

Heavy metal contamination in ground water typically originates from industrial contamination or due to the concentration of naturally occurring heavy metals in the environment. For example, rock types such as 'sandstone' are naturally high in metals such as arsenic. If a food business is abstracting water at rates of abstraction exceeding rates of groundwater recharge, and the groundwater level in the well drops to low levels, this can concentrate the heavy metals within the well to non-complaint levels. Additionally, if the pump is agitating the silt and rock at the bottom abstraction of the well, this can cause heavy metals to be released.

APPENDIX III: ADDITIONAL INFORMATION FOR RISK ASSESSMENT AND RISK MANAGEMENT

Performing a risk assessment consists of the five following steps as Figure 9 shows:

Figure 9 Steps involved in a risk assessment



A hazard can be any biological, chemical, or physical agent capable of causing adverse health effects (harm).

Risk = the probability or likelihood of the hazard occurring × the severity of the hazard's effect.

Module 3 in the World Health Organization's *Water Safety Plan Manual* outlines how to score potential hazards for their level of risk using risk matrices. An example of using risk scoring matrices can be found on page 32 of the manual. The steps involved in risk scoring are illustrated in Figure 10.

Figure 10 Steps involved in risk scoring

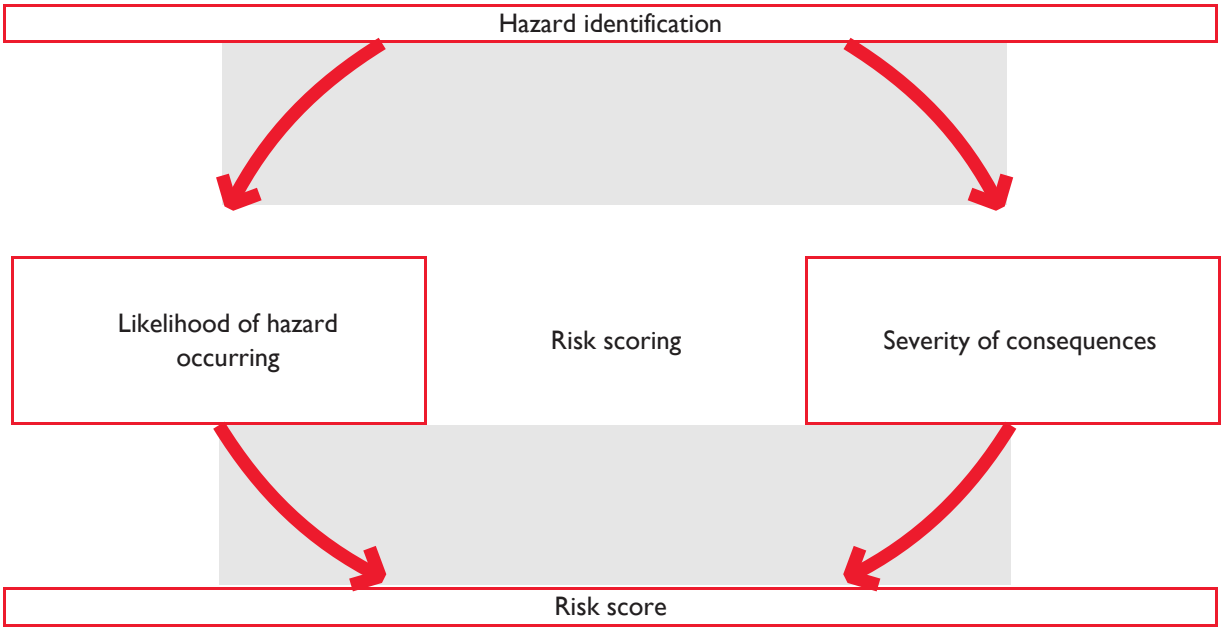


Table 15 Semi-quantitative risk matrix approach adapted from (Deere et al., 2001) World Health Organization's Water Safety Plan Manual

	Severity of consequence			
Likelihood of frequency	**Insignificant or no impact – rating 1**	**Moderate aesthetic impact – rating 2**	**Minor noncompliance – rating 3**	**Major noncompliance/ public health impact – rating 4**
Almost certain – once a day – rating 5	4	8	12	16
Moderate – once a month – rating 3	3	6	9	12
Unlikely – once a year – rating 2	2	4	6	8
Rare – once every 5 years – rating 1	1	2	3	4
Risk score/risk rating	≤5 Low	6–9 Medium	≥10 High	

Source: Adapted from (Deere *et al.*, 2001) World Health Organization's *Water Safety Plan Manual*

Risk management

Once the level of risk has been quantified, e.g. via a risk score, an FBO should establish procedures to manage the hazard based on the level of risk it poses to consumer health. These procedures can be followed to both prevent and deal with non-compliances.

Table 16 Example of control measures and corrective actions associated with identified hazards

Please note that the following risk scores (likelihood × severity) are examples only. *

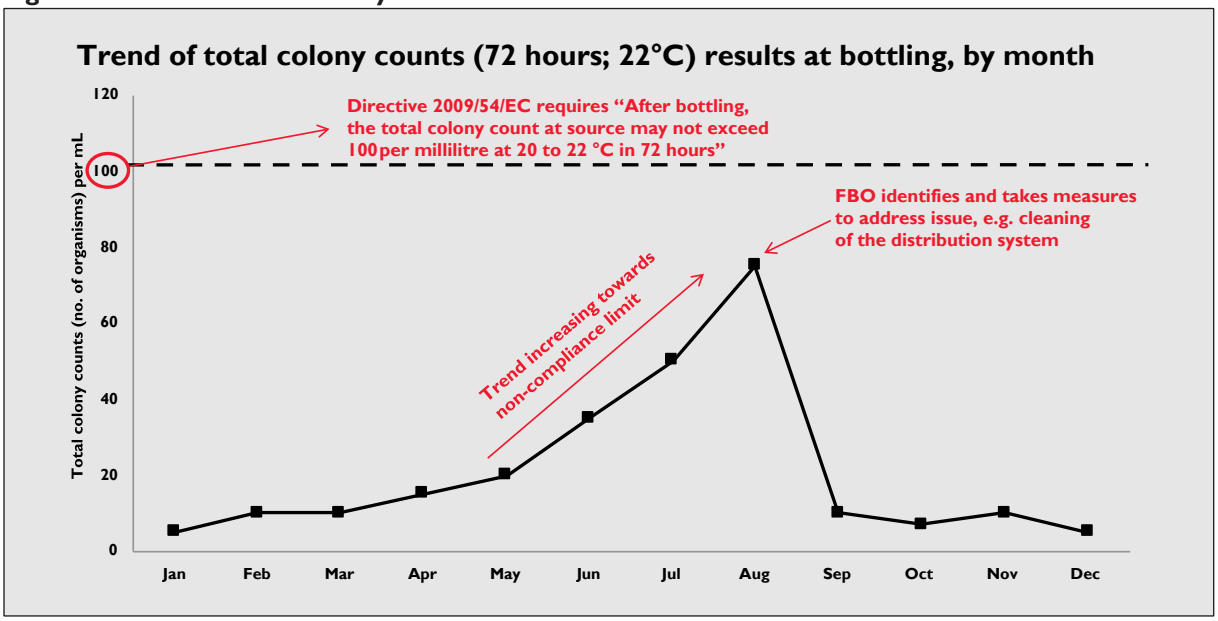
Event	Hazard type	Likelihood (1–4)	Severity (1–4)	Risk score	Control measure	Monitoring/ verification	Corrective action(s)
Land spreading	Microbiological (e.g. contamination with *Cryptosporidium*)	1	4	4 (low)	Protection of wellhead and monitoring of the catchment area (e.g. restriction of livestock/wildlife access)	Microbiological testing (e.g. absence of faecal indicator organisms in microbiological tests)	Notification of competent authority. Treatment of water with UV light or suspension of production until the water is free from parasites
Increases in abstraction volumes	Chemical (e.g. increases in iron concentrations)	1	4	4 (low)	Continuous monitoring for changes in chemical composition	Chemical testing to ensure that parameters are always within satisfactory limits	Notification of competent authority. Treatment of water using ozone to remove excess iron
Flooding	Microbiological/ chemical/physical	1	5	5 (low)	Placing of boreholes in areas that have low risk of flooding	Check history of flooding in new borehole locations	Notification of competent authority. Testing as necessary to ensure that water is compliant
Spraying of pesticides/ fertilisers	Chemical/ microbiological	2	2	4 (low)	200 m exclusion zone surrounding borehole for pesticides and organic fertilisers	Microbiological/ chemical testing	Actions to be determined on a case-bycase basis in consultation with competent authority
Changes in land use	Physical/ microbiological/ chemical	3	3	9 (medium)	Check planning applications	Keep copies of any new planning application documentation	Actions to be determined on a case-by-case basis (e.g. raise objection to application)

* Risk scores should be calculated by each FBO on a case-by-case basis and reviewed as necessary. Source: Adapted from the World Health Organization's *Water Safety Plan Manual*

Preventing non-compliances

One method to prevent non-compliances is to trend laboratory results in order to highlight an emerging problem before non-compliances occur, then take appropriate action to investigate the cause of any emerging problems and address them before they become non-compliances. For example:

Figure 11 Trend of total colony counts



Additional chemical parameters for consideration during risk assessment

In addition to monitoring and complying with the respective chemical legal limits for natural mineral water and spring water, the FSAI recommends monitoring for any additional possible chemical contaminants that are identified based on risk assessment. For example:

- Hormone run-off from nearby pharmaceutical plants or hospitals
- Solvent run-off from local industry
- Detergents from residential drainage
- Area-specific contaminants that may be naturally present, such as uranium, boron, or arsenic, in rocks or local geology
- Pesticides/fertilisers commonly used within the ZOC.

When monitoring for compliance with concentration limits set for chemical parameters in bottled water production, it is important to factor in changes in the well's water volume in order to ensure that chemical concentrations stay within specified limits. For example, seasonal changes in production volumes or hydrogeological conditions can result in groundwater being drawn in from different geological units, which may result in changes in the chemistry of the groundwater.

Additional considerations for risk assessment in Ireland

The following are the most commonly reported non-compliances in bottled water in Ireland and should be considered during the risk assessment:

- Microbiological
- Nitrates
- Pesticides
- Manganese
- Iron
- Barium
- pH
- Sodium
- Total ethanes

APPENDIX IV: DISINFECTION AND CLEANING OF THE WELL

Disinfection of the well borehole may be performed in the event that the well becomes contaminated or the FBO can prove the presence of a biofilm. It should be noted that in the case of natural mineral water and spring water, the FBO has a legal obligation to protect the well from sources of pollution under Annex II of Council Directive 2009/54/EC. As such, these disinfection events should be rare; a FBO should not need to regularly decontaminate a well, as this would indicate that the FBO is not meeting its obligations to protect the source from pollution under Annex II of Directive 2009/54/EC.

When a FBO disinfects a well, the water must return to its natural status and meet requirements under the respective Directives before it can be sold again.

'Shock chlorination' is the most commonly used form of well disinfection. However, any other suitable method may be used to disinfect the borehole, providing it can be validated as effective at killing pathogenic microorganisms of concern (bacteria, viruses, and parasites). However, for shock chlorination, it should be noted that sodium hypochlorite, the chlorine chemical found in bleach, is most effective at killing bacteria at a pH range of 5 to 7. But its effectiveness drops dramatically for water pH values greater than 7 or less than 5. As such, if the well is not within this range it may need to be subject to pH adjustment prior to cleaning, particularly if the chemical sodium hypochlorite (chlorine in its solid form) is used as the disinfectant in hard water areas.

Information on the shock chlorination method can be obtained in the procedures for well disinfection published in the IGI Guidelines (Section 2.8) and in the HSE advice leaflet. Health and safety precautions should be strictly adhered to during the following process.

- Step 1 Determine the volume of water in the borehole and system pipework;
- Step 2 Determine the amount of chlorine required to create a 200ppm solution of free chlorine throughout the borehole and system pipework;
- Step 3 Introduce the chlorine materials into the borehole and switch the pump on to ensure it has entered both the borehole and system pipework;
- Step 4 Switch off the borehole pump to allow the chlorine solution to stand in the borehole and system pipework ideally overnight to complete the disinfection process (12 to 24 hours);
- Step 5 Flush the system to waste until the smell of chlorine is gone to ensure the chlorine has been removed. Do not discharge the chlorine solution to a surface water body;
- Step 6 Retest the water supply for bacterial contamination.

Sodium hypochlorite is particularly ineffective and potentially damaging to well components when used in conjunction with water that is alkaline and hard. More information on the effects of water hardness (pH) on chlorine disinfectants can be found in Section 4 of the *EPA's* *Water Treatment Manual: Disinfection.* Temperature also impacts chlorine's effectiveness, with it being more effective at warmer temperatures (≥25 °C).

Please note: *Giardia* and *Cryptosporidium* are more resistant to chlorine disinfection than bacteria or viruses and will not be inactivated by chlorine disinfection. In these cases, their removal will have to be achieved by other treatment processes, such as ultraviolet (UV) disinfection.

Well disinfection and the removal of parasites

Disinfection of the well with chlorine will not inactivate or kill parasites such as *Cryptosporidium* or *Giardia*. *Cryptosporidium* in particular is highly resistant to chlorine disinfection, even when chlorine is used at very high concentrations. If a FBO has reason to believe these parasites have entered the well, e.g. via faecal contamination, then it is important to note that these organisms can survive chlorine disinfection. As such, a FBO may need to carry out testing to ensure that the well is free from these organisms even after carrying out a shock chlorination of the well. Should parasites be detected, their inactivation will need to be achieved through other treatment processes, e.g. via UV disinfection.

UV disinfection will inactivate *Cryptosporidium* and *Giardia*, but this is not approved for use in natural mineral waters or spring waters, only in other waters. To ensure the elimination of *Cryptosporidium* spores using ultraviolet -C disinfection, a critical control point of 40 millijoules per cm^2 (mJ/cm^2) will result in a 4-log inactivation of *Cryptosporidium spores.* This critical control point of 40 millijoules per cm^2 (mJ/cm^2) will ensure a high level of public health protection as concentrations of *Cryptosporidium* typically do not exceed 3-log in raw sewage.

Cryptosporidium and *Giardia* cannot multiply in groundwater, only in a host. Therefore, in the event that a well becomes contaminated with these parasites, their presence may decline over time as they die off or are removed as water is abstracted. Given that these parasites cannot reproduce in groundwater environments, their persistent detection in groundwater would be an indication of continuous groundwater contamination issues with faecal material.

Cleaning of the plant's distribution system and water storage tanks

Cleaning of the distribution system may be carried out as regularly as the FBO's food safety management system deems necessary. However, it should be noted that in the case of natural mineral water and spring water, the cleaning procedure should not contaminate the well with the cleaning agents, or this must be considered disinfection of the well. In these cases, the FBO has a legal obligation under Directive 2009/54/EC to protect the well from pollution, and frequent disinfection must be considered a failure to meet these obligations.

It may be necessary in some cases to disinfect the water distribution system more frequently than the well, for example, when biofilms are present. Biofilms build up at different rates on different types of surfaces and materials (iron or plastic; smooth or rough), which can make some surfaces more susceptible to biofilm development than others and require more frequent disinfection. In cases where a FBO wishes to clean the distribution system but not the source well, it may be necessary to completely and securely close off the distribution system from the wellhead. This reduces the risk of cleaning solution backwashing into the source well and contaminating it.

If disinfecting the distribution system on its own via methods other than shock chlorination, it is recommended that the FBO uses established Ct values (Ct = concentration of disinfectant (mg/L) × exposure time (minutes)) high enough to inactivate the target pathogens of concern. Table 4.3 (page 44) in Section 4 of the *EPA's Water Treatment Manual: Disinfection* gives recommended Ct values for 99% (2-log) inactivation for bacteria and viruses in water. In cases where biofilms are involved, these can confer increased disinfection resistance to a wide range of bacteria, viruses, and parasites. As such, in the event of biofilm formation, it may be necessary to use higher concentrations of disinfectant or for longer contact times in these cases.

Please note: Ct values are not relevant to shock chlorination protocols in wells or distribution systems, as in these cases the chlorine solution is left in the borehole and pipework for up to 24 hours.

Proper disposal of cleaning solution

In the case of chlorinated cleaning solutions, prior to the discharge of the used solution, the chlorinated water should be mixed with unchlorinated water in order to reduce the chlorine concentration to <5 ppm (parts per million). Alternatively, an appropriate concentration of sodium thiosulphate can be added to the chlorinated water in order to deactivate the chlorine. The deactivated/diluted wastewater should then be discharged at least 500 m away from the site of the borehole and away from any surface waters.

In the case of other (non-chlorine-based) disinfectants, the FBO must know the contamination/safety risks associated with the disinfectant and have proper disposal procedures put in place for its safe disposal. It is not acceptable to simply assume that heavily diluting any chemicals prior to discharge will render them safe, as some can cause environmental damage at very low concentrations and may require special disposal procedures. Advice on proper disposal of other disinfectants can be sourced from the manufacturer.

More information on the proper disposal of cleaning solutions can be found in Section 2.4 of *EPA Drinking Water Advice Note No. 10: Service Reservoir Inspection, Cleaning and Maintenance*.

APPENDIX V: GUIDANCE ON THE DEFINITION OF 'ORIGINAL PURITY' FOR NATURAL MINERAL WATER

The European Commission developed guidance on the definition of 'original purity' as stated in the definition of a natural mineral water that is laid down in Annex I of Directive 2009/54/EC. The guidance was agreed by Member States in order to ensure the common application, enforcement, and control of the compliance of a natural mineral water. This guidance developed by the European Commission can be located on Safety Net here, or alternatively, by contacting the FSAI advice line at info@fsai.ie

Parameters are listed in the guidance to assist in the assessment of whether a natural mineral water complies with the definition laid down by Directive 2009/54/EC.

The guidance parameters do not apply to spring water as defined by Directive 2009/54/EC.

For the purpose of assessing compliance of a natural mineral water with the requirement for 'original purity', the following specific parameters and their values should be taken into account:

Parameter	Guidance value
Polynuclear aromatic hydrocarbons (PAHs)	<0.01ug/L for individual substances
Volatile organic compounds (VOCs)	<1.0ug/L for individual substances
Trihalomethanes (THMs)	<1ug/L for individual substances
Pesticides	0.1ug/L for the sum of all individual pesticides and their relevant metabolites5 6 ; 0.03ug/L for aldrin, dieldrin, heptachlor and heptachlor epoxide. Member States may set individual limits for those pesticides considered to be relevant in the local, regional, or national context.

The guidance states that the presence of the above substances below the corresponding guidance value does not affect the level of quality of the natural mineral water concerned in a way that would make it incompatible with the definition of natural mineral water by reference to the concept of 'original purity'.

In cases where a specific natural mineral water does not comply with the above guidance values, the EHO may assess on a case-by-case basis what action to take, taking into account relevant factors such as hydrogeological variations and potential shortcomings in the protection of the spring or the aquifer. The operator exploiting the spring must investigate the cause of the pollution and take appropriate measures to eradicate it.

As hydrogeological variations may occur at a local or regional level, EHOs should assess on a local, regional, or national level whether additional criteria should be included when assessing the compliance of a natural mineral water with the definition laid down by Directive 2009/54/EC. This is because certain local factors may influence the presence of other substances, and this is best dealt with at a local level.

APPENDIX VI: GUIDANCE ON STORAGE TANKS

It is the responsibility of the food business operator to produce safe food. Accordingly, cleaning and maintenance of storage tanks is the responsibility of the food business operator. This should be addressed as part of the FBO's food safety management system, to the satisfaction of the EHO.

Storage tanks are sealed units which are only accessed by the intake (from the source) and the sampling ports (which are used aseptically during sampling). Therefore, storage tanks are not the source of contamination, but rather hold contamination introduced from the source. In the absence of an effective cleaning and maintenance programme, this contamination may accumulate to unsatisfactory levels.

Based on this, the FBO must demonstrate, to the satisfaction of the environmental health officer, that the source is satisfactory, and that the storage tank has been maintained and cleaned in line with its food safety management system.

Environmental health officers are advised to monitor storage tanks using a risk-based approach. If there is a significant trend of non-compliance, the inspecting EHO may raise any concerns or queries with the FSAI advice line at info@fsai.ie.

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