WELSH STATUTORY INSTRUMENTS

2015 No. 1867 (W. 274) FOOD, WALES

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

Made - - - - 4 November 2015
Laid before the National
Assembly for Wales - - 6 November 2015
Coming into force - - 28 November 2015

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4)(1), 16(1)(2), 17(1)(3), 26(1) and (3)(4), 31(5) and 48(1)(6) of the Food Safety Act 1990(7) and paragraph 1A of Schedule 2 to the European Communities Act 1972 (8).

The Welsh Ministers have had regard to the relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990(9).

There has been consultation during the preparation and evaluation of the following Regulations, as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(10).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972(11) and it appears to the Welsh Ministers that it is expedient for the references in these Regulations to the Annexes to the EU Instruments listed in regulation 2(3) to be construed as references to those Annexes as amended from time to time.

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

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

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

⁽⁴⁾ Section 26(3) was partially repealed by section 40(4) of, and Schedule 6 to, the 1999 Act.

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

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

^{(7) 1990} c. 16. Functions formerly exercisable by "the Ministers", so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c. 32).

^{(8) 1972} c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51).

⁽⁹⁾ Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.

⁽¹⁰⁾ OJ No L 31, 1.2.2002, p 1, last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council (OJ No L 189, 27.6.2014, p 1).

⁽¹¹⁾ Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7).

Introductory

Title, commencement and application

- **1.**—(1) The title of these Regulations is the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015.
 - (2) These Regulations come into force on 28 November 2015 and apply in relation to Wales.

Interpretation

- 2.—(1) In these Regulations—
 - "the Act" ("y Ddeddf") means the Food Safety Act 1990;
 - "advertisement" ("hysbyseb") means a representation in any form in connection with a trade or business in order to promote the supply of goods, and "advertise" ("hysbysebu") is to be construed accordingly;
 - "the Agency" ("yr Asiantaeth") means the Food Standards Agency;
 - "bottle" ("potel") where used as a noun, means a closed container of any kind in which water is sold for drinking by humans or from which water sold for drinking by humans is derived, and "bottle" ("potelu"), where used as a verb, and cognate expressions, are to be construed accordingly;
 - "Directive 98/83" ("Cyfarwyddeb 98/83") means Council Directive 98/83/EC on the quality of water intended for human consumption(12);
 - "Directive 2003/40" ("Cyfarwyddeb 2003/40") means Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters(13);
 - "Directive 2009/54" ("*Cyfarwyddeb 2009/54*") means Directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of natural mineral waters(14);
 - "Directive 2013/51" ("Cyfarwyddeb 2013/51") means Council Directive 2013/51/EURATOM laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption(15);
 - "drinking water" ("dŵr yfed") means water which is intended for sale for drinking by humans other than—
 - (a) natural mineral water, or
 - (b) water intended to be labelled and sold as "spring water", "dŵr ffynnon", or its equivalent in any other language;
 - "effervescent natural mineral water" ("dŵr mwynol naturiol eferw") means natural mineral water which, at source or after bottling, gives off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure;
 - "fluoride removal treatment" ("triniaeth tynnu fflworid") means—
 - (a) a treatment of natural mineral water or water intended to be bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, with activated alumina

⁽¹²⁾ OJ No L 330, 5.12.1998 p 32, last amended by Commission Directive (EU) 2015/1787 (OJ No L 260 7.10.2015, p 6).

⁽¹³⁾ OJ No L 126, 22.5.2003, p 34.

⁽¹⁴⁾ OJ No L 164, 26.6.2009, p 45.

⁽¹⁵⁾ OJ No L 296, 7.11.2013, p 12.

- in order to remove fluoride which is authorised in accordance with regulations 9(1)(a) (iii) or 15(a)(iii) and Schedule 2, or
- (b) in the case of water brought into Wales from another part of the United Kingdom or from another EEA state, a treatment which complies with Articles 1 to 3 of Regulation 115/2010;

"label" ("label") means any tag, brand, mark, pictorial or other descriptive matter, which is written, printed, stencilled, marked, embossed or impressed on, or attached to the bottle of water, and "labelled" ("wedi'i labelu") and "labelling" ("labelu") are to be construed accordingly;

"natural mineral water" ("dŵr mwynol naturiol") means water which—

- (a) is microbiologically wholesome within the meaning of Article 5 of Directive 2009/54,
- (b) originates in an underground water table or deposit and emerges from a spring tapped at one or more natural or bore exits,
- (c) can be clearly distinguished from drinking water on account of the following characteristics having been preserved intact because of the underground origin of the water, which has been protected from all risk of pollution—
 - (i) its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects, and
 - (ii) its original purity, and
- (d) is for the time being recognised pursuant to and in accordance with regulation 4;
- "ozone-enriched air treatment" ("triniaeth aer a gyfoethogir ag osôn") means—
- (a) a treatment of natural mineral water or water intended to be bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, with ozone-enriched air which is authorised in accordance with regulations 9(1)(a)(iv) or 15(a)(iv) and Schedule 3, or
- (b) in the case of water brought into Wales from other parts of the United Kingdom or from another EEA State, a treatment which complies with Article 5 of Directive 2003/40, as implemented in that part of the United Kingdom or that EEA State;

"parameter" ("paramedr") means a property, element, organism or substance listed in the second column of any table in Part 2, Part 3 or Part 4 of Schedule 7;

"Regulation 115/2010" ("*Rheoliad 115/2010*") means Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters(16); and

"sell" ("gwerthu") includes possess for sale and offer, expose or advertise for sale, and "sale" ("gwerthiant") is to be construed accordingly.

- (2) Expressions used in these Regulations that are also used in Directive 98/83, Directive 2009/54, Regulation 115/2010 or Directive 2013/51 have the same meaning in these Regulations as they have in those Directives or that Regulation.
- (3) References to the Annexes to Directive 98/83, Directive 2003/40, Directive 2009/54, Regulation 115/2010 and Directive 2013/51 are references to those Annexes as amended from time to time.
- (4) Any reference in these Regulations to the labelling of a bottle includes labelling done before any water is bottled and labelling after bottling.

Exemptions

- **3.**—(1) These Regulations do not apply to any water which—
 - (a) is a medicinal product within the meaning of Directive 2001/83 of the European Parliament and of the Council on the Community code relating to medicinal products for human use(17);
 - (b) is a natural mineral water which is used at source for curative purposes in thermal or hydromineral establishments;
 - (c) is not intended for sale for drinking by humans; or
 - (d) is a natural mineral water intended for export to a country other than an EEA State.
- (2) These Regulations do not apply to packaged ice portions intended for use in cooling food.

PART 2

Natural mineral water

Recognition as natural mineral water

- **4.**—(1) Natural mineral water may only be sold as natural mineral water if it is recognised in accordance with paragraph (2).
 - (2) Water is recognised as natural mineral water where—
 - (a) in the case of water extracted from the ground in Wales, a food authority grants recognition in accordance with Part 1 of Schedule 1;
 - (b) in the case of water extracted from the ground in another part of the United Kingdom, the responsible authority of that part of the United Kingdom recognises it pursuant to Directive 2009/54;
 - (c) in the case of water extracted from the ground in an EEA State other than the United Kingdom, a responsible authority of that EEA State recognises it pursuant to Directive 2009/54;
 - (d) in the case of water extracted from the ground in a country other than an EEA State—
 - (i) the Agency grants recognition in accordance with Part 2 of Schedule 1; or
 - (ii) it has an equivalent recognition, given by a responsible authority of—
 - (aa) another part of the United Kingdom; or
 - (bb) an EEA State other than the United Kingdom.
- (3) The publication in the Official Journal of the European Union of the name of any water as a natural mineral water recognised in the European Union for the purposes of Directive 2009/54 is, except where recognition is granted in accordance with Schedule 1, conclusive evidence that water is recognised for the purposes of that Directive.

Declining to grant or withdrawing recognition

- **5.**—(1) Where, in relation to any water that has been recognised under regulation 4(2)(a) or 4(2) (d)(i), it is found that—
 - (a) by analysis in accordance with Part 3 of Schedule 1, the requirements of paragraph 10(c) of that Part are not met;

- (b) the requirements of Schedule 4 are not met; or
- (c) the content of the water is not in accordance with paragraph 1(c) of Part 1 or, as the case may be, paragraph 5(c) of Part 2 of Schedule 1,

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

- (2) Where the food authority or, as the case may be, the Agency declines to grant or withdraws recognition of a water, the person who exploits or wishes to exploit the spring from which that water emerges or, if different, the person who owns the land on which that spring is situated, may within 6 months of being notified of the decision, appeal against it to a person appointed for the purpose by the Agency.
- (3) The appointed person must consider the appeal and any representations made by the food authority or the Agency, as appropriate, and within 3 months report in writing with a recommended course of action to the Agency.
 - (4) The Agency must either—
 - (a) confirm the decision together with the reasons; or
 - (b) direct the food authority to grant or restore, or itself restore, as appropriate, recognition of the water in question.
- (5) Where a food authority is directed by the Agency under paragraph (4)(b) to grant or restore recognition, it must immediately comply with that direction.

Application to withdraw recognition

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

Notification of changes

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

Exploitation of natural mineral water springs

- **8.**—(1) No person may exploit a spring for the purpose of marketing the water from it as natural mineral water unless—
 - (a) the water extracted from that spring is natural mineral water;
 - (b) the food authority of the area in which the spring is located has given permission for that spring to be exploited; and
 - (c) the requirements of Schedule 4 are met.
- (2) Where it is found during exploitation that natural mineral water is polluted and that bottling of the water would contravene paragraphs 6, 7 or 8 of Schedule 4, no person may exploit the spring from which the water is extracted until the cause of the pollution is eradicated and the bottling of the water would comply with those paragraphs.

Treatments and additions for natural mineral water

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

- (a) any treatment other than—
 - (i) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, whether or not preceded by oxygenation, in so far as the treatment does not alter the composition of the water as regards the essential constituents which give it its properties;
 - (ii) the total or partial elimination of free carbon dioxide by exclusively physical methods;
 - (iii) a fluoride removal treatment which is authorised in accordance with Schedule 2; or
 - (iv) an ozone-enriched air oxidation treatment which is authorised in accordance with Schedule 3:
- (b) any addition other than the introduction or the re-introduction of carbon dioxide to produce effervescent natural mineral water; or
- (c) any disinfection treatment by whatever means, or, subject to paragraph (1)(b), the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water.
- (2) Paragraph (1) does not prevent the use of natural mineral water in the manufacture of soft drinks.

Bottling of natural mineral water

- **10.**—(1) No person may bottle natural mineral water—
 - (a) unless the requirements of Schedule 4 are met;
 - (b) in a container other than a container which is fitted with closures designed to avoid any possibility of adulteration or contamination; and
 - (c) which, at the time of bottling, contains any substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.
- (2) The methods used for detection of the substances listed in Part 1 of Schedule 5 must conform to the performance characteristics for analysis specified in Part 2 of Schedule 5.

Labelling of natural mineral water

- 11.—(1) No person may bottle natural mineral water and label it with—
 - (a) a trade description which includes the name of a locality, hamlet or other place, unless that trade description refers to a natural mineral water, the spring of which is exploited at the place indicated by that name, and is not misleading as regards the place of exploitation of the spring;
 - (b) a trade description which is different from the name of the spring or the place of its exploitation, unless the name of the spring or the place of exploitation is also labelled on the bottle, using letters at least one and a half times the height and width of the largest of the letters used for that trade description;
 - (c) any indication, designation, trade mark, brand name, picture or other sign, whether figurative or not, the use of which suggests a characteristic which the water does not possess, in particular as regards its origin, the date of authorisation to exploit the spring, the results of analyses or any similar references to guarantees of authenticity;
 - (d) any indication other than those specified in sub-paragraphs (f) and (g), attributing to the natural mineral water properties relating to the prevention, treatment or cure of a human illness;

- (e) any indication listed in the first column of the Table in Schedule 6, except where the natural mineral water meets the criterion so listed and corresponds to the indication;
- (f) the indication "may be diuretic", "gall fod yn ddiwretig", or "may be laxative", "gall fod yn garthydd", or the equivalent in any other language, unless the natural mineral water has been assessed as possessing the property attributed by the indication in accordance with physico-chemical analysis and pharmacological, physiological or clinical examination as appropriate; or
- (g) the indication "stimulates digestion", "mae'n ysgogi treuliad", or "may facilitate the hepato-biliary functions", "gall hyrwyddo'r swyddogaethau hepato-bustlog", or the equivalent in any other language, unless the natural mineral water has been assessed as possessing the property attributed by the indication in accordance with the physico-chemical analysis and pharmacological, physiological and clinical examination.
- (2) No person may bottle natural mineral water and label it with a sales description other than—
 - (a) "natural mineral water"; or
 - (b) in the case of an effervescent natural mineral water, one of the following, as appropriate—
 - (i) "naturally carbonated natural mineral water" to describe water whose content of carbon dioxide from the spring after decanting, if any, and bottling is the same as at source, taking into account where appropriate, the reintroduction of a quantity of carbon dioxide from the same water table or deposit equivalent to that released in the course of those operations and subject to the usual technical tolerances;
 - (ii) "natural mineral water fortified with gas from the spring" to describe water whose content of carbon dioxide from the same water table or the same deposit after decanting, if any, and bottling is greater than that established at source; or
 - (iii) "carbonated natural mineral water" to describe water to which has been added carbon dioxide of an origin other than the water table or deposit from which the water comes:
 - (c) nothing in sub-paragraph (a) prevents a person from using the words "dŵr mwynol naturiol" in addition to the words "natural mineral water";
 - (d) nothing in sub-paragraph (b) prevents the use of the words "dŵr mwynol naturiol wedi'i garboneiddio'n naturiol" in addition to "naturally carbonated natural mineral water", "dŵr mwynol naturiol wedi'i gryfhau â nwy o'r ffynnon" in addition to "natural mineral water fortified with gas from the spring", "dŵr mwynol naturiol wedi'i garboneiddio" in addition to "carbonated natural mineral water"; and
 - (e) nothing in sub-paragraphs (a), (b), (c) or (d) prevents the use of equivalent words in any other language in addition to Welsh and English.
- (3) No person may bottle natural mineral water unless the bottle is labelled with—
 - (a) a statement of analytical composition indicating the characteristic constituents of the water:
 - (b) the name of the place where the spring is exploited and the name of the spring;
 - (c) where the water has undergone the treatment of total or partial elimination of free carbon dioxide by exclusively physical methods, the indication "fully de-carbonated" or "partially de-carbonated", as appropriate;
 - (d) where the water has undergone an ozone-enriched air treatment, the words "water subjected to an authorised ozone-enriched air oxidation technique", which must appear in proximity to the analytical composition of characteristic constituents;
 - (e) where its fluoride concentration exceeds 1.5 mg/l—

- (i) the words "contains more than 1.5 mg/l of fluoride; not suitable for regular consumption by infants and children under 7 years of age", which must appear in immediate proximity to the trade name and in clearly visible characters; and
- (ii) the actual fluoride content in relation to the physico-chemical composition, which must be included within the statement referred to in paragraph (3)(a);
- (f) nothing in sub-paragraph (c) prevents the use of the indication "cwbl ddad-garbonedig" in addition to "fully de-carbonated", or "rhannol ddad-garbonedig" in addition to "partially de-carbonated";
- (g) nothing in sub-paragraph (d) prevents the use of the words "dŵr wedi ei drin â thechneg awdurdodedig i'w ocsideiddio ag aer a gyfoethogir ag osôn" in addition to "water subjected to an authorised ozone-enriched air oxidation technique";
- (h) nothing in sub-paragraph (e)(i) prevents the use of the words "yn cynnwys mwy na 1.5 mg/l o fflworid; nid yw'n addas i'w yfed yn rheolaidd gan blant bach a phlant o dan 7 oed" in addition to "contains more than 1.5 mg/l of fluoride; not suitable for regular consumption by infants and children under 7 years of age"; and
- (i) nothing in sub-paragraphs (c), (d), (e)(i), (f), (g) and (h) prevents the use of equivalent words in any other language in addition to Welsh and English.

Advertising of natural mineral water

- 12.—(1) Where, in accordance with regulation 11(1)(b) a bottle containing natural mineral water is required to be labelled with the name of the spring or the place of its exploitation—
 - (a) the same requirement also applies to any written advertisement for that natural mineral water; and
 - (b) in any other advertisement, at least equivalent prominence must be given to the place of exploitation or the name of the spring as is given to the trade description.
 - (2) No person may advertise natural mineral water in contravention of paragraph (1).
- (3) No person may advertise natural mineral water under any indication, designation, trade mark, brand name, picture or other sign, whether figurative or not, the use of which suggests a characteristic which the water does not possess, in particular as regards its origin, the date of authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity.

Sale of natural mineral water

- 13.—(1) No person may sell water which is bottled and labelled "natural mineral water", "dŵr mwynol naturiol", or its equivalent in any other language, unless that water is natural mineral water recognised in accordance with regulation 4(2).
 - (2) No person may sell bottled natural mineral water if it—
 - (a) has been extracted from a spring which is exploited in contravention of regulation 8;
 - (b) has been subjected to any treatment or addition in contravention of regulation 9;
 - (c) is bottled in contravention of regulation 10;
 - (d) is labelled in contravention of regulation 11; or
 - (e) is advertised in contravention of regulation 12.
 - (3) No person may sell bottled natural mineral water—
 - (a) which contains—
 - (i) parasites or pathogenic micro-organisms;

- (ii) Escherichia coli or other coliforms and faecal streptococci in any 250ml sample examined;
- (iii) sporulated sulphite-reducing anaerobes in any 50ml sample examined; or
- (iv) Pseudomonas aeruginosa in any 250ml sample examined;
- (b) where the total colony count of the water at the source from which that water was taken does not comply with paragraph 7 of Schedule 4;
- (c) where the revivable total colony count of that water is in excess of that which would result from the normal increase in the bacterial count which it had at source; or
- (d) where that water contains any organoleptic defect.
- (4) No person may sell natural mineral water from the same spring under more than one trade description.

Water intended to be sold as "spring water" or "dŵr ffynnon"

Exploitation of springs and bottling of water intended to be labelled and sold as "spring water" or "dŵr ffynnon"

- **14.**—(1) No person may bottle water intended to be labelled and sold as "spring water", "dŵr ffynnon", or its equivalent in any other language, unless—
 - (a) the water has been extracted from a spring and is bottled at source;
 - (b) the water is intended for human consumption in its natural state;
 - (c) the requirements of Schedule 4 are met; and
 - (d) the water meets the requirements of Schedule 7.
- (2) Where it is found during exploitation that water from a spring is polluted and that bottling of the water would contravene paragraphs 6, 7 or 8 of Schedule 4, no person may exploit the spring from which the water is extracted until the cause of the pollution is eradicated and the bottling of the water would comply with those paragraphs.

Treatments and additions for water intended to be labelled and sold as "spring water" or "dŵr ffynnon"

- **15.** No person may subject water intended to be labelled and sold as "spring water", "dŵr ffynnon", or its equivalent in any other language, in its state at source to—
 - (a) any treatment, other than—
 - (i) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, whether or not preceded by oxygenation, in so far as the treatment does not alter the composition of the water as regards the essential constituents which give it its properties;
 - (ii) the total or partial elimination of free carbon dioxide by exclusively physical methods;
 - (iii) a fluoride removal treatment which is authorised in accordance with Schedule 2; or
 - (iv) an ozone-enriched air treatment which is authorised in accordance with Schedule 3; or
 - (b) any addition other than the introduction or the re-introduction of carbon dioxide; or

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

Labelling of water as "spring water" or "dŵr ffynnon"

- **16.**—(1) No person may label a bottle of water as "spring water", "dŵr ffynnon", or its equivalent in any other language, unless the water contained in it—
 - (a) meets the requirements of regulation 14(1); and
 - (b) if treated, has undergone a treatment or addition permitted under regulation 15.
- (2) If a bottle of water is labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, no person may label that bottle with a trade description which—
 - (a) includes the name of a locality, hamlet or other place, unless that trade description refers to water, the spring of which is exploited at the place indicated by that name, and is not misleading as regards the place of exploitation of the spring; or
 - (b) is different from the name of the spring or the place of its exploitation unless the name of the spring or the place of exploitation is also labelled on the bottle, using letters at least one and a half times the height and width of the largest of the letters used for that trade description.
- (3) No person may label a bottle of water as "spring water", "dŵr ffynnon", or its equivalent in any other language, unless the bottle is also labelled with—
 - (a) the name of the place where the spring is exploited;
 - (b) the name of the spring;
 - (c) where the water has undergone an ozone-enriched air treatment, the words "water subjected to an authorised ozone-enriched air oxidation technique", which must appear in proximity to the particulars referred to in sub-paragraphs (a) and (b);
 - (d) nothing in sub-paragraph (c) prevents the use of the words "dŵr wedi ei drin â thechneg awdurdodedig i'w ocsideiddio ag aer a gyfoethogir ag osôn" in addition to "water subjected to an authorised ozone-enriched air oxidation technique"; and
 - (e) nothing in sub-paragraphs (c) or (d) prevents the use of equivalent words in any other language in addition to Welsh and English.

Advertising of water as "spring water" or "dŵr ffynnon"

- 17.—(1) Where, in accordance with regulation 16(2)(b), a bottle of water is required to be labelled with the name of the spring or its place of exploitation in addition to a trade description—
 - (a) the same requirement also applies to any written advertisement for that water; and
 - (b) in any other advertisement, at least equivalent prominence must be given to the place of exploitation or the name of the spring as is given to the trade description.
- (2) No person may advertise a bottle of water as "spring water", "dŵr ffynnon", or its equivalent in any other language, in contravention of paragraph (1).

Sale of water as "spring water" or "dŵr ffynnon"

- **18.**—(1) No person may sell water which is bottled or labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, if it—
 - (a) is bottled in contravention of regulation 14(1);
 - (b) has been subjected to a treatment or addition in contravention of regulation 15;

- (c) is labelled in contravention of regulation 16; or
- (d) is advertised in contravention of regulation 17.
- (2) No person may sell water from the same spring as "spring water", "dŵr ffynnon", or its equivalent in any other language, under more than one trade description.

Bottled drinking water

Bottling of drinking water

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

Labelling of bottled drinking water

- 20. No person may bottle drinking water and label it with—
 - (a) a designation, proprietary name, trade mark, brand name, illustration or other sign, whether emblematic or not, the use of which is liable to cause confusion of the drinking water with a natural mineral water, or
 - (b) the description "mineral water", "dŵr mwynol", or its equivalent in any other language.

Advertising of bottled drinking water

- 21. No person may advertise bottled drinking water under—
 - (a) a designation, proprietary name, trade mark, brand name, illustration or other sign, whether emblematic or not, the use of which is liable to cause confusion of the water with a natural mineral water, or
 - (b) the description "mineral water", "dŵr mwynol", or its equivalent in any other language.

Sale of bottled drinking water

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

PART 5

Monitoring and sampling

CHAPTER 1

Natural mineral water

Monitoring of natural mineral water

23. In the case of natural mineral water, each food authority must carry out periodic checks to ensure that—

- (a) the composition, temperature and other essential characteristics of the water remain stable within the limits of natural fluctuation;
- (b) without prejudice to paragraph (a), the composition, temperature and other essential characteristics of the water are unaffected by any variations in the rate of flow;
- (c) the viable colony count at source (before the water is subjected to any treatment) is reasonably constant, taking into account the qualitative and quantitative composition of the water considered in the recognition of the water and whether it continues to satisfy the requirements of Part 1 of Schedule 1; and
- (d) the requirements of Schedule 4 are met in relation to the water.

CHAPTER 2

Water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

Monitoring of water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

- **24.**—(1) In the case of water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, and bottled drinking water, each food authority must carry out regular monitoring of the quality of the water to check that—
 - (a) it satisfies the requirements of Directive 98/83 and in particular complies with the parametric values set in accordance with Schedule 7; and
 - (b) where disinfection forms part of the preparation or distribution of bottled drinking water, the disinfection treatment applied is efficient and any contamination from disinfection byproducts is kept as low as possible without compromising the disinfection.
 - (2) In order to comply with paragraph (1), each food authority must carry out—
 - (a) monitoring in accordance with Schedule 8 to check whether the water complies with the relevant parametric values specified in Parts 2 and 3 of Schedule 7; and
 - (b) monitoring in accordance with Schedule 9 to check whether the water complies with the relevant parametric values specified in Part 4 of Schedule 7.
- (3) Each food authority must carry out additional monitoring, on a case-by-case basis, in relation to any property, element, substance or organism other than a parameter specified in Schedule 7, if the food authority has reason to suspect that it may be present in the water concerned in an amount or number which constitutes a potential danger to human health.

Samples and analysis

- **25.**—(1) For the purpose of monitoring water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, and bottled drinking water, each food authority must carry out—
 - (a) sampling and analysis in accordance with Schedule 10 to check compliance with the parametric values specified in Parts 2 and 3 of Schedule 7; and
 - (b) sampling and analysis in accordance with Schedule 11 to check compliance with the parametric value for indicative dose specified in Part 4 of Schedule 7.
 - (2) Each food authority must take samples at the point at which the water is bottled.

Remedial action

- **26.**—(1) If a food authority determines that water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, or bottled drinking water, does not comply with the parametric concentrations or values specified in Schedule 7, the food authority must—
 - (a) immediately investigate the non-compliance in order to identify the cause;
 - (b) assess whether the non-compliance poses a risk to human health which requires action;
 - (c) require the business operator to take remedial action as soon as possible to restore the quality of the water where that is necessary to protect human health;
 - (d) in respect of any parameter specified in Parts 2 and 3 of Schedule 7, notify the general public of the remedial action taken, unless the food authority considers that non-compliance with the parametric value is trivial; and
 - (e) in respect of any parameter specified in Part 4 of Schedule 7, notify the general public of the risks and remedial action taken and advise the general public on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.
- (2) If water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, or bottled drinking water, constitutes a potential danger to human health, irrespective of whether it meets the relevant parametric values in Schedule 7, the food authority must—
 - (a) prohibit or restrict the supply of that water in its area or take such other action as is necessary to protect human health; and
 - (b) inform the general public promptly of that fact and provide advice where necessary.
- (3) A food authority is not required to prohibit or restrict the supply of water under paragraph (2) (a) if it considers that such action will give rise to an unacceptable risk to human health.

CHAPTER 3

Treatments

Monitoring of certain treatments

- 27.—(1) Each food authority must carry out periodic checks on any fluoride removal treatment which it has authorised to ensure that the requirements of paragraph 3 of Schedule 2 continue to be satisfied.
- (2) Each food authority must carry out periodic checks on any ozone-enriched air treatment which it has authorised to ensure that the requirements of paragraph 4 of Schedule 3 continue to be satisfied.

CHAPTER 4

Samples

General

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

Delivery

29.—(1) An authorised officer of a food authority who has procured a sample under section 29 of the Act and is required to give part of that sample to the owner in accordance with regulation 7(3)

- (c) of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013(18) may deliver that sample——
 - (a) directly to the owner or the owner's agent; or
 - (b) by registered post or recorded delivery service.
- (2) If, after reasonable enquiry, the authorised officer is unable to ascertain the name and address of the owner, the authorised officer may retain the sample.
- (3) In this regulation, "owner" has the same meaning as in the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013.

Notification

- **30.**—(1) An authorised officer of a food authority who has procured a sample of water under section 29 of the Act for the purpose of analysis by a public analyst must serve notice in accordance with paragraph (2) if it appears that the water was exploited or bottled by a person (other than the owner) having a name and an address in the United Kingdom displayed on the bottle.
- (2) The authorised officer must, within 3 days of procuring the sample, send to that person a notice informing them—
 - (a) that the sample has been procured by the officer; and
 - (b) where the sample was taken or, as the case may be, from who it was purchased.
 - (3) Paragraph (1) does not apply if the authorised officer decides not to have the sample analysed.

Analysis by the Government Chemist

- **31.**—(1) Paragraphs (2) to (6) apply where a part of a sample procured under section 29 of the Act has been submitted for analysis and another part of the sample has been retained in accordance with regulation 7(3)(e) of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 and—
 - (a) an improvement notice has been served on a person under section 10(1) of the Act, as applied and modified by regulation 33, as read with Schedule 12, for a contravention of a provision of these Regulations in connection with that sample;
 - (b) an appeal against that improvement notice has been made by that person to the magistrates' court; and
 - (c) the authorised officer intends to adduce as evidence the result of the analysis mentioned above.
- (2) An authorised officer may send the retained part of the sample to the Government Chemist for analysis but must send it—
 - (a) if requested by the magistrates' court; or
 - (b) subject to paragraph (6), if requested by the recipient of the improvement notice.
- (3) The Government Chemist must analyse, or direct a food analyst to analyse, the part of the sample sent under paragraph (2) and send to the authorised officer a Government Chemist's certificate of analysis.
- (4) Any certificate sent by the Government Chemist must be signed by or on behalf of the Government Chemist, but the analysis may be carried out by a person under the direction of the person who signs the certificate.
- (5) On receipt of the certificate the authorised officer must, as soon as is reasonably practicable, supply a copy of it to the magistrates' court and to the recipient of the improvement notice.

- (6) Where a request is made under paragraph (2)(b), the authorised officer may request payment of a fee specified in writing from the recipient of the improvement notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3).
- (7) Where a notice is served under paragraph (6) and the recipient of the improvement notice refuses to pay the fee specified in the notice, the authorised officer may refuse to comply with the request made under paragraph (2)(b).

Enforcement and miscellaneous provisions

Enforcement

32. Each food authority must execute and enforce these Regulations in its area.

Application of the Act: improvement notices

- **33.**—(1) The provisions of section 10 of the Act specified in column 1 of Table 1 of Schedule 12 apply for the purpose of these Regulations, with the modifications specified in column 2 of that table to enable an authorised officer of a food authority to serve an improvement notice on any person who is failing to comply with regulations 8 to 22 of these Regulations or a provision of Regulation 115/2010 mentioned in column 2 of Table 1 of Schedule 12.
- (2) Paragraph (1) is without prejudice to the application of section 10 of the Act for purposes other than those specified in paragraph (1).
- (3) An authorised officer of a food authority must not serve an improvement notice under section 10(1) of the Act, as applied and modified in accordance with paragraph (1), if—
 - (a) the improvement notice would relate to water bottled and labelled before 28November 2015; and
 - (b) the matters constituting the alleged contravention would not have constituted an offence under the Regulations listed in regulation 37.
- (4) If water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, or bottled drinking water, does not meet the requirements of paragraph 1(c) of Part 1 of Schedule 7, an authorised officer of a food authority must not serve an improvement notice under section 10(1) of the Act, as applied and modified in accordance with paragraph (1), if—
 - (a) the water in question was bottled or sold in an EEA State other than the United Kingdom; and
 - (b) the water complied with the law in that EEA State when it was bottled or sold.

Application of the Act: powers of entry

- **34.**—(1) The provisions of section 32 of the Act specified in column 1 of Table 2 of Schedule 12 apply for the purposes of enabling these Regulations, with the modifications specified in column 2 of that table, to enable an authorised officer of a food authority—
 - (a) to exercise a power of entry to ascertain whether there is, or has been, any contravention of a provision of Regulation 115/2010 mentioned in column 2 of that table;
 - (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of such provisions; and
 - (c) where exercising a power of entry under the applied section 32 provisions, to exercise the associated powers in subsections (5) and (6) relating to records.

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

Application of other provisions of the Act

35. The provisions of the Act specified in column 1 of Table 3 of Schedule 12 apply for the purposes of these Regulations, with the modifications specified in column 2 of that table.

Savings and transitional provisions

- **36.**—(1) Any recognition of water as natural mineral water granted under the Natural Mineral Waters Regulations 1985, the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999, or the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007 and subsisting on the date that these Regulations come into force shall—
 - (a) in the case of water extracted from the ground in Wales, be treated as if it were recognition granted by the food authority under regulation 4(2)(a); and
 - (b) in the case of water extracted from the ground in a country other than an EEA State, be treated as if it were recognition granted by the Agency under regulation 4(2)(d)(i).
- (2) The revocation of the Regulations listed in regulation 37 does not affect the validity of any authorisation, recognition or notification made or given by the Agency or the food authority as the relevant authority under those Regulations, and any such authorisation, recognition or notification continues in effect.
- (3) Where an application has been made under the Regulations listed in regulation 37 to a food authority for recognition of water as natural mineral water, the application is to be treated as if it had been made under Parts 1 or 2 of Schedule 1 to these Regulations.

Revocations

- **37.** The following Regulations are revoked—
 - (a) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007(19);
 - (b) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2009(20);
 - (c) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2010(21);
 - (d) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) (Amendment) Regulations 2011(22).

Amendments to other legislation

38. Schedule 13 (amendments to other legislation) has effect.

⁽¹⁹⁾ S.I. 2007/3165 (W. 276), amended by S.I. 2009/1897 (W. 170), 2010/748 (W.76), 2011/400 (W.57).

⁽²⁰⁾ S.I. 2009/1897.

⁽²¹⁾ S.I. 2010/748.

⁽²²⁾ S.I. 2011/400.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Vaughan Gething
Deputy Minister for Health, one of the Welsh
Ministers

4 November 2015

Regulation 4(2)(a) and 4(2)(d)(i)

Recognition of natural mineral water

PART 1

Natural mineral water extracted from the ground in Wales

- 1. A person seeking to have water which is extracted from the ground in Wales recognised as natural mineral water for the purposes of Article 1 of Directive 2009/54 must apply in writing to the food authority within whose area the water is extracted, giving the following information—
 - (a) the particulars specified in paragraph 10(a) of Part 3;
 - (b) the information obtained as a result of the surveys and analyses required under paragraph 10(b) and (c), as read with paragraph 11, of Part 3; and
 - (c) evidence to show that the water contains no substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.
- 2. Where information on the anions, cations, non-ionised compounds and trace elements is required to be given pursuant to paragraph 1(b), the concentration of each anion, cation, non-ionised compound and trace element specified in the first column of the tables in Part 4 of this Schedule must be expressed in the unit of measurement specified in the second column of the tables in Part 4.
- **3.** Where information required by paragraph 1 has been given, the food authority must assess it and must recognise the water to which the information relates as natural mineral water if it is satisfied that—
 - (a) the water is natural mineral water which complies with paragraph 3 of Section I of Annex 1 to Directive 2009/54;
 - (b) the characteristics of the water have been assessed in accordance with—
 - (i) the points numbered 1 to 4 in paragraph 2(a) of Section I of Annex 1 to Directive 2009/54;
 - (ii) the particulars and criteria listed in Part 3 of this Schedule, and
 - (iii) recognised scientific methods.
- **4.** The food authority must, on recognising a natural mineral water in accordance with paragraph 3, publish an announcement of such recognition and the grounds on which it has been granted in the London Gazette.

PART 2

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

- **5.** A person seeking to have a water which is extracted from the ground in a country other than an EEA State recognised as a natural mineral water for the purposes of Article 1 of Directive 2009/54 must apply in writing to the Agency, giving the following information—
 - (a) the particulars specified in paragraph 10(a) of Part 3:
 - (b) the information obtained as a result of the surveys and analyses required under paragraph 10(b) and (c), as read with paragraph 11, of Part 3; and

- (c) evidence to show that the water contains no substance listed in Part 1 of Schedule 5 at a level which exceeds the maximum limit specified in relation to that substance in that Schedule.
- **6.** Where information on the anions, cations, non-ionised compounds and trace elements is required to be given pursuant to paragraph 5(b), the concentration of each anion, cation, non-ionised compound and trace element specified in the first column of the tables in Part 4 of this Schedule must be expressed in the unit of measurement specified in the second column of the tables in Part 4.
- 7. The Agency must recognise such a water if the responsible authority of the country in which the water is extracted has certified that—
 - (a) it is satisfied—
 - (i) that the requirements in paragraph 10(b) and (c) of Part 3 are established;
 - (ii) with the evidence given pursuant to paragraph 5(c); and
 - (b) periodic checks are made to ascertain that—
 - (i) the water is natural mineral water which complies with paragraph 3 of Section I of Annex I to Directive 2009/54;
 - (ii) the characteristics of the water are assessed in accordance with—
 - (aa) points numbered 1 to 4 in paragraph 2(a) of Section I of Annex I to Directive 2009/54;
 - (bb) the particulars and criteria listed in Part 3 of this Schedule; and
 - (cc) recognised scientific methods; and
 - (iii) the provisions of Schedule 4 are being applied by the person exploiting the spring.
- **8.** Recognition of such water lapses after a period of five years unless the responsible authority of the country in which the water is extracted has renewed the certification required by paragraph 7.
- **9.** The Agency must, on recognising water in accordance with this Part, publish an announcement of such recognition in the London Gazette, the Edinburgh Gazette and the Belfast Gazette.

Requirements and criteria for recognition as a natural mineral water

- **10.** A person seeking to have water recognised as natural mineral water in accordance with paragraph 1 of Part 1 or paragraph 5 of Part 2 of this Schedule, must carry out—
 - (a) geological and hydrological surveys which include the following particulars—
 - (i) the exact site of the catchment with an indication of its altitude, on a map with a scale of not more than 1:1,000;
 - (ii) a detailed geological report on the origin and nature of the terrain;
 - (iii) the stratigraphy of the hydrogeological layer;
 - (iv) a description of the catchment operations; and
 - (v) the demarcation of the area or details of other measures protecting the spring against pollution;
 - (b) physical, chemical and physico-chemical surveys which must establish—
 - (i) the rate of flow of the spring;
 - (ii) the temperature of the water at source and the ambient temperature;

- (iii) the relationship between the nature of the terrain and the nature and type of minerals in the water;
- (iv) the dry residues at 180°C and 260°C;
- (v) the electrical conductivity or resistivity, with the measurement temperature being specified;
- (vi) the hydrogen ion concentration (pH);
- (vii) the anions and cations;
- (viii) the non-ionised elements;
- (ix) the trace elements;
- (x) the radio-actinological properties at source;
- (xi) where appropriate, the relative isotope levels of the constituent elements of water, oxygen ($^{16}O^{-18}O$) and hydrogen (protium, deuterium, tritium); and
- (xii) the toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them;
- (c) a microbiological analysis at source which must show—
 - (i) the absence of parasites and pathogenic micro-organisms;
 - (ii) quantitative determination of the revivable colony count indicative of faecal contamination, demonstrating an absence of—
 - (aa) Escherichia coli and other coliforms in 250ml at 37°C and 44.5°C,
 - (bb) faecal streptococci in 250ml,
 - (cc) sporulated sulphite-reducing anaerobes in 50ml, and
 - (dd) Pseudomonas aeruginosa in 250ml; and
 - (iii) the revivable total colony count per ml of water—
 - (aa) at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture, and
 - (bb) at 37°C in 24 hours on agar-agar.
- 11.—(1) Subject to sub-paragraph (2), a person seeking to have water recognised as natural mineral water in accordance with paragraph 1 of Part 1 or paragraph 5 of Part 2 of this Schedule, must carry out clinical and pharmacological analyses in accordance with scientifically recognised methods which should be suited to the particular characteristics of the natural mineral water and its effect on the human body, such as diuresis, gastric and intestinal functions, and compensation for mineral deficiencies.
- (2) Clinical analyses may, in appropriate cases, take the place of the pharmacological analyses referred to in sub-paragraph (1), provided that the consistency and concordance of a substantial number of clinical observations enable the same results to be obtained.

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

Table A

Anions	Unit of measurement
Borate BO ₃	mg/l

Anions	Unit of measurement
Carbonate CO ₃ ²⁻	mg/l
Chloride Cl	mg/l
Fluoride F	mg/l
Hydrogen Carbonate HCO ₃	mg/l
Nitrate NO ₃	mg/l
Nitrite NO ₂	mg/l
Phosphate PO BO ₄ ³⁻	mg/l
Silicate SiO ₂ ²⁻	mg/l
Sulphate SO ₄ ²⁻	mg/l
Sulphide S ² -	mg/l

Table B

Cations	Unit of measurement	
Aluminium Al	mg/l	
Ammonium NH ₄ +	mg/l	
Calcium Ca	mg/l	
Magnesium Mg	mg/l	
Potassium K	mg/l	
Sodium Na	mg/l	

Table C

Non-ionised compounds	Unit of measurement	
Total organic carbon C	mg/l	
Free carbon dioxide CO ₂	mg/l	
Silica SiO ₂	mg/l	

Table D

Trace elements	Unit of measurement	
Barium Ba	mg/l	
Bromine (total) Br	mg/l	
Cobalt Co	mg/l	
Copper Cu	mg/l	
Iodine (total) I	mg/l	

Trace elements	Unit of measurement
Iron Fe	mg/l
Lithium Li	mg/l
Manganese Mn	mg/l
Molybdenum Mo	mg/l
Strontium Sr	mg/l
Zinc Zn	mg/l

Regulations 9(1)(a)(iii) and 15(a)(iii)

Fluoride removal treatment

- 1. No person may carry out fluoride removal treatment on natural mineral water or water intended to be bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, unless that treatment is authorised by the food authority within whose area the water is extracted.
 - 2. A person seeking authorisation to carry out fluoride removal treatment must—
 - (a) apply in writing to the food authority within whose area the water is extracted;
 - (b) permit representatives of that authority to examine the proposed method of treatment and place of treatment and take samples for analysis; and
 - (c) provide such information in support of the application as is requested by the food authority.
- **3.** The food authority must assess the application and any supporting information and must authorise the fluoride removal treatment if it is satisfied that—
 - (a) Articles 1 to 3 of Regulation 115/2010 are complied with in relation to the treatment; and
 - (b) the treatment does not have a disinfectant action.
- **4.** Where the food authority decides to authorise a fluoride removal treatment pursuant to paragraph 3, it must inform the applicant in writing and state the date from which the authorisation for use of the treatment has effect.
- **5.** Where the food authority decides to refuse to authorise a fluoride removal treatment pursuant to paragraph 3, it must inform the applicant in writing, stating its reasons.
- **6.** Where a fluoride removal treatment has been authorised pursuant to paragraph 3, the person carrying out the treatment must, for the purpose of enabling the food authority to assess whether the conditions in paragraph 3 continue to be satisfied—
 - (a) permit representatives of the authority to examine the method of treatment and place of treatment and take samples for analysis; and
 - (b) provide such information related to the treatment as is requested by the food authority.
- 7. The food authority may withdraw authorisation of a fluoride removal treatment if it is satisfied that the conditions specified in paragraph 3 are no longer fulfilled, by giving the person operating the treatment a written notice stating the grounds for withdrawal.
- **8.** Where the food authority notifies a person seeking authorisation of a fluoride removal treatment of the authority's refusal to authorise a treatment under paragraph 3, or notifies the person operating a treatment of its decision to withdraw authorisation under paragraph 7, that person may, within 6 months of being notified of the decision, apply to the Agency for a review.

- **9.** The Agency, upon receiving an application under paragraph 8, must within 3 months from the date of that application—
 - (a) make such inquiries into the matter as the Agency considers appropriate;
 - (b) consider the results of those inquiries and any other relevant facts; and
 - (c) either—
 - (i) confirm the decision; or
 - (ii) direct the food authority to grant or restore authorisation of a fluoride removal treatment as appropriate.
- **10.** The food authority must immediately comply with a direction of the Agency under paragraph 9(c)(ii).

Regulations 9(1)(a)(iv) and 15(a)(iv)

Ozone-enriched air treatment

- 1. No person may carry out an ozone-enriched air treatment on natural mineral water or water intended to be bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, unless—
 - (a) it is for the purpose of separating compounds of iron, manganese, sulphur and arsenic from water in which they occur naturally at source;
 - (b) prior to treatment the requirements of paragraphs 3, 4 and 5 of Schedule 4 are satisfied; and
 - (c) the treatment does not have a disinfectant action.
 - 2. An ozone-enriched air treatment must not—
 - (a) modify the physico-chemical composition of the water in terms of its characteristic constituents; or
 - (b) leave residues in the water which could pose a risk to public health, or, in the case of the substances listed below, above the levels specified.

Treatment residue	Maximum limit ug/l
Dissolved ozone	50
Bromate	3
Bromoform	1

- 3. A person seeking authorisation to carry out an ozone-enriched air treatment must—
 - (a) make an application in writing to the food authority in whose area the water is extracted;
 - (b) permit representatives of that authority to examine the proposed method of treatment and place of treatment and take samples for analysis; and
 - (c) provide such information in support of the application as is requested by the food authority.
- **4.** The food authority must assess the application and any supporting information and must authorise the ozone-enriched air treatment if it is satisfied that—
 - (a) the treatment process is justified by the composition of the water at source in terms of compounds of iron, manganese, sulphur and arsenic;
 - (b) the person carrying out the treatment is taking all necessary measures to ensure that the treatment is effective and safe; and

- (c) the treatment otherwise complies with paragraphs 1 and 2.
- 5. Where the food authority decides to authorise an ozone-enriched air treatment pursuant to paragraph 4, it must inform the applicant in writing and state the date from which the authorisation for use of the treatment has effect.
- **6.** Where the food authority refuses to authorise an ozone-enriched air treatment pursuant to paragraph 4, it must inform the applicant in writing, stating its reasons.
- 7. Where an ozone-enriched air treatment has been authorised pursuant to paragraph 4, the person carrying out the treatment must, for the purpose of enabling the food authority to assess whether the conditions in paragraph 4(a) and (b) continue to be satisfied—
 - (a) permit representatives of the authority to examine the method of treatment and place of treatment and take samples for analysis; and
 - (b) provide such information related to the treatment as is requested by the food authority.
- **8.** The food authority may withdraw authorisation of an ozone-enriched air treatment if it is satisfied that the conditions specified in paragraph 4 are no longer fulfilled, by giving the person operating the treatment a written notice stating the grounds for withdrawal.
- **9.** Where the food authority notifies a person seeking authorisation of an ozone-enriched air treatment of the authority's refusal to authorise a treatment under paragraph 4, or notifies the person operating a treatment of its decision to withdraw authorisation under paragraph 8, that person may, within 6 months of being notified of the decision, apply to the Agency for a review.
- **10.** The Agency, upon receiving an application under paragraph 9, must within 3 months from the date of that application—
 - (a) make such inquiries into the matter as the Agency considers appropriate;
 - (b) consider the results of those inquiries and any other relevant facts; and
 - (c) either—
 - (i) confirm the decision; or
 - (ii) direct the food authority to grant or restore authorisation of the ozone-enriched air treatment as appropriate.
- 11. The food authority must immediately comply with a direction of the Agency under paragraph 10(c)(ii).

Regulations 8, 10, 13 and 14

Exploitation and bottling requirements for natural mineral water and water intended to be labelled and sold as "spring water" or "dŵr ffynnon"

- 1. Equipment for exploiting the water must be so installed as to avoid any possibility of contamination and to preserve the properties corresponding to those ascribed to it which the water possesses at source.
 - 2. The spring or outlet must be protected against the risks of pollution.
- **3.** The catchment, pipes and reservoirs must be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water.
- **4.** The conditions of exploitation, particularly the washing and bottling equipment, must meet hygiene requirements including, in particular, that containers must be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the water.

- **5.**—(1) Subject to sub-paragraphs (2) and (3), water must not be transported in containers other than those authorised for distribution to the ultimate consumer.
- (2) Natural mineral water may be transported from the spring to the bottling plant in a container which is not for distribution to the ultimate consumer if on or before 17 July 1980 water from that spring was so transported.
- (3) Water intended to be labelled and sold as "spring water", "dŵr ffynnon", or its equivalent in any other language, may be transported from the spring to the bottling plant in a container which is not for distribution to the ultimate consumer if, on or before 13 December 1996, water from that spring was so transported.
- **6.**—(1) The revivable total colony count of the water at source, determined according to subparagraph (2), must conform to the normal viable colony count of that water and must not show that the source of that water is contaminated.
 - (2) The colony count is that determined per ml of water—
 - (a) at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture; and
 - (b) at 37°C in 24 hours on agar-agar.
 - 7.—(1) After bottling, the total colony count of the water at source may not exceed—
 - (a) 100 per ml at 20 to 22°C in 72 hours on agar-agar or on agar-gelatine mixture; and
 - (b) 20 per ml at 37°C in 24 hours on agar-agar.
- (2) The total colony count of the water must be measured within a period of 12 hours following bottling, the water being maintained at 4°C +/- 1°C during that period.
 - **8.** Water must be free from—
 - (a) parasites and pathogenic micro-organisms;
 - (b) Escherichia coli and other coliforms and faecal streptococci in any 250ml sample examined;
 - (c) sporulated sulphite-reducing anaerobes in any 50ml sample examined; and
 - (d) Pseudomonas aeruginosa in any 250ml sample examined.

Regulation 10

Constituents of natural mineral water

PART 1

Maximum limits for constituents of natural mineral water

Constituents ⁽¹⁾	Maximum limits (mg/l)
Antimony	0.0050
Arsenic	0.010 (as total)
Barium	1.0

⁽¹⁾ The constituents described above refer to constituents naturally present in the water at source and not to substances present as the result of contamination.

Constituents ⁽¹⁾	Maximum limits (mg/l)
Cadmium	0.003
Chromium	0.050
Copper	1.0
Cyanide	0.070
Fluoride	5.0
Lead	0.010
Manganese	0.50
Mercury	0.0010
Nickel	0.020
Nitrate	50
Nitrite	0.1
Selenium	0.010

⁽¹⁾ The constituents described above refer to constituents naturally present in the water at source and not to substances present as the result of contamination.

PART 2
Performance characteristics for analysing the constituents in Part 1

Constituents ⁽¹⁾	Accuracy of parametric value in %(2)	Precision of parametric value ⁽³⁾	Detection limit of parametric value in %
Antimony	25	25	25
Arsenic	10	10	10
Barium	25	25	25
Cadmium	10	10	10
Chromium	10	10	10
Copper	10	10	10
Cyanide ⁽⁵⁾	10	10	10
Fluoride	10	10	10
Lead	10	10	10
Manganese	10	10	10
Mercury	20	10	20
Nickel	10	10	10
Nitrate	10	10	10

(1)

Constituents ⁽¹⁾	Accuracy of parametric value in % ⁽²⁾	· ·	Detection limit of parametric value in %
Nitrite	10	10	10
Selenium	10	10	10

- (1) The method of analysis used to measure the concentration of the constituents in Part 1 must be capable of measuring concentrations equal to the parametric value with the specified accuracy, precision and detection limits. Regardless of the sensitivity of the method of analysis, the result must be expressed to at least the same number of decimal places as the maximum limit set out in Part 1 for the particular constituent being analysed.
- (2) Accuracy is the systematic error and represents the difference between the average value of a large number of repeated measurements and the exact value.
- (3) Precision represents the random error and is expressed in general as the standard deviation (within a batch and between batches) of a sample of results from the average. Acceptable precision is equal to twice the relative standard deviation.
- (4) The detection limit is—
- (a) three times the relative standard deviation within a batch of a natural sample containing a low concentration of the constituent; or
- (b) five times the relative standard deviation within a batch of a virgin sample.
- (5) The method should make it possible to determine cyanide in all its forms.

SCHEDULE 6 Regulation 11(1)(e)

Labelling indications for natural mineral water

Indication	Criteria	
Low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 500 mg/l	
Very low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 50 mg/l	
Rich in mineral salts	Mineral salt content, calculated as a fixed residue, greater than 1500 mg/l	
Contains bicarbonate	Bicarbonate content greater than 600 mg/l	
Contains sulphate	Sulphate content greater than 200 mg/l	
Contains chloride	Chloride content greater than 200 mg/l	
Contains calcium	Calcium content greater than 150 mg/l	
Contains magnesium	Magnesium content greater than 50 mg/l	
Contains fluoride	Fluoride content greater than 1 mg/l	
Contains iron	Bivalent iron content greater than 1 mg/l	
Acidic	Free carbon dioxide content greater than 250 mg/ l	
Contains sodium	Sodium content greater than 200 mg/l	
Suitable for a low-sodium diet	Sodium content less than 20 mg/l	

Regulations 14(1)(d) and 19

Requirements for water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water including prescribed concentrations or values of parameters

PART 1

Requirements for water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

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

PART 2 Parametric values for microbiological and chemical parameters

Table A: Microbiological Parameters

Item	Parameter	Units of Measurement	Maximum Concentration or Value
1.	Escherichia coli	number/250 ml	0/250 ml
	(E coli)		
2.	Enterococci	number/250 ml	0/250 ml
3.	Pseudomonas aeruginosa	number/250ml	0/250 ml
4.	Colony count 22°C	number/ml	100/ml (1)(2)

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

(3) In 24 hours on agar-agar.

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

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⁽¹⁾

Item	Parameter	Units of Measurement	Maximum Concentration or Value
5.	Colony count 37°C	number/ml	$20/\text{ml}^{(1)(3)}$

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

Table B: Chemical Parameters

Item	Parameter	Units of Measurement	Maximum Concentration or Value
1.	Acrylamide	μg/l	0.10 (1)
2.	Antimony	μg Sb/l	5
3.	Arsenic	μg As/l	10
4.	Benzene	μg/l	1.0
5.	Benzo (a) pyrene	μg/l	0.010
6.	Boron	mg/l	1.0
7.	Bromate	$\mu g/l \; BrO_3/l$	10
8.	Cadmium	μg Cd/l	5
9.	Chromium	μg Cr/l	50
10.	Copper	mg Cu/l	2
11.	Cyanide	μg CN/l	50
12.	1,2-dichloroethane	μg/l	3.0
13.	Epicholorohydrin	μg/l	0.10 (1)
14.	Fluoride	mg F/l	1.5
15.	Lead	μg Pb/l	10
16.	Mercury	μg Hg/l	1
17.	Nickel	μg Ni/l	20
18.	Nitrate	mg NO _{3/} l	50 ⁽²⁾
19.	Nitrite	mg NO ₂ /l	0.5 (2)
20.	Pesticides and relaproducts:	ated	

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

⁽³⁾ In 24 hours on agar-agar.

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Item	Parameter	Units of Measurement	Maximum Concentration or Value
	- individual substances	μg/l	0.10 (3)(4)
	- total substances	$\mu g/l$	0.50 (3)(5)
21.	Polycyclic aromatic hydrocarbons	μg/l	0.1 sum of concentrations of specified compounds ⁽⁶⁾
22.	Selenium	μg Se/l	10
23.	Tetrachloroethene and Trichloroethene	$\mu g/l$	10 (7)
24.	Trichloromethane,	$\mu g/l$	100 (7)
	Dicholrorbromomethane, Dibromocholromethane and Tribromomethane		
25.	Vinyl chloride	μg/l	0.50 (1)

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

- (2) The concentration (mg/l) of nitrate divided by 50 added to the concentration (mg/l) of nitrite divided by 3 must not exceed 1.
- (3) "Pesticides" means:
- organic insecticides,
- organic herbicides,
- organic fungicides,
- organic nematocides,
- organic acaricides,
- organic algicides,
- organic rodenticides,
- organic slimicides, and
- related products (inter alia, growth regulators) and their relevant metabolites, degradation and reaction products.

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

- (4) The maximum concentration applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the maximum concentration is 0.030 μg/l.
- (5) The maximum concentration for "total substances" refers to the sum of the concentrations of all individual pesticides detected and quantified in the monitoring procedure.
- (6) The specified compounds are benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(ghi)perylene, indeno(1,2,3-cd)pyrene.
- (7) The maximum concentration specified applies to the sum of the concentrations of the specified parameters.

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PART 3 Parametric values for indicator parameters

Table C: Indicator Parameters

Item	Parameter	Units of Measurement	Maximum Concentration or Value
1.	Aluminium	μg/l	200
2.	Ammonium	mg/l	0.50
3.	Chloride	mg/l	250 ⁽¹⁾
4.	Clostridium perfringens (including spores)	number/100ml	0 (2)
5.	Colour	Mg/1 Pt/Co scale	20
6.	Conductivity	μS cm ⁻¹ at 20°C	2500 (1)
7.	Hydrogen ion concentration	pH units	4.5 (minimum)
			9.5 (maximum) (1)
8.	Iron	$\mu g/l$	200
9.	Manganese	$\mu g/l$	50
10.	Odour	Dilution number	3 at 25°C
11.	Oxidisability	mg/l O_2	5 (3)
12.	Sulphate	mg/l	250 ⁽¹⁾
13.	Sodium	mg/l	200
14.	Taste	Dilution number	3 at 25°C
15.	Colony Count 22°C	No abnormal change	
16.	Coliform bacteria	number/250ml	0
17.	Total Organic Carbon	No abnormal change	(4)

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

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Item	Parameter	Units of Measurement	Maximum Concentration or Value
18.	Turbidity	Acceptable to consumers and no abnormal change	

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

PART 4 Parametric values for radon, tritium and indicative dose (ID)

Table D:

Item	Parameter	Unit of Measurement	Maximum Concentration or Value
1.	Radon	Bq/l	100 (1)
2.	Tritium	Bq/l	100 (2)
3.	Indicative Dose	mSv	0.10

⁽¹⁾ Remedial action is deemed to be justified on radiological protection grounds, without further consideration, where radon concentrations exceed 1000 Bq/l.

SCHEDULE 8

Regulation 24(2)(a)

Monitoring for parameters other than radioactive substances in water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

PART 1

Check monitoring

Sampling

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

⁽²⁾ Elevated levels of tritium may indicate the presence of other artificial radionuclides. If the tritium concentration exceeds its parametric value, an analysis of the presence of other artificial radionuclides is required.

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- **2.** Check monitoring means sampling water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, and bottled drinking water, for each parameter listed in Table 1 in the circumstances listed in that table in order—
 - (a) to determine whether the water complies with the relevant parametric concentrations or values specified in Parts 2 and 3 of Schedule 7;
 - (b) to provide information on the organoleptic and microbiological quality of the water; and
 - (c) to establish the effectiveness of the treatment of the water, including disinfection.

Table 1

Parameter	Circumstances
Aluminium	Necessary only when used as flocculant.
Ammonium	In all supplies
Colour	In all supplies
Conductivity	In all supplies
Clostridium perfringens (including spores)	Necessary only if the water originates from or is influenced by surface water.
Escherichia coli (E. Coli)	In all supplies
Hydrogen ion concentration	In all supplies
Iron	Necessary only when used as flocculant.
Nitrite	Necessary only when chloramination is used as a disinfectant.
Odour	In all supplies
Pseudomonas aeruginosa	In all supplies
Taste	In all supplies
Colony count 22°C and 37°C	In all supplies
Coliform bacteria	In all supplies
Turbidity	In all supplies

Frequency of sampling

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

Table 2

Volume of water produced for offering for sale in bottles or containers each day $(m^3)^{(1)}$	Number of samples per year
≤ 10	1
> 10 \le 60	12
> 60	1 for each 5m ³ and part thereof of the total volume

 $[\]begin{tabular}{ll} \textbf{(1)} & The volumes are calculated as averages taken over a calendar year. \\ \end{tabular}$

Audit monitoring

Sampling

- 4. Each food authority must undertake audit monitoring in accordance with this Part.
- **5.** Audit monitoring means sampling water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, and drinking water in a bottle, for each parameter specified in Parts 2 and 3 of Schedule 7 (other than parameters already being sampled under check monitoring) in order to—
 - (a) provide the information necessary to determine whether the water complies with the relevant parametric concentrations or values specified in Parts 2 and 3 of Schedule 7; and
 - (b) check that, if disinfection is used in the case of bottled drinking water, disinfection byproducts are kept as low as possible without compromising disinfection.

Frequency of sampling

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

Table 3

Volume of water produced for offering for sale in bottles or containers each day $(m^3)^{(1)}$	Number of samples per year
≤ 10	1
> 10 ≥ 60	1
> 60	1 for each 100 m ³ and part thereof of the total volume

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

SCHEDULE 9

Regulation 24(2)(b)

Monitoring for radioactive substances in water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

PART 1

General

1. Each food authority must monitor water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, and bottled drinking water, for radon, tritium and indicative dose in accordance with this Part.

Radon

- **2.** Each food authority must undertake representative surveys to determine the scale and nature of likely exposure to radon originating from different types of ground water sources and wells in different geological areas.
- **3.** The representative surveys must be designed in such a way that underlying parameters, including 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.
- **4.** Each food authority must monitor for radon if there is reason to believe, on the basis of the results of the representative surveys or other reliable information, that the parametric value for radon specified in Part 4 of Schedule 7 might be exceeded.

Tritium

- **5.** Each food authority must monitor for tritium if an anthropogenic source of tritium or other artificial radionuclide 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 specified in Part 4 of Schedule 7.
 - 6. Sampling must be carried out at the frequencies specified in the Table in Part 2 of this Schedule.
- 7. If the concentration of tritium exceeds the parametric value specified in Part 4 of Schedule 7, the food authority must investigate the presence of other artificial radionuclides.

Indicative dose

- **8.** Each food authority must monitor for indicative dose if a source of artificial or elevated natural radioactivity is present and it cannot be shown on the basis of representative monitoring programmes or other investigations that the level of indicative dose is below the parametric value specified in Part 4 of Schedule 7.
 - 9. Sampling must be carried out at the frequencies specified in the Table in Part 2 of this Schedule.
- **10.** The food authority may use various reliable screening strategies to monitor for the parametric indicator value for indicative dose.
 - 11. If the food authority screens for an individual radionuclide or certain radionuclides and—
 - (a) one of the activity concentrations exceeds 20% of the corresponding derived value specified in Table 1 in Part 2 of Schedule 11; or
 - (b) where applicable, the concentration of tritium exceeds the parametric value specified in Part 4 of Schedule 7, the food authority must investigate the presence of other radionuclides, as determined by the food authority, taking into account all relevant information about likely sources of radioactivity.
 - 12.—(1) If the food authority screens for gross alpha activity and gross beta activity and—
 - (a) the screening level for gross alpha activity exceeds 0.1 Bq/l; or
 - (b) the screening level for gross beta activity exceeds 1.0 Bq/l, the food authority must investigate the presence of other radionuclides as determined by the food authority, taking into account all relevant information about likely sources of radioactivity.
- (2) The food authority may set alternative screening levels for gross alpha activity and gross beta activity if it can demonstrate that the alternative levels are in compliance with an indicative dose of 0.1mSv.

- (3) If elevated levels of tritium are detected which indicate the presence of other artificial radionuclides, tritium, gross alpha activity and gross beta activity must be measured in the same sample.
- (4) If the gross alpha activity and gross beta activity are less than 0.1 Bq/l and 1.0 Bq/l respectively, the food authority may assume that the indicative dose is less than the parametric value of 0.1 mSv in which case further radiological investigation is not required unless it is known from other sources of information that specific radionuclides are present in the water that are liable to cause an indicative dose in excess of 0.1 mSv.

Exemption from monitoring

- **13.** A food authority is not required to monitor water bottled and labelled as "spring water", "dŵr ffynnon", or its equivalent in any other language, or bottled drinking water, for radon, tritium or indicative dose if—
 - (a) it is satisfied on the basis of representative surveys, monitoring data or other reliable information that, for a minimum period of 5 years, the parameter in question will remain below the respective parametric value specified in Part 4 of Schedule 7; and
 - (b) it notifies the Agency of that decision and provides the Agency with a copy of the representative surveys, monitoring data or other reliable information referred to in subparagraph (a).

Treatment of bottled drinking water

14. Where bottled drinking water has been treated to reduce the level of radionuclides, the food authority must carry out monitoring at the frequencies indicated in the Table in Part 2 to ensure the continued efficacy of that treatment.

Averaging

15. If a parametric value specified in Part 4 of Schedule 7 is exceeded in a sample of water, the food authority must take further samples as appropriate, having regard to guidance issued by the Agency, to ensure that the measured values are representative of an average activity concentration for a full year.

PART 2 Minimum sampling and analysis frequencies

Volume of water produced each day within a supply zone (1)(2)	Number of samples per year ⁽³⁾
<i>m</i> 3	
volume ≤ 100	1
$100 < volume \le 100$	1

- (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.
- (2) The volumes are calculated as averages taken over a calendar year.
- (3) As far as possible, the number of samples should be distributed equally in time and location.

Volume of water produced each day within a supply zone (1)(2)	Number of samples per year (3)
m3	
1,000 < volume ≤ 10,000	1+1 for each 3,300m ³ /d and part thereof of the total volume
10, 000 < volume ≤ 100,000	$3+1$ for each $10,000 \text{ m}^3/\text{d}$ 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

- (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.
- (2) The volumes are calculated as averages taken over a calendar year.
- (3) As far as possible, the number of samples should be distributed equally in time and location.

Regulation 25(1)(a)

Sampling and analysis for parameters other than radioactive substances in water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

PART 1

General

Analysis of samples

- 1.—(1) The food authority must ensure that each sample is analysed in accordance with Annex III to Directive 98/83 and this Schedule.
- (2) For each parameter specified in the first column of Table 1 in Part 2 of this Schedule the method of analysis is specified in the second column of that table.
- (3) For each parameter specified in the first column of Table 2 in Part 2 of this Schedule the method of analysis is one that is capable of—
 - (a) measuring concentrations and values with the trueness and precision specified in the second and third columns of that table; and
 - (b) detecting the parameter at the limit of detection specified in the fourth column of that table.
- (4) For hydrogen ion, the method of analysis must be capable of measuring a value with a trueness of 0.2pH unit and a precision of 0.2pH unit.
- (5) The method of analysis used for odour and taste parameters must be capable of measuring values equal to the parametric value with a precision of 1 dilution number at 25°C.
 - (6) For the purposes of this paragraph—
 - "limit of detection" ("terfyn canfod") is-
 - (a) three times the relative within-batch standard deviation of a natural sample containing a low concentration of the parameter; or
 - (b) five times the relative within-batch standard deviation of a blank sample;

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

"trueness" ("cywirdeb") (the systematic error) is the difference between the mean value of the large number of repeated measurements and the true value.

Authorisation of alternative methods of analysis

- **2.**—(1) The Agency may authorise a method different from that set out in Part 2 of this Schedule if satisfied that it is at least as reliable.
 - (2) An authorisation may be time-limited and may be revoked at any time.

Sampling and analysis by persons other than food authorities

- **3.**—(1) A food authority may enter into an arrangement for any person to take and analyse samples on its behalf.
 - (2) A food authority must not enter into an arrangement under sub-paragraph (1) unless—
 - (a) it is satisfied that the task will be carried out promptly by a person competent to perform it; and
 - (b) it has made arrangements that ensure that any breach of these Regulations is communicated to it immediately, and any other result is communicated to it within 28 days.

PART 2

Methods of analysis and performance characteristics

Table 1

Prescribed	methods	of ans	lveie
i i esci incu	memous	VI AIIZ	11 7 212

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

⁽¹⁾ Use the following method to make m-CP agar:

Parameter	Method
Make a basal medium consisting of—	
Tryptose	30.0g
Yeast extract	20.0g
Sucrose	5.0g
L-cysteine hydrochloride	1.0g
$MgSO_4.7H_2O$	0.1g
Bromocresol purple	40.0mg
Agar	15.0g
Water	1,000.0ml

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

Dissolve-

D-cycloserine	400.0mg
Polymyxine-B sulphate	25.0mg
Indoxl-β-D-glucoside	60.0mg
into 8ml sterile water and add it to the medium.	Add to the medium—

Filter-sterilised 0.5% phenolphthalein 20.0ml

diphosphate solution

Filter-sterilised 4.5% FeCl₃.6H₂O 2.0ml

Table 2

Prescribed performance characteristics for methods of analysis

Parameters	Trueness % of prescribed	Precision % of prescribed	Limit of detection % of prescribed
	concentration or	concentration or	concentration or
	value or specification	value or specification	value or specification
Aluminium	10	10	10
Ammonium	10	10	10
Antimony	25	25	25
Arsenic	10	10	10

⁽¹⁾ The method of analysis should determine total cyanide in all forms.

⁽¹⁾ Use the following method to make m-CP agar:

⁽²⁾ Oxidation should be carried out for 10 minutes at 100°C under acid conditions using permanganate.

⁽³⁾ The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned.

⁽⁴⁾ The performance characteristics apply to the individual substances specified at 25% of the parametric value in Table B in Part 2, Schedule 7.

⁽⁵⁾ The performance characteristics apply to the individual substance specified at 50% of the parametric value in Table B in Part 2, Schedule 7.

Benzene	25	25	25
Benzo(a)pyrene	25	25	25
Boron	10	10	10
Bromate	25	25	25
Cadmium	10	10	10
Chloride	10	10	10
Chromium	10	10	10
Conductivity	10	10	10
Copper	10	10	10
Cyanide ⁽¹⁾	10	10	10
1,2-dichloroethane	25	25	10
Fluoride	10	10	10
Iron	10	10	10
Lead	10	10	10
Manganese	10	10	10
Mercury	20	10	20
Nickel	10	10	10
Nitrate	10	10	10
Nititre	10	10	10
Oxidisability ⁽²⁾	25	25	10
Pesticides and related products ⁽³⁾	25	25	25
Polycyclic aromatic hydrocarbons ⁽⁴⁾	25	25	25
Selenium	10	10	10
Sodium	10	10	10
Sulphate	10	10	10
(4) TI 41 1 C 1 : 1	1114 : 441 :11:	11 C	

- (1) The method of analysis should determine total cyanide in all forms.
- (2) Oxidation should be carried out for 10 minutes at 100°C under acid conditions using permanganate.
- (3) The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned.
- (4) The performance characteristics apply to the individual substances specified at 25% of the parametric value in Table B in Part 2, Schedule 7.
- (5) The performance characteristics apply to the individual substance specified at 50% of the parametric value in Table B in Part 2, Schedule 7.

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Tetrachloroethene ⁽⁵⁾	25	25	10
Trichloroethene ⁽⁵⁾	25	25	10
Trihalomethanes ⁽⁴⁾	25	25	10

- (1) The method of analysis should determine total cyanide in all forms.
- (2) Oxidation should be carried out for 10 minutes at 100°C under acid conditions using permanganate.
- (3) The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned.
- (4) The performance characteristics apply to the individual substances specified at 25% of the parametric value in Table B in Part 2, Schedule 7.
- (5) The performance characteristics apply to the individual substance specified at 50% of the parametric value in Table B in Part 2, Schedule 7.

Regulation 25(1)(b)

Sampling and analysis for indicative dose in water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water

PART 1

General

Analysis of samples

- **1.** The food authority must ensure that each sample is analysed for indicative dose in accordance with Annex III to Directive 2013/51 and this Part.
- **2.** For each parameter and radionuclide specified in the first column of Table 1 in Part 2 of this Schedule, the derived concentration and dose coefficient for calculating the indicative dose is specified in the second column of that table.
- **3.** For each parameter specified in the first column of Table 2 in Part 2 of this Schedule, the method of analysis must be one that is capable of detecting the parameter at the limit of detection specified in the second column of that table.
- **4.** If the following formula is satisfied, the indicative dose is considered to be less than the parametric value of 0.1 mSv and no further investigation is required—

$$\sum_{i=1}^{n} \frac{C_i(obs)}{C_i(der)} \le 1$$

where

Ci(obs) = observed concentration radionuclide i

⁽¹⁾

⁽¹⁾

⁽¹⁾

Ci(der) = derived concentration of radionuclide i n = number of radionuclides detected

PART 2 Methods of analysis and performance characteristics

Table 1

Derived concentrations for radioactivity

Origin	Nuclide	Derived concentration
Natural	U-238 ⁽¹⁾	3.0 Bq/l
	U-234 ⁽¹⁾	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 allows only for the radiological properties of uranium, not for its chemical toxicity.

Table 2
Performance characteristics and methods of analysis

Parameters and radionuclides	Limit of detection (1)(2)
Tritium	10 Bq/l ⁽³⁾
Radon	10 Bq/l ⁽³⁾
gross alpha activity	$0.04 \text{ Bq/l}^{(4)}$

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Parameters and radionuclides	Limit of detection (1)(2)
gross beta activity	0.4 Bq/l ⁽⁴⁾
U-238	0.02 Bq/l
U-234	0.02 Bq/l
Ra-226	0.04 Bq/l
Ra-228	$0.02 \text{ Bq/l}^{(5)}$
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

- (1) The limit of detection is 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.
- (2) Measurement uncertainties are 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
- (3) The limit of detection for tritium and for radon is 10% of its parametric value of 100 Bq/l.
- (4) The limit of detection for gross alpha activity and gross beta activities are 40% of the screening values of 0.1 and 1.0 Bq/l respectively.
- (5) This limit of detection applies only to initial screening for indicative dose 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.

Regulations 33, 34 and 35

Application and modification of provisions of the Act

Table 1

Improvement notices

Provision of the Act	Modifications
Section 10(1) and (2) (improvement notices)	(1) For subsection (1) substitute—

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Provision of the Act

Modifications

"(2) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with any provision specified in subsection (1A) or is carrying out either a fluoride removal treatment or an ozone-enriched air treatment that has a disinfectant action, the authorised officer may, by a notice served on that person (in this Act referred to as an "improvement notice")

- (a) state the authorised officer's grounds for believing that the person is failing to comply with the relevant provision;
- (b) specify the matters which constitute the person's failure so to comply;
- (c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures or measures that are at least equivalent to them, within such period as may be specified in the notice.
- (1A) The provisions referred to in subsection (1) are—
 - (a) any of regulations 8 to 22 of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015; and
 - (a) any of the following provisions of Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters(23)—

⁽²³⁾ OJ No L 37, 10.2.2010, p 13.

Provision of the Act

Modifications

- (i) Article 1.2 (requirement that any fluoride removal treatment be performed in accordance with the technical requirements set out in the Annex);
- (ii) the first sentence of Article 2 (requirement that the release of residues into natural mineral water or spring water as a result of any fluoride removal treatment be as low as technically feasible according to the best practices and not pose a risk to public health);
- (iii) the second sentence of Article 2 (requirement to ensure compliance with the first sentence of Article 2, operators implement and monitor the critical processing steps set out in the Annex);
- (iv) Article 3.1 (requirement that the application of any fluoride removal treatment be notified to the competent authorities at least three months prior to use); and
- (v) Article 4 (requirement that the label on natural mineral water or spring water subjected to any fluoride removal treatment include specified information in proximity to the statement of the analytical composition)."

Table 2
Powers of entry

Provision of the Act	Modifications
Section 32(1) to (7) (powers of entry)	In subsection (1), for paragraphs (a) to (c) substitute—

- "(a) to enter any premises within the authority's area for the purpose of ascertaining whether there is or has been on the premises a contravention of any of the following provisions of Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters—
 - (i) Article 1.2 (requirement that any fluoride removal treatment be performed in accordance with the technical requirements set out in the Annex);
 - (ii) the first sentence of Article 2 (requirement that the release of residues into natural mineral water or spring water as a result of any fluoride removal treatment be as low as technically feasible according to the best practices and not pose a risk to public health);
 - (iii) the second sentence of Article 2 (requirement to ensure compliance with the first sentence of Article 2, operators implement and monitor the critical processing steps set out in the Annex);
 - (iv) Article 3.1 (requirement that the application of any fluoride removal treatment be notified to the competent authorities at least three months prior to use); and
 - (v) Article 4 (requirement that the label on natural mineral water or spring water subjected to any fluoride removal

Provision of the Act	Modifications
	treatment include specified information in proximity to the statement of the analytical composition); and
	(b) to enter any business premises, whether within or outside the authority's area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention within that area of the provisions set out in paragraph (a);".

Table 3 Other provisions of the Act

Provision of the Act	Modifications
Section 2(24) (extended meaning of "sale" etc.)	In subsection (1), for "this Act" substitute "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015". In subsection (2), for "This Act" substitute "The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for "this Act" substitute "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 20 (offences due to fault of another person)	For "any of the preceding provisions of this part" substitute "section 10(2) as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,".
Section 21(1) and (5)(25) (defence of due diligence)	In subsection (1), for "any of the preceding provisions of this Part" substitute "section 10(2) as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,".
Section 22 (defence of publication in the course of business)	For "any of the preceding provisions of this Part" substitute "section 10(2) as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 29 (procurement of samples)	In paragraph (b)(ii), after "under section 32 below", insert "as applied by regulation 34

⁽²⁴⁾ Section 2(1) was amended by the section 40(1) of, and paragraph 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28). (25) Section 21(2) was amended by S.I. 2004/3279.

Provision of the Act	Modifications
	of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
	In subsection (8), for "this Act" substitute "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 33 (obstruction etc. of officers)	In subsection (1), for "this Act" (in each place where it occurs) substitute "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 35(1)(26) and (2) (punishment of offences)	In subsection (1), after "section 33(1) above" insert ", as applied and modified by regulation 35 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,".
	After subsection (1), insert—
	"(1A) A person guilty of an offence under section 10(2), as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015 shall be liable, on summary conviction, to a fine not exceeding level 4 on the standard scale."
	In subsection (2), in the opening words, for "any other offence under this Act" substitute "an offence under section 33(2), as applied by regulation 35 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015,".
Section 36 (offences by bodies corporate)	In subsection (1), for "this Act" substitute "section 10(2) as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 36A(27) (offences by Scottish partnerships)	For "this Act" substitute "section 10(2) as applied by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".
Section 37(1) and (6) (appeals)	For subsection (1) substitute—

 ⁽²⁶⁾ Section 35(1) is to be amended by section 280(2) of, and paragraph 42 of Schedule 26 to, the Criminal Justice Act 2003 (c. 44) from a date to be appointed.
 (27) Section 36A was inserted by section 40(1) of, and paragraph 16 of Schedule 5 to, the Food Standards Act 1999.

Provision of the Act	Modifications
	"Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 33 of, and Schedule 12 to, the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015, may appeal to a magistrates' court."
	In subsection (6)—
	for "(3) and (4)" substitute "(1)"; and
	in paragraph (a), omit "or to the sheriff".
Section 39 (appeals against improvement	For subsection (1) substitute—
notices)	"(1) On an appeal against an improvement notice served under section 10(1), as applied and modified by regulation 33 of, and Schedule 12 to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015, the magistrates' court may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the magistrates' court may in the circumstances think fit."
	In subsection (3), omit "for want of prosecution".
Section 44 (protection of officers acting in good faith)	For "this Act" (in each place where it occurs) substitute "the Natural Mineral Water, Spring

Regulations 2015".

Regulation 38

Water and Bottled Drinking Water (Wales)

Amendments to other legislation

The Private Water Supplies (Wales) Regulations 2010

- 1. The Private Water Supplies (Wales) Regulations 2010(28) are amended as follows.
- **2.** In regulation 3(a), for "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007" substitute "the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015".

The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013

- **3.** The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013(29) are amended as follows.
- **4.** In Schedule 1, omit the reference to "The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007".

The Food Information (Wales) Regulations 2014

- **5.** The Food Information (Wales) Regulations 2014(**30**) are amended as follows.
- **6.** In Schedule 7, omit paragraphs 49 and 50.

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

- (a) Council Directive 98/83/EC relating to the quality of water intended for human consumption (OJ No L 330, 3.11.1998, p 32), so far as it applies to water intended to be labelled and sold as "spring water" or "dŵr ffynnon" and bottled drinking water;
- (b) Directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of natural mineral waters (OJ No L 164, 26.6.2009, p 45);
- (c) Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters (OJ No L 126, 22.5.2003, p 34);
- (d) Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters (OJ No L 37, 10.2.2010, p 13); and
- (e) Council Directive 2013/51/Euratom laying down the requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (OJ No L 296, 7.11.2013, p 12), so far as it applies to water intended to be labelled and sold as "spring water" or "dŵr ffynnon" and bottled drinking water.

The Regulations revoke and replace the Natural Mineral Water, Spring Water and Bottled Water (Wales) Regulations 2007 (S.I. 2007/3165 (W.276)) and amending instruments.

Part 1 is introductory and includes relevant definitions.

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

⁽²⁹⁾ S.I. 2013/479 (W.55), amended by S.I. 2013/2493 (W.242).

⁽**30**) S.I. 2014/2303 (W.227).

Part 3 applies restrictions on exploiting springs and the treatment, bottling, labelling, advertisement and sale of water intended to be sold as "spring water" or "dŵr ffynnon".

Part 4 applies restrictions on the bottling, labelling, advertisement and sale of bottled drinking water.

Part 5 prescribes the requirements for monitoring natural mineral water, water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water for the purpose of ensuring that the requirements of these Regulations are satisfied.

Regulation 26 prescribes the remedial action that must be taken by a food authority in relation to water bottled and labelled as "spring water" or "dŵr ffynnon" and bottled drinking water in the event of non-compliance with the parametric values for the parameters set out in Schedule 7.

Part 6 provides for enforcement, transitional provisions, revocations and amendments to other legislation. Regulation 32 imposes an obligation on food authorities to execute and enforce the Regulations.

Regulations 33 to 35 and Schedule 12 apply certain provisions of the Food Safety Act 1990 (1990 c. 16), with modifications. This includes the application (with modifications) of section 10(1), enabling an improvement notice to be served requiring compliance with specified provisions of the Regulations. The provisions, as applied, make the failure to comply with an improvement notice an offence.

Regulation 38 and Schedule 13 make amendments to the Private Water Supplies (Wales) Regulations 2010, the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 and the Food Information (Wales) Regulations 2014.

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