



STATUTORY INSTRUMENTS.

S.I. No. 282 of 2016

EUROPEAN UNION (NATURAL MINERAL WATERS, SPRING
WATERS AND OTHER WATERS IN BOTTLES OR CONTAINERS)
REGULATIONS 2016

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WATERS AND OTHER WATERS IN BOTTLES OR CONTAINERS)
REGULATIONS 2016

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EUROPEAN UNION (NATURAL MINERAL WATERS, SPRING
WATERS AND OTHER WATERS IN BOTTLES OR CONTAINERS)
REGULATIONS 2016

I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Council Directive 98/83/EC of 3 November 1998¹ and Commission Directive 2003/40/EC of 16 May 2003², and giving effect to Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009³, Commission Regulation (EU) No. 115/2010 of 9 February 2010⁴, Council Directive 2013/51/EURATOM of 22 October 2013⁵ and Commission Directive (EU) 2015/1787 of 6 October 2015⁶, hereby make the following regulations:

Part 1

PRELIMINARY

Citation

1. These Regulations may be cited as the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016.

Interpretation

2. (1) In these Regulations—

“Act of 1998” means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

“approved examiner” means—

(a) a Chief Medical Scientist located at an Official Microbiology Laboratory,

(b) a Consultant Microbiologist located at an Official Microbiology Laboratory,

(c) a Deputy Public Analyst located at a Public Analyst’s Laboratory,

¹OJ No. L 330, 5.12.98, p. 32.

²OJ No. L 126, 22.5.2003, p. 34.

³OJ No. L 164, 26.6.2009, p. 45.

⁴OJ No. L 37, 10.2.2010, p. 13.

⁵OJ No. L 296, 7.11.2013, p. 12.

⁶OJ No. L 260, 7.10.2015, p. 6.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 31st May, 2016.*

- (d) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,
- (e) a Public Analyst located at a Public Analyst’s Laboratory,
- (f) a Scientific Officer at Level 3 or higher at the Office of Radiological Protection, Environmental Protection Agency, or
- (g) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 29(b);

“authorised officer” means an authorised officer appointed under section 49 of the Act of 1998;

“Authority” means the Food Safety Authority of Ireland established under section 9 of the Act of 1998;

“bottled waters” means—

- (a) natural mineral waters,
- (b) spring waters, and
- (c) other waters

intended for human consumption and supplied in a bottle or container, other than waters which are medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001⁷, as amended by Article 1(1)(b) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004⁸;

“Commission Directive 2003/40/EC” means Commission Directive 2003/40/EC of 16 May 2003² establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters;

“Commission Regulation 115/2010” means Commission Regulation (EU) No. 115/2010 of 9 February 2010⁴ laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters;

“Council Directive 98/83/EC” means Council Directive 98/83/EC of 3 November 1998¹ on the quality of water intended for human consumption, as affected by the Corrigendum to Council Directive 98/83/EC of 20 April 2001⁹, and as amended by Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003¹⁰, Regulation (EC) No. 596/2009 of the

⁷OJ No. L 311, 28.11.2001, p. 67.

⁸OJ No. L 136, 30.4.2004, p. 34.

⁹OJ No. L 111, 20.4.2001, p. 31.

¹⁰OJ No. L 284, 31.10.2003, p. 1.

European Parliament and of the Council of 18 June 2009¹¹ and Commission Directive (EU) 2015/1787 of 6 October 2015⁶;

“Council Directive 2013/51/EURATOM” means Council Directive 2013/51/EURATOM of 22 October 2013⁵ laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption;

“Directive 2009/54/EC” means Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009³ on the exploitation and marketing of natural mineral waters;

“General Food Law Regulation” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002¹², as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council of 22 July 2003¹³, Commission Regulation (EC) No. 575/2006 of 7 April 2006¹⁴, Commission Regulation (EC) No. 202/2008 of 4 March 2008¹⁵, Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009¹⁶ and Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15 May 2014¹⁷;

“Minister” means the Minister for Health;

“Member State” means a state which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;

“natural mineral waters” has the meaning assigned to it in Regulation 4(2);

“official agency” means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

“Official Controls Regulation” means Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004¹⁸, as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004¹⁹, as amended by Commission Regulation (EC) No. 1029/2008 of 20 October 2008²⁰, Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009¹⁶, Commission Regulation (EU) No. 208/2011 of 2 March 2011²¹ (as corrected by Commission Regulation (EU) No. 880/2011 of 2 September 2011²²),

¹¹OJ No. L 188, 18.7.2009, p. 14.

¹²OJ No. L 31, 1.2.2002, p. 1.

¹³OJ No. L 245, 29.9.2003, p. 4.

¹⁴OJ No. L 100, 8.4.2006, p. 3.

¹⁵OJ No. L 60, 5.3.2008, p. 17.

¹⁶OJ No. L 188, 18.7.2009, p. 14.

¹⁷OJ No. L 189, 27.6.2014, p. 1.

¹⁸OJ No. L 165, 30.4.2004, p. 1.

¹⁹OJ No. L 191, 28.5.2004, p. 1.

²⁰OJ No. L 278, 21.10.2008, p. 6.

²¹OJ No. L 58, 3.3.2011, p. 29.

²²OJ No. L 228, 3.9.2011, p. 8.

Commission Regulation (EU) No. 563/2012 of 27 June 2012²³, Council Regulation (EU) No. 517/2013 of 13 May 2013²⁴ and Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15 May 2014¹⁷;

“official laboratory” means—

- (a) the Office of Radiological Protection, Environmental Protection Agency,
- (b) the Public Analyst’s Laboratory, Cork,
- (c) the Public Analyst’s Laboratory, Dublin,
- (d) the Public Analyst’s Laboratory, Galway,
- (e) the Public Health Microbiology Laboratory, Limerick,
- (f) the Public Health Laboratory, Sligo,
- (g) the Public Health Laboratory, Waterford,
- (h) the Public Health Microbiology Laboratory, Cork,
- (i) the Public Health Microbiology Laboratory, HSE, Dublin Mid-Leinster,
- (j) the Public Health Microbiology Laboratory, Galway, or
- (k) a laboratory designated by the Minister pursuant to Regulation 29(a);

“other waters” has the meaning assigned to it in Regulation 15(2);

“relevant thing” means—

- (a) a label, labelling, packaging, a bottle, a container or commercial documents relating to bottled waters, or
- (b) materials or media used in the advertising, marketing or presentation of bottled waters or other accompanying material;

“responsible authority” in relation to the State means the Authority, or an official agency acting pursuant to a service contract;

“service contract” means a contract entered into between the Authority and an official agency pursuant to section 48 of the Act of 1998;

“spring waters” has the meaning assigned to it in Regulation 13(2);

“waters intended for human consumption” means—

²³OJ No. L 168, 28.6.2012, p. 24.

²⁴OJ No. L 158, 10.6.2013, p. 1.

- (a) all waters either in their original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of their origin, and
- (b) all waters used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the Authority, or an official agency, is satisfied that the quality of the waters cannot affect the wholesomeness of the foodstuff in its finished form.

(2) A word or expression which is used in these Regulations and which is also used in Commission Directive 2003/40/EC, Commission Regulation 115/2010, Council Directive 98/83/EC, Council Directive 2013/51/EURATOM, Directive 2009/54/EC or the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in such Directive or Regulation.

Scope of Regulations

3. These Regulations apply to bottled waters intended to be placed on the market in a Member State.

Part 2

NATURAL MINERAL WATERS

Scope of Part 2

4. (1) This Part applies to natural mineral waters.

(2) Subject to paragraph (6), in these Regulations “natural mineral waters” means waters derived from a natural mineral water spring, which—

- (a) have been extracted from the ground of a Member State and are recognised by the responsible authority of that Member State as satisfying the provisions of Section I of Annex I to Directive 2009/54/EC, or
- (b) have been extracted from the ground of a country which is not a Member State and imported into the European Economic Area, and have been recognised as a natural mineral water by the responsible authority of a Member State pursuant to certification in the country of extraction,

and are intended to be placed on the market in a Member State.

(3) For the purposes of paragraph (2)(b), “certification in the country of extraction” means certification by the responsible authority in the country of extraction that—

- (a) the waters satisfy Section I of Annex I to Directive 2009/54/EC, and

(b) regular checks are made on the application of the provisions of point 2 of Annex II to Directive 2009/54/EC.

(4) The validity of the certification referred to in paragraph (3) shall not exceed a period of five years.

(5) It shall not be necessary to repeat the recognition procedure referred to in paragraph (2)(b) if the certification is renewed before the end of the period referred to in paragraph (4).

(6) Waters used at source for curative purposes in thermal or hydromineral establishments shall not constitute “natural mineral waters”.

Recognition of natural mineral waters in State

5. (1) Where natural mineral waters are extracted within the State or imported into the State from a country that is not a Member State, recognition pursuant to Regulation 4(2)(a) or (b) shall be carried out by the Authority or an official agency.

(2) The Authority shall publish the grounds for granting recognition pursuant to Regulation 4(2)(a) and (b).

(3) The Authority or an official agency may charge a fee (the “appropriate fee”) which shall be equal to the amount which the Authority or the official agency estimates it will incur in, or in connection with, recognition pursuant to Regulation 4(2)(a) and (b).

(4) The appropriate fee shall be payable by the seller or producer, as appropriate, of the natural mineral waters, in respect of which recognition is sought.

(5) Without prejudice to paragraph (4), where the costs incurred are greater than the appropriate fee, the differences between those costs and that fee shall be payable by the seller or producer of the natural mineral waters, as appropriate, and where those costs are less than the appropriate fee, the difference between those costs and that fee shall be repayable by the Authority or the official agency to the seller or producer, as appropriate.

(6) Natural mineral waters recognised by the Authority or an official agency, before the coming into operation of these Regulations, pursuant to Regulation 3(3) of the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007 (S.I. No. 225 of 2007) shall be regarded as having been recognised pursuant to Regulation 4(2)(a) or (b), as appropriate.

Marketing, exploitation and packaging

6. A person shall not—

(a) market any natural mineral waters unless the provisions of this Part are complied with,

- (b) use the description “natural mineral waters” in the marketing of any products which are not natural mineral waters within the meaning of Regulation 4(2),
- (c) exploit natural mineral water springs other than in accordance with Annex II to Directive 2009/54/EC, or
- (d) package natural mineral waters other than in accordance with Annex II to Directive 2009/54/EC.

Treatments

7. (1) Subject to paragraph (5), a person shall not cause natural mineral waters, in their state at source, to be the subject of any treatment other than—

- (a) the separation of their unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the waters as regards the essential constituents which give them their properties,
- (b) the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the waters as regards the essential constituents which give them their properties, and provided that the treatment—
 - (i) is notified in advance to, and specifically controlled by, the Authority, or an official agency, in accordance with paragraph (6), and
 - (ii) complies with all of the conditions referred to in paragraph (7),
- (c) the separation of undesirable constituents other than those specified in subparagraph (a) or (b), in so far as this treatment does not alter the composition of the waters as regards the essential constituents which give them their properties, and provided that the treatment is notified to, and specifically controlled by, the Authority, or an official agency,
- (d) the total or partial elimination of free carbon dioxide by exclusively physical methods, or
- (e) the treatment of natural mineral waters with activated alumina to remove fluoride, provided that—
 - (i) the treatment is performed in accordance with the technical requirements set out in the Annex to Commission Regulation 115/2010,
 - (ii) the treatment is notified to the Authority, or an official agency, pursuant to Article 3 of Commission Regulation 115/2010,

- (iii) the release of residues into the water as a result of the treatment is as low as technically feasible according to the best practices and does not pose a risk to public health,
- (iv) the critical processing steps set out in the Annex to Commission Regulation 115/2010 are implemented and monitored, and
- (v) the label on the natural mineral waters includes, in proximity to the statement of the analytical composition, the indication “water subjected to an authorised adsorption technique”.

(2) A person shall not cause natural mineral waters, in their state at source, to be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in Section III of Annex I to Directive 2009/54/EC.

(3) A person shall not cause natural mineral waters to be the subject of any disinfection treatment by whatever means.

(4) Subject to paragraph (2), a person shall not cause natural mineral waters to be the subject of the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the water.

(5) Paragraph (1)(a) to (d) shall not constitute a bar to the utilisation of natural mineral waters in the manufacture of soft drinks.

(6) In controlling the treatment of natural mineral waters with ozone-enriched air, the Authority or official agency shall ensure that—

- (a) use of such treatment is justified by the composition of the waters in terms of compounds of iron, manganese, sulphur and arsenic, and
- (b) the operator takes all measures necessary to guarantee that the treatment is effective and safe and allows it to be checked by the Authority or official agency.

(7) A person shall not cause natural mineral waters to be the subject of ozone-enriched air treatment unless the following conditions are complied with:

- (a) the physico-chemical composition of the waters in terms of essential constituents is not modified by the treatment;
- (b) the waters before treatment comply with the microbiological criteria laid down in Regulation 8(1) to (7); and
- (c) the treatment does not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Annex III to Commission Directive 2003/40/EC or residues which could pose a risk to public health.

Microbiological requirements

8. (1) A person engaged in the extraction of natural mineral waters shall ensure that the revivable total colony count of the waters at source conforms to its normal viable colony count and shall, upon request by the Authority or an official agency, give satisfactory evidence of the protection of the source against all contamination.

(2) For the purposes of paragraph (1), the total colony count shall be determined under the conditions laid down in Section II, point 1.3.3 of Annex I to Directive 2009/54/EC.

(3) A person engaged in the extraction of natural mineral waters shall ensure that, after bottling, the total colony count of the waters at source does not exceed 100 per millilitre at 20°C to 22°C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37°C in 24 hours on agar-agar.

(4) For the purposes of paragraph (3), the total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4°C ± 1°C during this 12-hour period.

(5) A person engaged in the extraction of natural mineral waters shall ensure that, at source, the values laid down in paragraph (3) do not normally exceed 20 per millilitre at 20°C to 22°C in 72 hours and 5 per millilitre at 37°C in 24 hours respectively, on the understanding that they are to be considered as guide figures and not as maximum permitted concentrations.

(6) A person engaged in the extraction of natural mineral waters shall ensure that, at source, the waters are free from—

- (a) parasites and pathogenic micro-organisms,
- (b) *Escherichia coli* and other coliforms and faecal streptococci in any 250 millilitre sample examined,
- (c) sporulated sulphite-reducing anaerobes in any 50 millilitre sample examined, and
- (d) *Pseudomonas aeruginosa* in any 250 millilitre sample examined.

(7) A person shall not place on the market natural mineral waters which contain—

- (a) parasites and pathogenic micro-organisms,
- (b) *Escherichia coli* or other coliforms or faecal streptococci in any 250 millilitre sample examined,
- (c) sporulated sulphite-reducing anaerobes in any 50 millilitre sample examined,
- (d) *Pseudomonas aeruginosa* in any 250 millilitre sample examined.

(8) Without prejudice to the provisions of paragraphs (1) to (7) and the conditions of exploitation laid down in Annex II to Directive 2009/54/EC, a person shall not place on the market natural mineral waters if—

- (a) the revivable total colony count of the waters is more than that resulting from the normal increase in the bacterial count which it had at source, and
- (b) the waters contain any organoleptic defects.

(9) Subject to paragraphs (11), a person shall not package natural mineral waters which—

- (a) do not comply with the maximum concentration limits set out in Annex I to Commission Directive 2003/40/EC for the constituents listed in that Annex, or
- (b) contain a constituent listed in that Annex as a result of contamination at source.

(10) During the procedure for official recognition of natural mineral waters collected within the State, the Authority or an official agency may take a lower reference value for nitrates and nitrites than that set out in Annex I to Commission Directive 2003/40/EC, provided that the same reference value is applied to all applications made to them.

(11) Where the Authority or an official agency takes a lower reference value for nitrates or nitrites in accordance with paragraph (10), a person shall not package natural mineral waters to which that reference value was applied which do not comply with that limit.

(12) For the purposes of official controls carried out by the Authority or an official agency, the specifications listed in Annex II to Commission Directive 2003/40/EC shall apply for analysing the constituents listed in Annex I to that Directive.

Containers

9. A person shall not package natural mineral waters unless the containers used for that purpose are fitted with closures designed to avoid any possibility of adulteration or contamination.

Sales descriptions and labels

10. (1) Subject to paragraph (2), a person shall not place on the market natural mineral waters under a sales description other than “natural mineral water”, or, in the case of effervescent natural mineral waters as defined in Section III of Annex I to Directive 2009/54/EC, as appropriate, “naturally carbonated natural mineral water”, “natural mineral water fortified with gas from the spring” or “carbonated natural mineral water”.

(2) A person shall not place on the market natural mineral waters which have undergone any of the treatments referred to in Regulation 7(1)(d) unless the

sales description required under paragraph (1) has added to it, as appropriate, the indication “fully de-carbonated” or “partially de-carbonated”.

(3) A person shall not place on the market natural mineral waters unless the labels on the waters also give the following mandatory information:

- (a) a statement of the analytical composition, giving its characteristic constituents;
- (b) the place where the spring is exploited and the name of the spring; and
- (c) information on any treatments referred to in Regulation 7(1)(b) and (c).

(4) A person shall not place on the market natural mineral waters with a fluoride concentration exceeding 1.5 milligrams per litre unless the labels on the waters bear—

- (a) 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”, placed in immediate proximity to the trade name and in clearly visible characters, and
- (b) an indication of the actual fluoride content in relation to the physico-chemical composition in terms of essential constituents, as referred to in paragraph 3(a).

(5) A person shall not place on the market, natural mineral waters which have been treated with ozone-enriched air unless the labels on the waters bear, in proximity to the analytical composition of characteristic constituents, the words “water subjected to an authorised ozone-enriched air oxidation technique”.

Trade descriptions

11. (1) A person may not use the name of a locality, hamlet or place in the wording of a trade description of natural mineral waters unless it refers to waters the spring of which is exploited at the place indicated by that description and it is not misleading as regards the place of exploitation of the spring.

(2) A person shall not market natural mineral waters from one and the same spring under more than one trade description.

(3) When—

- (a) the labels or inscriptions on the containers in which natural mineral waters are offered for sale, or
- (b) the advertising of natural mineral waters,

include a trade description different from the name of the spring from which they were exploited or the place of their exploitation, a person shall not place

on the market or advertise the waters unless the place of exploitation or the name of the spring is indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

Indications

12. (1) A person shall not use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, on the packaging, labelling or advertising, in any form whatsoever, of natural mineral waters, which suggest a characteristic which the waters do not possess, in particular as regards their origin, the date of the authorisation to exploit them, the results of analyses or any similar references to guarantees of authenticity.

(2) Subject to paragraph (3), a person shall not use any indications, on the packaging, labelling or advertising of natural mineral waters, attributing to the waters properties relating to the prevention, treatment or cure of a human illness.

(3) A person may use the indications listed in Annex III to Directive 2009/54/EC, on the packaging, labelling or advertising of natural mineral waters, if they meet the relevant criteria laid down in that Annex.

Part 3

SPRING WATERS

Scope of Part 3

13. (1) This Part applies to spring waters.

(2) Subject to paragraph (4), in these Regulations “spring waters” means waters which—

- (a) are intended for human consumption in their natural state,
- (b) are placed in a bottle or container at source,
- (c) satisfy the conditions of exploitation laid down in points 2 and 3 of Annex II to Directive 2009/54/EC, which shall be fully applicable to spring waters,
- (d) satisfy the microbiological requirements imposed in respect of natural mineral waters in Regulation 8(1) to (8),
- (e) satisfy the labelling requirements imposed in respect of natural mineral waters at Regulation 10(3)(b) and (c), 10(5) and Regulation 11,
- (f) have not undergone any treatment other than those referred to in Regulation 7(1)(a) to (e),

and are intended to be placed on the market in a Member State.

(3) Paragraph (2)(f) shall not constitute a bar to the utilisation of spring waters in the manufacture of soft drinks.

(4) For the purposes of these Regulations, waters used at source for curative purposes in thermal or hydromineral establishments shall not constitute “spring waters”.

General requirements

14. (1) A person shall not—

- (a) place on the market any spring waters unless the provisions of this Part are complied with, or
- (b) use the description “spring waters” in the marketing of any products which are not spring waters within the meaning of Regulation 13(2).

(2) A person shall not use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, on the packaging, labelling or advertising, in any form whatsoever, of spring waters, which are liable to cause confusion with a natural mineral water, in particular the description “mineral water”.

(3) The requirements applicable to other waters in Regulations 16 and 19 shall also be applicable to spring waters.

(4) The obligations imposed on the Authority, or on an official agency, in respect of other waters in Regulations 17 and 18, shall also apply in respect of spring waters.

(5) A person shall not treat spring waters with ozone-enriched air unless such treatment has been notified to the Authority or official agency in advance.

(6) Where the Authority or official agency is notified of the treatment of spring waters with ozone-enriched air, pursuant to paragraph (5), it shall ensure that—

- (a) use of such treatment is justified by the composition of the waters in terms of compounds of iron, manganese, sulphur and arsenic,
- (b) the operator takes all measures necessary to guarantee that the treatment is effective and safe and allows it to be checked by the Authority or official agency, and
- (c) the requirements of paragraph (7) have been complied with.

(7) A person shall not cause spring waters to be the subject of ozone-enriched air treatment unless the following conditions are complied with:

- (a) the physico-chemical composition of the waters in terms of essential constituents is not modified by the treatment;
- (b) the waters before treatment comply with the microbiological criteria laid down in Regulation 8(1) to (7) for natural mineral waters; and

- (c) the treatment does not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Annex III to Commission Directive 2003/40/EC or residues which could pose a risk to public health.

Part 4

OTHER WATERS IN BOTTLES OR CONTAINERS

Scope of Part 4

15. (1) This Part applies to other waters.

(2) In these Regulations “other waters” means those waters which are not—

- (a) natural mineral waters within the meaning of Regulation 4(2), or
- (b) spring waters within the meaning of Regulation 13(2),

and are intended to be placed on the market in a Member State.

General requirements

16. (1) A person shall not place on the market other waters unless—

- (a) they are wholesome and clean,
- (b) the parametric values set down in Annex I to Council Directive 98/83/EC are complied with at the point at which the waters are put into bottles or containers,
- (c) the parametric value for radon of 500 Bq/l is complied with at the point at which the waters are put into bottles or containers, and
- (d) the parametric values set down in Annex I to Council Directive 2013/51/EURATOM for tritium and indicative dose are complied with at the point at which the waters are put into the bottles or containers.

(2) For the purposes of paragraph (1), other waters shall be regarded as wholesome and clean if they—

- (a) are free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health,
- (b) meet the minimum requirements set out in Parts A and B of Annex I to Council Directive 98/83/EC, and
- (c) meet the other requirements of this Part.

(3) In taking measures to apply the provisions of this Part, a person engaged in the production, processing or distribution of bottled waters, or the Authority, or an official agency, shall not allow, whether directly or indirectly—

- (a) any deterioration in the existing quality of water intended for human consumption, insofar as that is relevant for the protection of human health, or
- (b) any increase in the pollution of waters used for the production of drinking water.

Monitoring and sampling

17. (1) The Authority, or an official agency, shall take all measures necessary to ensure that regular monitoring of the quality of other waters is carried out, in order to check that the waters available to consumers meet the requirements of this Part and in particular the parametric values set down in Annex I to Council Directive 98/83/EC.

(2) The Authority, or an official agency, shall, for the purpose of paragraph (1), take samples of other waters so that they are representative of the quality of the waters consumed throughout the year.

(3) The sampling points for the purpose of paragraph (2) shall be determined by the Authority, or by an official agency, and shall meet the relevant requirements set out in Annex II to Council Directive 98/83/EC.

(4) The Authority, or an official agency, shall take all measures necessary to ensure that, where disinfection forms part of the preparation or distribution of other waters, the efficiency of the disinfection treatment applied is verified, and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection.

(5) In order to ensure that the obligations imposed by paragraphs (1), (2) and (4) are met, the Authority, or an official agency, shall establish appropriate monitoring programmes for other waters.

(6) The monitoring programmes referred to at paragraph (5) shall meet the minimum requirements set out in Annex II to Council Directive 98/83/EC.

(7) The Authority, or an official laboratory, shall comply with the specifications for the analyses of parameters set out in Annex III to Council Directive 98/83/EC.

(8) Notwithstanding paragraph (7), methods other than those specified in Part I of Annex III to Council Directive 98/83/EC, may be used by the Authority, or an official laboratory, for the analyses set out in that Part, provided that it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified.

(9) For those parameters listed in Parts 2 and 3 of Annex III, to Council Directive 98/83/EC, any method of analysis may be used by the Authority, or an official laboratory, provided that it meets the requirements set out therein.

(10) The Authority, or an official agency, shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms

for which no parametric value has been set under Annex I to Council Directive 98/83/EC, if there is reason to suspect that they may be present in amounts or numbers which constitute a potential danger to human health.

(11) The Authority, or an official agency, shall monitor for radioactive substances in other waters in accordance with the monitoring strategies and frequencies set out in Annex II to Council Directive 2013/51/EURATOM, in order to check whether the values of radioactive substances comply with the parametric values referred to in Regulation 16(1)(c) and (d).

(12) Monitoring under paragraph (11) shall ensure that the measured values obtained are representative of the quality of the water consumed throughout the year.

(13) Paragraph (12) is without prejudice to the principles of hazard analysis and critical control point (HACCP) as required by the European Communities (Hygiene of Foodstuffs) Regulations 2006 (S.I. No. 369 of 2006) and to the principles of official controls as laid down in the European Communities (Official Control of Foodstuffs) Regulations 2010 (S.I. No. 117 of 2010).

(14) In monitoring under paragraph (11), monitoring for the indicative dose of other waters shall be carried out, and analytical performance characteristics shall be, in accordance with the requirements set out in Annex III to Council Directive 2013/51/EURATOM.

Investigation and remedial action

18. (1) The Authority, or an official agency, shall ensure that any failure to meet the parametric values referred to in Regulation 16(1) is immediately investigated in order to identify the cause.

(2) Where, despite measures taken under Regulation 16(1) and (2), other waters do not meet the parametric values set down in Annex I to Council Directive 98/83/EC, the Authority, or an official agency, shall ensure that the necessary remedial action is taken as soon as possible to restore their quality and shall give priority to enforcement action, having regard, *inter alia*, to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

(3) Whether or not any failure to meet the parametric values set down in Annex I to Council Directive 98/83/EC has occurred, the Authority, or an official agency, shall ensure that other waters which constitute a potential danger to human health are prohibited or their use restricted, or other such action is taken as is necessary to protect human health.

(4) In the event of the Authority, or an official agency, taking action under paragraph (3), it shall promptly inform consumers thereof and furnish them with the necessary advice.

(5) The Authority, or an official agency, shall decide what action should be taken under paragraph (3), bearing in mind the risks to human health which

would be caused by an interruption of the supply or a restriction in the use of other waters.

(6) The Authority may establish guidelines in relation to the obligations under paragraph (5).

(7) In the event of non-compliance, in relation other waters, with the parametric values or with the specifications set out in Part C of Annex I to Council Directive 98/83/EC, the Authority, or an official agency, shall—

- (a) consider whether that non-compliance poses any risk to human health, and
- (b) take remedial action to restore the quality of the other waters where that is necessary to protect human health.

(8) In the event of the Authority, or an official agency, taking remedial action pursuant to paragraph (7), it shall further ensure that consumers are notified, except where the Authority or the official agency, as the case may be, considers the non-compliance with the parametric value to be trivial.

(9) Without prejudice to Article 9(1) of the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000), in the event of non-compliance with the parametric values referred to in Regulation 16(1)(c) and (d), the Authority, or an official agency, shall—

- (a) assess whether the non-compliance poses a risk to human health which requires action, and
- (b) where such a risk exists—
 - (i) take remedial action to improve the quality of other water to a level which complies with requirements for the protection of human health from a radiation protection point of view, and
 - (ii) ensure that the general public is—
 - (I) notified of the risk and the remedial action taken, and
 - (II) advised on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.

Materials in contact with other waters

19. A person engaged in the production, processing or distribution of other waters shall ensure that substances and materials for new installations used in the preparation or distribution of such waters, and impurities associated with such substances or materials for new installations—

- (a) do not remain in other waters in concentrations higher than is necessary for the purpose of their use, and

- (b) do not directly or indirectly reduce the protection of human health provided for in this Part.

Marketing of other waters

20. A person shall not use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, on the packaging, labelling or advertising, in any form whatsoever, of other waters, which are liable to cause confusion with natural mineral water, in particular the description “mineral water”.

Part 5

ENFORCEMENT, OFFENCES AND PENALTIES

Enforcement generally

21. (1) The enforcement of these Regulations, Commission Directive 2003/40/EC, Commission Regulation 115/2010, Council Directive 98/83/EC, Council Directive 2013/51/EURATOM and Directive 2009/54/EC shall be carried out in accordance with the provisions of this Part.

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

(3) Subject to Regulation 30, these Regulations shall be enforced by the Authority or by an official agency acting pursuant to a service contract with the Authority, or by both, and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

Taking of bottled water samples

22. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of bottled waters or a sample from the spring or source from which bottled waters are derived.

(2) An authorised officer may, for the purpose of taking a sample of bottled waters open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample referred to in paragraph (1) with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the food business operator or person in apparent charge or control of the bottled waters, spring or source, of his or her intention of having the sample analysed.

(4) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample referred to in paragraph (1) which is suspected by him or her of failing to comply with the provisions of these Regulations, he or she may, by notice in writing to the food business operator or person in apparent charge or control of the bottled waters, spring or source, prohibit the removal of the bottled waters except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 working days from the date of the taking of the sample.

Division of samples

23. (1) Where a sample of bottled waters, or a sample from the spring or source from which bottled waters are derived, is taken pursuant to Regulation 22, for the purposes of official analysis, and where the division of the sample is reasonably practicable, the authorised officer concerned shall divide the sample into three approximately equal parts (enforcement, trade (defence) and referee), each of which he or she shall mark in such a way as to identify it as a part of the sample taken by the officer.

(2) Where an authorised officer divides a sample in accordance with paragraph (1), he or she shall—

- (a) in the presence of the food business operator or person in apparent charge or control of such bottled waters, spring or source, mark, seal and fasten each part in such a manner as its nature will permit and in such a way that the integrity of the sample is not compromised,
- (b) forward one part to the approved examiner in an official laboratory for analysis,
- (c) give or send one part to the food business business operator or person in apparent charge or control of such bottled waters, spring or source, and
- (d) retain the third part.

(3) Where an authorised officer takes a sample of bottled waters contained in unopened bottles or containers and its division into parts—

- (a) is not reasonably practicable, or
- (b) might affect the composition or impede the proper analysis of the sample,

the provisions of paragraph (1) and (2) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the bottles or containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1) and (2).

(4) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on, a sample of bottled waters or a sample from the spring or source from which bottled waters are derived, taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in this Regulation and the part, bottle or container retained by the authorised officer is produced at the hearing.

Taking of relevant things

24. (1) An authorised officer may, for the purposes of these Regulations, inspect, take or make copies, whether in writing, by photography, electronically or otherwise, of a relevant thing.

(2) Where a sample of a relevant thing related to a sample of bottled waters, or a sample taken from the spring or source from which bottled waters are derived, taken in accordance with Regulations 22 and 23 is taken pursuant to these Regulations, for the purposes of official analysis, the authorised officer shall obtain three identical such relevant things, or take three copies or photographs of such relevant thing.

(3) Where an authorised officer takes a relevant thing related to a sample of bottled waters, or a sample from the spring or source from which bottled waters are derived, taken in accordance with Regulations 22 and 23, or a copy or photograph thereof, with the intention of having it analysed, he or she shall—

- (a) forthwith notify the food business operator or person in apparent charge or control of the relevant thing, of his or her intention of having the relevant thing, copy or photograph analysed,
- (b) mark, seal and fasten each relevant thing, or copy or photograph of the relevant thing, in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,
- (c) forward one of the relevant things, or one of the copies or photographs of the relevant thing, to the approved examiner in an official laboratory for analysis,
- (d) give or send one of the relevant things, or one of the copies or photographs of the relevant thing, to the food business operator or person in apparent charge or control of the relevant thing, and
- (e) retain the third relevant thing, or the third copy or photograph of the relevant thing.

(4) Where a sample of a relevant thing is taken pursuant to these Regulations, for the purpose of inspection, the authorised officer shall obtain three identical such relevant things, or take three copies or photographs of such relevant thing.

(5) Where an authorised officer takes a relevant thing, or a copy or photograph thereof, with the intention of having it inspected, he or she shall—

- (a) forthwith notify the food business operator or person in apparent charge or control of the relevant thing, of his or her intention of having the relevant thing, copy or photograph inspected,
- (b) mark, seal and fasten each relevant thing, or copy or photograph of the relevant thing, in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,
- (c) give or send one of the relevant things, or one of the copies or photographs of the relevant thing, to the food business operator or person in apparent charge or control of the relevant thing,

- (d) retain one of the relevant things, or one of the copies or photographs of the relevant thing, for the purpose of inspection, and
- (e) retain the third relevant thing, or the third copy or photograph of the relevant thing.

(6) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on, a sample of a relevant thing taken pursuant to these Regulations shall not be adduced unless before the proceedings were instituted the sample was divided as specified in this Regulation and the relevant thing or the copy or photograph of the relevant thing retained by the authorised officer is produced at the hearing.

Analysis of samples and relevant things

25. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis.

(2) The form of certificate set out in the Schedule to these Regulations or a certificate in like form shall be used for the purpose of paragraph (1).

(3) An official certificate given in accordance with paragraph (1) shall be evidence of the matters contained therein until the contrary is shown.

Report on official controls

26. (1) Where a sample is taken by an authorised officer in pursuance of these Regulations for inspection or analysis, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation.

(2) Where the certificate given in accordance with Regulation 25 indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator or person in apparent charge or control of the sampled bottled waters, spring, source or relevant thing with a copy of the report referred to in paragraph (1).

Powers of authorised officers

27. An authorised officer may, for the purposes of these Regulations—

- (a) examine any procedure connected with the production, processing or distribution of bottled waters, and
- (b) require a person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

Seizure, removal, detention and destruction

28. (1) An authorised officer may seize, remove or detain bottled waters or a relevant thing which are suspected by him or her of failing to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator or person in apparent charge or control of such bottled waters, or in accordance with an order of a judge of the District Court under paragraph (5), destroy or otherwise dispose of bottled waters so as to prevent the bottled waters being used for human consumption.

(3) An authorised officer may, with the consent in writing of the food business operator or person in apparent charge or control of such relevant thing, or in accordance with an order of a judge of the District Court under paragraph (5), destroy or otherwise dispose of a relevant thing so as to prevent consumers from being misled or a risk to human health.

(4) An authorised officer who has seized, removed or detained bottled waters or a relevant thing in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator or person in apparent charge or control of such bottled waters or relevant thing, of his or her intention to do so, apply to a judge of the District Court for an order directing that such bottled waters or relevant thing be destroyed or otherwise disposed of.

(5) A judge of the District Court, to whom an application is made for an order under paragraph (4), may, if satisfied that the bottled waters or relevant thing fail to comply with these Regulations, order that same be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of the bottled waters or relevant thing accordingly.

Designation of official laboratories and approved examiners

29. The Minister may, for the purposes of these Regulations, designate, by notice in writing published in *Iris Oifigiúil*—

- (a) a laboratory as a laboratory at which samples taken under these Regulations may be analysed, and testing and verification may be carried out, and
- (b) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory, engage in analysis, testing and verification for the purposes of these Regulations.

Temporary restriction or suspension

30. (1) The Minister, after consultation with the Authority, may, by notice in writing, temporarily restrict or suspend trade in a particular natural mineral water within the State where there are detailed grounds to suspect that such natural mineral water does not comply with the provisions laid down in these Regulations or endangers public health.

(2) Any notice issued under this Regulation shall be published in *Iris Oifigiúil*.

Offences

31. (1) A person who contravenes Regulation 5(4) or (5), 6, 7(1), (2), (3), (4) or (7), 8(1), (3), (5), (6), (7), (8), (9) or (11), 9, 10, 11, 12(1) or (2), 14(1), (2), (5) or (7), 16(1) or (3), 19 or 20 shall be guilty of an offence.

(2) The offences provided for in these Regulations shall not apply to an authorised officer or an approved examiner, or to a person acting under such an officer's or examiner's express direction, acting in the course of his or her duties pursuant to these Regulations.

(3) A person is guilty of an offence if he or she—

- (a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations,
- (b) fails or refuses to state his or her name or address in compliance with a request under these Regulations,
- (c) fails to comply with a request or notice from an authorised officer under these Regulations,
- (d) makes a statement or provides information to an authorised officer which the person knows is false or misleading,
- (e) provides records or documents, or copies thereof, which the person knows to be false or misleading in content, or
- (f) gives, in purported compliance with a request under these Regulations, a name, an address or corroborative evidence which is false or misleading.

(4) A person is guilty of an offence if he or she forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations (hereafter referred to as "a forged document").

(5) A person is guilty of an offence if he or she alters with intent to defraud or deceive, or utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (hereafter referred to as "an altered document").

(6) A person is guilty of an offence if he or she, without lawful authority, has in his or her possession a forged document or an altered document.

(7) A person is guilty of an offence if he or she with the intent to defraud or deceive:

- (a) tampers with any bottled waters, any spring or source from which bottled waters are derived or any relevant thing; or
- (b) tampers or interferes with any sample taken under these Regulations.

(8) A person is guilty of an offence if he or she falsely represents himself or herself to be an authorised officer.

(9) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a

paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation.

Bodies corporate

32. Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

Prosecution of offences

33. (1) A person who is guilty of an offence under these Regulations is liable—

- (a) on summary conviction, to a class A fine or at the discretion of the Court to imprisonment for a term not exceeding 6 months, or both, or
- (b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority or the official agency, as the case may be, the costs and expenses, measured by the court, incurred by the Authority or official agency in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority or official agency.

(3) An order for costs and expenses under paragraph (2) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

(4) Notwithstanding section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by—

- (a) the Authority, or
- (b) an official agency.

PART 6

REVOCATIONS

Revocations

34. (1) The following are revoked:

- (a) the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007 (S.I. No. 225 of 2007); and
- (b) the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2007 (S.I. No. 686 of 2007).

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations as appropriate.

Schedule

European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016.

Certificate of Analysis

To⁽¹⁾.....

I, the undersigned⁽²⁾.....

being an approved examiner for the purpose of the above Regulations certify that on

the.....day of..... 20.....

a sample marked⁽³⁾.....

Date.....

Number.....

Weight or Measure⁽⁴⁾.....

was submitted to me by you and I certify that the sample / relevant thing / copy / photograph of relevant thing was prepared and analysed/examined by me or under my direction ⁽⁵⁾

and as a result I am of the opinion that⁽⁶⁾

Observations:⁽⁷⁾

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this..... day of..... 20.....

At⁽⁸⁾.....

Name in BLOCK LETTERS.....

Status.....

Signature.....

.....

Official Stamp

NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Public Analyst located at a Public Analyst's Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.).
- (4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.
- (5) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.
- (6) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (7) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add such other observations as he or she may consider relevant.
- (8) Insert the name and address of the laboratory carrying out the analysis/examination.



Given under my Official Seal,
26 May 2016.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Council Directive 98/83/EC of 3 November 1998, Commission Directive 2003/40/EC of 16 May 2003, Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009, Commission Regulation (EU) No. 115/2010 of 9 February 2010, Council Directive 2013/51/EURATOM of 22 October 2013 and Commission Directive (EU) 2015/1787 of 6 October 2015.

These Regulations set down requirements in relation to bottled waters, in particular natural mineral waters, spring waters and other waters.

These Regulations revoke the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007 (S.I. No. 225 of 2007) and the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2007 (S.I. No. 686 of 2007).

These Regulations may be cited as the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016.

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