# S.I. No. 225/2007 — European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles Or Containers) Regulations 2007

S.I. No. 225 of 2007

EUROPEAN COMMUNITIES (NATURAL MINERAL WATERS, SPRING WATERS AND OTHER WATERS IN BOTTLES OR CONTAINERS) REGULATIONS 2007

I, MARY HARNEY, Minister for Health and Children, 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 80/777/EEC [1] of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters, as amended by Directive 96/70/EC [2] of the European Parliament and of the Council of 28 October 1996, and for the purpose of giving further effect to Council Directive 98/83/EC [3] of 3 November 1998 on the quality of water intended for human consumption, and for the purpose of giving further effect to Commission Directive 2003/40/EC [4] of 16 May 2003 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, hereby make the following regulations—

*Notice of the making of this Statutory Instrument was published in*

*"Iris Oifigiúil" of* 18*th May*, 2007.

## PART 1 Preliminary

1. These Regulations may be cited as the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007.

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 Chemist in the State Laboratory,

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

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

(*d*) a Deputy Public Analyst located at a Public Analyst's Laboratory,

(*e*) an Executive Analytical Chemist located at a Public Analyst's Laboratory,

(*f*) a Public Analyst located at a Public Analyst's Laboratory;

"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 Council Directive 65/65/EEC [5] of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products;

"Directives" means Council Directive 80/777/EEC [1] of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters, as amended by Directive 96/70/EC [2] of the European Parliament and of the Council of 28 October 1996, and Council Directive 98/83/EC [3] of 3 November 1998 on the quality of water intended for human consumption, and Commission Directive 2003/40/EC [4] of 16 May 2003 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;

"General Food Law Regulation" means Regulation (EC) No 178/2002 [6] of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety;

"natural mineral waters" means waters which comply with the requirements of Regulation 3(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 [7] of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

"official laboratory" means—

(*a*) the Public Analyst's Laboratory, Cork,

(*b*) the Public Analyst's Laboratory, Dublin,

(*c*) the Public Analyst's Laboratory, Galway,

(*d*) the Public Health Microbiology Laboratory, Limerick,

(*e*) the Public Health Laboratory, Sligo,

(*f*) the Public Health Laboratory, Waterford,

(*g*) the Public Health Microbiology Laboratory, Cork,

(*h*) the Public Health Microbiology Laboratory, HSE, Dublin Mid-Leinster, or

(*i*) the Public Health Microbiology Laboratory, Galway;

"other waters" means waters which comply with the requirements of Regulation 13(2);

"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" means waters which comply with the requirements of Regulation 11(2);

"waters intended for human consumption" means—

(*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 acting pursuant to a service contract, 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 the Directives or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directives or in the General Food Law Regulation.

(3) (*a*) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(*b*) A reference in these Regulations to a paragraph or subparagraph is to a paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(*c*) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

## PART 2 Bottled Natural Mineral Waters

3. (1) These Regulations are concerned with bottled waters and this Part is concerned with natural mineral waters.

(2) (*a*) "Natural mineral waters" are waters derived from a natural mineral water spring, which—

(i) 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 Schedule 1, Part 1, or

(ii) have been extracted from the ground of a third country and imported into the Community, and have been recognised as a natural mineral water by the responsible authority of a Member State pursuant to certification in the third country,

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

(*b*) For the purposes of subparagraph (*a*)(ii), "certification in the third country" means certification by the responsible authority in the third country that—

(i) the waters satisfy Annex I, Section 1 of Council Directive 80/777/EEC [1] , and

(ii) regular checks are made on the application of the provisions of Annex II, paragraph 2 of Council Directive 80/777/EEC [1] .

(*c*) The validity of the certification referred to at subparagraph (*b*) shall not exceed a period of five years. It shall not be necessary to repeat the recognition procedure referred to in subparagraph (*a*)(ii) if the certification is renewed before the end of the said period.

(*d*) For the purposes of these Regulations, waters used at source for curative purposes in thermal or hydromineral establishments shall not constitute "natural mineral waters".

(3) (*a*) Where natural mineral waters are extracted within the State or imported into the State from a third country, recognition pursuant to paragraph 2(*a*)(i) or (ii) shall be carried out by the Authority, or by an official agency acting pursuant to a service contract.

(*b*) (i) The Authority or an official agency carrying out functions under a service contract 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 under subparagraph (*a*).

(ii) 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.

(iii) Without prejudice to clause (ii), 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.

4. (1) From the date of coming into operation of these Regulations, 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 as defined in Regulation 3(2),

(*c*) exploit natural mineral water springs other than in accordance with Schedule 2, or

(*d*) package natural mineral waters other than in accordance with Schedule 2.

(2) Where the Authority has detailed grounds for considering that natural mineral waters circulating freely in one or more Member States do not comply with this Part, or endanger public health, it may temporarily restrict or suspend trade in that product in the State.

5. (1) Natural mineral waters, in their state at source, may not 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 is notified to, and specifically controlled by, the Authority, or an official agency acting pursuant to a service contract;

(*c*) the separation of undesirable constituents other than those specified in (*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 acting pursuant to a service contract;

(*d*) the total or partial elimination of free carbon dioxide by exclusively physical methods.

(2) Natural mineral waters, in their state at source, may not be the subject of any addition other than the introduction or reintroduction of carbon dioxide under the conditions laid down in Schedule 1, Part 3.

(3) In particular, any disinfection treatment of natural mineral waters by whatever means and, subject to paragraph (2), the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral waters shall be prohibited.

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

(5) Without prejudice to paragraph (1)(*b*), application of the treatment of natural mineral waters with ozone-enriched air must be notified in advance to the Authority, which 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 has taken all measures necessary to guarantee that the treatment is effective and safe and has allowed it to be checked by the Authority, or an official agency acting pursuant to a service contract.

(6) Ozone-enriched air treatment of natural mineral waters must comply with all the following conditions—

(*a*) the physico-chemical composition of the natural mineral waters in terms of essential constituents shall not be modified by the treatment,

(*b*) the natural mineral waters before treatment must comply with the microbiological criteria laid down in paragraphs (1) to (4) of Regulation 6, and

(*c*) the treatment shall not lead to the formation of residues with a concentration exceeding the maximum limits laid down in Schedule 10 or residues which could pose a risk to public health.

6. (1) The revivable total colony count of natural mineral waters at source shall conform to their normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. This total colony count shall be determined under the conditions laid down in Schedule 1, Part 2, section 1.3.3.

(2) After bottling, the total colony count at source may not exceed 100 per millilitre at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37°C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4°C 1°C during this 12-hour period.

(3) At source, these values should not normally exceed 20 per millilitre at 20 to 22°C in 72 hours and 5 per millilitre at 37°C in 24 hours respectively, on the understanding that they are to be considered as guide figures and not as maximum permitted concentrations.

(4) At source and during their marketing, natural mineral waters shall be 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;

(*d*) Pseudomonas aeruginosa in any 250 millilitre sample examined.

(5) Without prejudice to the provisions of the above paragraphs and the conditions of exploitation laid down in Schedule 2, at the marketing stage—

(*a*) the revivable total colony count of natural mineral waters may only be that resulting from the normal increase in the bacteria content which it had at source, and

(*b*) the natural mineral waters may not contain any organoleptic defects.

(6) Natural mineral waters shall, at the time of packaging, comply with the maximum concentration limits set out in Schedule 8 for the constituents listed in that Schedule.

(7) The constituents listed in Schedule 8 must be present in the waters naturally and not result from contamination at source.

(8) The requirements of paragraph (6) in the case of fluorides and nickel shall come into effect on 1 January 2008.

(9) By way of derogation from paragraph (6), during the procedure for official recognition of natural mineral waters collected within the State, the Authority or an official agency acting pursuant to a service contract, may take a lower reference value for nitrates and nitrites, provided that the same reference value is applied to all applications made to them.

(10) For the purposes of official controls, the specifications listed in Schedule 9 shall apply in analysing the constituents listed in Schedule 8.

7. Any containers used for packaging natural mineral waters shall be fitted with closures designed to avoid any possibility of adulteration or contamination.

8. (1) The sales description of natural mineral waters shall be “natural mineral water”, or, in the case of effervescent natural mineral waters as defined in Schedule 1, Part 3, as appropriate, “naturally carbonated natural mineral water”, “natural mineral water fortified with gas from the spring” or “carbonated natural mineral water”.

(2) The sales description of natural mineral waters which have undergone any of the treatments referred to in Regulation 5(1)(*d*) shall have added to it as appropriate the indication “fully de-carbonated” or “partially de-carbonated”.

(3) Labels on natural mineral waters shall also give the following mandatory information—

(*a*) a statement of the analytical composition, giving its characteristic constituents,

(*b*) the place where the spring is exploited and the name of the spring, and

(*c*) information on any treatments referred to in Regulation 5(1)(*b*) and (*c*).

(4) Natural mineral waters with a fluoride concentration exceeding 1.5 milligrams per litre shall bear on the label—

(*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", and

(*b*) an indication as to the actual fluoride content in relation to the physico-chemical composition in terms of essential constituents, as referred to in paragraph 3(*a*).

(5) The label information referred to in paragraph (4)(*a*) shall be placed in immediate proximity to the trade name and in clearly visible characters.

(6) In accordance with paragraph 3(*c*), the labelling of natural mineral waters which have been treated with ozone-enriched air shall bear, in proximity to the analytical composition of characteristic constituents, the words "water subjected to an authorised ozone-enriched air oxidation technique".

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

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

(3) When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, this place or the name of the spring shall be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

(4) The provisions of paragraph (3) shall apply, mutatis mutandis and with the same intention as regards the importance attributed to the name of the spring or the place of its exploitation, with regard to the trade description used in advertising, in whatsoever form, relating to natural mineral waters.

10. (1) From the date of coming into operation of these Regulations, a person shall not in the packaging, labelling or advertising in whatsoever form of natural mineral waters, use designations, proprietary names, trade marks, brand names, illustrations or other signs, whether emblematic or not, 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 the analyses or any similar references to guarantees of authenticity.

(2) All indications attributing to natural mineral waters properties relating to the prevention, treatment or cure of a human illness shall be prohibited.

(3) Notwithstanding the provisions of paragraph (2), the indications listed in Schedule 3 shall be authorised if they meet the relevant criteria laid down in that Schedule.

## PART 3 Bottled Spring Waters

11. (1) This Part is concerned with spring waters.

(2) "Spring waters" are those waters which—

(*a*) are intended for human consumption in their natural state,

(*b*) are bottled at source,

(*c*) satisfy the conditions of exploitation laid down in Schedule 4,

(*d*) satisfy the microbiological requirements imposed in respect of natural mineral waters at paragraphs (1) to (5) of Regulation 6,

(*e*) satisfy the labelling requirements imposed in respect of natural mineral waters at Regulation 9 and at subparagraphs (*b*) and (*c*) of Regulation 8(3),

(*f*) have not undergone any treatment other than those referred to in paragraphs (1) to (3) of Regulation 5,

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

(3) From the date of coming into operation of these Regulations, a person shall not—

(*a*) 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 as defined in paragraph (2).

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

(5) From the date of coming into operation of these Regulations, a person shall not in the packaging, labelling or advertising in whatsoever form of spring waters, use designations, proprietary names, trade marks, brand names, illustrations or other signs, whether emblematic or not, which are liable to cause confusion with natural mineral waters, in particular the description "mineral water".

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

12. (1) The requirements applicable to other waters in Regulations 14 and 17 shall also be applicable to spring waters.

(2) The obligations imposed on the Authority, or on an official agency acting pursuant to a service contract, in respect of other waters in Regulations 15 and 16, shall also apply in respect of spring waters.

(3) The requirements applicable to natural mineral waters in paragraphs (5) and (6) of Regulation 5, and paragraph (6) of Regulation 8, shall also be applicable to spring waters.

## PART 4 Other Waters in Bottles or Containers

13. (1) This Part is concerned with waters intended for human consumption other than natural mineral waters and spring waters.

(2) "Other waters" are those waters which—

(*a*) are intended for human consumption,

(*b*) are not natural mineral waters within the meaning of Regulation 3(2), and

(*c*) are not spring waters within the meaning of Regulation 11(2),

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

(3) From the date of coming into operation of these Regulations, a person shall not market any other waters unless the provisions of this Part are complied with.

14. (1) Other waters shall not be placed on the market unless—

(*a*) they are wholesome and clean, and

(*b*) the parametric values set down in Schedule 5 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,

and

(*b*) meet the minimum requirements set out in Schedule 5, Parts 1 and 2

and if they meet the other requirements of this Part.

(3) Measures taken by a person engaged in the production, processing and distribution of bottled waters, or the Authority, or an official agency acting pursuant to a service contract to apply the provisions of these Regulations shall in no case have the effect of allowing, directly or indirectly, either any deterioration in the existing quality of water intended for human consumption insofar as that is relevant for the protection of human health or any increase in the pollution of waters used for the production of drinking water.

15. (1) The Authority, or an official agency acting pursuant to a service contract, 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 Schedule 5.

(2) The Authority, or an official agency acting pursuant to a service contract, shall take samples so that they are representative of the quality of the waters consumed throughout the year.

(3) The sampling points shall be determined by the Authority, or by an official agency acting pursuant to a service contract, and shall meet the relevant requirements set out in Schedule 6.

(4) The Authority, or an official agency acting pursuant to a service contract, 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 acting pursuant to a service contract, shall establish appropriate monitoring programmes for other waters.

(6) The monitoring programmes referred to at paragraph (5) shall meet the minimum requirements set down in Schedule 6.

(7) The Authority, or an official agency acting pursuant to a service contract, shall comply with the specifications for the analyses of parameters set out in Schedule 7.

(8) Methods other than those specified in Schedule 7, Part 1, may be used, providing 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 Schedule 7, Parts 2 and 3, any method of analysis may be used provided that it meets the requirements set out therein.

(10) The Authority, or an official agency acting pursuant to a service contract, 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, if there is reason to suspect that they may be present in amounts or numbers which constitute a potential danger to human health.

16. (1) The Authority, or an official agency acting pursuant to a service contract, shall ensure that any failure to meet the parametric values set down in Schedule 5 is immediately investigated in order to identify the cause.

(2) If other waters do not meet the parametric values set down in Schedule 5, the Authority, or an official agency acting pursuant to a service contract, shall ensure that the necessary remedial action is taken as soon as possible to restore their quality and shall give priority to their 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 has occurred, the Authority, or an official agency acting pursuant to a service contract, 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 acting pursuant to a service contract, 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 acting pursuant to a service contract, 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. The Authority may establish guidelines to assist the Authority, or an official agency acting pursuant to a service contract, to fulfil its obligations under this paragraph.

(6) In the event of non-compliance with the parametric values or with the specifications set out in Schedule 5, Part 3, the Authority, or an official agency acting pursuant to a service contract, 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.

(7) In the event of the Authority, or an official agency acting pursuant to a service contract, taking remedial action pursuant to paragraph (6), 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 values to be trivial.

17. (1) Substances and materials for new installations used in the preparation or distribution of other waters, and impurities associated with such substances or materials for new installations, shall not remain in other waters in concentrations higher than is necessary for the purpose of their use.

(2) Substances and materials for new installations used in the preparation or distribution of other waters, and impurities associated with such substances or materials for new installations, shall not directly or indirectly reduce the protection of human health provided for in this Part.

(3) The interpretative document and technical specifications pursuant to Article 3 and Article 4(1) of Council Directive 89/106/EEC [8] of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products shall respect the requirements of this Part.

18. From the date of coming into operation of these Regulations, a person shall not in the packaging, labelling or advertising in whatsoever form of other waters, use designations, proprietary names, trade marks, brand names, illustrations or other signs, whether emblematic or not, which are liable to cause confusion with natural mineral waters, in particular the description “mineral water”.

## PART 5 Enforcement

19. The enforcement of these Regulations and of the Directives shall be carried out in accordance with the provisions of these Regulations.

20. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

21. 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 Regulation 19, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

22. (1) A person who fails to comply with these Regulations is guilty of an offence.

(2) Paragraph (1) shall not apply to an authorised officer acting in the course of his or her duties pursuant to these Regulations.

(3) A person who—

(*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 requirement under these Regulations,

(*c*) fails to comply with a request from an authorised officer under these Regulations,

(*d*) makes a statement to an authorised officer which the person knows is false or misleading, or

(*e*) gives in purported compliance with a requirement under these Regulations a name, address or corroborative evidence which is false or misleading,

is guilty of an offence.

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

24. (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 or of another relevant substance.

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

(3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of bottled waters or of another relevant substance which are suspected by him or her to fail to comply with the provisions of these Regulations, he or she may, by notice in writing to the seller, owner or person in apparent charge or control of such bottled waters, 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 days from the date of the detention of the sample.

(4) Where an authorised officer purchases or takes without payment a sample of bottled waters, or a sample from the spring or source from which bottled waters are derived or of another relevant substance with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the seller, owner or person in apparent charge or control of the bottled waters, or the spring or source, or of another relevant substance of his or her intention of having the sample analysed.

25. (1) Where a sample of bottled waters, or a sample from the spring or source from which bottled waters are derived or of another substance, is taken pursuant to these Regulations, and where the division of the sample is reasonably practicable, the

authorised officer concerned may divide the sample into not more than three approximately equal parts 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. The authorised officer shall mark, seal and fasten each part in such a manner as its nature will permit, forward one part to the approved examiner in an official laboratory for analysis, give or send one part to the seller, owner or person in apparent charge or control of the bottled waters, or the spring or source or of another relevant substance, and retain the third part.

(2) Where an authorised officer takes a sample consisting of bottled waters or of another relevant substance contained in unopened 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 provision of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).

(3) 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 or of another relevant substance, taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) and (2). The part, package or container retained by the authorised officer shall be produced at the hearing.

26. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of bottled waters, or a sample from the spring or source from which bottled waters are derived or of another relevant substance, 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. The form of certificate set out in Schedule 11 to these Regulations or a certificate in like form shall be used.

(2) An official certificate given in accordance with paragraph (1) shall be prima facie evidence of the matters contained therein until the contrary is proved.

27. Where a sample of bottled waters, or a sample from the spring or source from which bottled waters are derived or of another relevant article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the certificate given in accordance with Regulation 26 indicates that there has been non-compliance with these Regulations, 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, and shall provide the food business operator with a copy of the report.

28. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on bottled waters or of another relevant substance.

29. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any bottled waters which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the owner 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 (4), destroy or otherwise dispose of same as to prevent them being used for human consumption.

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

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such bottled waters fail to comply with these Regulations, order that they 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 them accordingly.

30. (1) Any person who 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 in this Regulation referred to as ‘a forged document’), is guilty of an offence.

(2) Any person who alters with intent to defraud or deceive, or who 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 in this Regulation referred to as ‘an altered document’), is guilty of an offence.

(3) Any person who, without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be, is guilty of an offence.

(4) Any person who, with intent to defraud or deceive—

(*a*) tampers with any thing so as to purport that any sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

(*b*) tampers or interferes with any sample taken under these Regulations is guilty of an offence.

(5) A person who falsely represents himself of herself to be an authorised officer is guilty of an offence.

31. (1) 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 of these Regulations.

(2) A person who is guilty of an offence under these Regulations is liable on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 6 months or both.

32. An offence under these Regulations may be prosecuted by—

(*a*) the Authority, or

(*b*) an official agency,

or both.

## PART 6 Revocation

33. (1) The European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2005 (S.I. No. 79 of 2005) are revoked.

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

## SCHEDULE 1

### *PART 1* DEFINITION

1. Natural mineral water means microbiologically wholesome water, within the meaning of Article 5 of Council Directive 80/777/EEC, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.

Natural mineral water can be clearly distinguished from ordinary drinking water—

(*a*) by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;

(*b*) by its original state,

both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.

2. These characteristics, which may give natural mineral water properties favourable to health, must have been assessed—

(*a*) from the following points of view—

1. geological and hydrological,

2. physical, chemical and physico-chemical,

3. microbiological,

4. if necessary, pharmacological, physiological and clinical;

(*b*) according to the criteria listed in Part 2 of this Schedule;

(*c*) according to scientific methods approved by the responsible authority.

The analyses referred to in (*a*) (4) may be optional where the water presents the compositional characteristics on the strength of which it was considered a natural mineral water in the Member State of origin prior to the entry into force of Directive 80/777/EEC. This is the case in particular when the water in question contains, per kg, both at source and after bottling, a minimum of 1,000 milligrams of total solids in solution or a minimum of 250 milligrams of free carbon dioxide.

3. The composition, temperature and other essential characteristics of natural mineral water must remain stable within the limits of natural fluctuation; in particular, they must not be affected by possible variations in the rate of flow.

Within the meaning of Article 5(1) of Directive 80/777/EEC, the normal viable colony count of natural mineral water means the reasonably constant total colony count at source before any treatment, whose qualitative and quantitative composition taken into account in the recognition of that water is checked by periodic analysis.

## *PART 2* REQUIREMENTS AND CRITERIA FOR APPLYING THE DEFINITION

1.1. Requirements for geological and hydrological surveys

There must be a requirement to supply the following particulars—

1.1.1. the exact site of the catchment with indication of its altitude, on a map with a scale of not more than 1:1,000;

1.1.2. a detailed geological report on the origin and nature of the terrain;

1.1.3. the stratigraphy of the hydrogeological layer;

1.1.4. a description of the catchment operations;

1.1.5. the demarcation of the area or details of other measures protecting the spring against pollution.

1.2. Requirements for physical, chemical and physico-chemical surveys

These surveys shall establish—

1.2.1. the rate of flow of the spring;

1.2.2. the temperature of the water at source and the ambient temperature;

1.2.3. the relationship between the nature of the terrain and the nature and type of minerals in the water;

1.2.4. the dry residues at 180°C and 260°C;

1.2.5. the electrical conductivity or resistivity, with the measurement temperature having to be specified;

1.2.6. the hydrogen ion concentration (pH);

1.2.7. the anions and cations;

1.2.8. the non-ionized elements;

1.2.9. the trace elements;

1.2.10. the radio-actinological properties at source;

1.2.11. where appropriate, the relative isotope levels of the constituent elements of water, oxygen ( 16 O — 18 O) and hydrogen (protium, deuterium, tritium);

1.2.12. the toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.

1.3. Criteria for microbiological analyses at source

These analyses must include—

1.3.1. demonstration of the absence of parasites and pathogenic micro-organisms;

1.3.2. quantitative determination of the revivable colony count indicative of

faecal contamination—

(*a*) the absence of *Escherichia coli* and other coliforms in 250 millilitres at 37°C and 44.5°C;

(*b*) the absence of faecal streptococci in 250 millilitre;

(*c*) the absence of sporulated sulphite-reducing anaerobes in 50 millilitre;

(*d*) the absence of *Pseudomonas aeruginosa* in 250 millilitre.

1.3.3. determination of the revivable total colony count per millilitre of water —

(*a*) at 20 to 22°C in 72 hours on agar-agar or an agar-gelatine mixture,

(*b*) at 37°C in 24 hours on agar-agar.

1.4. Requirements for clinical and pharmacological analyses

1.4.1. The analyses, which must be carried out in accordance with scientifically recognised methods, should be suited to the particular characteristics of the natural mineral water and its effects on the human organism, such as diuresis, gastric and intestinal functions, compensation for mineral deficiencies.

1.4.2. The establishment of the consistency and concordance of a substantial number of clinical observations may, if appropriate, take the place of the analyses referred to in 1.4.1. Clinical analyses may, in appropriate cases, take the place of the analyses referred to in 1.4.1 provided that the consistency and concordance of a substantial number of observations enable the same results to be obtained.

## *PART 3* SUPPLEMENTARY QUALIFICATIONS RELATING TO EFFERVESCENT NATURAL MINERAL WATERS

At source or after bottling, effervescent natural mineral waters give off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure. They fall into three categories to which the following descriptions respectively shall apply—

(*a*) naturally carbonated natural mineral water means water 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;

(*b*) natural mineral water fortified with gas from the spring means water whose content of carbon dioxide from the water table or deposit after decanting, if any, and bottling is greater than that established at source;

(*c*) carbonated natural mineral water means water to which has been added

carbon dioxide of an origin other than the water table or deposit from which the water comes.

## SCHEDULE 2 CONDITIONS FOR THE EXPLOITATION AND MARKETING OF NATURAL MINERAL WATER

1. Exploitation of a natural mineral water spring shall be subject to permission from the responsible authority of the country where the water has been extracted, after it has been established that the water in question complies with the provisions laid down in point 1 of Schedule 1.

2. 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.

To this end, in particular—

(*a*) the spring or outlet must be protected against the risks of pollution;

(*b*) 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;

(*c*) the conditions of exploitation, particularly the washing and bottling plant, must meet hygiene requirements. In particular, the containers must be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the natural mineral water;

(*d*) the transport of natural mineral water in containers other than those authorised for distribution to the ultimate consumer is prohibited.

However, point (*d*) need not be applied to mineral waters exploited and marketed in the territory of a Member State if, in that Member State at the time of notification of Council Directive 80/777/EEC, transport of the natural mineral water in tanks from the spring to the bottling plant was authorised.

3. Where it is found during exploitation that the natural mineral water is polluted and no longer presents the microbiological characteristics laid down in Article 5 of Council Directive 80/777/EEC, the person exploiting the spring must forthwith suspend all operations, particularly the bottling process, until the cause of pollution is eradicated and the water complies with the provisions of Article 5 of Council Directive 80/777/EEC.

4. The responsible authority in the country of origin shall carry out periodic checks to see whether—

(*a*) the natural mineral water in respect of which exploitation of the spring has been authorised complies with Part 1 of Schedule 1;

(*b*) the provisions of paragraphs 2 and 3 are being applied by the person exploiting the spring.

## SCHEDULE 3 INDICATIONS AND CRITERIA LAID DOWN IN ARTICLE 9 OF COUNCIL DIRECTIVE 80/777/EEC

| Indications | 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 1,500 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 the preparation of infant food | _____ |
| Suitable for a low-sodium diet | Sodium content less than 20 mg/l |
| May be laxative | _____ |
| May be diuretic | _____ |

## SCHEDULE 4 CONDITIONS FOR THE EXPLOITATION AND MARKETING OF SPRING WATERS

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.

To this end, in particular—

(*a*) the spring or outlet must be protected against the risks of pollution;

(*b*) 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;

(*c*) the conditions of exploitation, particularly the washing and bottling plant, must meet hygiene requirements. In particular, the containers must be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the spring waters;

(*d*) the transport of spring waters in containers other than those authorised for distribution to the ultimate consumer is prohibited.

However, point (*d*) need not be applied to spring waters exploited and marketed in the territory of a Member State if, in that Member State at the time of notification of Council Directive 80/777/EEC, transport of the spring waters in tanks from the spring to the bottling plant was authorised.

2. Where it is found during exploitation that the spring waters are polluted and no longer present the microbiological characteristics laid down in Article 5 of Council Directive 80/777/EEC, the person exploiting the spring must forthwith suspend all operations, particularly the bottling process, until the cause of pollution

is eradicated and the water complies with the provisions of Article 5 of Council Directive 80/777/EEC.

## SCHEDULE 5 PARAMETERS AND PARAMETRIC VALUES

### *PART 1* Microbiological parameters

The following applies to water offered for sale in bottles or containers—

| Parameter | Parametric value |
|---|---|
| *Escherichia coli (E. coli)* | 0/250 ml |
| Enterococci | 0/250 ml |
| *Pseudomonas aeruginosa* | 0/250 ml |
| Colony count 22°C | 100/ml |
| Colony count 37°C | 20/ml |

### *PART 2* Chemical parameters

| Parameter | Parametric value | Unit | Notes |
|---|---|---|---|
| Acrylamide | 0.10 | g/l | Note 1 |
| Antimony | 5.0 | g/l | |
| Arsenic | 10 | g/l | |
| Benzene | 1.0 | g/l | |
| Benzo(a)pyrene | 0.010 | g/l | |
| Boron | 1.0 | mg/l | |
| Bromate | 10 | g/l | Note 2 |

| | | | |
|---|---|---|---|
| Cadmium | 5.0 | g/l | |
| Chromium | 50 | g/l | |
| Copper | 2.0 | mg/l | Note 3 |
| Cyanide | 50 | g/l | |
| 1,2-dichloroethane | 3.0 | g/l | |
| Epichlorohydrin | 0.10 | g/l | Note 1 |
| Fluoride | 1.5 | mg/l | |
| Lead | 10 | g/l | Notes 3 and 4 |
| Mercury | 1.0 | g/l | |
| Nickel | 20 | g/l | Note 3 |
| Nitrate | 50 | mg/l | Note 5 |
| Nitrite | 0.50 | mg/l | Note 5 |
| Pesticides | 0.10 | g/l | Notes 6 and 7 |
| Pesticides — Total | 0.50 | g/l | Notes 6 and 8 |
| Polycyclic aromatic hydrocarbons | 0.10 | g/l | Sum of concentrations of specified compounds; Note 9 |
| Selenium | 10 | g/l | |
| Tetrachloroethene | 10 | g/l | Sum of |

| | | | |
|---|---|---|---|
| and Trichloroethene | | | concentrations of specified parameters |
| Trihalomethanes — Total | 100 | g/l | Sum of concentrations of specified compounds; Note 10 |
| Vinyl chloride | 0.50 | g/l | Note 1 |

Notes

Note 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.

Note 2: Where possible, without compromising disinfection, Member States should strive for a lower value.

For the water referred to in Article 6(1)(*a*), (*b*) and (*d*) of Council Directive 98/83/EC, the value must be met, at the latest, 10 calendar years after the entry into force of Council Directive 98/83/EC. The parametric value for bromate from five years after the entry into force of Council Directive 98/83/EC until 10 years after its entry into force is 25 g/l.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method (1) at the tap and taken so as to be representative of a weekly average value ingested by consumers. Where appropriate the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4) of Council Directive 98/83/EC. Member States must take account of the occurrence of peak levels that may cause adverse effects on human health.

Note 4: For water referred to in Article 6(1)(*a*), (*b*) and (*d*) of Council Directive 98/83/EC, the value must be met, at the latest, 15 calendar years after the entry into force of Council Directive 98/83/EC. The parametric value for lead from five years after the entry into force of Council Directive 98/83/EC until 15 years after its entry into force is 25 g/l. Member States must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value. When implementing the measures to achieve compliance with that value Member States must progressively give priority where lead concentrations in water intended for human consumption are highest.

Note 5: Member States must ensure that the condition that [nitrate]/50 + [nitrite]/3 1, the square brackets signifying the concentrations in mg/l for nitrate ($NO_3$) and nitrite

(NO 2 ), is complied with and that the value of 0.10 mg/l for nitrites is complied with ex water treatment works.

Note 6: “Pesticides” means:

— organic insecticides,

— organic herbicides,

— organic fungicides,

— organic nematocides,

— organic acaricides,

— organic algicides,

— organic rodenticides,

— organic slimicides,

— related products (including, inter alia, growth regulators)

and their relevant metabolites, degradation and reaction products.

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

Note 7: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0.030 g/l.

Note 8: “Pesticides — Total” means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are—

— benzo(b)fluoranthene,

— benzo(k)fluoranthene,

— benzo(ghi)perylene,

— indeno(1,2,3-cd)pyrene.

Note 10: The specified compounds are: chloroform, bromoform, dibromochloromethane and bromodichloromethane. For the water referred to in Article 6(1)(*a*), (*b*) and (*d*) of Council Directive 98/83/EC, the value must be met, at the latest, 10 calendar years after the entry into force of Council Directive 98/83/EC. The parametric value for total THMs from five years after the entry into force of Council Directive 98/83/EC until 10 years after its entry into force is 150 g/l.

Member States must ensure that all appropriate measures are taken to reduce the concentration of Trihalomethanes (THMs) in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value. When implementing the measures to achieve this value, Member States must progressively give priority to those areas where THM concentrations in water intended for human consumption are highest.

Where possible, without compromising disinfection, Member States should strive for a lower value.

*PART 3* Indicator parameters

| Parameter | Parametric value | Unit | Notes |
|---|---|---|---|
| Aluminium | 200 | g/l | |
| Ammonium | 0.50 | mg/l | |
| Chloride | 250 | mg/l | Note 1 |
| Clostridium perfringens(including spores) | 0 | number/100 ml | Note 2 |
| Colour | Acceptable to consumers and no abnormal change | | |
| Conductivity | 2 500 | S cm -1 at | Note 1 |

| | | | |
|---|---|---|---|
| | | 20°C | |
| Hydrogen ion concentration | 6.5 and 9.5 | pH units | Notes 1 and 3 |
| Iron | 200 | g/l | |
| Manganese | 50 | g/l | |
| Odour | Acceptable to consumers and no abnormal change | | |
| Oxidisability | 5.0 | mg/l O 2 | Note 4 |
| Sulphate | 250 | mg/l | Note 1 |
| Sodium | 200 | mg/l | |
| Taste | Acceptable to consumers and no abnormal change | | |
| Colony count 22° | No abnormal change | | |
| Coliform bacteria | 0 | number/100 ml | Note 5 |
| Total organic carbon (TOC) | No abnormal change | | Note 6 |
| Turbidity | Acceptable to consumers and no abnormal | | Note 7 |

change

RADIOACTIVITY

| Parameter | Parametric value | Unit | Notes |
|---|---|---|---|
| Tritium | 100 | Bq/l | Notes 8 and 10 |
| Total indicative dose | 0.10 | mSv/year | Notes 9 and 10 |

Note 1: The water should not be aggressive.

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water. In the event of non-compliance with this parametric value, the Member State concerned must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium. Member States must include the results of all such investigations in the reports they must submit under Article13(2) of Council Directive 98/83/EC.

Note 3: For still water put into bottles or containers, the minimum value may be reduced to 4.5 pH units. For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10,000 m 3 per day.

Note 7: In the case of surface water treatment, Member States should strive for a parametric value not exceeding 1.0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies to be set later in Schedule 6.

Note 9: Excluding tritium, potassium -40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points

to be set later in Schedule 6.

Note 10: (1) The proposals required by Note 8 on monitoring frequencies, and Note 9 on monitoring frequencies, monitoring methods and the most relevant locations for monitoring points in Schedule 6 shall be adopted in accordance with the procedure laid down in Article 12 of Council Directive 98/83/EC. When elaborating these proposals the Commission shall take into account, inter alia, the relevant provisions under existing legislation or appropriate monitoring programmes including monitoring results as derived from them. The Commission shall submit these proposals at the latest within 18 months following the date referred to in Article 18 of Council Directive 98/83/EC.

(2) A Member State is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value. In that case, it shall communicate the grounds for its decision to the Commission, including the results of this other monitoring carried out.

## SCHEDULE 6 MONITORING

### *PART 1* Parameters to be analysed

1. *Check monitoring*

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in Council Directive 98/83/EC.

The following parameters must be subject to check monitoring. Member States may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)

Ammonium

Colour

Conductivity

Clostridium perfringens (including spores) (Note 2)

Escherichia coli (E. coli)

Hydrogen ion concentration

Iron (Note 1)

Nitrite (Note 3)

Odour

Pseudomonas aeruginosa Taste

Colony count 22°C and 37°C

Coliform bacteria

Turbidity

Note 1: Necessary only when used as flocculant*.

Note 2: Necessary only if the water originates from or is influenced by surface water*.

Note 3: Necessary only when chloramination is used as a disinfectant*.

* In all other cases, the parameters are in the list for audit monitoring.

*2. Audit monitoring*

The purpose of audit monitoring is to provide the information necessary to determine whether or not all of Council Directive's 98/83/EC parametric values are being complied with. All parameters set in accordance with Article 5(2) and (3) of Council Directive 98/83/EC must be subject to audit monitoring unless it can be established by the competent authorities, for a period of time to be determined by them, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in

Schedule 5, Part 3, will be monitored in accordance with monitoring requirements adopted under Article 12 of Council Directive 98/83/EC.

*PART 2* Minimum frequency of sampling and analysis for water put into bottles or containers intended for sale

| Volume of water produced for offering for sale in bottles or containers each day ( 1 ) m 3 | Check monitoring number of samples per year | Audit monitoring number of samples per year |
|---|---|---|
| 10 | 1 | 1 |
| >10 60 | 12 | 1 |
| >60 | 1 for each 5 m 3 and part thereof of the total volume | 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 7 SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

Each Member State must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the competent authority for that purpose.

*PART 1* PARAMETERS FOR WHICH METHODS OF ANALYSIS ARE SPECIFIED

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance, pending the possible future adoption, in accordance with the procedure laid down in Article 12 of Council Directive 98/83/EC, of further CEN/ISO international methods for these parameters. Member States may use alternative methods, providing the provisions of Article 7(5) of Council Directive 98/83/EC are met.

Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1)

Enterococci (ISO 7899-2)

*Pseudomonas aeruginosa* (prEN ISO 12780)

Enumeration of culturable microorganisms — Colony count 22°C (prEN ISO 6222)

Enumeration of culturable microorganisms — Colony count 37°C (prEN ISO 6222)

*Clostridium perfringens* (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 1°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.

Note 1: The composition of m-CP agar is:

| | |
|---|---|
| Basal medium | |
| Tryptose | 30g |
| Yeast extract | 20g |
| Sucrose | 5g |
| L-cysteine hydrochloride | 1g |
| MgSO 4 7H 2 O | 0.1g |
| Bromocresol purple | 40mg |
| Agar | 15g |
| Water | 1,000ml |

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

| | |
|---|---|
| D-cycloserine | 400 mg |
| Polymyxine-B sulphate | 25 mg |

| | |
|---|---|
| Indoxyl--D-glucoside to be dissolved in 8 ml sterile water before addition | 60 mg |
| Filter — sterilised 0.5% phenolphthalein diphosphate solution | 20 ml |
| Filter — sterilised 4.5% FeCl 3 6H 2 O | 2 ml |

*PART 2* PARAMETERS FOR WHICH PERFORMANCE CHARACTERISTICS ARE SPECIFIED

2.1. For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Schedule 5, Parts B and C.

| Parameters | Trueness % of parametric value (Note 1) | Precision % of parametric value (Note 2) | Limit of detection % of parametric value (Note 3) | Conditions | Notes |
|---|---|---|---|---|---|
| Acrylamide | | | | To be controlled by product specification | |
| Aluminium | 10 | 10 | 10 | | |
| Ammonium | 10 | 10 | 10 | | |
| Antimony | 25 | 25 | 25 | | |
| Arsenic | 10 | 10 | 10 | | |
| Benzo(a)pyrene | 25 | 25 | 25 | | |
| Benzene | 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 | 10 | 10 | 10 | | Note 4 |
| 1,2-dichloroethane | 25 | 25 | 10 | | |
| Epichlorohydrin | | | | To be controlled by product specification | |
| 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 | | |

| | | | | | |
|---|---|---|---|---|---|
| Nitrite | 10 | 10 | 10 | | |
| Oxidisability | 25 | 25 | 10 | | Note 5 |
| Pesticide | 25 | 25 | 25 | | Note 6 |
| Polycyclic aromatic hydrocarbons | 25 | 25 | 25 | | Note 7 |
| Selenium | 10 | 10 | 10 | | |
| Sodium | 10 | 10 | 10 | | |
| Sulphate | 10 | 10 | 10 | | |
| Tetrachloroethene | 25 | 25 | 10 | | Note 8 |
| Trichloroethene | 25 | 25 | 10 | | Note 8 |
| Trihalomethanes — Total | 25 | 25 | 10 | | Note 7 |
| Vinyl chloride | | | | To be controlled by product specification | |

2.2 For hydrogen ion concentration the specified performance characteristics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0.2 pH unit and a precision of 0.2 pH unit.

Note 1: Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value. This term is further defined in ISO 5725.

Note 2: Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation. This term is further defined in ISO 5725.

Note 3:Limit of detection is either—

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

— five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100°C under acid conditions using permanganate.

Note 6: The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but Member States should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 25% of the parametric value in Schedule 5.

Note 8: The performance characteristics apply to the individual substances specified at 50% of the parametric value in Schedule 5.

*PART 3* PARAMETERS FOR WHICH NO METHOD OF ANALYSIS IS SPECIFIED

Colour

Odour

Taste

Total organic carbon

Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 25%, precision of 25% and a 25% limit of detection.

## SCHEDULE 8 CONSTITUENTS NATURALLY PRESENT IN NATURAL MINERAL WATERS AND MAXIMUM LIMITS WHICH, IF EXCEEDED, MAY POSE A RISK TO PUBLIC HEALTH

| Constituents | Maximum limits (mg/l) |
|---|---|
| Antimony | 0.0050 |
| Arsenic | 0.010 (as total) |
| Barium | 1.0 |
| Boron | For the record* |
| Cadmium | 0.003 |
| Chromium | 0.050 |
| Copper | 1.0 |
| Cyanide | 0.070 |
| Fluorides | 5.0 |
| Lead | 0.010 |
| Manganese | 0.50 |
| Mercury | 0.0010 |
| Nickel | 0.020 |
| Nitrates | 50 |
| Nitrites | 0.1 |
| Selenium | 0.010 |

* The maximum limit for boron will be fixed, where necessary, following an opinion of the European Food Safety Authority and on a proposal from the Commission.

## SCHEDULE 9 PERFORMANCE CHARACTERISTICS* FOR ANALYSING THE CONSTITUENTS IN SCHEDULE 8

| Constituents | Accuracy of parametric value in % (Note 1) | Precision of parametric value (Note 2) | Detection limit in % of parametric value (Note 3) | Notes |
|---|---|---|---|---|
| Antimony | 25 | 25 | 25 | |
| Arsenic | 10 | 10 | 10 | |
| Barium | 25 | 25 | 25 | |
| Boron | | | | See Schedule 8 |
| Cadmium | 10 | 10 | 10 | |
| Chromium | 10 | 10 | 10 | |
| Copper | 10 | 10 | 10 | |
| Cyanides | 10 | 10 | 10 | Note 4 |
| Fluorides | 10 | 10 | 10 | |
| Lead | 10 | 10 | 10 | |
| Manganese | 10 | 10 | 10 | |
| Mercury | 20 | 10 | 20 | |
| Nickel | 10 | 10 | 10 | |
| Nitrates | 10 | 10 | 10 | |
| Nitrites | 10 | 10 | 10 | |

| | | | |
|---|---|---|---|
| Selenium | 10 | 10 | 10 |

*Analytical methods for measuring concentrations of the constituents listed in Schedule 8 must be able to measure, as a minimum, concentrations equal to the parametric value with a specified accuracy, precision and detection limit. Whatever the sensitivity of the method of analysis used, the result will be expressed using at least the same number of decimal places as for the maximum limit laid down in Schedule 8.

Note 1: accuracy is the systematic error and is the difference between the average value of a large number of repeated measurements and the exact value.

Note 2: precision is the random error and is expressed in general as the standard deviation (within a batch and between batches) of a sample of results from the average. Acceptable precision is equal to twice the relative standard deviation.

Note 3: the detection limit is:

— either three times the relative standard deviation within a batch of a natural sample containing a low concentration of the parameter,

— or five times the relative standard deviation within a batch of a virgin sample.

Note 4: the method should make it possible to determine total cyanide in all its forms.

## SCHEDULE 10 MAXIMUM LIMITS FOR RESIDUES FROM TREATMENT OF NATURAL MINERAL WATERS AND SPRING WATERS BY OZONE-ENRICHED AIR

| Treatment Residue | Maximum limit* (g/l) |
|---|---|
| Dissolved Ozone | 50 |
| Bromates | 3 |
| Bromoforms | 1 |

* compliance with the maximum limits is monitored by the competent authorities in the Member States at the time of bottling or other form of packaging intended for the final consumer.

## SCHEDULE 11 FORM OF OFFICIAL CERTIFICATE TO BE GIVEN BY AN APPROVED EXAMINER TO AN AUTHORISED OFFICER.

# European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007

## 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.....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction (4)

and as a result I am of the opinion that (5)

Observations: (6)

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 (7) .....

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. Executive Analytical Chemist located at a Public Analyst Laboratory).

(3) Insert particulars of marking (e.g. name, date etc.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).

(4) 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.

(5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.

(6) 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 any other observations as he or she may consider relevant.

(7) Insert the name and address of the laboratory carrying out the analysis/examination.

GIVEN under my Official Seal

2 May 2007

MARY HARNEY,

Minister for Health and Children.

## EXPLANATORY NOTE

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

These Regulations, which may be cited as the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2007, give further effect to Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters, as amended by Directive 96/70/EC of the European Parliament and of the Council of 28 October 1996. They also give further effect to Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and to Commission Directive 2003/40/EC of 16 May 2003 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.

These Regulations set certain requirements in respect of the exploitation, treatment, packaging and marketing of bottled waters and also include requirements in relation to labelling and various parametric values.

These Regulations revoke the European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2005 (S.I. No. 79 of 2005).

1 OJ L 229, 30.8.1980, p. 1.

2 OJ L 299, 23.11.1996, p. 26.

3 OJ L 330, 5.12.1998, p. 32.

4 OJ L 126, 22.5.2003, p. 34.

5 OJ L 22, 9.2.1965, p. 369, as amended.

6 OJ L 31,1.2.2002, p.1.

7 OJ L 165, 30.4.2004, p.1.

8 OJ L 040, 11.2.1989, p.12.