COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 21.12.2007 COM(2007) 858 final 2007/0292 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the exploitation and marketing of natural mineral waters

(Recast)

EN EN

EXPLANATORY MEMORANDUM

- 1. On 1 April 1987 the Commission decided¹ to instruct its staff that all legislative acts should be <u>codified</u> after <u>no more</u> than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the Community rules are clear and readily understandable.
- 2. The codification of 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 waters² has been initiated by the Commission. The new Directive was to have superseded the various acts incorporated in it³.
- 3. In the meantime Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁴ has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.
- 4. In accordance with the joint statement of the European Parliament, the Council and the Commission⁵ on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the procedure laid down in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.
- 5. It is therefore appropriate to transform the codification of Directive 80/777/EEC into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.

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¹ COM(87) 868 PV.

Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

See Annex IV, Part A of this proposal.

OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

⁵ OJ C 255, 21.10.2006, p. 1.

▼ 80/777/EEC (adapted) 2007/0292 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the exploitation and marketing of natural mineral waters

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article № 95 thereof,

Having regard to the proposal from the Commission⁶,

Having regard to the opinion of the European Economic and Social Committee⁷,

Acting in accordance with procedure laid down in Article 251 of the Treaty⁸,

Whereas:

□ new

(1) 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 has been substantially amended several times 10. Since further amendments are to be made, it should be recast in the interests of clarity.

♦ 80/777/EEC Recital 1 (adapted)

(2) The laws of the Member States define natural mineral waters. Those laws lay down the terms on which natural mineral waters are recognised as such and govern the conditions for exploiting springs. They furthermore stipulate specific rules for marketing the waters in question.

⁶ OJ C [...], [...], p. [...].

⁷ OJ C [...], [...], p. [...].

⁸ OJ C [...], [...], p. [...].

OJ L 229, 30.8.1980, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

See Annex IV, Part A.

♦ 80/777/EEC Recital 2 (adapted)

(3) The differences between those laws hinder the free movement of natural mineral waters, creating disparate competitive situations, and consequently directly affect the functioning of the ⋈ internal ⋈ market.

♦ 80/777/EEC Recital 3

(4) In this particular case, the elimination of these barriers may be achieved both by an obligation on each Member State to allow the marketing in its territory of the natural mineral waters recognised as such by each of the other Member States and by laying down common rules concerning in particular the microbiological requirements to be fulfilled and the conditions in which specific names must be used for certain of the mineral waters.

♦ 96/70/EC Recital 2

(5) The primary purposes of any rules on natural mineral waters should be to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading.

♦ 80/777/EEC Recital 4

(6) Pending the conclusion of agreements on mutual recognition of natural mineral waters between the Community and third countries, the terms should be laid down on which, until implementation of those agreements, similar products imported from third countries may be allowed to enter the Community as natural mineral waters.

♦ 80/777/EEC Recital 5

(7) Care should be taken to ensure that natural mineral waters retain at the marketing stage those characteristics which enabled them to be recognised as such. Therefore, the containers used for packaging them should have suitable closures.

♦ 80/777/EEC Recital 6

(8) In respect of labelling, natural mineral waters are subject to the general rules laid down by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs¹¹. Accordingly, this Directive may

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OJ L109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2006/142/EC (OJ L 368, 23.12.2006, p. 110).

be limited to laying down the additions and derogations which should be made to those general rules.

▶ 96/70/EC Recital 6 (adapted)

(9) The inclusion of the statement of the analytical composition of a natural mineral water should be compulsory in order to ensure that consumers are informed.

new

- (10) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹².
- (11) Power should be conferred on the Commission in particular to adopt limits for the levels of constituents of natural mineral waters, any necessary provisions for the indication on the labelling of high levels of certain constituents, the conditions of use of ozone-enriched air for the treatment of natural mineral water, the information on the treatments of natural mineral water, methods of analysis to determine the absence of pollution of natural mineral waters, as well as the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia, by supplementing it, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (12) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to this Directive necessary in order to ensure the protection of public health.
- (13) The new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States.
- (14) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B,

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OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

♦ 80/777/EEC	
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HAVE ADOPTED THIS DIRECTIVE:

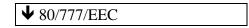
Article 1

- 1. This Directive concerns waters extracted from the ground of a Member State and recognised by the responsible authority of that Member State as natural mineral waters satisfying the provisions of Annex I, Section I.
- 2. This Directive also concerns waters extracted from the ground of a third country, imported into the Community and recognised as natural mineral waters by the responsible authority of a Member State.

The waters referred to in the first subparagraph may be so recognised only if the responsible authority in the country of extraction has certified that they satisfy Annex I, Section I, and that regular checks are made on the application of the provisions of Annex II, point 2.



The validity of the certification referred to in the second subparagraph may not exceed a period of five years. It shall not be necessary to repeat the recognition procedure referred to in the first subparagraph if the certification is renewed before the end of that period.



- 3. This Directive shall not apply to:
- (a) waters which are medicinal products within the meaning of Directive 2001/83/EC of the European Parliament and of the Council¹³;
- (b) natural mineral waters used at source for curative purposes in thermal or hydromineral establishments.
- 4. The grounds for granting the recognition referred to in paragraphs 1 and 2, shall be stated in due form by the responsible authority of the Member State and shall be officially published.
- 5. Each Member State shall inform the Commission of the cases where the recognition referred to in paragraphs 1 and 2 has been granted or withdrawn. The list of natural mineral waters so recognised shall be published in the *Official Journal of the European Union*.

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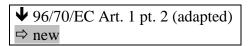
¹³ OJ L 311, 28.11.2001, p. 67.

Article 2

Member States shall take the measures necessary to ensure that only the waters referred to in Article 1 which comply with the provisions of this Directive may be marketed as natural mineral waters.

Article 3

Natural mineral water springs may be exploited and their waters bottled only in accordance with Annex II.



Article 4

- 1. Natural mineral water, in its state at source, may not be the subject of any treatment other than:
- (a) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties;
- (b) the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:
 - (i) the treatment complies with the conditions for use to be laid down ⇒ by the Commission ⇔ in accordance with the procedure laid down in Article 12 and following consultation of the European Food Safety Authority;
 - (ii) the treatment is notified to, and specifically controlled by, the competent authorities;
- (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 water as regards the essential constituents which give it its properties, and provided that:
 - (i) the treatment complies with the conditions for use to be laid down ⇒ by the Commission ⇔ in accordance with the procedure laid down in Article 12 and following consultation of the European Food Safety Authority;
 - (ii) the treatment is notified to, and specifically controlled by, the competent authorities;
- (d) the total or partial elimination of free carbon dioxide by exclusively physical methods.

The measures referred to in points (b)(i) and (c)(i), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

▶ 96/70/EC Art. 1 pt. 2 (adapted)

 \boxtimes The first subparagraph \boxtimes shall not constitute a bar to the utilisation of natural mineral waters and spring waters in the manufacture of soft drinks.

♦ 96/70/EC Art. 1 pt. 2

2. Natural mineral water, in its state at source, may not be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in Annex I, Section III.

♦ 96/70/EC Art. 1 pt. 2 (adapted)

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

♦ 80/777/EEC

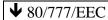
Article 5

1. The revivable total colony count of a natural mineral water at source shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. This total colony count shall be determined under the conditions laid down in Annex I, Section II, point 1.3.3.

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

♦ 80/777/EEC (adapted)

At source, those values \boxtimes must \boxtimes 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 \boxtimes shall \boxtimes be considered as guide figures and not as maximum permitted concentrations.



- 2. At source and during its marketing, a natural mineral water shall be free from:
- (a) parasites and pathogenic micro-organisms;
- (b) Escherichia coli and other coliforms and faecal streptococci in any 250 ml sample examined:
- (c) sporulated sulphite-reducing anaerobes in any 50 ml sample examined;
- (d) Pseudomonas aeruginosa in any 250 ml sample examined.
- 3. Without prejudice to paragraphs 1 and 2 and the conditions of exploitation laid down in Annex II, at the marketing stage:
- (a) the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacteria content which it had at source;
- (b) the natural mineral water may not contain any organoleptic defects.

Article 6

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

Article 7

1. The sales description of natural mineral waters shall be 'natural mineral water' or, in the case of an effervescent natural mineral water as defined in Annex I, Section III, as appropriate, 'naturally carbonated natural mineral water', 'natural mineral water fortified with gas from the spring' or 'carbonated natural mineral water'.

♦ 80/777/EEC (adapted)

The sales description of natural mineral waters which have undergone any of the treatments referred to in \boxtimes point (d) of the first subparagraph of Article 4(1), \boxtimes shall have added to it, as appropriate, the indication 'fully de-carbonated' or 'partially de-carbonated'.

♥ 96/70/EC Art. 1 pt. 3

- 2. Labels on natural mineral waters shall also give the following mandatory information:
- (a) a statement of the analytical composition, giving its characteristic constituents;
- (b) the place where the spring is exploited and the name of the spring;

(c) information on any treatments referred to in points (b) and (c) of the first subparagraph of Article 4(1).

♦ 96/70/EC Art. 1 pt. 3 (adapted)

3. In the absence of Community provisions on information on any treatments referred to in point (c) of paragraph 2, Member States may maintain \boxtimes their \boxtimes national \boxtimes provisions \boxtimes .

♦ 80/777/EEC

Article 8

- 1. The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring.
- 2. It shall be prohibited to market natural mineral water from one and the same spring under more than one trade description.

♦ 80/777/EEC (adapted)

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 \boxtimes of exploitation \boxtimes 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.

♦ 80/777/EEC

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

Article 9

- 1. It shall be prohibited, both on packaging or labels and in advertising in any form whatsoever, to use designations, proprietary names, trade marks, brand names, illustrations or other signs, whether emblematic or not, which:
- (a) in the case of a natural mineral water, suggest a characteristic which the water does not possess, in particular as regards its origin, the date of the authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity;

- (b) in the case of drinking water, packaged in containers, which does not satisfy the provisions of Annex I, Section I, are liable to cause confusion with a natural mineral water, in particular the description 'mineral water'.
- 2. All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited.

♦ 80/777/EEC (adapted)

However, the indications listed in Annex III shall be authorised if they meet the relevant criteria laid down in that Annex or, in the absence thereof, criteria laid down in national provisions and provided that they have been drawn up on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognised scientific methods, in accordance with Annex I, Section I, point 2.

Member States may authorise the indications 'stimulates digestion', 'may facilitate the hepato-biliary functions' or similar indications. They may also authorise the inclusion of other indications, provided that the latter do not conflict with the principles \boxtimes provided for \boxtimes in the first subparagraph and are compatible with those \boxtimes provided for \boxtimes in the second subparagraph.

♦ 80/777/EEC

3. Member States may adopt special provisions regarding information — both on packaging or labels and in advertising — concerning the suitability of a natural mineral water for the feeding of infants. Such provisions may also concern the properties of the water which determine the use of that information.

Member States which intend taking such measures shall inform the other Member States and the Commission of them beforehand.

♦ 96/70/EC Art. 1 pt. 5 (adapted) ⇒ new

- 4. The term 'spring water' shall be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which:
- (a) satisfies the conditions of exploitation laid down in Annex II, points 2 and 3, which shall be fully applicable to spring waters;
- (b) satisfies the microbiological requirements laid down in Article 5;
- (c) satisfies the labelling requirements of Article 7(2)(b) and (c) and Article 8;
- (d) has not undergone any treatment other than those referred to in Article 4. Other treatments may be authorised ⇒ by the Commission. ⇔ in accordance with the procedure laid down in Article 12.

The measures referred to in point (d), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

♦ 96/70/EC Art. 1 pt. 5

In addition, spring waters shall comply with the provisions of Council Directive 98/83/EC¹⁴.

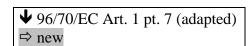
♦ 96/70/EC Art. 1 pt. 5 (adapted)

5. In the absence of Community provisions on the treatment for spring waters referred to in point (d) of the first subparagraph of paragraph 4, Member States may maintain \boxtimes their \boxtimes national provisions on the treatments.

♦ 80/777/EEC

Article 10

Member States shall adopt the measures necessary to ensure that trade in natural mineral waters which comply with the definitions and rules laid down in this Directive cannot be impeded by the application of non-harmonised national provisions governing the properties, composition, conditions of exploitation, packaging or labelling of natural mineral waters or foodstuffs in general.



Article 11

- 1. Where a Member State has detailed grounds for considering that a natural mineral water does not comply with the provisions laid down in this Directive, or endangers public health, albeit freely circulating in one or more Member States, that Member State may temporarily restrict or suspend trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.
- 2. At the request of any Member State or the Commission, the Member State which has recognised the water shall provide all relevant information concerning recognition of the water, together with the results of the regular checks.

OJ L 330, 5.12.1998, p. 32.

- 3. The Commission shall examine as soon as possible the grounds adduced by the Member State referred to in paragraph 1 within the Standing Committee referred to in Article 14(1), and shall then deliver its opinion forthwith and take appropriate measures.
- 4. If the Commission considers that amendments to this Directive are necessary in order to ensure the protection of public health, it shall ⇒ adopt those amendments. ⇔ initiate the procedure laid down in Article 12, with a view to adopting those amendments.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

♦ 96/70/EC Art. 1 pt. 7

The Member State which has adopted safeguard measures may, in that event, retain them until the amendments have been adopted.

♦ 96/70/EC Art. 1 pt. 8 (adapted) ⇒ new

Article 12

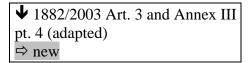
- + The following \Rightarrow measures \Leftarrow shall be adopted \Rightarrow by the Commission \Leftarrow in accordance with the procedure laid down in Article 1214(2):
- (a) limits for the levels of constituents of natural mineral waters;
- (b) any necessary provisions for the indication on the labelling of high levels of certain constituents;
- (c) the conditions of use of ozone-enriched air referred to in point (b) of the first subparagraph of Article 4(1);
- (d) the information on the treatments referred to in point (c) of Article 7(2);
- 2. The following may be adopted in accordance with the procedure laid down to in Article 12:
- (e) methods of analysis, including limits of detection, to determine the absence of pollution of natural mineral waters;
- (f) the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

♦ 96/70/EC Art. 1 pt. 9

Article 13

Any decision likely to have an effect on public health shall be adopted by the Commission following consultation of the European Food Safety Authority.

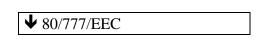


Article 14

- 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council¹⁵, hereinafter referred to as "the Committee".
- 2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

- ⇒ 2. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. 与
- ⇒ 3. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. \Leftarrow
- 3. The Committee shall adopt its rules of procedure.



Article 15

This Directive shall not apply to natural mineral waters intended for export to third countries.

EN 14 EN

OJ L 31, 1.2.2002, p. 1.

Article 16

Directive 80/777/EEC, as amended by the acts listed in Annex IV, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V

Article 17

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

♦ 80/777/EEC

Article 18

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament The President For the Council The President

ANNEX I

I. **DEFINITION**

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

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

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

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

♦ 80/777/EEC (adapted)

- 2. \boxtimes The \boxtimes characteristics \boxtimes referred to in point $1 \boxtimes$, which may give natural mineral water properties favourable to health, shall have been assessed:
 - (a) from the following points of view:
 - (i) geological and hydrological;
 - (ii) physical, chemical and physico-chemical;
 - (iii) microbiological;
 - (iv) if necessary, pharmacological, physiological and clinical;
 - (b) according to the criteria listed in Section II;
 - (c) according to scientific methods approved by the responsible authority.

The analyses referred to in point (a)(iv) of the first subparagraph may be optional where the water presents the compositional characteristics on the strength of which it was considered a natural mineral water in the Member State of origin prior to the entry into force of this Directive. 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 mg of total solids in solution or a minimum of 250 mg of free carbon dioxide.

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

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

II. REQUIREMENTS AND CRITERIA FOR APPLYING THE DEFINITION

1.1. Requirements for geological and hydrological surveys

There shall 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-ionised elements;
- 1.2.9. the trace elements;
- 1.2.10. the radio-actinological properties at source;
- 1.2.11. where appropriate, the relative isotope levels of the constituent elements of water, oxygen ($^{16}0 ^{18}0$) 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 shall include:

- 1.3.1. a demonstration of the absence of parasites and pathogenic micro-organisms;
- 1.3.2. a quantitative determination of the revivable colony count indicative of faecal contamination:
 - (a) absence of Escherichia coli and other coliforms in 250 ml at 37 °C and 44.5 °C;
 - (b) absence of faecal streptococci in 250 ml;
 - (c) absence of sporulated sulphite-reducing anaerobes in 50 ml;
 - (d) absence of Pseudomonas aeruginosa in 250 ml.
- 1.3.3. determination of the revivable total colony count per ml of water:
 - (a) at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture,
 - (b) at 37 °C in 24 hours on agar-agar.

1.4. Requirements for clinical and pharmacological analyses

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

III. SUPPLEMENTARY QUALIFICATIONS RELATING TO EFFERVESCENT NATURAL MINERAL WATERS

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

(a) 'naturally carbonated natural mineral water' means water 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.

ANNEX II

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 Annex I, \boxtimes Section I \boxtimes .

♦ 80/777/EEC

2. Equipment for exploiting the water shall be so installed as to avoid any possibility of contamination and to preserve the properties, corresponding to those ascribed to it, which the water possesses at source.

To that end, in particular:

- (a) the spring or outlet shall be protected against the risks of pollution;
- (b) the catchment, pipes and reservoirs shall be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water;
- (c) the conditions of exploitation, particularly the washing and bottling plant, shall meet hygiene requirements; in particular, the containers shall be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the natural mineral water;
- (d) the transport of natural mineral water in containers other than those authorised for distribution to the ultimate consumer shall bei 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 this Directive, 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, the person exploiting the spring shall 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.

- 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 Annex I, Section I;
 - (b) the provisions of \boxtimes points \boxtimes 2 and 3 are being applied by the person exploiting the spring.



ANNEX III

INDICATIONS AND CRITERIA LAID DOWN IN ARTICLE 9(2)

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	

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ANNEX IV

Part A

Repealed Directive with list of its successive amendments

(referred to in Article 16)

Council Directive 80/777/EEC (OJ L 229, 30.8.1980, p. 1)

Council Directive 80/1276/EEC (OJ L 375, 31.12.1980, p. 77)

Article 1, third indent only

Council Directive 85/7/EEC (OJ L 2, 3.1.1985, p. 22)

Article 1, point 10 only

Point B.1.0 of Annex I to the 1985 Act of Accession (OJ L 302, 15.11.1985, p. 214)

Directive 96/70/EC of the European Parliament and of the Council (OJ L 299, 23.11.1996, p. 26)

Regulation (EC) No 1882/2003 of the European Parliament Annex III, point 4 only and of the Council (OJ L 284, 31.10.2003, p. 1)

Part B
List of time-limits for transposition into national law

(referred to in Article 16)

Directive	Time-limit for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive
80/777/EEC	-	18 July 1982	18 July 1984
80/1276/EEC	-	-	-
85/7/EEC	-	-	-
96/70/EC	-	28 October 1997	28 October 1998 ¹⁷

However, trade in products placed on the market or labelled before the date and not conforming with this Directive may continue until stocks run out.

ANNEX V

CORRELATION TABLE

Directive 80/777/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)
Article 1(3), first and second indents	Article 1(3)(a) and (b)
Article 1(4)	Article 1(4)
Article 1(5)	Article 1(5)
Article 2	Article 2
Article 3	Article 3
Article 4(1)(a)	Article 4(1), first subparagraph, (a)
Article 4(1)(b), first and second indents	Article 4(1), first subparagraph, (b)(i) and (ii)
Article 4(1)(c), first and second indents	Article 4(1), first subparagraph, (c)(i) and (ii)
Article 4(1)(d)	Article 4(1), first subparagraph, (d)
	Article 4(1), second subparagraph
Article 4(2)	Article 4(2)
Article 4(3)	Article 4(3)
Article 4(4)	Article 4(1), third subparagraph
Article 5(1)	Article 5(1)
Article 5(2)	Article 5(2)
Article 5(3), first and second indents	Article 5(3)(a) and (b)
Article 6	Article 6
Article 7(1)	Article 7(1)
Article 7(2)	Article 7(2)
Article 7(2a)	Article 7(3)
Article 8	Article 8

Article 9(1)	Article 9(1)	
Article 9(2)(a), (b) and (c)	Article 9(2), first, second and third subparagraphs	
Article 9(3)	Article 9(3)	
Article 9(4)		
Article 9(4a), first subparagraph, first to fourth indents	Article 9(4), first subparagraph, (a) to (d)	
Article 9(4a), second subparagraph	Article 9(4), second subparagraph	
Article 9(4b)	Article 9(5)	
Article 10(1)	Article 10	
Article 10a	Article 11	
Article 11(1), first to fourth indents	Article 12(a) to (d)	
Article 11(2), first and second indents	Article 12(e) and (f)	
Article 11a	Article 13	
Article 12(1)	Article 14(1)	
Article 12(2)	Article 14(2) and (3)	
Article 12(3)		
Article 13		
Article 14	Article 15	
Article 15		
Article 16		
	Article 16	
	Article 17	
Article 17	Article 18	
Annex I(I)(1)	Annex I(I)(1)	
Annex I(I)(2), first subparagraph, (a)(1) to (4)	Annex I(I)(2), first subparagraph, (a)(i) to(iv)	
Annex I(I)(2), first subparagraph, (b)	Annex I(I)(2), first subparagraph, (b)	
Annex I(I)(2), first subparagraph, (c)	Annex I(I)(2), first subparagraph, (c)	

Annex I(I)(2), second subparagraph	Annex I(I)(2), second subparagraph
Annex I(I)(3)	Annex I(I)(3)
Annex I(II), 1.1	Annex I(II), 1.1
Annex I(II), 1.2	Annex I(II), 1.2
Annex I(II), 1.3	Annex I(II), 1.3
Annex I(II), 1.3.1	Annex I(II), 1.3.1
Annex I(II), 1.3.2	Annex I(II), 1.3.2
Annex I(II), 1.3.3, (i) and (ii)	Annex I(II), 1.3.3, (a) and (b)
Annex I(II), 1.4	Annex I(II), 1.4
Annex I(III)	Annex I(III)
Annex II	Annex II
Annex III	Annex III
	Annex IV
	Annex V