

Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (Recast) (Text with EEA relevance)

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 the provisions of Annex I, Section I, and that regular checks are made on the application of the provisions of Annex II, point 2.

The validity of the certification referred to 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 Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽¹⁾;
- 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shall inform the Commission of the cases where the recognition referred to in paragraphs 1 and 2 has been granted or withdrawn.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*.

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 following consultation of the European Food Safety Authority, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽²⁾;
 - (ii) the treatment is notified to, and specifically controlled by, the competent authorities;
 - c the separation of undesirable constituents other than those specified in points (a) or (b), in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:
 - (i) the treatment complies with the conditions for use to be laid down by the Commission following consultation of the European Food Safety Authority;
 - (ii) the treatment is notified to, and specifically controlled by, the competent authorities;
 - d the total or partial elimination of free carbon dioxide by exclusively physical methods.

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

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

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.

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.

Article 5

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

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

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

- 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 bacterial count 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’.

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

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

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.

3 When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, that place of exploitation or the name of the spring shall be indicated in letters

at least one and a half times the height and width of the largest of the letters used for that trade description.

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

Article 9

1 It shall be prohibited, both on packaging or labels and in advertising in any form whatsoever, to use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, which:

- a in the case of a natural mineral water, suggest a characteristic which the water does not possess, in particular as regards its origin, the date of the authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity;
- b in the case of drinking water packaged in containers, which does not satisfy the provisions of Annex I, Section I, are liable to cause confusion with a natural mineral water, in particular the description 'mineral water'.

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

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

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

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

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

4 The term 'spring water' shall be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which:

- a satisfies the conditions of exploitation laid down in Annex II, points 2 and 3, which shall be fully applicable to spring waters;
- b satisfies the microbiological requirements laid down in Article 5;
- c satisfies the labelling requirements of Article 7(2), points (b) and (c), and Article 8;
- d has not undergone any treatment other than those referred to in Article 4. Other treatments may be authorised by the Commission.

The measures referred to in point (d), designed to amend 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).

In addition, spring waters shall comply with the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption⁽³⁾.

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

Article 10

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

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 that water shall provide all relevant information concerning recognition of that water, together with the results of the regular checks.

3 The Commission shall examine as soon as possible the grounds adduced by the Member State referred to in paragraph 1 within the Standing Committee referred to in Article 14(1), and shall deliver its opinion forthwith and take appropriate measures.

4 If the Commission considers that amendments to this Directive are necessary in order to ensure the protection of public health, it shall adopt those amendments.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 14(3).

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

Article 12

The following measures shall be adopted by the Commission:

- (a) limits for the concentrations of constituents of natural mineral waters;
- (b) any necessary provisions for the indication on the labelling of high levels of certain constituents;
- (c) the conditions of use of ozone-enriched air referred to in point (b) of the first subparagraph of Article 4(1);

- (d) the information on the treatments referred to in Article 7(2)(c);
- (e) methods of analysis, including limits of detection, to verify the absence of pollution of natural mineral waters;
- (f) the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters.

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

Article 13

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

Article 14

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 15

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

Article 16

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

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

Article 17

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 18

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

Š. FÜLE

Status: This is the original version (as it was originally adopted).

- (1) OJ L 311, 28.11.2001, p. 67.
- (2) OJ L 31, 1.2.2002, p. 1.
- (3) OJ L 330, 5.12.1998, p. 32.