

## Health protection requirements for mineral water

Passed with the Regulation No. 83 of the Minister of Social Affairs from the date of June 22, 2004 ([RTL<sup>2</sup> 2004, 90, 1412](#)), entered into force on 9.07.2004

Amended by the following Regulation (date of passing, number, date of publishing in *Riigi Teataja*, date of entering into force):

11.12.2009 No. 94 ([RTL 2009, 96, 1437](#)) 1.01.2010

This Regulation is established on grounds of the clause 8 (2) 14) of the [Public Health Act](#).

### Chapter 1 GENERAL PROVISIONS

#### § 1. Scope of application of Regulation

- (1) The purpose of this Regulation is to establish requirements for natural mineral water, its recognition and handling.
- (2) The quality requirements for potable water provided for in Water Act and the special requirements for treatment, water extraction equipment, labelling and microbiological conditions of spring water provided for in this Regulation shall be applied to spring water used for drinking purposes.
- (3) The Regulation shall not apply to natural mineral water which:
  - 1) is a medicinal product in the sense of the Medicinal Products Act;
  - 2) is used for medical purposes in a thermal or a mineral water bath, or
  - 3) is exported to third countries.

### Chapter 2 NATURAL MINERAL WATER

#### § 2. Assessment and recognition of natural mineral water

(1) Natural mineral water may be marketed if the water extracted from the earth's crust in a Member State is recognised by the responsible authority of the Member State as a natural mineral water. The Health Board shall recognise the conformity of natural mineral water to requirements in Estonia pursuant to the provisions of section 3 of this Regulation.

[[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

(2) Natural mineral water extracted from the earth's crust in a non-Community state and imported into the Community must be recognised as natural mineral water by a responsible authority of at least one Member State.

(3) A responsible authority of a Member State may recognise a natural mineral water provided for in subsection (2) of this section only if the responsible authority of the origin state of such water has confirmed that:

- 1) the water conforms to the requirements for natural mineral water provided for in section 3 of this Regulation;
- 2) the applying of the provisions regulating the protection of the water source and the water extraction site against contamination, the installation and operating conditions of the water extraction equipment, and the conformity to the hygiene requirements is inspected regularly.

(4) The validity period of the confirmation provided for in subsection (3) of this section must not exceed five years, but the repeating of the procedure of recognising natural mineral water shall not be required if the responsible authority of the origin state has confirmed the conformity to the requirements provided for in the same subsection again before five years have passed.

(5) The Health Board shall justify the recognition, shall publish the justification on its website and shall notify the European Commission about each recognition of natural mineral water and each revoking of such recognition pursuant to the procedure in force.

[\[RTL 2009, 96, 1437\]](#) – entered into force 1.01.2010]

(6) The list of natural mineral waters recognised by the Member States, including natural mineral waters of third states recognised by Member States, shall be published on the website of the Official Journal of the European Community.

(7) The list of natural mineral waters recognised by the Health Board and a reference to the list provided for in subsection (6) of this section shall be published on the website of the Health Board. Also, data about revoking recognition of natural mineral water shall be published there.

[\[RTL 2009, 96, 1437\]](#) – entered into force 1.01.2010]

### § 3. Composition and properties of natural mineral water

(1) Natural mineral water in the sense of this Regulation shall mean water used for the purpose of drinking and being microbiologically beneficial to health, originating from the groundwater layer and exiting in a spring which is protected against contamination, where water is extracted via one or several water extraction sites which are natural or artificially made usable.

(2) Natural mineral water is clearly different from usual potable water:

- 1) by composition and by characteristic content of minerals, microelements or other constituents and, if applicable, by specific effect;
- 2) by natural clearness; and
- 3) by stability of properties due to the water originating from under ground and being protected against all types of contamination.

(3) The properties of natural mineral water, on grounds of which the water can be considered beneficial to health, shall be assessed:

- 1) on the basis of geological and hydrological, physical, chemical and physico-chemical, microbiological and, if necessary, pharmacological, physiological and clinical aspects;
- 2) pursuant to the requirements for geological and hydrological, physical, chemical and physico-chemical surveys, microbiological analysis performed at the extraction site and, if necessary, pharmacological, physiological and clinical requirements, as provided for in subsection 4 (1) to (4) of this Regulation;
- 3) according to scientific methods approved by a responsible authority.

(4) If the water has composition properties, on grounds of which it has been recognised as natural mineral water in the Member State that is the origin state of the water and if, at the extraction site and after bottling, the natural mineral water has a dry substances content of at least 1,000 mg/kg or a free carbon dioxide content of at least 250 mg/kg, then the pharmacological, physiological and clinical analyses provided for in clause (3) 1) shall not be required for assessing the properties of the natural mineral water.

(5) In the course of extracting the mineral water, the composition, temperature and other significant properties of the natural mineral water must remain stable within the natural tolerances. These properties must not be affected by changes in the flow speed.

(6) The usual amount of viable microorganisms at the extraction site of natural mineral water shall be considered the amount of viable microorganisms in the water which is stable before any treatment of the water. The quantitative and qualitative composition of viable microorganisms taken into account upon recognising the water shall be inspected periodically.

(7) The constituents of the natural mineral water which could pose a health risk must remain within the tolerances provided for in Annex 1 to this Regulation, taking into account the analytical parameters and the requirements for labelling constituents.

(8) The constituents provided for in Annex 1 to this Regulation must be naturally present in the water and must not originate from a source of contamination.

#### § 4. Requirements for identifying natural mineral water

(1) The following data must be present regarding geological and hydrogeological surveys:

- 1) exact location of the water intake, with reference to its absolute height from the sea level, marked on a map with the scale of up to 1:1000;
- 2) detailed report of the geological structure and its origins;
- 3) stratigraphy of the hydrogeological layer;
- 4) description of activities conducted in the water intake;
- 5) borders of the sanitary protection area of the region or other measures for protecting the spring against contamination.

(2) Physical and chemical surveys shall identify:

- 1) productivity of the spring;
- 2) water temperature and air temperature at the extraction site;
- 3) relations between the geological structure of the area and the kind and type of minerals present

in the water;

- 4) dry substances content at 180°C and at 260°C;
- 5) electrical conductance or electrical resistance, with a determined measuring temperature;
- 6) concentration of hydrogen ions (pH);
- 7) anions and cations;
- 8) non-ionic compounds;
- 9) microelements;
- 10) radiation ratios at the extraction site;
- 11) if necessary, the relative isotope levels of the components for the water, oxygen ( $^{16}\text{O}$ – $^{18}\text{O}$ ) and hydrogen (protium, deuterium, tritium);
- 12) toxicity of certain constituents of the water, taking into account their established limit contents.

(3) The data of the microbiological analyses of the water samples taken from the extraction site must include:

- 1) proof of the lack of pathogenic microorganisms and parasites;
- 2) qualitative ratios of viable microorganisms characterising faecal contamination – lack of *Escherichia coli* and bacteria similar to *coli* in 250 millilitres of natural mineral water at 37°C and 44.5°C; lack of faecal streptococcus in 250 millilitres; lack of sulfite-reducing anaerobes (with spores) in 50 millilitres and lack of *Pseudomonas aeruginosa* in 250 millilitres;
- 3) total quantities of viable microorganisms in one millilitre of water at 20–22°C in 72 hours on agar-agar or a mixture of agar and gelatine and at 37°C in 24 hours on agar-agar.

(4) The following requirements shall be applied to clinical and pharmacological analyses:

- 1) analyses shall be performed according to scientifically recognised methods which are relevant and allow determining the special properties of the natural mineral water and its effects on human, e.g. diuresis, functions of stomach and intestines, compensating for low mineral levels;
- 2) if necessary, the analyses provided for in clause 1) may be replaced by a sufficient amount of relevant clinical studies on the condition that these studies ensure equivalent results to those provided by clinical analyses.

#### § 5. Requirements for extraction site, water extraction equipment and use thereof

(1) Natural mineral water spring shall be taken into use after it has been determined that the water conforms to the requirements provided for in subsections 3 (1) and (2) of this Regulation.

(2) The water extraction equipment must be installed in such a way as to avoid any possibilities of contamination and to preserve the conformant properties that the water has at the extraction site.

(3) The following conditions must be fulfilled in order to ensure conformity to the requirements provided for in subsection (2):

- 1) the spring and the extraction site must be protected against contamination;
- 2) the bore well, pipes and tanks must be made of materials suitable for water and must be manufactured in such a way as to avoid any chemical, physical, physico-chemical changes of the natural mineral water;

3) the operating conditions of the water extraction equipment, particularly the washing of the equipment and the bottling of the water, must conform to hygiene requirements. Primarily, the tanks must be manufactured and maintained in such a way as to avoid any harmful effects to the microbiological and chemical properties of the natural mineral water.

(4) If, in the course of using the bore well, it is discovered that the natural mineral water has been contaminated and does not conform to the established microbiological requirements, the person using the spring shall immediately suspend the bottling and all other activities until the contamination and its cause has been eliminated and the water conforms to the microbiological requirements provided for in section 7 of this Regulation..

#### § 6. Requirements for separating unwanted constituents from natural mineral water, treatment with ozone-enriched air and enrichment with carbon dioxide

(1) It shall be forbidden to treat the natural mineral water extracted from the spring, except if the treatment does not change the composition of the water regarding significant constituents which provide the specific properties to the water:

- 1) separating unstable elements of the water, e.g. compounds of iron and sulphur via filtration or decanting, which may be preceded by treating with oxygen;
- 2) separating iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by way of treating with ozone-enriched air, if the Health Board is notified about such treatment beforehand and assesses whether such treatment is necessary;

[\[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

3) in addition to separation of unwanted constituents provided for in clauses 1) and 2), regarding also other constituents, if the Health Board is notified about such treatment and inspects it;

[\[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

4) full or partial removal of free carbon dioxide with physical methods only.

(2) Treatment of natural mineral water with ozone-enriched air must conform to the following requirements:

- 1) the content of significant constituents of the natural mineral water shall not change;
- 2) before treatment, the natural mineral water shall conform to the microbiological requirements provided for in subsections 7 (1) up to (4) of this Regulation;
- 3) the treatment must not cause any residue in excess of the limit contents provided for in Annex 2 to this Regulation and constituting a possible health risk;
- 4) the entrepreneur shall take measures to ensure efficient and safe treatment of the water and shall allow the Health Board to inspect this.

[\[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

(3) The Health Board shall be notified about treatment of natural mineral water with ozone-enriched air and the Health Board shall verify that:

[[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

- 1) such treatment is necessary for separation of iron, manganese, sulphur and arsenic; and
- 2) the entrepreneur takes measures to ensure efficient and safe treatment of the water and allows the Health Board to inspect this.

[[RTL 2009, 96, 1437](#) – entered into force 1.01.2010]

(4) Natural mineral water as it is at the extraction site may be supplemented by only carbon dioxide for the purpose of restoring or increasing its natural level.

(5) It shall be forbidden to treat the natural mineral water with any means in a disinfecting way and, unless provided for otherwise in subsection (2), to add bacteriostatic agents to the water or to treat the water in any other way that probably changes the number of viable colonies in the natural mineral water.

(6) The provisions of subsections (1) and (2) shall not apply to the use of natural mineral water in manufacturing soft drinks.

#### § 7. Microbiological requirements

(1) The amount of viable microorganisms in the natural mineral water at the extraction site shall prove that the extraction site is protected from any contamination; the amount of such microorganisms in one millilitre of water shall be determined:

- 1) at 20°C to 22°C in 72 hours on agar-agar or a mixture of agar and gelatine;
- 2) at 37°C in 24 hours on agar-agar;
- 3) no later than within 12 hours after bottling, preserving the water at the temperature of 4°C ± 1°C during the entire 12-hour period.

(2) At the extraction site, the usual amount of viable microorganisms in natural mineral water may be up to:

- 1) 20 colonies per one millilitre at 20–22°C in 72 hours;
- 2) 5 colonies per one millilitre at 37°C in 24 hours, considering these to be target values and not the maximum allowed concentrations.

(3) After bottling, the amount of microorganisms at the extraction site may be up to:

- 1) 100 colonies per one millilitre at 20–22°C on agar-agar or a mixture of agar and gelatine in 72 hours;
- 2) 20 colonies per one millilitre at 37°C on agar-agar in 24 hours.

(4) The natural mineral water must not contain:

- 1) any parasites or pathogenic microorganisms;
- 2) any *Escherichia coli* or bacteria similar to *coli* or faecal streptococcus in any of the analysed 250 ml samples;
- 3) any sulfite-reducing anaerobes or their spores in any of the analysed 50 ml samples;
- 4) any *Pseudomonas aeruginosa* in any of the analysed 250 ml samples.

(5) the natural mineral water may contain only the microorganisms initially present at the extraction site and the viable microorganisms resulting from usual growth thereof.

(6) The natural mineral water must not have any organoleptic deficiencies.

#### § 8. Requirements for bottling, packaging and transport

(1) Transportation of natural mineral water shall be allowed only if using sales packages intended for consumers.

(2) The sales packages used for bottling and packaging natural mineral water must have the relevant closing means avoiding any possibility of falsification or contamination.

#### § 9. Requirements for labelling

(1) The sales packages of natural mineral water shall bear the sales description “natural mineral water” or in case of effervescent, i.e. sizzling natural mineral waters also the following sales descriptions as necessary:

- 1) “naturally carbonised natural mineral water”;
- 2) “natural mineral water enriched with spring-originating gas”;
- 3) “carbonised natural mineral water”.

(2) The sales descriptions of effervescent natural mineral waters provided for in subsection (1) which clearly visibly and on its own release carbon dioxide at the extraction site and after bottling at the usual temperature and pressure must conform to the following requirements:

- 1) “naturally carbonised natural mineral water” shall mean water, the carbon dioxide content of which after extracting water from the spring, decanting and bottling is the same as at the extraction site, taking into account that carbon dioxide from the groundwater layer is added as necessary in the same quantity as it was released in the above stated activities and taking also into account the usual technical deviations;
- 2) “natural mineral water enriched with spring-originating gas” shall mean water, the carbon dioxide content of which originates from the groundwater layer and after extracting water from the spring, decanting and bottling is higher than the carbon dioxide content determined at the extraction site;
- 3) “carbonised natural mineral water” shall mean water with added carbon dioxide from other origin besides the groundwater layer or deposit.

(3) The relevant labelling “fully decarbonised” or “partially decarbonised” shall be added to the sales description of natural mineral water treated in the way provided for in subsection 6 (3) of this Regulation.

(4) The labelling of natural mineral water must state the following obligatory information in a written form:

- 1) analytical composition data, presenting the characteristic constituents of the water;
- 2) location and name of the spring used;
- 3) data about treatments provided for in clauses 6 (1) 2) and 3) of this Regulation;

4) in case of water treated with ozone-enriched air, the words “Water has been treated with ozone-enriched air via allowed oxidation method” near the analytical composition data.

(5) If the fluoride content of the natural mineral water exceeds 1.5 mg/l, the labelling must bear the words “Contains fluorides in excess of 1.5 mg/l: not suitable for continuous use for babies and children under 7 years of age”. This information must be stated in the labelling in immediate vicinity of the sales description of the product, using clearly visible and easily legible lettering.

(6) In case of natural mineral water with labelling bearing the information conforming to the requirements provided for in subsection (5) of this section, the actual fluoride content shall also be stated in the labelling pursuant to clause (4) 1).

(7) The name of a region, village or location may be included in the sales description under the condition that the name refers to use of a natural mineral water spring at the location referred to in the sales description and that the name is not misleading regarding the location of use of the spring.

(8) It shall be forbidden to market the natural mineral water from one spring under several sales descriptions.

(9) If the marking or label of the sales package of natural mineral water bears a sales description which differs from the name of the spring or its location of use, then the name of the spring or its location of use shall be marked with lettering which is at least one and a half times higher and wider than the largest letters used for the sales description. This requirement shall apply for the same purpose to any form of the sales description used in an advertisement of the natural mineral water.

(10) The labelling may use the claims provided for in Annex 3 to this Regulation, if these claims conform to the criteria provided for in the same Annex, assessed on the basis of physico-chemical analyses and, if necessary, pharmacological, physiological and clinical studies conducted pursuant to subsection 3 (3) of this Regulation.

(11) The claims “facilitates digestion”, “may improve biliary excretion” or other similar claims may be used under the condition that the claims conform to the requirements provided for in subsection (10) of this section and in subsection 10 (2) of this Regulation.

#### § 10. Misleading information and forbidden claims

(1) It shall be forbidden to use names, sales descriptions, trademarks, brand names, illustrations or other marks on sales packages and labelling and in any form of information delivery as symbols or in any other way if it:

1) in case of natural mineral water, refers to usage license date, analysis results or other similar proofs of authenticity or to properties that the water does not have;

2) in case of packaged potable water, does not conform to the provisions of subsections 2 (1) and (2) of this Regulation and may cause confusion with a natural mineral water regarding the description “mineral water”.

(2) All claims assigning properties of illness prevention or illness treatment to a natural mineral water shall be forbidden, except the claims provided for in Annex 3 which conform to the requirements and conditions provided for in subsections 9 (10) and (11) of this Regulation.

### Chapter 3 SPECIAL REQUIREMENTS FOR SPRING WATER

#### § 11. Spring water

Spring water in the sense of this Regulation shall mean water which is intended for consumption as potable water in its initial natural form and which is bottled at the extraction site and which:

- 1) conforms to the usage conditions provided for in subsections 5 (2), (3) and (4) and subsection 8 (1) of this Regulation which are applied in full to spring water;
- 2) conforms to the microbiological requirements provided for in subsections 7 (1) to (5) of this Regulation;
- 3) has not been treated in any way except the treatments provided for in section 6 of this Regulation. Other treatments may be allowed on grounds of a request submitted to the committee pursuant to the established procedure;
- 4) conforms to the labelling requirements provided for in clauses 9 (4) 2) and 3) and subsections 9 (7), (8) and (9) of this Regulation.

### Chapter 4 IMPLEMENTING PROVISIONS

#### § 12. [Omitted from this text]

#### § 13. Implementing the Regulation

(1) It shall be allowed to label and package natural mineral water pursuant to the previously valid Regulation referred to in section 12 of this Regulation until July 1, 2004, but after this date it shall be forbidden to release to the market any natural mineral water or spring water which does not conform to the requirements provided for in this Regulation.

(2) Natural mineral water conforming to the previously valid Regulation may be sold in Estonia until the stock runs out, but not after the date of January 1, 2006.

#### § 14. Entering into force of this Regulation

Subsection 3 (7) of this Regulation shall enter into force on January 1, 2006, except the limit contents established for fluorides and nickel which shall enter into force on January 1, 2008.

<sup>1</sup> This Regulation takes into account the requirements provided for in the Council Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation

and marketing of natural mineral waters (OJ L 229, 30.08.1980, pp 1–10), the Directive 96/70/EC of the European Parliament and of the Council of 28 October 1996 amending Council Directive 80/777/EEC on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (OJ L 299, 23.11.1996, pp 26–28) and the 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 (OJ L 126, 22.5.2003, pp 34–39).

Annex 1 to the Regulation No. 83 of the Minister of Social Affairs from the date of June 22, 2004 “Health protection requirements for mineral water”

CONSTITUENTS OF NATURAL MINERAL WATER WHICH POSE A HEALTH RISK,  
LIMIT CONTENTS THEREOF AND ANALYTICAL PARAMETERS<sup>1</sup>

Name and marking of the constituent (cations, anions, non-ionic compounds and microelements)	Maximum allowed content (mg/l)	Allowed accuracy in percentage (Note 1)	Precision of parameter values (Note 2)	Detection limit of parameter values (Note 3)	Notes
Cations					
Antimony, Sb	0.0050	25	25	25	
Arsenic, As	0.010 (total)	10	10	10	
Barium, Ba	1.0	25	25	25	
Boron	To be established <sup>2</sup>				
Mercury, Hg	0.0010	20	10	20	
Cadmium, Cd	0.003	10	10	10	
Chrome, Cr	0.050	10	10	10	
Manganese, Mn	0.50	10	10	10	

Nickel, Ni	0.020	10	10	10	
Lead, Pb	0.010	10	10	10	
Selene, Se	0.010	10	10	10	
Cuprum, Cu	1.0	10	10	10	
Anions					
Cyanide, CN <sup>-</sup>	0.070	10	10	10	Note 4
Fluorides, F <sup>-</sup>	5.0	10	10	10	
Nitrate, NO <sub>3</sub> <sup>-</sup>	50	10	10	10	
Nitrite, NO <sub>2</sub> <sup>-</sup>	0.1	10	10	10	
<p><sup>1</sup> Analytical methods for determining the content of constituents must allow determining at least concentrations equivalent to the parameter value regarding measurement tolerance, repeat measurement tolerance and detection limit. Regardless of the sensitivity of the analysis method used, the result shall be presented with at least the same precision of decimal places as provided for the allowed limit content of the constituent.</p>					
<p><sup>2</sup> The limit content of boron shall be established as necessary pursuant to the opinion of the European Food Safety Authority and upon proposal from the European Commission by January 1, 2006.</p>					
<p>Note 1: Accuracy shall mean a systematic error expressed as the difference between the average value of the results of a large number of repeated tests and the actual values of such tests. It is the precision of the average value to the precise value.</p>					
<p>Note 2: Precision shall mean a random error generally expressed as the average standard deviation of the results within the batch or from the average across batches. The acceptable precision shall be equal to up to two times the value of the relative standard deviation.</p>					
<p>Note 3: Detection limit shall mean the three times the value of the relative standard deviation of a batch of natural sample containing low amount of the parameter or five times the value of the relative standard deviation of the comparison sample of a batch.</p>					
<p>Note 4: The method must allow identifying the overall amount of cyanide in any form.</p>					

Annex 2 to the Regulation No. 83  
of the Minister of Social Affairs  
from the date of June 22, 2004

“Health protection requirements for mineral water”

LIMIT CONTENT OF RESIDUE IN TREATMENT OF NATURAL MINERAL WATER AND  
SPRING WATER WITH OZONE-ENRICHED AIR

Treatment residue	Allowed limit content*, not over µg/l
Dissolved ozone	50
Bromates	3
Bromoform (tri-bromo-methane)	1

\* The competent authorities of Member States shall perform supervision over allowed limit content at the time of bottling or other types of packaging into sales packages intended for the consumer.

Annex 3 to the Regulation No. 83  
of the Minister of Social Affairs  
from the date of June 22, 2004  
“Health protection requirements for  
mineral water”

PROVEN CLAIMS ALLOWED ON LABELLING OF NATURAL MINERAL WATER

Claims	Criteria
Low mineral content	Mineral content not above 500 mg/l (as dry residue)
Very low mineral content	Mineral content not above 50 mg/l (as dry residue)
High mineral content	Mineral content above 1,500 mg/l (as dry residue)
Contains bicarbonates	Bicarbonate content above 600 mg/l
Contains sulphates	Sulphate content above 200 mg/l
Contains chlorides	Chloride content above 200 mg/l
Contains calcium	Calcium content above 150 mg/l
Contains magnesium	Magnesium content above 50 mg/l

Contains fluorides	Fluoride content above 1 mg/l
Contains iron	Divalent iron content above 1 mg/l
Acidity content	Free carbon dioxide content above 250 mg/l
Contains sodium	Sodium content above 200 mg/l
Suitable for preparing food for babies and small children	–
Suitable for low sodium diet	Sodium content below 20 mg/l
May have a laxative effect	–
May facilitate urine production (diuresis)	–

<sup>2</sup> RTL = *Riigi Teataja*, Part III = *State Gazette*, Part III