Unified Sanitary Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Control (Supervision)

Chapter II

Section 9. Requirements for Bottled Drinking Water

(as amended by Decision of the Customs Union Commission N 456 of 18.11.2010)

Requirements for Bottled Drinking Water (Code under the Nomenclature of Goods subject to Foreign Trade of the Customs Union: 2201 10)

1. SCOPE OF APPLICATION

- 1.1. The present Section of the Unified Sanitary Requirements prescribes hygienic safety requirements of drinking water for human consumption packaged in large jugs, bottles, containers, bags (hereinafter bottled water) intended for sale to the consumer.
- 1.2. The present Section of the Unified Sanitary Requirements shall not apply to natural mineral waters (medicinal and medicinal table waters).
 - 1.3. When carrying out testing, standard sample/type may be specified.

Standard sample/ type of drinking bottled water - a sample of finished products of the single name, produced by the single manufacturer in accordance with the developed norms and specifications, regulating product release (technical specifications, technical instruction). (point 1.3 was added by Decision of the Customs Union Commission N 456 of 18.11.2010)

2. GENERAL PROVISIONS

- 2.1. The production and sale of bottled water shall be permitted provided the presence of the following:
- a document confirming the safety of bottled drinking water issued in compliance with the procedure prescribed by legislation;
- regulatory documents (specifications and technical guidelines) approved and coordinated in compliance in the prescribed manner.
- 2.2. The terms and temperature conditions of storage of water packaged in synthetic containers shall comply with the requirements set out in regulatory documents for finished goods.
- 2.3. No chlorine agent shall be used for the treatment of drinking waters intended for bottling; the preferable disinfection methods include treatment with ozone-enriched air and physical treatment methods like ultra-violet treatment.
- 2.4. The producers of bottled waters shall ensure that disinfection of bottling containers is conducted as appropriate as well as the disinfection or conservation of water is conducted in such a way as to guarantee their epidemic and chemical safety.
- 2.5. For the bottling of water it is allowed to use containers that conform to the requirements hereof with regard to the maximum storage life of products which they contain.

3. CLASSIFICATION OF QUALITY CATEGORIES OF BOTTLED DRINKING WATERS

- 3.1. Depending on the water source, drinking waters fall in the following categories:
- artesian water, spring water (from wells), underground (infiltration) water from an underground water source;
 - waters of rivers, lakes, glacial waters from a ground water source;
 - 3.2. Depending on the method of water treatment, drinking water can be:
 - purified or tertiary treated water from water supply system;
 - conditioned (additionally enriched with vital macro- and microelements);
- 3.3. Depending on the quality of water improved in respect of the hygienic parameters prescribed for water from central water supply system as well as additional medical and biological requirements, bottled waters fall under two categories:

First category – drinking quality water (notwithstanding its origin), which is safe for human health and entirely compliant with the criteria of favorable organoleptic attributes, epidemic and radioactive safety, chemical safety and stable in preserving its high drinking properties;

Prime category – drinking quality water which is safe for human health from individual underground water sources (preferably spring or artesian), securely protected from biological and chemical contamination and with optimal quality ensured. While retaining compliance with all criteria set for the first category water, drinking water of prime category shall satisfy human physiological needs as to the contents of essential biologically vital macro- and microelements and more stringent regulations for a range of organoleptic, physical and chemical parameters as well as chemical composition.

4. SAFETY REQUIREMENTS OF BOTTLED WATERS

- 4.1. Bottled water shall conform to hygienic standards at the time of its production, transportation and storage as well as throughout its stipulated shelf life.
 - 4.2. Safety requirements of bottled water:
 - favorable organoleptic attributes;
- chemical composition safety (content of essential salt components, toxic metals of hazard classes I, II and III, toxic non-metal elements and halogens, organic elements of anthropogenic and natural origin);
- epidemic safety of water (based on bacteriological, virological and parasitological parameters);
 - radiation safety.
- 4.3. Physiological sufficiency of macro- and microelements in bottled water is assessed based on its compliance with stipulated standards.
- 4.4. The following reagents are permitted for use as preservatives in bottled waters: silver, iodine, carbon dioxide.
- 4.5. Bottled water for the production of child nourishment (in case of bottle-feeding of babies) shall conform to standard parametric values of essential parameters set out for water of prime category as well as shall satisfy the following additional requirements:
 - silver and carbon dioxide shall not be used as preservatives;
 - the concentration of fluoride ion shall not exceed the range of 0.6 1.0 mg/l;
 - the concentration of iodide ion shall not exceed the range of 0.04 0.06 mg/1*.

5. REQUIREMENTS AS TO THE PACKAGING, LABELLING, TRANSPORTATION AND STORAGE OF BOTTLED WATER

5.1. Drinking water shall be packaged in consumer containers prescribed by the Ministry of Health for contact with food products.

^{*} iodine conditioning of bottled water for the production of child nutrition is optional, since child nutrition products generally retain an adequate iodine balance

5.2. The labeling of bottled water shall contain information in conformity with the requirements of technical and statutory regulations in effect.

The labeling of bottled water intended for child nutrition shall contain information regarding the conditions of use after the opening of a bottle.

5.3. Conditions of storage and transportation of bottled water shall conform to the requirements stipulated in producer's regulatory documents for finished goods approved in the prescribed manner.

6. GENERAL REQUIREMENTS AS TO THE RADIATION SAFETY OF DRINKING WATER AND BEVERAGES BASED THEREON

The concentration of radionuclides in drinking water shall remain at such a level as to ensure that the annual radiation dose to which the consumers are subjected in the course of drinking water consumption shall not exceed 0.1 mSv per annum.

The preliminary assessment of drinking water quality for radiation safety can be carried out based on the specific cumulative alfa- (A_{α}) and beta-activity (A_{β}) . When values of A_{α} and A_{β} do not exceed 0.2 and 1.0 Bk/kg respectively, further water testing is not mandatory. Should the above-indicated levels be exceeded, the analysis of concentration of specific radionuclides in water is conducted.

Should the following condition be observed given the simultaneous presence of several naturally occurring and anthropogenic radionuclides in water: $\sum_i A_i / IL_i \le 1,$

$$\sum_{i} A_i / IL_i \le 1,$$

where A_i – specific activity of radionuclide i, Bk/kg;

IL_i - respective intervention levels as per Table 7 of Supplement 9.1 to Section 9 of Chapter II hereof;

than measures aimed at the reduction of drinking water radioactivity shall be optional.

Should the above condition fail, protective actions on the reduction of drinking water radioactivity shall be taken with due regard to the optimization principle.

Quality criteria and safety standards for bottled drinking water are set out in Supplement 9.1 to Section 9 of Chapter II.

Supplement 9.1 to Section 9 of Chapter II of the Unified sanitary epidemiological and hygienic requirements for goods subject to sanitary and epidemiological control (supervision)

QUALITY AND SAFETY CRITERIA FOR BOTTLED WATER

1. The organoleptic attributes of water are assessed pursuant to the standards stipulated in Table 1, as well as standards set out for the concentration of essential salt components which influence the organoleptic attributes of water specified in Tables 1 (No. I.b) and 2 (No. II.a).

Table 1

Parameters	Unit of measurement	Quality standards for bottled drinking waters, maximum parametric value First Category Prime Category		Hazard parameter**		
I. CRITE	RIA FOR AES	THETIC ATTRI	BUTES:			
	I.a. Organolept	tic parameters:				
Odor at 20 °C	Point	0	0	org.		
When heated up to 60 °C		1	0			
Taste	Point	0	0	org.		
Color	Degree	5	5	org.		
Turbidity	FTU	1.0	0.5	org.		
	(Formazine					
	Turbidity					
	Unit)					
pH value, within the limit 5)	Unit	6.5-8.5	6.5-8.5	org.		
I.b. Salt composition parameters*:						
Chlorides	mg/l	250	150	org.		
Sulphates	- " -	250	150	org.		
Phosphates (PO ₄ ³⁻)	mg/l	3.5	3.5	org.		

Note: <*> Salt composition parameters which are regulated with regard to their influence on organoleptic (aesthetic) attributes of water.

2. The chemical safety of water is determined by its compliance with the standards pertaining to:

- the essential salts content (Table 2, No. II.a);
- the content of toxic metals of hazard classes I, II and III (Table 2, No. II.b);
- the content of toxic non-metal elements and (Table 2, No. II.c, d);
- the content of organic elements of anthropogenic and natural origin as per generalized and individual parameters (Table 2, No. II.e).

Table 2

Parameters	Unit of	Quality standards for		Hazard	Hazard
	measurement	bottled	bottled waters,		class
		maximum	maximum parametric		
		value			
		First Prime			
		Category Category			
1	2	3	4	5	6

	CRITERIA FO				
Silicates (for Si)	mg/l	10	10	st.	2
Nitrates (for NO ₃)	mg/l	20	5	org.	3
Cyanides (for CN ⁻)	mg/l	0.035	0.035	st.	2
Hydrogen sulfide (H ₂ S)	mg/l	0.003	0.003	org. odor	4
Tij diogon sumue (1125)		oxic metals:		018. 00.01	•
Aluminum (Al)	mg/l	0.2	0.1	st.	2
Barium (Ba)	mg/l	0.7	0.1	st.	2
Beryllium (Be)	mg/l	0.0002	0.0002	st.	1
Iron (Fe, in sum)	mg/l	0.3	0.3	org.	3
Cadmium (Cd, in sum)	mg/l	0.001	0.001	st.	2
Cobalt (Co)	mg/l	0.1	0.1	st.	2
Lithium (Li)	mg/l	0.03	0.03	st.	2
Manganese (Mn)	mg/l	0.05	0.05	org.	3
Copper (Cu, in sum)	mg/l	1	1	org.	3
Molybdenum (Mo, in sum)	mg/l	0.07	0.07	st.	2
Sodium (Na)	mg/l	200	20	st.	2
Nickel (Ni, in sum)	mg/l	0.02	0.02	st.	3
Mercury (Hg, in sum)	mg/l	0.0005	0.0002	st.	1
Selenium (Se)	mg/l	0.01	0.01	st.	2
Silver (Ag)	mg/l	0.025	0.0025	st.	3
Lead (Pb, in sum)	mg/l	0.01	0.005	st.	2
Strontium (Sr ²⁺)	mg/l	7	7	st.	2
Antimony (Sb)	mg/l	0.005	0.005	st.	2
Chromium (Cr ⁶⁺)	mg/l	0.05	0.03	st.	3
Zink (Zn ²⁺)	mg/l	5	3	org.	3
	II.c. Toxic n	on-metal ele	ments:		
Boron (B)	mg/l	0.5	0.3	st.	2
Arsenic (As)	_ " _	0.01	0.006	_ " _	2
Ozone ²⁾	_ " _	0.1	0.1	org.	3
	II.d.	Halogens:			
Bromide - ion	mg/l	0.2	0.1	st.	2
Bonded chlorine residual 4)					
	_ '' _	0.1	0.1	org.	3
Free chlorine residual 4)					
	- " -	0.05	0.05	org.	3
II	.e. Organic con	tamination p	arameters:		
Permanganate oxidation					
	mg O ₂ /l	3	2	-	-
Ammonia and ammonia-ion	mg/l	0.1	0.05		
Nitrites (for NO ₂)	mg/l	0.5	0.005	org.	2
Organic carbon	mg/l	10	5	-	-
Surface-active substances (SAS), anionic					
	mg/l	0.05	0.05	org.	-
Petrochemicals	mg/l	0.05	0.01	org.	_
Volatile phenols (in sum)	<i>O'</i> -			- 8	
1 (mcg/l	0.5	0.5	org. odor	4

Chloroform ⁴⁾	mcg/l	60	1	st.	2		
Bromoform ⁴⁾	mcg/l	20	1	st.	2		
Dibromchlorometane 4)	mcg/l	10	1	st.	2		
Bromdichlormethane ⁴⁾	mcg/l	10	1	st.	2		
Carbon tetrachloride ⁴⁾	mcg/l						
		2	1	st.	2		
Formaldehyde	mcg/l	25	25	st.	2		
Benzo (a) pyrene	mcg/l	0.005	0.001	st.	2		
Di (2-ethylhexyl) phthalate	mcg/l	6	0.1	st.	2		
Hexachlorobenzene	mcg/l	0.2	0.2	st.	2		
Lindane	mcg/l						
(gamma –isomer HCH		0.5	0.2	st.	1		
(Hexachlorocyclohexane)							
2,4-D (2,4-	mcg/l	1	1	st.	2		
dichlorophenoxyacetic acid)							
Heptachlor	mcg/l	0.05	0.05	st.	2		
DDT(Dichlorodiphenyltrichlo	mcg/l	0.5	0.5	st.	2		
roethane) (sum of isomers)							
Atrazine	mcg/l	0.2	0.2	st.	2		
Simazine	mcg/l	0.2	0.2	org.	4		
II.f. Integrated parameters of toxicity ³⁾ :							
For Σ NO ₂ and NO ₃	units	≤ 1	≤ 1	-	-		
For Σ trihalomethanes	_ " _	≤ 1	≤1	- · · · · · ·	-		

Notes: <**> Salt composition parameters standardized based on toxic influence on the organism.

- 1) Limiting hazard parameters for which the standard is set: "s.-t." sanitary and toxicological, "org." organoleptic.
- 2) Control and monitoring over the concentration of residual ozone is executed following the mixing chamber with contact time of at least 12 minutes.

3) Calculated with the following formula:
$$\sum = \frac{C_1}{MAC_1} + \frac{C_2}{MAC_2} + \dots + \frac{C_B}{MAC_B}, \text{ where }$$

C – concentration of the specific substance in bottled water in mg (mcg)/l;

MAC – maximum allowable concentration of the substance in bottled water in relation to its category in mg (mcg)/l.

Recommended value $\Sigma \leq 1$.

- 4) The analysis applies solely to bottled water that originates from drinking water from central water supply systems of potable water distribution.
 - 5) For carbonated waters may be less than 6.5 units (down to 4.5).

3. The assessment of drinking water quality based on radiation safety parameters

Table 3

Parameters	Unit of measurement	Quality standards f maximum par	Hazard parameter ¹⁾		
		First Category			
Radiation safety parameters:					
Specific cumulative α - radioactivity	Bq/l	0.2	0.2	radiation.	
Specific cumulative β - radioactivity	_ ' ' _	1	1	- « -	

Note: Effective dose obtained throughout the annual consumption of bottled water shall not exceed 0.1 mSv.

${\it 4. Epidemic safety is assessed based on microbiological and parasitological parameters in compliance with Table~4}$

Table 4

Parameter	Parameter Quality standards for bottled waters			
	First Category	Prime Category		
IV	a. Bacteriological parameters	:		
Total bacteria count at 37 °C	maximum 20 CFU (Colony-	maximum 20 CFU in 1ml		
Total bacteria count at 22 °C	forming Unit) in 1ml	maximum 100 CFU in 1ml		
	maximum 100 CFU in 1ml			
General coliform bacteria	absence of CFU in 300 ml	absence of CFU in 300 ml		
Thermotolerant coliform bacteria	absence of CFU in 300 ml	absence of CFU in 300 ml		
Change monitive coliform	absence of CFU in 300 ml	absence of CFU in 300 ml		
Glucose-positive coliform bacteria	absence of CFU in 300 mi	absence of CFU in 300 mi		
Sulphate-reducing clostridia	absence of CFU in 20 ml	absence of CFU in 20 ml		
spores				
Davidomones comiginase	absonae in 1 000 ml	absence in 1,000 ml		
Pseudomonas aeruginosa	absence in 1,000 ml	absence in 1,000 iiii		
	V.b. Virological parameters:			
Coliphages	absence of PFU (Plaque-	absence of PFU		
	forming Units)	in 1,000 ml		
	in 1,000 ml			
	c. Parasitological parameters			
Cryptosporidium oocysts	absence in 50 l	absence in 50 l		
Giardia cysts	absence in 50 l	absence in 50 l		
Helminth eggs	absence in 50 l	absence in 50 l		

5. Physiological sufficiency of macro- and microelements is assessed in compliance with the standards stipulated in Table 5.

Table 5

				1 00010 0
Parameter	Unit of	Parametric value for	Quality standa	rd for bottled
	measuremen	physiological	wat	ers
	t	sufficiency of	First category	Prime
		drinking water,		category
		in the range		
1	2	3	4	5
Total mineralization (dry				
residue), within the range				
	mg/l	100 - 1000	50 - 1000	200 - 500
Hardness	mEq/l	1.5 - 7	maximum 7	1.5 - 7
Alkalinity	- " -	0.5 - 6.5	maximum 6.5	0.5 - 6.5
Calcium (Ca)	mg/l	25 - 130 ^{<*>}	maximum 130	25 - 80
Magnesium (Mg)	mg/l	5 - 65 <*>	maximum 65	5 - 50
Potassium (K)	mg/l	-	maximum 20	2 - 20

Bicarbonate (HCO ₃ ⁻)	mg/l	30 - 400	maximum 400	30 - 400
Fluoride - ion (F)	mg/l	0.5 - 1.5	maximum 1.5	0.6 - 1.2
Iodide - ion (J)	mcg/l	10 - 125	maximum 125 <**>	40 - 60<***>

Notes:

- <*> Estimated: based on maximum acceptable hardness of 7 mEq/l and with regard to minimal required level of magnesium while calculating the maximum allowable concentration of calcium and vice versa.
- <**> The iodizing of water pursuant to the MAC level is permitted provided that no prevention of iodine deficiency is carried out by means of iodized salt subject to the permissible daily allowance (PDA) of iodine ion, taken in from the environment to the organism.
- <***> The iodizing of water at the level of 40-60 mcg/l is permitted as a means of mass prevention of iodine deficiency in case of other preventive measures are applied.

6. The following reagents may be used as preservatives as per table 6.

Table 6

Preservatives	Unit of	Maximum	Quality standards for bottled	
	measurement	allowable	waters, maximum	
		concentration in	First category	Prime category
		drinking water		
Silver (Ag)	mg/l	0.05	0.025	0.0025
Iodine (J)	- " -	0.125	0.06	0.06
Carbon dioxide (CO ₂)	%	0.4 <*>	0.4	0.2

Note: <*> concentration exceeding 0.4 is permissible provided the content of CO₂ is disclosed on the label.

7. Paragraph deleted. - Decision of the Customs Union Commission N 456 of 18.11.2010

8. The intervention level values (IL Bq/kg) of specific radionuclides in drinking water are given in Table 7.

Table 7

Nuclide	IL,	Nuclide	IL,
	Bq/kg		Bq/kg
H-3	7,600	Tc-97	2,000
Be-7	4,900	Tc-97m	250
C-14	240	Tc-99	210
Na-22	43	Ru-97	910
P-32	57	Ru-103	190
P-33	570	Ru-106	20
S-35	178	Rh-105	370
Cl-36	150	Pd-103	720
Ca-45	190	Ag-105	290
Ca-47	86	Ag-110m	49
Sc-46	91	Ag-111	110
Sc-47	250	Cd-109	69
Sc-48	81	Cd-115	98
V-48	69	Cd-115m	42
Cr-51	3,600	In-111	470
Mn-51	1,500	In-114m	33
Mn-52	76	Sn-113	190

Nuclide	IL,	Nuclide	IL,
1,00100	Bq/kg		Bq/kg
Mn-53	4,600	Sn-125	44
Mn-54	193	Sb-122	81
Fe-55	420	Sb-124	55
Fe-59	76	Sb-125	120
Co-56	55	Te-123m	86
Co-57	650	Te-127	810
Co-58	190	Te-127m	60
Co-60	40	Te-129	2100
Ni-59	2,200	Te-129m	46
Ni-63	910	Te-131	1600
Zn-65	35	Te-131m	72
Ge-71	11,400	Te-132	36
As-73	530	I-123	650
As-74	110	I-125	9.1
As-76	86	I-126	4.7
As-77	340	I-129	1.3
Se-75	53	I-130	69
Br-82	250	I-131	6.2
Rb-86	49	Cs-129	2,300
Sr-85	240	Cs-131	2,400
Sr-89	53	Cs-132	270
Sr-90	4,9	Cs-134	7.2
Y-90	51	Cs-135	69
Y-91	57	Cs-136	46
Zr-93	120	Cs-137	11
Zr-95	140	Cs-138	1,500
Nb-93m	1,100	Ba-131	300
Nb-94	81	Ba-140	53
Nb-95	240	La-140	69
Mo-93	44	Ce-139	530
Mo-99	220	Ce-141	190
Tc-96	120	Ce-143	120
Ce-144	26	Th-231	400
Pr-143	110	Th-232	0.60
Nd-147	120	Th-234	40
Pm-147	530	U-230	2.5
Pm-149	140	U-231	490
Sm-151	1,400	U-232	0.42
Sm-153	190	U-233	2.7
Eu-152	98	U-234	2.8
Eu-154	69	U-235	2.9
Eu-155	430	U-236	2.9
Gd-153	510	U-237	180
Tb-160	86	U-238	3.0
Er-169	370	Pa-230	150
Tm-171	1,200	Pa-231	0.19
Yb-175	310	Pa-233	160
Ta-182	91	Np-237	1.3
	1	1 1	1

Nuclide	IL,		Nuclide	IL,
	Bq/kg			Bq/kg
W-181	1,800		Np-239	170
W-185	310		Pu-236	1.6
Re-186	91		Pu-237	1,400
Os-185	270		Pu-238	0.60
Os-191	240		Pu-239	0.55
Os-193	170		Pu-240	0.55
Ir-190	110		Pu-241	29
Ir-192	98		Pu-242	0.57
Pt-191	400		Pu-244	0.57
Pt-193m	300		Am-241	0.69
Au-198	140		Am-242	460
Au-199	310		Am-242m	0.72
Hg-197	600		Am-243	0.69
Hg-203	72		Cm-242	14
T1-200	690		Cm-243	0.91
T1-201	1,400		Cm-244	1.1
T1-202	300		Cm-245	0.65
T1-204	110		Cm-246	0.65
Pb-203	570		Cm-247	0.72
Pb-210	0.20		Cm-248	0.18
Bi-206	72		Bk-249	240
Bi-207	110		Cf-246	42
Bi-210	110		Cf-248	4.9
Po-210	0.11		Cf-249	0.39
Ra-223	1.4		Cf-250	0.86
Ra-224	2,1	[Cf-251	0.38
Ra-225	1.4		Cf-252	1.5
Ra-226	0.49	[Cf-253	98
Ra-228	0.20	[Cf-254	0.34
Th-227	16	[Es-253	22
Th-228	1.9		Es-254	4.9
Th-229	0.28		Es-254m	33
Th-230	0.65			