



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

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MATTERS OF INTEREST ARISING FROM FAO AND WHO (INCLUDING JECFA)

**WHO GUIDELINES FOR DRINKING-WATER QUALITY AND HEALTH-RELATED LIMITS
FOR CERTAIN SUBSTANCES IN THE STANDARD FOR NATURAL MINERAL WATERS
(CODEX STAN 108-1981)**

BACKGROUND

Codex work on health-related limits for certain substances in the Standard for Natural Mineral Waters (CODEX STAN 108-1981)

1. The 7th Session of the Committee on Natural Mineral Waters (CCNMW) (October 2000) considered the health-related limits for certain substances in the Standard for Natural Mineral Waters and proceed with their amendment so they would be consistent with the Guidelines¹. The 33rd Session of the Committee on Food Additives and Contaminants (CCFAC) (March 2001) endorsed the levels of health related substances in CODEX STAN 108-1981 as proposed by CCNMW².
2. In February 2008, the Committee resumed its work to exclusively consider the health-related limits in the 3rd edition of the Guidelines. Not all limits were aligned with the Guidelines but were considered on a case-by-case basis. All limits except for boron were consistent with or lower than the levels in the Guidelines. The Committee also agreed to refer Section 3.2 "Health-related limits for certain substances" of the Standard for Natural Mineral Waters to the Committee on Contaminants in Foods (CCCF) for endorsement.³
3. The 2nd Session of CCCF (April 2008) endorsed the amendments to Section 3.2 and agreed to keep the limits in the Standard for Natural Mineral Waters. The Committee further noted that iron, zinc and copper had been considered as quality factors rather than safety factors and therefore the levels for those substances had been not included in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CODEX STAN 193-1995).⁴
4. The 4th Session of CCCF agreed to consider the development of criteria to differentiate between safety and quality parameters; based on these criteria, determine which of the compounds in Section 3.2 of the Standard on Natural Mineral Waters are safety parameters; and consider whether all safety parameters identified in Section 3.2 should be integrated into the GSCTFF or retained in the Standard for Natural Mineral Waters.⁵
5. The 5th Session of CCCF (March 2011) noted that the compounds in sections 3.2.17 to 3.2.20 should not be present in natural mineral waters but permitted at levels below the LOQ, and so they should be considered quality parameters. Consequently, there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee took no further action on the integration of the safety parameters in sections 3.2.1 to 3.2.16 into the GSCTFF.⁶

¹ ALINORM 01/20, paras. 35-36, Appendix III

² ALINORM 01/12A, para. 110

³ ALINORM 08/31/20

⁴ ALINORM 08/31/41, paras. 23 - 27

⁵ ALINORM 10/33/41, paras. 10 – 17.

⁶ REP11/CF, paras. 85 – 90.

6. The entire discussion on the health-related limits for natural mineral waters can be found in the reports of CCNMW, CCFAC and CCCF. Reports of Codex meetings are available on the Codex website at: <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/en/>. For easy of reference, Section 3.2 is reproduced in the Appendix.

WHO work on the Guidelines for Drinking-Water Quality

7. The WHO Guidelines for Drinking-Water Quality (GDWQ) were developed to protect public health. Their first edition published in 1984 as science-based recommendations for national regulations and standards for water safety. The Guidelines are based upon the best available evidence and include risk assessments and risk management advice for various hazards that may be present in drinking-water. They describe reasonable minimum requirements of safe practice to protect the health of consumers and contains numerical “guideline values” for constituents of water or indicators of water quality. Guideline values are not mandatory limits; countries should consider their own needs, priorities, economic and other factors for standard setting and regulation.
8. The Guidelines are subject to a rolling revision process. Through this process, microbial, chemical, radiological and protection and control aspects of drinking-water are subject to periodic review, and documentation is accordingly prepared/updated. The 3rd edition of the Guidelines was published in 2004, the current 4th edition in 2011, and the first addendum to the 4th edition will be published in first quarter of 2017.
9. This document presents revised guideline values of the GDWQ and presents a set of recommendations on the next steps.
10. The process for revising the guideline values in the GDWQ is described in the Policies and Procedures Manual. The criteria used for deciding whether to revise the review for a constituent already considered in the GDWQ are:
- for substances with provisional guideline values, new evidence that might affect “provisional” status;
 - new high quality health risk evaluation made available by WHO and other agencies;
 - new evaluation of the carcinogenic hazard of a chemical by the International Agency for Research on Cancer (IARC);
 - listing of a chemical in relevant Prior Informed Consent (PIC) (Rotterdam Convention) or Persistent Organic Pollutant (POP) (Stockholm convention) listings.

THE GUIDELINE VALUES IN THE GDWQ

11. The Guideline Values for the following substances were revised:

Table 1 The Revisions of the Guideline Values in the GDWQ

Chemicals	3 rd Edition	4 th Edition	Addendum to the 4 th Edition
Barium	0.7 mg/l	-	1.3 mg/l
Boron	0.5 mg/l	2.4 mg/l	-
Cyanide	0.07 mg/l	Withdrawn	-
Manganese	0.4 mg/l	Changed to a health-based value	-
Selenium	0.01 mg/l	0.04 mg/l	-

*Limits in the Standard for Natural Mineral Waters:

Barium 0.7 mg/l, Boron 0.5 mg/l, Cyanide 0.07 mg/l, Manganese 0.4 mg/l, Selenium 0.01 mg/l

12. Barium: The existing guideline value derivation is based on an epidemiological study by Brenniman & Levy (1985). However, this study has been identified as having several limitations (e.g. no effect observed at the single dose evaluated, limitations in the exposure methodology and design, no control for important risk factors for hypertension). For this proposed update, an NTP chronic study in mice (USNTP, 1994) is considered the best available study in the absence of appropriate studies evaluating chronic exposure of humans to barium. The kidney appears to be the target tissue for barium-mediated toxicity, and mice were found to be more sensitive for the nephrotoxicity effects.

The background document can be accessed at http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/barium/en/ (currently being prepared)

13. Boron: The point of departure for the guideline value in the third edition is a NOAEL of 9.6 mg/kg /day for developmental toxicity, derived based on an animal study by Price et al., 1996a while the point of departure for the guideline value for the fourth edition is based on a BMDL05 of 10.3 mg/kg body weight/day for developmental toxicity based on the studies of Heindel et al. (1992), Price, Marr & Myers (1994) and Price et al. (1996a). All other aspects of the risk assessment from the third to the fourth edition remained the same, except that the fraction of the TDI allocated to drinking-water changed from 10% to 40%. 10% as well as 20% (the current default allocation factor) was considered too conservative based on extensive dietary intake data from the United Kingdom and the USA, which indicated that intake from sources other than water is low.

For more information see http://who.int/water_sanitation_health/dwq/chemicals/boron/en/.

14. Cyanide: For the fourth edition, the guideline value was withdrawn as cyanide generally occurs in drinking-water at concentrations well below those of health concern, except in emergency situations following a spill to a water source. A health-based value of 0.5 mg/l can be calculated for short-term exposure. The lowest reported odour threshold in drinking-water is 0.17 mg/l.

For more information see http://who.int/water_sanitation_health/dwq/chemicals/cyanide/en/.

15. Manganese: For the fourth edition, the guideline value was changed to a health based value, since manganese is generally not of health concern at levels causing acceptability problems in drinking-water. For the addendum to the GDWQ, the guideline highlights that aesthetic as well as health aspects should be considered in the setting of national standards and regulations and confirming the acceptability of drinking-water. The health-based value is 0.4 mg/l while levels exceeding 0.1 mg/l can cause taste issues and staining of laundry and concentrations at 0.2 mg/l may cause the formation of a coating on pipes, which may slough off into drinking-water as a black precipitate. Manganese is naturally occurring in many surface water and groundwater sources, particularly in anaerobic or low oxidation conditions where it may stay in solution above 0.1 mg/l. For more information see

For more information see http://who.int/water_sanitation_health/dwq/chemicals/manganese/en/.

16. Selenium: For the fourth edition, the guideline value was changed from 0.01 mg/l to a provisional guideline value of 0.04 mg/l. The provisional designation was based on uncertainties inherent in the scientific database. It was noted that a drinking-water guideline or standard for selenium would be unnecessary for most Member States and that achieving a proper balance between recommended intakes and undesirable intakes was essential. For the fourth edition, the guideline value was determined by taking an allocation of 20% of the upper tolerable intake of 400 µg/day to drinking-water. For more information see

For more information see http://who.int/water_sanitation_health/dwq/chemicals/selenium/en/

RECOMMENDATIONS

17. The Committee is invited to review the limits in the Standard for Natural Mineral Waters in light of the revised values included in the GDWQ.
 - For limits of barium, boron and selenium, consider aligning with the guideline values in the GDWQ as appropriate.
 - For cyanide consider reviewing the current level taking into account that the guideline value in the GDWQ was withdrawn.
 - For manganese consider reviewing the current level taking into account that the guideline value in the GDWQ was changed to a health-based values.

References

- Brenniman GR, Levy PS (1985) Epidemiological study of barium in Illinois drinking water supplies. In: Calabrese EJ, Tuthill RW, Condie L, eds. *Inorganics in water and cardiovascular disease*. Princeton, NJ, Princeton Scientific Publishing Co., pp. 231–240 (Advances in Modern Environmental Toxicology, Vol. 9).
- US NTP (1994) *NTP technical report on the toxicology and carcinogenesis studies of barium chloride dihydrate (CAS No. 10326-27-9) in F344/N rats and B6C3F1 mice (drinking water studies)*. Research Triangle Park, NC, US Department of Health and Human Services, Public Health Service, National Toxicology Program (NTP TR 432; NIH Publication No. 94-3163; NTIS PB94-214178).
- Heindel JJ et al. (1992) Developmental toxicity of boric acid in mice and rats. *Fundamental and Applied Toxicology*, 18:266–277.
- Price CJ, Marr MC, Myers CB (1994) *Determination of the no-observable adverse-effect-level (NOAEL) for developmental toxicity in Sprague-Dawley (CD) rats exposed to boric acid in feed on gestational days 0 to 20 and evaluation of postnatal recovery through postnatal day 21*. Research Triangle Park, NC, Research Triangle Institute (RTI Identification No. 65C-5657-200).
- Price CJ et al. (1996a) Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. *Fundamental and Applied Toxicology*, 32:179–193.
- Price CJ et al. (1996b) The developmental toxicity of boric acid in rabbits. *Fundamental and Applied Toxicology*, 34:176–187.

APPENDIX**SECTION 3.2 HEALTH-RELATED LIMITES FOR CERTAIN SUBSTANCES
(STANDARD FOR NATURAL MINERAL WATERS – CODEX STAN 108-1981)****3. COMPOSITION AND QUALITY FACTORS**

3.2 Health-related limits for certain substances

Natural mineral water in its packaged state shall contain not more than the following amounts of the substances indicated hereunder:

3.2.1	Antimony	0.005 mg/l
3.2.2	Arsenic	0.01 mg/l, calculated as total As
3.2.3	Barium	0.7 mg/l ¹
3.2.4	Borate	5 mg/l, calculated as B
3.2.5	Cadmium	0.003 mg/l
3.2.6	Chromium	0.05 mg/l, calculated as total Cr
3.2.7	Copper	1 mg/l
3.2.8	Cyanide	0.07 mg/l
3.2.9	Fluoride	See section 6.3.2
3.2.10	Lead	0.01 mg/l
3.2.11	Manganese	0.4 mg/l
3.2.12	Mercury	0.001 mg/l
3.2.13	Nickel	0.02 mg/l
3.2.14	Nitrate	50 mg/l, calculated as nitrate
3.2.15	Nitrite	0.1 mg/l as nitrite
3.2.16	Selenium	0.01 mg/l

The following substances shall be below the limit of quantification² when tested, in accordance with the methods prescribed in Section 7:

3.2.17	Surface active agents
3.2.18	Pesticides and PCBs
3.2.19	Mineral oil
3.2.20	Polynuclear aromatic hydrocarbons

¹ Pending further review of new scientific evidence by an appropriate scientific body to be determined by FAO/WHO.

² As stated in the relevant ISO methods.