

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NATURAL MINERAL WATERS

Eighth Session
Lugano, Switzerland, 11 - 15 February 2008

In reply to the Codex Circular Letter CL 2007/25-NMW, the following Member countries and organizations submitted their comments:

Australia, Cuba, Ghana, Kenya, Malaysia, Mexico, South Africa, United Arab Emirates, European Federation of Bottled Waters (EFBW), International Council of Beverages Association (ICBWA).

AUSTRALIA

Australia believes that the levels in the *Codex Standards for Natural Mineral Waters* should be consistent with the *WHO Drinking Water Guideline Levels* to the extent possible. We do not believe that differences between these Codex levels and the WHO Natural Mineral Water Guidelines should persist. However, due regard should be given to the policy of the Codex Committee on Contaminants in Food with respect to the establishment of contaminant levels. In particular, “maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer”.¹

Australia therefore considers that while the Codex Committee on Natural Mineral Waters should consider the adoption of the *WHO Drinking Water Guideline Levels* where they differ from the Codex level, we only consider it necessary for Codex levels to be maintained where the substance in natural mineral waters is a significant contributor to the total consumer exposure.

CUBA

Cuba believes that the limits for Natural Mineral Water do not necessarily have to correspond to the limits for Drinking Water established by the WHO, since by definition Natural Mineral Water is clearly

¹ Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants; and CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups - Procedural Manual; 16th Edition.

Working documents will be uploaded onto the Codex website:

www.codexalimentarius.net/web/index_en.jsp

Delegates are kindly requested to bring with them to the meeting all documents which have been distributed, as the number of additional copies which can be made available at the session is limited.

distinguishable from ordinary Drinking Water “by its content of certain mineral salts and their relative proportions and the presence of trace elements or of other constituents.”

Cuba proposes the following as regards the values proposed by the WHO Guideline, in cases where they differ from the Codex Standard values:

1. Replace the values set forth in the CODEX STAN 108 by the values in the 3rd edition of the WHO Guideline for Antimony, Copper, Mercury, Nickel and Nitrite, since these limits are not considered harmful to the health by oral ingestion in average consumption levels in Natural Mineral Water and can be accurately detected using testing methods and machinery routinely available in most laboratories in our country.

This also allows more types of Water to be classified as Natural Mineral Water.

2. Keep the value established by the CODEX STAN 108 for Borate, since we believe that there is insufficient scientific evidence to demonstrate that this value is harmful to health. Moreover, the provisional value proposed by the WHO may be attainable in Drinking Water using physical and chemical treatment methods such as reverse osmosis, but not in Natural Mineral Water productions with a higher content than the proposed value, since Natural Mineral Water cannot be subjected to this or any other type of selective treatment.

GHANA

The Codex Standard for Natural Mineral Waters would generally have lower limits of substances compared to the WHO Guidelines for drinking Water quality (surface water) because Natural Mineral Water undergoes through a natural filtration system thus retaining minimal amounts of these substances in the natural mineral water as can be seen for the substances: Antimony, Copper, Mercury, Nickel and Nitrite.

However, the substance limits for Borate and Manganese in the Codex Standard for Mineral Water are higher than the levels in the WHO Guidelines for Drinking Water Quality. Hence, we propose that the limits of all these substances in the Codex Standard for Natural Mineral Water are set at the same levels as that of the WHO Guidelines for drinking water since these limits provide minimum levels of protection.

KENYA

SUBSTANCE	CODEX HEALTH-RELATED LIMITS FOR CERTAIN SUBSTANCES (mg/l)	WHO GUIDELINE VALUES FOR CHEMICALS THAT ARE OF HEALTH SIGNIFICANCE IN DRINKING WATER (mg/l)	KENYA POSITION (mg/l)
Antimony	0.005	0.02	0.02 Our data from natural mineral water sources give this figure
Arsenic	0.01, calculated as total As	0.01 (P)	0.01 Our data from natural mineral water sources give this figure

Barium	0.7	0.7	0.1 Our data from natural mineral water sources give this figure
Borate	5, calculated as B	0.5 (T), for Boron	5, calculated as Boron Our data from natural mineral water sources give this figure
Cadmium	0.003	0.003	0.003 Our data from natural mineral water sources give this figure
Chromium	0.05, calculated as total Cr.	0.05 (P), for total chromium	0.05, total chromium Our data from natural mineral water sources give this figure
Copper	1	2	0.01 Our data from natural mineral water sources give this figure
Cyanide	0.07	0.07	0.01 : Our data from natural mineral water sources give this figure and even below. cyanide is from steel, plastics and fertilizer factories or plants which is minimal activity in Kenya
Fluoride	See note 1	1.5 ²	4 max see below: To contain 4 mg/l maximum. If the product contains more than 2mg/L fluoride “the product is not suitable for infants and children under the age of seven year. The note in the document CL 2007/25-NMW of July 2007 is taken and also giving a maximum value of 4mg/L
Lead	0.01	0.01	0.01 Our data from natural mineral water sources give this figure and even below
Manganese	0.5	0.4 (C)	0.5 Our data from natural mineral water sources give this figure and even below
Mercury	0.001	0.006 (For inorganic mercury)	0.001 (Total Mercury) Our data from natural mineral water sources give this figure and even below
Nickel	0.02	0.07	0.07 Our data from natural mineral water sources give this figure.

Nitrate	50, calculated as nitrate	50, as NO ₃ (short-term exposure)	50 Our data from natural mineral water sources give this figure and even below
Nitrite	0.02, as Nitrite ³	3, as NO ₂ (short-term exposure) 0.2 (P) (long-term exposure)	0.005 Our data from mineral water sources give this figure and even below and takes in to consideration of all general public. We propose that the limit be declared on the label since it not safe for children at a certain level.
Selenium	0.01	0.01	0.01 Our data from natural mineral water sources give this figure and even below

MALAYSIA

Malaysia would like to forward comments with reference to each of the substances listed in the Annex to CL 2006/13-NMW including new discrepancies between the health-related limits for certain substances in Section 3.2 of the Codex Standard on Natural Mineral Waters (CODEX STAN 108-1981, rev. 1 – 1997, amend. 2001) in the light of the discrepancies that exist between the Codex Standard and the WHO Guidelines for Drinking-water Quality, Third Edition, Volume1, Recommendations, WHO, Geneva, 2004.

Antimony

Malaysia supports the current Codex Health-related Limit of 0.005 mg/l antimony in Natural Mineral Water as the lower level is achievable in natural mineral water.

Borate

Malaysia supports the level of 0.5 mg/l, calculated as boron. This level is achievable through source protection.

Copper

Malaysia supports the current Codex Health-related Limit of 1 mg/l copper in Natural Mineral Water as the lower level is achievable in natural mineral water and provides protection against acute gastrointestinal effects of copper and an adequate margin of safety in populations with normal copper homeostasis.

Manganese

Malaysia supports the WHO Guideline Value of 0.4 mg/l manganese in natural mineral water as this level is achievable with treatment of water.

Mercury

Malaysia supports the current Codex Standard limit of 0.001 mg/l mercury in natural mineral water as the lower limit will provide public health protection.

Nickel

Malaysia supports the current Codex Standard limit of 0.02 mg/l nickel in natural mineral water as the lower limit will provide protection to individuals sensitive to nickel.

Nitrite

Malaysia supports the current Codex Standard limit of 0.02 mg/l nitrite in natural mineral water as the lower limit is achievable and will provide public health protection.

MEXICO

Mexico support the Codex Commission's decision last July to reactivate the natural mineral water Codex Committee.

Any decision to reduce the concentration limits for natural constituents could have a direct impact on a significant number of producers, in particular in Europe where a substantial proportion of the world's total of natural mineral waters springs are being exploited. This is because some producers will no longer be allowed to exploit a source (in the absence of authorised separation techniques or treatments).

In that context, Mexican Industries and Health Authorities reviewed the scientific data available for each natural substance covered by the Codex Commission's requirement. A summary of their agreements is attached to the present together with an industry position on each natural constituent.

We want to stress that:

- Due to the specificities of natural mineral waters (in particular geological underground origin), some substances occur naturally in natural mineral waters;
- While a whole range of treatments including disinfection are allowed for purified and processes waters, chemical treatments are still not allowed in the Natural Mineral Water Codex Standard, so in some cases it is difficult to decrease some substances with physical treatments only;
- A given concentration limit on a constituent in WHO Guidelines for drinking water may have been set for reasons not linked to health (quality reasons -taste or colour- or other - see the case of manganese); in this case our position is to leave companies bottling natural mineral water to remove the constituent involved or not.

Taking all those elements into account, our national position is maintaining the limits currently found in the Natural Mineral Water Codex except the following:

- **Barium:** Although there is no discrepancy between WHO Guideline value and the NMW Codex limit for barium, EFBW would like to take the opportunity to suggest asking for a modification of the current limit due to there is no evidence of health risk, so we suggest to increase the limit to 2 mg/l.
- **Fluoride:** retain existing limit and labelling rules but in our national regulations we will have stronger limits due to our Health Authorities have detected sanitary risk.

WHO guidelines stress that dental fluorosis could be increased in concentrations from 0,9-1,2 mg/l and that the major exposition in child is in a very short period of time, but this period coincides with a great sensibility, which could have irreversible effects and if it is at a very early age, the social and public health consequences are serious.

International Standard recommends to control Fluor limits in water from 0,6-0,8 mg/l at warmest temperatures (26.3-32.6 °C) and from 0.9-1.7 mg/l at coldest temperatures (10-12°C), due to the water consumption varies according to the weather, physical activity and culture. When the temperatures reach 25°C liquid consumption increase to respond to natural transpiration amounts.

According to this and due to dental fluorosis is an endemic public health problem which affects child and teenagers in Mexico, mainly in central and north regions of our country (with temperatures from 22-26°C) we support the position of maintaining the current limit with labelling rules in Codex STAN 108, but in Mexico we will have strict limit of 0,7 mg/lit, based on some studies which found that at 1 mg/lit we have incidence of dental fluorosis.

- **Manganese**: retain the current limit at 0,5 mg/litre; because there is no reason linked to health there is only quality reasons (taste or colour).
- **Mercury**: maintain the current limit of 0.001 mg/lit for total mercury instead of 0.006 from WHO guidelines because the detection limits established in the same guidelines are higher than the limit.
- **Nickel**: raise it to 0,07 mg/litre in line with new WHO guideline, not the obsolete one;
- **Nitrite**: raise the limit to 0,2 mg/litre (long term exposure) according to WHO guidelines.

Today in Mexico the natural mineral waters market is not part of our culture but currently consumers are demanding more natural products including water, so it could grow faster and we want to be aligned with Health recommendations.

SOUTH AFRICA

The WHO factsheet No. 256 indicates that bottled drinking water is also considered drinking water and that levels of substances may differ between piped drinking water and bottled water (or any other types of packaged water). Furthermore, it is understood that bottled natural mineral waters are consumed to a lesser extent than piped drinking water/tap water (consumption by an adult is 2 L per day over a lifetime) and thus exposure to substances in each of these drinking waters could differ.

In light of the differing consumption of piped drinking water and bottled natural mineral waters, the comments to the limits in the Codex standard as compared to the revised WHO limits are as follows:

- **Barium** in ground waters is found in concentrations of up to 2 mg/L. No toxicity concerns have as yet been associated with barium. Therefore if the existing WHO guideline limit and the current Codex standard limit can be changed, a proposed change to a limit of 2 mg/L would be supported.
- **Boron** also occurs naturally in the Earths crust and levels of up to 5 mg/L are found in groundwater. This element also has no toxicity concerns and therefore poses little health risk. The existing limit as indicated in the Codex standard, 5 mg/L, is supported.
- **Fluoride** is also found naturally in rocks and groundwater concentrations do not exceed 10 mg/L. Typical concentrations are around 0.1-1 mg/L. Since dental fluorosis is possible at concentrations over 1.5 mg/L, especially in children, South Africa would support the existing Codex labelling stipulations but would amend the second label such that the statement: "*the product is not suitable for infants and children under the age of seven years*" be included in the label where concentrations are over 1.5 mg/L rather than 2 mg/L. Therefore the current limit as indicated in the WHO guidelines is not supported.
- **Manganese** is also present naturally in ground waters and is an essential micro-nutrient. Principal sources of manganese are from food and the intake from natural mineral waters or drinking water does not contribute significantly to dietary intake. It is proposed that the current limit in the Codex standard is retained at 0.5 mg/L.
- **Nickel** is also found naturally in groundwater and food is again the principal source of this element. It is understood that waters only contribute about 10 % of the intake. Health risks via the oral route are not confirmed and therefore, the WHO guideline limit of 0.07 mg/L is supported.

- The **nitrite** limit in the Codex standard is set as a quality limit because of the risk of methaemoglobinaemia in bottle-fed babies. The WHO guideline limit of 0.2 mg/L is supported but a similar label like that in the case of fluoride is also suggested where limits present in the water are likely to pose a health risk to babies.

However, South Africa would ideally propose the setting of standards of two categories of Natural Mineral Waters, i.e. low-to-medium natural mineral waters whose mineralization would be lower than 1000 mg/L and highly mineralised Natural Mineral Waters (mineralization exceeding 2000 mg/L). This latter category would not exclude natural mineral waters where there is a demand by a niche market and whose consumption is irregular and considerably lesser than piped drinking water/tap water. This differentiation and categorisation would ideally allow the Codex standard to adopt WHO guideline limits for low-to-medium natural mineral waters. Highly mineralised natural water would then be guided by a different set of standards. This view is preferred.

UNITED ARAB EMIRATES

Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters

Abu Dhabi Food Control Authority (ADFCA) appreciates the opportunity to address the Codex Alimentarius Commission's request for comments (CL 2007/25-NMW) on the revision of section 3.2 of Codex standard on Natural Mineral Waters on health related limits for certain substances (Codex STAN 108-1981, Rev 1-1997).

a. The need to proceed with an amendment to section 3.2 of the Codex Standard on Natural mineral Waters (NMW) in the light of discrepancies that exist between the Codex standard and WHO guidelines.

ADFCA can agree that the new WHO guidelines for drinking-water quality as regards the health related limits for certain substances should be taken into consideration in view of an eventual revision of section 3.2 of the above Codex standard. ADFCA is in favour of ensuring a high level of consumer protection.

However, the revision of these limits should also take into account the specific characteristics of NMW as regards their underground origin, the required protection of sources from any environmental contamination, the data on individual consumption and specific technological constraints due to the ban of removal treatments -other than filtration- for these substances.

b. What amendment is considered necessary and the choice between the direct reference to WHO guidelines or the revision of upper limits in section 3.2 on a case by case approach.

It should be noted that the alignment of health related limits of section 3.2 on WHO guidelines would lead simultaneously to the decrease of the limits for boron, fluoride and manganese and to the increase of the limits for antimony, copper and nitrites.

The decrease of the boron limit from 5 mg/l to 0.5 mg/l is supported by ADFCA.

The increase of the limits for nitrites is supported by ADFCA, where as increase of the limits copper and antimony appears contradictory to the requirement in section 2.1 of the above Codex standard about the protection of sources from any environmental contamination, which is one of the specific characteristics of NMW.

For easy reference, a comparative table is attached as Annex below.

Annex: Table displays Abu Dhabi Food Control Authority (ADFCA) Proposal for Bottled Drinking Water (mg/l) Comparable to that of Codex & WHO

Substance	Codex Health-Related Limits for Certain Substances in Mineral Water (mg/l)	WHO Guideline Values for Chemicals that are of Health Significance in Drinking Water (mg/l)	ADFCA Proposal for Bottled Drinking water (mg/l)
Antimony	0.005	0.02	<u>0.005</u>
Arsenic	0.01, calculated as total As	0.01 (P)	0.01
Barium	0.7	0.7	0.7
Borate	5, calculated as B	0.5 (T), for Boron	0.5 *
Cadmium	0.003	0.003	0.003
Chromium	0.05, calculated as total Cr	0.05 (P), for total chromium	0.05
Copper	1	2	<u>1</u>
Cyanide	0.07	0.07	0.07
Fluoride	See Note ¹	1.5 ²	1.5
Lead	0.01	0.01	0.01
Manganese	0.5	0.4 (C)	0.4 *
Mercury	0.001	0.006 (For inorganic mercury)	<u>0.001</u>
Nickel	0.02	0.07	<u>0.02</u>
Nitrate	50, calculated as nitrate	50, as NO ₃ (short-term exposure)	50
Nitrite	0.02, as nitrite ³	3, as NO ₂ (short-term exposure) 0.2 (P) (long-term exposure)	0.2 *
Selenium	0.01	0.01	0.01

1 If the product contains more than 1 mg/l of fluoride, the following term shall appear on the label as part of, or in close proximity to, the name of the product or in an otherwise prominent position: “contains fluoride”. In addition, the following sentence should be included on the label: “The product is not suitable for infants and children under the age of seven years” where the product contains more than 2 mg/l fluorides.

2 Volume of water consumed and intake from other sources should be considered when setting national standards.

3 Set as a quality limit (except for infants).

P Provisional guideline value, as there is evidence of a hazard, but the available information on health effects is limited.

T Provisional guideline value because calculated guideline value is below the level that can be achieved through practical treatment methods, source protection, etc.

C Concentrations of the substance at or below the health-based guideline value may affect the appearance, taste or odor of the water, leading to consumer complaints.

— Single underlines indicate those levels that are similar to Codex.

- Indicate those levels that are same values in the WHO guidelines.

EUROPEAN FEDERATION OF BOTTLED WATERS (EFBW)

The European Federation of Bottled Waters ('EFBW') welcomes the opportunity to address the Codex Alimentarius Commission's request for comments in the context of the revision of section 3.2 of the Codex Standard for Natural Mineral Waters.

The bottled water market in the EU amounts to over fifty billion litres. Through its 21 national member associations, EFBW represents over 600 bottled water producers across Europe engaged in the production of natural mineral water. The revision of the natural mineral water Codex Standard is therefore an issue of great importance for EFBW's members.

First of all, EFBW would like to stress the bottled water industry's commitment towards providing the consumer with healthy and safe products. EFBW's members therefore appreciate this opportunity to discuss health issues in relation to natural mineral waters and support the Codex Commission's decision last July to reactivate the natural mineral water Codex Committee.

Any decision to reduce the concentration limits for natural constituents could have a direct impact on a significant number of producers, in particular in Europe where a substantial proportion of the world's total of natural mineral waters springs are being exploited. This is because some producers will no longer be allowed to exploit a source (in the absence of authorised separation techniques or treatments).

Therefore, it is essential that any new or reduced concentration limit set for a constituent in natural mineral waters be based on sound science and justified by a clear health purpose. In that context, EFBW experts reviewed the scientific data available for each natural substance covered by the Codex Commission's enquiry. A summary of their findings is attached to the present together with an industry position on each natural constituent.

EFBW would like to underline that:

- Due to the specificities of natural mineral waters (in particular geological underground origin), some substances may be of anthropogenic origin in drinking water but occur naturally in natural mineral waters.
- A given concentration limit on a constituent in WHO Guidelines for drinking water may have been set for reasons not linked to health (quality reasons -taste or colour- or other - see the case of manganese); on such instances the choice should be left to companies bottling natural mineral water to remove the constituent involved or not.
- The consumption patterns taken into account by WHO to set concentration limits for drinking water are not realistic when applied to natural mineral water; the daily ingestion of two litres of the same water over a long period of time may be relevant where a single source of water will be used for the preparation of food, hot drinks and for drinking as such but is not a reality for the consumption of natural mineral water the consumption of which will only complement mains water (used for the preparation of food and hot drinks) and not replace it. The 2 litres a day reference is even less appropriate in the case of the highly mineralised waters, generally carbonated natural mineral waters which are at the core of the

issue in this dossier, and whose characteristics make them unsuited for preparation of most other drinks or foods. Indeed, those are typically consumed in smaller than average quantities and in conjunction with other less mineralised waters;

- EFBW would also like to stress that while a whole range of treatments including disinfection are allowed for table and processed waters, treatments are still not allowed in the Natural Mineral Water Codex Standard (except filtration for unstable elements). Besides, for some substances such as boron and barium, no reliable treatments exist at all.

For all those reasons, where discrepancies exist between Codex limits and WHO's revised guidelines, alignment should only be very carefully considered on a case per case basis as decided by the Codex Commission at its last session; direct alignment of section 3.2 in Codex Stan 108 with WHO Guidelines, one of the options envisaged by the Codex Commission in July 2006 in its first circular would be scientifically unfounded and economically damaging. Such an option tends to be supported by countries where processed waters are the norm and which are not familiar with the concept of natural mineral water as it was developed centuries ago in Europe and later defined in the Natural Mineral Water Codex Standard 108.

In conclusion, before setting or lowering a limit on a substance naturally present in natural mineral waters, one should ensure that the limit truly serves to achieve a health-related purpose, and that the potential impact caused to the industry by the limit is proportionate to the objective pursued and necessary to achieve it.

Taking all those elements into account, EFBW would recommend the following:

- Boron: retain current limit;
- Barium²: raise the limit to 2 mg/litre;
- Fluoride: retain existing limit and labelling rules;
- Manganese: retain the current limit at 0,5 mg/litre;
- Nickel: delete the current limit (based on an obsolete guideline) or raise it to 0,07 mg/litre in line with new WHO guideline);
- Nitrite: raise the limit to 0,2 mg/litre.

For other constituents, EFBW members are in favour of maintaining the limits currently found in the Natural Mineral Water Codex Standard. A summary of the relevant scientific references and justifications for each constituent is attached to the present.

Alongside thermal and spring waters, natural mineral waters are part of Europe's cultural heritage and enjoyed all over the world. On the European continent, natural mineral waters constitute the bulk of bottled water consumption.

EFBW will be taking great interest in the review to be undertaken by the Natural Mineral Water Committee and is looking forward to assisting its experts whenever required.

² Although there is no discrepancy between WHO Guideline value and the NMW Codex limit for barium, EFBW would like to take the opportunity of the discussions to come to ask for a modification of the current limit.

NITRITE (NO₂) IN DRINKING WATER AND NATURAL MINERAL WATER

Parameter	Nitrite
Occurrence	<p>Closely associated with the occurrence of nitrate, and often ammonium.</p> <p>Natural</p> <ul style="list-style-type: none"> • Part of the nitrogen cycle – in soil, plants and water: NH₄ (ammonium) - NO₂ (nitrite) - NO₃ (nitrate). <p>Manmade</p> <ul style="list-style-type: none"> • Processes that create nitrates and/or ammonium • Inorganic fertilizers • Sewage and animal waste • Explosives production • Food preservative: sodium nitrite (especially in cured meats)
Range of natural concentrations in groundwater	<0.01 to approx 0.5
Human intake	From food and drink (including water). Cured meats (containing sodium nitrite preservative). Typical intake of nitrite in EU is <0.1 to 8.7 mg/day.
Health	<p>Primary concern (short term exposure): Methaemoglobinaemia ('blue-baby syndrome'), as a short term risk. Nitrite can prevent a proportion of haemoglobin (Hb) from carrying oxygen. This can lead to cyanosis (bluish skin), or asphyxia in the worst cases. Greatest risk is to young bottled-fed infants.</p> <p>Secondary concern (long term exposure): Tests on laboratory rats indicated potential effects on adrenals, heart and lungs. But no link to humans identified. This concern is provisional and precautionary.</p>
Limits	<p>WHO:</p> <ul style="list-style-type: none"> • For methaemoglobinaemia (short term exposure): 3 mg/l. • For long term exposure: 0.2 mg/l (provisional guideline) <p>Dir 2003/40/EC on concentration limits for natural mineral water: 0.1 mg/l</p> <p>Dir 98/83/EC on water intended for human consumption: 0.5 mg/l.</p> <p>Codex: 0.02 mg/l (but no clear justification for this)</p>
Comment	Risks are highly dependent on total nitrate and nitrite intake from all sources (mostly food), with water being a proportion.
Recommendation	Raise the limit to 0.2 mg/litre

BARIUM IN NATURAL MINERAL WATER

Parameter	Barium
Occurrence	<p>Natural</p> <ul style="list-style-type: none"> Occurs naturally in the earth's crust, from where it is taken up by passing groundwater. <p>Manmade</p> <ul style="list-style-type: none"> Wide industrial uses: metallurgy; glass, paper, chemical industry; electronic components; medicine.
Range of natural concentrations in groundwater	From "non detectable" up to about 2 mg/l.
Human intake	Mean dietary intake from foods and fluids is about 0.75 mg/day (range 0.44 – 1.8 mg/day).
Health	<p>Of minor toxicological relevance: Not carcinogenous, not genotoxic, no reproductive or developmental toxicity.</p> <p>Positive effects:</p> <ul style="list-style-type: none"> May be good for the structure of bones and teeth, but probably not an essential micro-nutrient for humans. <p>Negative effects:</p> <ul style="list-style-type: none"> Animal studies: Hypertension and effects on the kidney at high concentrations.
Limits	<p>WHO: 0.7 mg/l</p> <p>NMW Dir 2003/40/EC: 1.0 mg/l</p> <p>DW Dir 98/83/EC: no limit</p> <p>Codex: 0.7 mg/l</p> <p>US-EPA (drinking water in the USA): 2 mg/l</p>
Comment	No authorized removal treatment available for NMW.
Recommendation	Raise the limit to 2 mg/l.

BORON IN NATURAL MINERAL WATER

Parameter	Boron
Occurrence	<p>Natural</p> <ul style="list-style-type: none"> Occurs naturally in the earth's crust, from where it is taken up by passing groundwater. <p>Manmade</p> <ul style="list-style-type: none"> Wide industrial uses: glass and galvanic industry; fire inhibitor; fertilizers; cleaning; bleaching. Compound of detergents for private use.
Range of natural concentrations in groundwater	From "non detectable" up to well above 5 mg/l.
Human intake	Mean dietary intake from foods and water is about 1 – 2 mg/day.
Health	<p>Of minor toxicological relevance: Not carcinogenous, not genotoxic.</p> <p>Negative effects:</p> <ul style="list-style-type: none"> Animal studies: Negative reproductive and developmental effects.
Limits	<p>WHO: 0.5 mg/l (provisional)</p> <p>NMW Dir 2003/40/EC: no limit fixed yet</p> <p>DW Dir 98/83/EC: 1 mg/l</p> <p>Codex: 5 mg/l</p> <p>US-EPA (drinking water in the USA): no limit .</p>
Comment	<p>No removal treatment available for NMW.</p> <p>Higher amounts may occur in highly mineralised waters. They are only consumed in limited quantities, because they are inappropriate for a lot of typical consumption situations, i.e. brand exclusivity is rather low:</p> <ul style="list-style-type: none"> they are inappropriate to substitute drinking water (preparation of tea, coffee, etc.) they are unsuitable to accompany foods and other drinks with delicate tastes <p>they are inappropriate for bulk consumption</p>
Recommendation	Retain current limit.

MANGANESE IN NATURAL MINERAL WATER

Parameter	Manganese
Occurrence	<p>Natural</p> <ul style="list-style-type: none"> Occurs naturally in the earth's crust, from where it is taken up by passing groundwater. <p>Manmade</p> <ul style="list-style-type: none"> Manufacture of iron and steel alloys and as an oxidant.
Range of natural concentrations in groundwater	From "non detectable" up to some mg/l.
Human intake	Food is the principal source of intake, which varies widely between 1 and 10 mg/day (and even higher values for vegetarians). Water does not contribute significantly to the total intake.
Health	<p>Positive effects:</p> <ul style="list-style-type: none"> Essential micro-nutrient for humans (health of bones, activation of enzymes) <p>Negative effects:</p> <ul style="list-style-type: none"> Inhaled manganese compounds may affect the central nervous system. Animal studies: Negative reproductive and developmental effects.
Limits	<p>WHO: 0.4 mg/l (new: 3rd ed.; 2nd ed. was: 0.5 mg/l)</p> <p>NMW Dir 2003/40/EC: 0.5 mg/l</p> <p>DW Dir 98/83/EC: 0.05 mg/l</p> <p>Codex: 0.5 mg/l</p>
Comment	The drinking water limit is a technical rather than health-based one. Manganese can precipitate as black manganese dioxide which can stain washed clothes (irrelevant to bottled water). .
Recommendation	Retain the NMW limit at 0,5 mg/l

NICKEL IN NATURAL MINERAL WATER

Parameter	Nickel
Occurrence	<p>Natural</p> <ul style="list-style-type: none"> Occurs naturally in the Earth's crust, from where it is taken up by passing groundwater. <p>Manmade</p> <ul style="list-style-type: none"> Manufacture of stainless steel and alloys.
Range of natural concentrations in groundwater	From "non detectable" up to about 0.05 mg/l
Human intake	Food is the principal source of intake with about 0.2 mg/day (double this for vegetarians). Water contributes about 10 % to the total intake.
Health	<ul style="list-style-type: none"> Allergic contact dermatitis is the most prevalent effect in the general population. Although inhaled nickel compounds are carcinogenous, <u>there is no such evidence for the oral route.</u>
Limits	<p>WHO: 0.07 mg/l (new:1st add. to 3rd ed.; former versions: 0.02 mg/l)</p> <p>NMW Dir 2003/40/EC: 0.02 mg/l (as of 2008-01-01)</p> <p>DW Dir 98/83/EC: 0.02 mg/l</p> <p>Codex: 0.02 mg/l</p>
Comment	WHO guideline is increased to 0,07 mg/l, thus, there is no justification for a NMW limit of 0,02 mg/l
Recommendation	Delete the NMW limit (based on an obsolete WHO guideline) or raise it to 0.07 mg/l (in line with new WHO guideline).

INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATION (ICBA)

The International Council of Beverages Associations (ICBA) is a nongovernmental organization that represents the interests of the worldwide nonalcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of water-based beverages, including sparkling and still beverages such as soft drinks, juice drinks, bottled waters, and ready-to-drink coffees and teas. ICBA is pleased to provide the following comments on **Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters** (CODEX STAN 108-1981, Rev. 1-1997).

General comments

While we support that the WHO Guidelines for Drinking Water Quality (“WHO Guidelines”) should be considered as a reference on a case-by-case basis, we note that there are differences between drinking water and natural mineral water that should be taken into account when considering aligning the parametric values:

- The consumption of natural mineral water generally differs from that of drinking water, especially for products with a high mineral content. The WHO Guidelines allocate a certain percentage of the intake to drinking water and the default assumption for consumption by an adult is 2 liters of water per day over a lifetime. This is untypical for natural mineral water which represents only one source or choice of daily liquids.
- Permitted treatments for natural mineral water are limited to separation of unstable elements, such as compounds containing iron, manganese, sulphur or arsenic, by decantation and/or filtration, if necessary, possibly preceded by oxygenation with air or ozone-enriched air. Further, they may only be carried out on condition that the mineral content of the water is not modified in its essential constituents (principally the major ions), which give the water its properties. Other separation techniques used in drinking water treatment are not applicable to separate elements that may be naturally present in mineral water, and not authorized because they are not selective and may lead to the modification of the characteristic composition of the water.
- Some of the parameters in the WHO Guidelines are based on issues other than health, such as staining of laundry, and other quality and organoleptic considerations that may not be applicable to natural mineral water.

Antimony

While we believe that the current limit of 0.005 mg/L can be achieved, it is based on a previous WHO guideline value and **we suggest adopting the current WHO guideline value (0.02 mg/kg)** that is based on a revised risk assessment (in 2003). Further, there are no data indicating its carcinogenicity by oral ingestion.

Arsenic

Arsenic is widely distributed in the Earth’s crust and it may be naturally present in mineral waters at measurable levels. The safety concern is based on a long-term consumption of drinking water with elevated levels. **We support maintaining the current limit of 0.01 mg/L.**

Barium

Barium in water comes primarily from natural sources since it is present as a trace element in both igneous and sedimentary rocks and thus can be present in natural mineral water at levels higher than found in drinking water after treatment. The natural concentrations in groundwater are up to 2 mg/L. Although the WHO Guidelines note that 0.1 mg/L should be achievable using either ion exchange or precipitation softening (other conventional processes are ineffective), neither are permitted treatments for natural mineral water. Further, the WHO guideline value is based on an epidemiological study in which no adverse effects were observed. The WHO Guidelines also note that “the guideline value for barium maybe highly conservative and the margin of safety is likely to be high.” Based on this, we believe that levels up to 2 mg/L in natural mineral water are safe.

We suggest increasing the current level to 2 mg/L to reflect the level of natural occurrence considering the high safety margin and the different consumption pattern of natural mineral water.

Borate (calculated as boron)

Boron is found naturally in groundwater at concentrations that vary widely depending on the surrounding geology. High levels (5 mg/L and above) may occur in products with a high mineral content, but these are

unlikely to be consumed in volumes relevant to drinking water. There are not approved treatments for natural mineral water. According to the WHO Guidelines, conventional water treatment (coagulation, sedimentation and filtration) does not significantly remove boron, and special methods need to be installed in order to remove boron from waters with high boron concentrations. Ion exchange and reverse osmosis processes may enable substantial reduction but are not permitted for natural mineral water because they would modify the characteristic composition of a natural mineral water. Blending with low-boron supplies may be the only economical method to reduce boron concentrations in waters where these concentrations are high (but blending is not permitted for natural mineral water).

We note that the WHO guideline level is designated as provisional because it will be difficult to achieve in areas with high natural boron levels with the treatment technology available even for drinking water. **We support maintaining the current maximum limit (5 mg/L as boron)** for natural mineral water due to 1) absence of evidence to show that levels up to 5 mg/L present a health risk, 2) naturally high levels are generally found only in products with a high mineral content that have a different consumption pattern than that of drinking water, and 3) lack of approved treatments.

Cadmium

We support maintaining to current limit of 0.003 mg/L since cadmium is a contaminant and typically does not occur in natural waters at levels above the limit.

Chromium

We support maintaining the current limit of 0.05 mg/L (calculated as total chromium) although we note that the guideline value is designated as provisional by WHO because of uncertainties in the toxicological database although the value was considered to be unlikely to give rise to significant health risks.

Copper

The current limit (1 mg/L) is based on a previous WHO guideline value that was lifted up to 2 mg/L in the subsequent risk evaluation (in 2003). **We suggest adopting the current WHO guideline value of 2 mg/L** for consistency. However, the current limit can be met in natural mineral waters since copper is present only as a natural trace element.

Cyanide

We note that cyanide is only occasionally found in drinking water, primarily as a consequence of industrial contamination. **While we have no objection to the limit (0.07 mg/L), we suggest considering if there still is a need to maintain it** since cyanide is not an issue with natural mineral waters.

Fluoride

Fluoride is found in groundwater at concentrations that vary with the type of rock the water flows through but do not usually exceed 10 mg/L. The highest natural level reported is 2800 mg/L. We note that the WHO guideline value (1.5 mg/L) is based on epidemiological evidence that concentrations above this value carry an increasing risk of dental fluorosis, and progressively higher concentrations lead to increasing risks of skeletal fluorosis. There is suggestive evidence of an increased risk of effects on the skeleton at total fluoride intakes above about 6 mg/day. The WHO Guidelines make a note that, in areas with high natural fluoride levels in drinking-water, the guideline value may be difficult to achieve, in some circumstances, with the treatment technology available.

In Europe, where natural mineral water constitutes the bulk of bottled water consumption, the maximum level is 5 mg/L (EC Directive 2003/40/EC) with a warning “unsuitable for infants” if the level is above 1.5 mg/L. **We suggest considering the currently permitted level in the EC** with the existing labeling provisions but revising the warning “*The product is not suitable for regular consumption by infants and children under the age of seven years*” where the product contains **more than 1.5 mg/l** fluorides (instead of

the current 2 mg/L). The reduction would be in line with the WHO Guidelines that state that consumption may give rise to mild dental fluorosis at drinking-water concentrations between 0.9 and 1.2 mg/L.

Lead

We suggest **maintaining the current limit of 0.01 mg/L**. Lead is rarely present in natural waters and not a raw water contaminant but a result of plumbing and fittings containing lead, i.e., a contaminant.

Manganese

Manganese is an essential element for humans and other animals and occurs naturally in many food sources. Manganese is naturally occurring in many groundwater sources. Levels as high as 10 mg/L in acidic groundwater have been reported. Since manganese can be removed with authorized treatments, **we support adopting the WHO guideline value of 0.4 mg/L for consistency**.

Mercury

Mercury is present in the inorganic form in surface water and groundwater at concentrations usually below 0.5 µg/L, although local mineral deposits may produce higher levels in groundwater. We note that the WHO guideline value was increased to 0.006 mg/L based on a more current risk assessment (in 2004). **We suggest adopting the WHO guideline value of 0.006 mg/L (for inorganic mercury) for consistency**. However, the current limit of 0.001 mg/L is achievable in natural mineral water.

Nickel

The concentration of nickel in drinking-water is normally less than 0.02 mg/L. In special cases of release from natural or industrial nickel deposits in the ground, the nickel concentrations in drinking-water may be higher. The current maximum limit is based on a previous WHO guideline that has been increased to 0.07 mg/L based on a new risk assessment (in 2004). **We suggest adopting the WHO guideline value of 0.07 mg/L**.

Nitrate

We suggest maintaining the current limit of 50 mg/L, as nitrate, since it is the same as the existing WHO guideline value although we note that it is intended to protect against methaemoglobulinaemia in bottle-fed infants (short term exposure).

Nitrite

Nitrite may be naturally present in mineral water as part of the natural nitrogen cycle. The Codex limit is set as a quality limit and cannot be met in many natural mineral waters, especially if there is ammonium present. Further, this limit is far below the WHO guideline values for short-term and long-term exposures. **We suggest adopting the WHO guideline value of 0.2 mg/L** (based on a long-term exposure and the JECFA ADI) as a health-based limit.

Selenium

Selenium is present in the Earth's crust, often in association with sulfur-containing minerals. It is an essential element for humans with a recommended daily intake of about 1 µg/kg of body weight for adults. Levels in drinking-water vary greatly in different geographical areas but are usually much less than 0.01 mg/L. The 1993 WHO Guidelines proposed a health-based guideline value of 0.01 mg/L on the basis of human studies. This value was maintained in the 2003 WHO Guidelines. **We suggest maintaining the current limit of 0.01 mg/L**.