

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 3

CX/NMW 08/8/3-Add.2
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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:

Argentina, Brazil, Canada, Egypt, European Community, Georgia, Malaysia, Mali and Tunisia.

ARGENTINA

Argentina is pleased to comment on the above-mentioned Circular Letter.

First, we wish to point out that Codex has always made a clear distinction between “natural mineral waters” and “drinking water” and that it is worth highlighting that in natural mineral water specifications, some substances that may not occur naturally in drinking water may occur in natural mineral waters. However, we would like to make a few remarks.

For those substances for which the Codex level is lower than that established in the WHO Guidelines (antimony, copper, mercury, nickel and nitrite), we believe that a lower value is in itself safer for human health and we would not support any changes.

For manganese, the value of which is above that established in the WHO Guidelines, Argentina has lowered the level to 0.4 mg/l in accordance with the new scientific information available. For boron, Argentina is now examining the results of new research on harmful health effects in order to take a decision. However, we give special consideration to the fact that the level proposed by the WHO is provisional and may be difficult to achieve in natural mineral waters.

In addition, it is worth taking into account that a wide range of treatments are permitted for drinking water, whereas only some physical treatments (filtration, aeration and similar) are permitted in natural mineral waters, so consideration needs to be given to the possibility that setting new values for regulated substances could bring about changes in the identity of some products that are now considered “natural mineral waters” but would no longer be if they were subjected to new treatments necessary to meet stricter levels.

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.

Last, we believe that before taking a decision it is worth bearing in mind the consumers' actual level of exposure to these substances as a result of natural mineral water consumption, as the measures adopted should be proportional to the assessed risk.

BRAZIL

Brazil thanks for the opportunity to comment on CL 2007/13-NMW - CL 2007/25-NMW CX 5/40.2 - Health Related Limits for Certain Substances in the Standard Codex for Natural Mineral Waters (CODEX STAN 108 - 1981, Rev. 1-1997).

Brazil will not comment on the values of Arsenic, Barium, Cadmium, Cyanides, Lead, Nitrate, Selenium, which are the same of those proposed by the Codex Alimentarius and by WHO.

In reference to the other substances, Brazil proposes:

a) Antimony: we propose to adopt the limit established by Codex (0,005mg/l) considering other countries comments (Annex Comments Received in Reply to CL 2006/13/NMW of Alinorm 07/30/9D) and the European Community's value that matches with the Codex Alimentarius one.

b) Borate: we propose to maintain the value of 5 mg/l as in the CODEX STAN 108--1981, Rev.1-1997, Amended in 2001, since the value proposed by WHO - Guidelines values for chemicals that are of Health Significance in Drinking Water 3^a ed. - is temporary. In Brazil, the analysis of 541 natural mineral water samples conducted between 01/09/06 and 07/16/07 showed borate values ranging from 0,002 to 2,321 mg/l.

c) Copper: the delegation proposes to maintain the value of 1 mg/l as in the CODEX STAN 108--1981, Rev.1-1997, Amended in 2001, considering that there are no data showing copper occurrence in natural mineral water in Brazil at toxicological levels that would represent health risk. Furthermore, the value recommended by WHO may include copper originated from the treatment and distribution systems of the supplying water. The Recommended Daily Ingestion for adults of 990 microgram of copper, adopted by Brazil in the Resolution RDC n° 269, 22nd November, 2005, was based on data from the Institute of Medicine (Food and Nutrition Board. Dietary Reference Intakes. National Academic Press, Washington A.D., 1999-2001).

d) Fluoride: Brazil maintains the same position forwarded and described in Annex Comments Received in Reply to CL 2006/13/NMW of Alinorm 07/30/9D:

The WHO establishes a maximum limit of 1,5 mg/l for water for human consumption and the CODEX STAN 108-1981, Rev.1-1997, Amended in 2001, does not recommend the maximum value for this substance. It only proposes warning sentences on the labeling of products with fluoride. The fluoride is naturally present in natural mineral water and its presence in the supplying water, when it is not underground water, is mainly due to addition. Therefore, Brazil proposes to maintain the warning sentences recommended by the CODEX changing the value of 2 mg/l to 1,5 mg/l, with the following composition: *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 1,5 mg/l fluorides.*

e) Manganese: Brazil proposes the value of 0,4 mg/l established for WHO - Guidelines values for chemicals that are of Health Significance in Drinking Water 3^a ed. The Recommended Daily Ingestion of 2,3mg of manganese for adults, adopted by Brazil in the Resolution RDC n° 269, 22nd November, 2005, is based on data from the Institute of Medicine (Food and Nutrition Board. Dietary Reference Intakes. National Academic Press, Washington A.D., 1999-2001).

f) Mercury: Brazil proposes the maintenance of the value of 0,001 mg/l as in the Codex Alimentarius STAN 108-1981, REV.1-1997, Amended in 2001, considering that, according to WHO, usually the

occurrence in the inorganic form (Hg +2) is at most of 0,0005mg/l in underground waters, except at places where there are deposits of this mineral and; also, the need of preserving the natural mineral water not originated from places with mercury deposits as a consequence of the industrial pollution.

g) Nitrite: Brazil proposes to adopt the established value for nitrites of 0,1mg/l as in the Commission Directive 2003/40/EC of 16 may 2003.

CANADA

Canada is pleased to offer the attached comments on Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters (CL 2007/25-NMW).

Canada supports, in principle, the view that the health-related limits for the various substances listed in the Codex Standard for Natural Mineral Waters and the WHO Guidelines for Drinking Water Quality should be harmonized to the greatest extent possible. Nevertheless, Canada also recognizes that there are differences between natural mineral water and regular drinking water both in the way they are used and consumed and in some of their chemical characteristics. Therefore, it is important to consider such differences when reviewing health-related limits for various chemical substances. In addition, the potential impact of any changes to the Codex limits would require careful consideration.

Before proposing any changes, an analysis of the following situations would be useful:

1) When the current Codex limits in the Standard for Natural Mineral Water are lower than the WHO Guidelines.

In all cases where the limits specified in the Codex Standard for Natural Mineral Waters are lower than the values outlined in the WHO Guidelines for Drinking Water Quality (i.e. antimony, copper, mercury, nickel, and nitrite) the following questions should be considered.

Have there been any examples where these limits in the Codex Standard for Natural Mineral Waters have caused problems in international trade?

If yes, which limits caused the problem? Would harmonization with the WHO Guidelines have avoided the problem?

If no, what value would there be in raising the Codex limits to harmonize with the WHO Guidelines, bearing in mind the fact that they are identified as health-related limits?

2) When the current Codex limits in the Standard for Natural Mineral Water are higher than the WHO Guidelines.

In all cases where the limits specified in the Codex Standard for Natural Mineral Waters are higher than the values outlined in the WHO Guidelines for Drinking Water Quality (i.e. borate and manganese) the following questions should be considered.

Is there a need, for health and safety reasons, to lower these limits to match the WHO Guidelines?

If yes, what would be the impact on international trade in natural mineral water?

If no, what value would there be in lowering these Codex limits to harmonize with the WHO Guidelines?

While harmonization with the WHO guidelines remains a worthwhile objective to the extent possible, it is Canada's view that, unless specific human health issues or problems in international trade have been identified as a result of analysis such as mentioned above, any changes to the Codex Standard for Natural Mineral Waters would serve little useful purpose.

EGYPT

Referring to your document no.(CL2007/25-NMW) dated July 2007 concerning the request for comments on Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981, Rev. 1-1997).

We would like to inform you that the health related limits for certain metals in the codex standard for mineral waters have to be kept as the same levels prepared by the WHO guidelines and as mg/l.. And of course the same as what have been in the Egyptian Standard 1588/2005.

EUROPEAN COMMUNITY

General comments

The European Community (EC) welcomes the opportunity to give comments in response to Circular Letter CL 2007/25-NMW on health related limits for certain substances of the Codex standard for Natural Mineral Waters (Codex STAN 108-1981, Rev1-1997).

The EC supports the revision of current Codex maximum limits for health related constituents for ensuring a high level of protection of public health and fair practices in the trade of natural mineral waters.

The EC is in agreement with the Codex Alimentarius Commission position reached in July 2007 and is not in favour of a systematic alignment with the levels laid down in the WHO guidelines for drinking water quality, but for a case by case approach, for the following reasons:

- NMW specificities refer mainly to the natural origin of health related constituents linked to NMW of underground origin, the required protection of sources from any environmental contamination, the data on individual consumption and the applicable technical constraints such as the ban on removal treatments other than filtration.
- The EC considers that current limits should be reduced only when there is an evidence of a risk for public health based on scientific data. The proportionality of any measures would be of great importance. A systematic alignment on WHO guidelines would, for some substances, imply the ban of a large number of NMW from the market without a clear public health justification. For other substances, WHO guidelines integrate other quality factors (distribution network, colour and visual aspect etc) which are not relevant for bottled waters and do not justify the reducing of Codex limits.
- The EC also considers that there is no justification to amend current Codex limits just because they are below the WHO guidelines. A higher value can be justified for drinking water, while ensuring the protection of public health, to take into account the influence of the environment on surface waters. The increase of Codex limits would be contradictory to other mandatory requirements applicable to NMW.

Specific comments

In the light of the above position, the E.C. can make the following specific comments:

- Antimony, Copper, Mercury, Nickel.

There is no justification to increase the current limits as higher levels in drinking water can result from the influence of environment which should not occur for ground waters such as NMW.

- Nitrites.

The justification for the low current limit (0.02 mg/l) is not clear and it can be a concern for NMW producers. Indeed a certain level of nitrites may naturally occur due to ammonium ions in water from anaerobic sources being converted into nitrites (and ultimately nitrates) when exposed to the air. Therefore the EC is in favour of an increase in the current limit up to 0,1 mg/l.

- Borate (measured as boron).

NMW may contain relatively high concentrations of boron from natural origin, in particular for highly mineralised NMW.

In the case of boron, there is no technology available to remove it without modifying the mineral composition of NMW as required by the Codex standard.

As regards food safety, it should be taken into account that the exposure to boron from NMW differs significantly from the exposure due to drinking water. The European Food Safety Authority (EFSA) has delivered a scientific opinion¹ on boron in NMW which shows that there is no evidence of a risk for public health for consumers older than 14 years of age due to NMW consumption with the highest boron concentration registered in the E.U.

There is a good basis to have higher boron values for natural mineral waters than for drinking water.

- Fluoride.

The Codex standard does not foresee any maximum limit but two different labelling requirements depending on the fluoride concentration.

In its opinion, the European Food Safety Authority (EFSA) estimates that there is no risk of dental fluorosis for the adult population with a fluoride concentration in NMW up to 5 mg/l and for children older than 3 years with a concentration up to 1,5 mg/l.

The EC considers that the protection of these populations can be achieved through a maximum limit of 5 mg/l and labelling requirements as laid down in the Codex standard with an adaptation of the labelling threshold to 1.5 mg/l.

- Manganese.

The WHO guideline (0,4 mg/l) is lower than the Codex limit (0.5 mg/l). However, it is not only based on the risk for public health but on other quality and technological considerations which are not relevant for bottled waters. Therefore there is no justification to reduce the Codex limit.

GEORGIA

The Ministry of Agriculture of Georgia 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 Georgia amounts to over thirty million liters. Through its 10 active water producers across the country that are 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 the Georgian water producers.

¹ Opinion of the scientific panel on contaminants in the food chain on a request of the Commission related to concentration limits for boron and fluoride in natural mineral waters adopted on 22 June 2005.

First of all, Ministry of Agriculture of Georgia would like to stress the bottled water industry's commitment towards providing the consumer with healthy and safe products. Georgian water producers 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.

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, Georgian experts reviewed the scientific data available for each natural substance covered by the Codex Commission's enquiry. A summary of their findings is attached (Appendix 1) to the present together with an industry position on each natural constituent.

Georgian Ministry of Agriculture 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; on such instances the choice should be left to Georgian companies bottling natural mineral water to remove the constituent involved or not.
- The Ministry 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;
- All Georgian Mineral waters including famous *Borjomi* with a hundred-year industry experience have been produced according to former Soviet and today's National standards. Despite the slightly higher mineralization content Georgian mineral waters have proved to be excellent for health and in case of *Borjomi* it has been well confirmed by hundreds of medical surveys since the soviet time;

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.

Natural mineral waters are part of Georgian's cultural heritage and enjoyed all over the CIS and Baltic States. Ministry of Agriculture of Georgia will be taking great interest in the review to be undertaken by the Natural Mineral Water Committee and is looking forward to assisting it's experts whenever required.

Appendix 1 MAIN CONSTRAINTS FOR NATURAL MINERAL WATERS & REGULATION STATEMENT

	Current EEC limit	Codex limit	National limit	Comments	Recommandation
BARYUM	1 mg/l.	0.7 mg/l.	Not defined for Natural Mineral Water	No authorized removal treatment available for NMW	Delete the NMW limit or lift it to 5 mg/l.
FLUORINE	5 mg/l. – 1,5mg/l	No limit, but warning if > 1mg/l.	< 10 mg/l.	No risk from NMW	Retain existing NMW limit and labeling rules
NITRITE	0,1 mg/l.	0.02 mg/l.	< 2 mg/l.		Keep current EC

(NO2)					limit
BORON	Not defined for Natural Mineral Water	5 mg/l.	Not defined for Natural Mineral Water	No removal treatment available for NMW	No setting a limit for NMW

MALAYSIA

With reference to our letter dated 25 November 2007, we would like to submit ammended Comments by Malaysia for your kind attention. We apologize for any inconvenience in this matter.

Malaysia would like to forward comments with reference to each of the substances listed in the Annex to CL 2007/25-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.

MALI

Mali is pleased to submit the following comments in response to the Circular Letter CL 2007/25-NMW, concerning the health limits applicable to certain substances listed in the Codex Standard for natural mineral waters (CODEX STAN 108-1981, Rev. 1-1997).

Substance	Codex Standard health limits applicable to certain listed substances (mg/l)	WHO guideline values for chemicals that are of health significance in drinking water (mg/l)	Position of Mali
Antimony	0.005	0.02	0.02
Arsenic	0.01 calculated as As total	0.01 (P)	0.01 calculated as As total
Barium	0.7	0.7	0.7
Borate	5 calculated as B	0,5 (T) for boron	5 calculated as B
Cadmium	0.003	0.003	0.003
Chrome	0.05 calculated as total Cr	0.05 (P) for total chromium	0.05 calculated as total Cr
Copper	1	2	1
Cyanide	0.07	0.07	0.07
Fluoride	see note ¹	1.5	1.5 with the Codex Standard warning included: “Contains fluoride”: “This product is not recommended for infants and children under 7 years”
Lead	0.01	0.01	0.01
Manganese	0,5	0,4 (C)	0.5
Mercury	0.001	0.006 (as inorganic mercury)	0.001
Nickel	0.02	0.02	0.02
Nitrate	50 calculated as nitrate	50 as NO ₃ (short time exposure)	50 calculated as nitrate
Nitrite	0.02 as nitrite ³	3 for No ₂ (short time exposure) 0,2 (P) (long term exposure)	0.02 as nitrite ³
Selenium	0.01	0.01	0.01

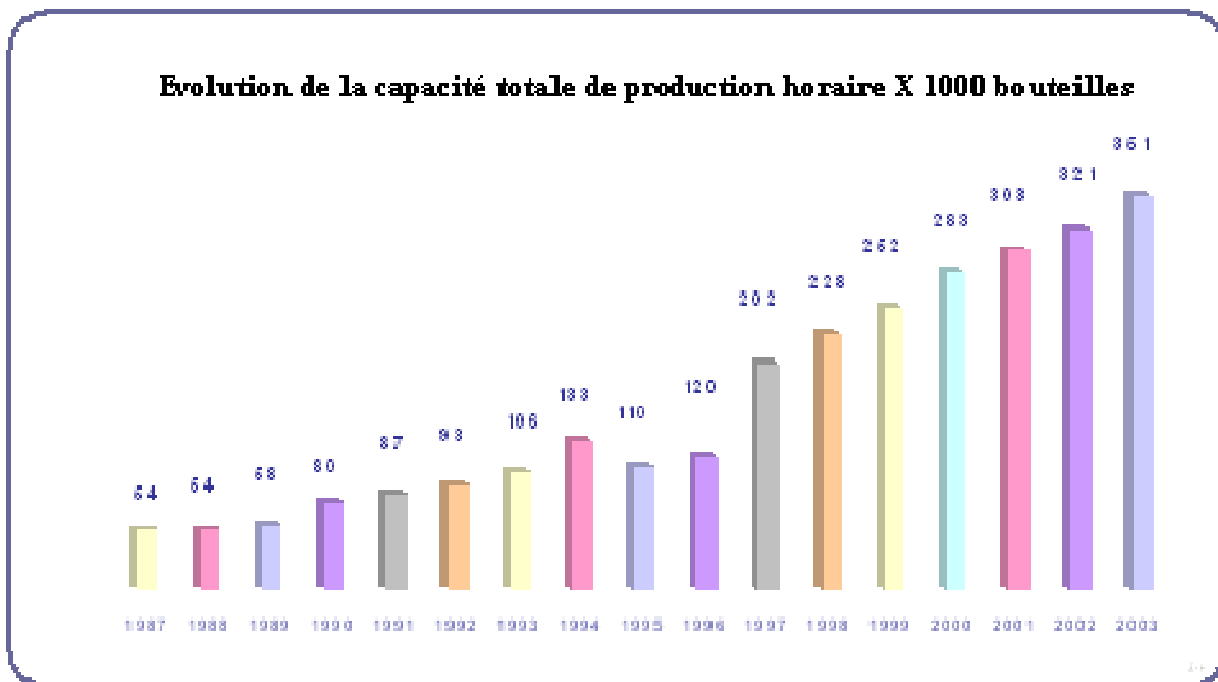
TUNISIA

DETAILS OF MINERAL WATER CONSUMPTION IN TUNISIA

The bottled drinking water sector has experienced a high degree of development as regards quantity, thus enabling it to satisfy consumer needs as well as local market demand. The figures recorded for the period 1987-2005 are encouraging and the sector has gained solid foundations that have generated an increase in sales and on-going progression, improvement in quality and a growing development in investment.

PRODUCTION CAPACITY

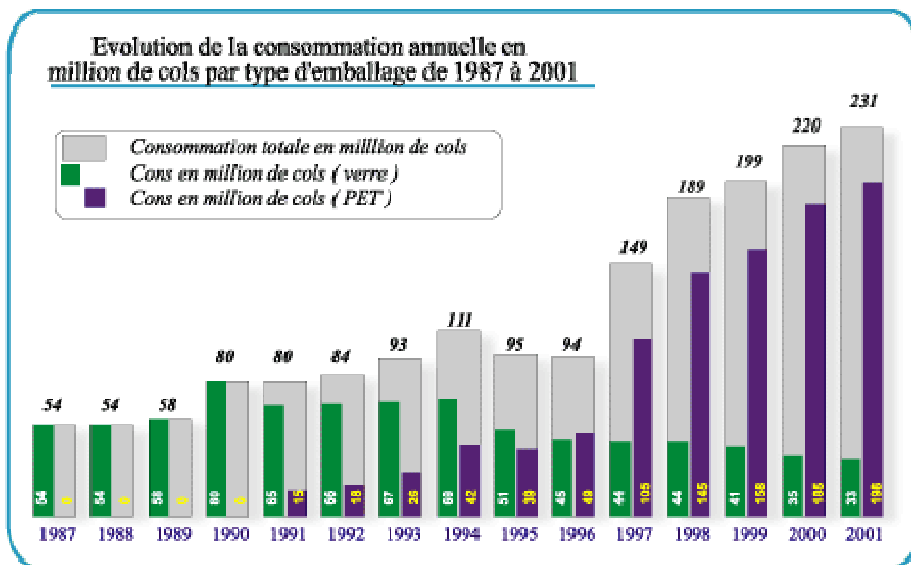
During the period from 1987 to 2005, ten new bottled drinking water plants have been set up for the bottling of mineral water and overall production capacity has gone from 29,000 to 261,200 bottles per hour.



Development of total production capacity per hour per thousand bottles

Evolution of bottled water sales

From 1987 to 2005, sales went from 54 million to 368 million bottles, representing average annual growth of 10.62%. Carbonated mineral waters represent 3% of overall consumption.



Development of annual consumption in millions of bottles per bottling type from 1987 to 2001

Overall consumption in millions of bottles

Consumption in millions of glass bottles

Consumption in millions of PET bottles

The annual consumption thus increased from 4 litres to 37 litres per head of population between 1987 and 2005.

THE STANDARDISATION OF BOTTLED WATER IN TUNISIA

The standardisation of water quality includes: the vocabulary used, sampling, the measuring of the characteristics of the water and their expression as well as the acceptable limits of the various types of mineral waters. The following standards are essentially applicable:

- **NT 09.33 on natural mineral waters, ratified by Ministerial Order issued by the Tunisian Ministry of Industry of 17 June 1997. This standard is being revised and will be equivalent to the Codex standard (CODEX STAN 108-1981, Rev. 1 - 1997).**
- **NT 09.83 on bottled table water, ratified by a Ministerial Order issued by the Tunisian Ministry of Industry of 17 June 1997.**

THE REGULATION OF MINERAL WATER IN TUNISIA

Control of bottled waters is subjected to a range of legislative and regulatory stipulations, of which the principal are:

- The Tunisian Water Code (Act 75/16 of 31 March 1975), which gives in Article 97 the definitions of water for consumption and drinking purposes: “water for purposes of consumption means untreated water or treated water suitable for drinking, for domestic use, for the manufacture of sparkling beverages, mineral water, ice and all foodstuff products.”
- The Tunisian Act 92-117 of 7 December 1992 concerning consumer protection.
- The Tunisian Act 89-102 of 11 December 1989 amending the Tunisian Act 75-58 of 14 June 1975 and setting up the agency governing the spas in the country.

As well as their associated regulations:

- Decree No.: 1718-2003 of 11 August 2003, concerning the laying down of the general criteria for the production, utilisation and commercialisation of materials and other objects coming into contact with foodstuffs.
- Decree of the Tunisian Ministry of Tourism and Artisanal Trades of 8 March 2004 giving approval to the specifications setting up the general organisational conditions, exploitation and production in the bottled water sector.
- Decree of the Tunisian Ministry of Public Health of 12 January 2005, setting up a body for the issuing of health certifications for the utilisation of materials and objects coming into contact with foodstuffs as well as the conditions for the granting of such certification.

SUMMARY OF ANALYTICAL RESULTS OF THE AVERAGE CONCENTRATION OF BORON IN THE VARIOUS WATERS BOTTLED IN TUNISIA

Types of Water	Product No.:	Concentration of Boron	
		(ppb)= $\mu\text{g/l}$	mg/l
N.M.W. ⁽¹⁾	1	28.43	0.028
" "	2	115.50	0.115
" "	3	10.12	0.010
" "	4	143.70	0.143
" "	5	1.60	0.001
" "	6	162.50	0.162
" "	7	112.50	0.112
" "	8	50.00	0.050
" "	9	68.75	0.068
" "	10	90.62	0.090
T.W. ⁽²⁾	11	D.T. ⁽³⁾	D.T. ⁽³⁾
" "	12	275.60	0.275

(1) N.M.W. : Natural Mineral Water

(2) T.W. : Table Water

(3) D.T. : Detection Threshold

Analytical method: atomic absorption: nitrogen peroxide modulus

OPINION GIVEN BY TUNISIA

The Secretariat of the Tunisian Codex Committee for Standards has studied the Circular Letter CL 2007/25-NMW it received concerning a request for comments on health related limits for certain substances in the Codex Standard for Natural Mineral Water (CODEX STAN 108-1981, Rev.1 - 1997), namely on the study

of new discrepancies between the health related limits for certain substances in the Codex Standard and the third edition of the WHO guidelines on values of chemical substances in drinking water that have an impact on health, and has prepared the following Comments in this regard:

In view of analytical results in Tunisia, of the toxicological data and scientific opinions available, Tunisia proposes to adopt the issued by the WHO, as concerns the limits for boron, being 0.5 mg/l, and to maintain the limits proposed in the Codex Standard (CODEX STAN 108-1981, Rev. 1 - 1997) for the remaining elements.