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# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 13

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

#### *Thirtieth Session*

*FAO Headquarters, Rome, Italy, 2 – 7 July 2007*

### MATTERS ARISING FROM THE REPORTS OF THE COMMISSION, CODEX COMMITTEES AND TASK FORCES

#### Matters Arising by 9 March 2007

#### I. MATTER FOR ACTION BY THE COMMISSION

#### THE 29<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION

##### **Revision of WHO Guidelines for Drinking-Water Quality <sup>1</sup>**

1. The 29<sup>th</sup> Session of the Commission was informed that WHO had issued its third edition of the Guidelines in 2004, which had been comprehensively updated to take account of developments in risk assessment and risk management. The Commission noted that, while the General Standard for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) (CODEX STAN 227-2001) made explicit reference to the WHO guidelines, the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981) listed the health-related limits for certain substances in numerical values, some of which had become inconsistent with the updated WHO Guidelines.
2. In May 2006, a Circular Letter<sup>2</sup> was issued in order to obtain the views of members and observers on (a) the need to proceed with an amendment to Section 3.2 “Health-Related Limits for Certain Substances” of the Codex Standard on Natural Mineral Waters in the light of the discrepancies that exist between the Codex Standard and the WHO guidelines and (b) what amendment is considered necessary.
3. Comments were received from Australia, Brazil, Canada, Costa Rica, European Community, Norway, Paraguay, Peru, United States, Vietnam, ICBA and ICBWA. These comments are presented in the Annex to this document.
4. The Commission is hereby requested to determine, in the light of the comments received, whether the amendment to the Codex Standard on Natural Mineral Waters (Codex STAN 108-1981) is necessary and in the affirmative, how to proceed.

<sup>1</sup> ALINORM 06/29/9F-Add.1.

<sup>2</sup> CL 2006/13-NMW.

## THE 38<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE (CCFH)

### **The Use of the Lactoperoxidase System for Milk and Milk Products in International Trade**<sup>3</sup>

5. The 27<sup>th</sup> Session of the Commission adopted the draft Code of Practice for Milk and Milk Products at Step 8, with the amendment to add the following text to the end of footnote 9 of Appendix II of the draft Code: “The use of the lactoperoxidase system for milk and milk products in international trade will be reexamined by the Committee on Food Hygiene (CCFH) after completion of an expert review by FAO and WHO of available data and considering the FAO Lactoperoxidase Expert Group report about potential risks and benefits of lactoperoxidase system. CCFH will then review the issue in 2006”.<sup>4</sup>

6. The Committee reexamined the issue based on the conclusions and recommendations by the FAO/WHO expert meeting on the benefits and potential risks of the lactoperoxidase system of raw milk preservation. While some delegations indicated their agreement with the recommendations of the report and confirmed that the lactoperoxidase system could be very useful in their developing dairy sectors, other delegations expressed concerns over the safety of this system as well as its practical application. In this regard, the Representatives of FAO and WHO noted that JECFA had already undertaken work on this issue at its 35<sup>th</sup> session and considered that the system was safe when used according to the guidelines developed by Codex (CAC/GL 13 - 1991).

7. The Committee noted that there was no consensus on the removal of restriction on the use of the Lactoperoxidase System in milk and milk products intended for international trade and decided to refer this matter to the Commission for guidance on how to proceed.

8. The Commission is hereby invited to provide guidance to the CCFH on this issue.

## THE CODEX COMMITTEE ON SUGARS (CCS)

### **Codex Standard for Sugars: Consideration of the Methods for the Determination of Colour in Plantation and Mill White Sugar**

9. The 24<sup>th</sup> Session of the Commission (2001) agreed to a request to change the method for the determination of colour in plantation or mill white sugar (PMWS) in the Codex Standards for Sugars from GS2/3-9, to GS2/3-10. However, in doing so it also requested that the CCS examine whether a change in method of analysis for determination of colour may additionally require a change in the specification of colour for plantation or mill white sugar.<sup>5</sup> The CCS is guided on methodology for colour determination in the Codex standard by the International Commission for Uniform Methods of Sugar Analysis (ICUMSA), the body responsible for methods of analysis for sugars. ICUMSA had been examining the methodology of colour determination and the appropriateness of a variety of methods including GS 2/3-9 and GS 2/3-10 for PMWS in detail.

10. Following completion of ICUMSA’s review and publication of its recommendations at its meeting in Atlanta 2004, a letter was circulated in July 2006 (CL 2006/32-CCS) seeking comments on the conclusions of ICUMSA, including:

**Recommendation No. 3: Method GS2/3-10** “The Determination of White Sugar Solution Colour” should have the scope changed to limit it to a maximum of 50 iu (N.B. The method used to determine the colour value should still be quoted with the result.);

**Recommendation No. 4: Method GS2/3-9 (2002)** “The Determination of Sugar Solution Colour at pH 7.0” continues to be limited to a maximum of 600 IU and its status should be changed to “accepted”; and

**Recommendation No. 6: Method GS1/2-8** “The determination of Raw Sugar Solution Colour, White Sugar and Plantation White Sugar at pH 7.0 by the MOPS Method” The scope of the method should be changed to remove the lower limit and its status changed to Official.

Particular attention was drawn to recommendation No. 6, in which ICUMSA viewed method GS1/2-8 to be the ‘official’ method. An official method is one which meets all requirements, whereas an accepted method

<sup>3</sup> ALINORM 07/30/13, paras 29-32 and 188-195.

<sup>4</sup> ALINORM 04/27/41, paras 45-46.

<sup>5</sup> ALINORM 01/41, para. 104.

is one that is demonstrably useful and has found an established application, or which do not lend themselves to collaborative testing.

11. In view of ICUMSA's recommendations above CL 2006/32-CCS sought comments by 15 November 2006 from Codex members and interested international organizations on whether method GS1/2-8 would be more appropriate as the new method for colour determination in all white sugars including PMWS.

12. Comments were received from Australia, Brazil, Canada, Germany, Mexico, Peru, Poland, EC, CEFS (Comité Européen des Fabricants de Sucre) and WRSO (World Sugar Research Organisation). There was a general consensus that method "GS 1/2-8" should become the new method for colour determination in all white sugars, including PMWS, and replace the current method in the Codex Standard for Sugars (GS2/3-10). It was also noted by many that, in 2005, method GS 1/2-8 was renamed as "**Method GS9/1/2/3-8 (2005)**" and it would be more appropriate for Codex to use this denomination.

13. In addition many of the responses from delegations commented that the application of method GS2/3-10 (2005) should still be allowed for sugars with a maximum colour of 50 IU as this is a simpler and more environmentally friendly alternative method which could be used at national or regional level.

14. The CCS therefore makes the following recommendations for consideration by the Commission:

- that if only a single method is to be endorsed in the Codex Standard for Sugars that **Method GS9/1/2/3-8 (2005)** should be applied to the determination of colour for all sugars covered by the Standard, including PMWS. As a result no change to the colour specification for PMWS is required.
- however if it is acceptable (to CCMAS) to site two methods then CCS also recommends that the application of method GS2/3-10 (2005) could still be allowed for colour determination of white sugars with a maximum colour of 50 IU as a simpler and more environmentally friendly alternative method at national or regional level.

#### THE 28<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

##### **WHO/FAO Global Strategy on Diet, Physical Activity and Health <sup>6</sup>**

15. The Committee considered the proposed actions contained in the Draft Action Plan for Implementation of the Global Strategy on Diet, Physical Activity and Health prepared by WHO and FAO.<sup>7</sup>

16. The Committee agreed to proceed with the consideration of the revision of the Nutrient Reference Values (NRVs) for vitamins and minerals and to ask the Committee on Food Labelling its advice concerning the revision and extension of the list of NRVs in the Guidelines for Nutrition Labelling to other nutrients associated with increased and decreased risk of non communicable diseases. The Committee agreed that if this reply was positive it would consider new work on the revision and extension of the list to relevant nutrients at its next session.

17. The Committee concluded that there was no support to initiate work for claims for trans fatty acids and include restrictions on both saturated and trans fatty acids in the conditions for comparative claims. The Committee agreed to consider reviewing and re-establishing the Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts at the next session of the Committee based on a document which would provide more explanation on the development of such guidelines.

18. The Commission, in light of the discussion at the Committee on Nutrition and Foods for Special Dietary Uses (see above) and at the Committee on Food Labelling (see Addendum 1 of this document), may wish to provide further guidance on this matter, as appropriate.

<sup>6</sup> ALIMORM 07/30/26, paras 144-156.

<sup>7</sup> CL 2006/44-CAC.

## THE 28<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (CCMAS)

### **Reference to the IUPAC/ISO/AOAC Protocols<sup>8</sup>**

19. The Committee recalled that the 29<sup>th</sup> Session of the Commission, while considering the update of the reference to the International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories, had noted that the Food Control Laboratory Management Recommendations (CAC/GL 28-1995) mentioned the above Protocol together with two other texts adopted by reference in 1997, but not with reference numbers as Codex guidelines, and had asked the CCMAS to clarify whether these texts should be identified separately or under a single reference.<sup>9</sup>

20. The Committee agreed that it would be easier for the purposes of reference to identify each text separately and therefore proposed to the Commission to identify as separate Guidelines the following texts:

- International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories (1995, revised 2006)
- Protocol for the Design, Conduct and Interpretation of Method Performance Studies (1997)
- Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (1997)

21. The Commission is invited to endorse the above proposal of the Committee on Methods of Analysis and Sampling and to replace the Food Control Laboratory Management Recommendations (CAC/GL 28-1995) with the three separate Guidelines.

## **II. MATTER FOR INFORMATION TO THE COMMISSION**

### THE 28<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION

#### **Cooperation with World Organization for Animal Health (OIE)<sup>10</sup>**

22. The 28<sup>th</sup> Session of the Commission noted the recommendation of the Executive Committee that the effectiveness of cooperative arrangements being made between Codex and OIE should be reviewed by the 30<sup>th</sup> Session of the Commission (2007).

23. This issue will be discussed under Agenda Item 14, "Relations between the Codex Alimentarius Commission and other International Organizations" (ALINORM 07/30/9E).

### THE 38<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE (CCFH)

#### **Elaboration of Risk-based Standards for Microbiological Hazards: Enhancing the Process<sup>11</sup>**

24. At the 56<sup>th</sup> Session of the Executive Committee, The Member for South West Pacific introduced a proposal which had been prepared by New Zealand describing the need and approach for enhanced elaboration of risk-based microbiological standards by the CCFH. The Executive Committee welcomed the proposal and recommended that the Commission invite the CCFH to discuss the document in detail.

25. However, the Committee agreed not to consider the document, as this matter was already taken and addressed by FAO/WHO Expert Meeting in Kiel in 2006, the workshop on this specific issue held in Brussels in September 2006 and the Workshop on Re-examination of Performance Objectives as related to quantitative microbiological risk assessment in Bilthoven, the Netherlands (27 November – 1 December 2006).

#### **Management of the work of the Committee on Food Hygiene<sup>12</sup>**

26. The Committee agreed with amendments made to the Proposed Process by Which the Committee on Food Hygiene will undertake its Work by the CCGP and to utilize the amended document for the management of its work..

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<sup>8</sup> ALIMORM 07/30/23, paras 16-17.

<sup>9</sup> ALINORM 06/29/41, paras 197-198.

<sup>10</sup> ALINORM 05/28/41, paras 202-203.

<sup>11</sup> ALINORM 07/30/13, para 9.

<sup>12</sup> ALINORM 07/30/13, paras 15-17.

27. The Committee, noting the recommendation of the CCGP to develop a document on the application of risk analysis policies applied by the Food Hygiene Committee that might include interaction between the CCFH and JEMRA for possible inclusion in the Procedural Manual, referred the proposal for the work on the development of the CCFH Risk Analysis Policies document to the CCFH Working Group on Priorities that would meet the day before the next Session of CCFH.

#### THE 20<sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FATS AND OILS (CCFO)

##### **Linolenic Acid Level for the Standard for Olive Oils and Olive Pomace Oils<sup>13</sup>**

28. The 26th Session of the Commission had adopted the Standard for Olive Oils and Olive Pomace Oils without a level for linolenic acid and with a footnote stating “Pending the result of the IOOC survey and further consideration by the Committee on Fats and Oils, national limits may remain in place”. The Committee considered the comprehensive survey submitted by the International Olive Council (IOC).

29. After an extensive discussion, the Committee agreed to circulate a Proposed Draft Linolenic Acid Level in Section 3.9 of the Standard with a footnote which was discussed during the meeting, as a proposed draft amendment to the Standard at Step 3 for comments and to inform the Commission that it resumed the consideration of the level of linolenic acid in the Standard.

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<sup>13</sup> ALINORM 07/30/17, paras. 91-108 and Appendix VII.

ANNEX**Comments Received in Reply to CL 2006/13-NMW****“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)”**AUSTRALIA

Australia is pleased to make the following comments in response to CL 2006/13-NMW on Health Related Limits for Certain Substances in the *Codex Standard for Natural Mineral Waters (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***

Australia supports addressing the discrepancies that exist between the Codex Standard and the third edition of the WHO *Guidelines for Drinking Water Quality*, especially with regard to health-related parameters.

**b) What amendment is considered necessary?**

Australia supports option (ii) i.e. to align, as necessary, the upper limits in Section 3.2 of the Codex Standard with those values found in the WHO Guidelines.

Australia considers that these parameters need to address the goal of protecting the health of the consumers and ensuring fair practices in the trade of natural mineral waters. Australia notes that national regulations might differ from the WHO guidelines and Codex standard, as they will be set with reference to domestic consumption patterns and health factors (e.g. an appropriate level of protection) which may not be generally applicable or relevant world-wide.<sup>14</sup>

BRAZIL

Brazil thanks for the opportunity to present its comments on the CL 2006/13 - NMW.

It presents suggestions for the contaminants: antimony, copper, manganese and nitrite, considering that the limits proposed by the World Health Organization-WHO are different from the established limits in the CODEX STAN 108-1981, Rev.1-1997, Amended in 2001 - CODEX STANDARD FOR NATURAL MINERAL WATER:

1. **Antimony** - Brazil agrees with the proposed value by WHO of 0.02 mg/L.

Justification:

The WHO studies point out that the toxicological risk happens through inhalation and not through oral ingestion.

2. **Copper** - Brazil proposes the adoption of 2 mg/L established by the WHO.

Justification:

In Brazil there are no data of copper in natural mineral water considering the toxicological level that represents risk to health. Usually the copper is presented in supplying water, which comes mainly from distribution systems.

3. **Manganese** - Brazil suggests to maintain the value of 0.4 mg/L established by WHO.

Justification:

In Brazil there are no data of this contaminant in natural mineral water considering the toxicological level that represents risk to health. The WHO studies point out that the toxicological risk happens through inhalation and not through oral ingestion.

4. **Nitrite** - we propose the value of 0.1 mg/L established in the Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral water and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

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<sup>14</sup> Refer to the Codex Procedural Manual, 15<sup>th</sup> Edition, p 160.

Justification:

Considering: i) that the established limit by WHO refers to treated water originated from distribution systems and not to untreated natural mineral water, whose origins and consumptions are different; ii) the presence of nitrite as an indicator of organic matter; iii) the need to establish maximum values, since the Acceptable Daily Intake of nitrites can overcome the consumption of other food; Brazil proposes the adoption of 0.1 mg/L for nitrite established by the European Community.

**NOTES**

1 - Brazil proposes to maintain the warning sentences recommended by CODEX modifying the value from 2 mg/L to 1.5 mg/L with the following writing:

*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.*

Justification: Considering that WHO establishes the maximum limit of 1.5 mg/L for the fluorine and the CODEX STAN 108-1981, Rev.1-1997, Amended in 2001, does not recommend the maximum value for this substance; on the contrary, it only proposes warning sentences on the labelling of the products with fluorine. Moreover, considering that the fluorine is naturally presented in the mineral water and its presence in the supplying water is, mainly, due to its addition.

**CANADA**

Canada has reviewed the *Codex Standard for Natural Mineral Waters* in light of the 3<sup>rd</sup> Edition of the *WHO Guidelines for Drinking Water Quality*. We note that there are two instances where the Codex standard does not meet the health and safety levels recommended in the WHO Guidelines; specifically the levels for borate (5 ppm vs. 0.5ppm) and manganese (0.5 ppm vs. 0.4). This results in an inconsistency between the two international standards.

However, it should be recognized that the WHO Guidelines apply to “drinking water” whereas the Codex standard applies to a specific type of water - natural mineral water. As such, the consumption patterns of the two different types of water may be very dissimilar. Nevertheless, it is our opinion that a review of the *Codex Standard for Natural Mineral Waters*, in light of the revised WHO Guidelines, is warranted.

**COSTA RICA**

Costa Rica welcomes this opportunity to comment on the health-related limits for certain substances in the Codex Standard for Natural Mineral Waters (CODEX STAN 108 - 1981, Rev. 1 - 1997).

Its principal bottled-water producers follow the natural water specifications of the IBWA (International Bottled Water Association). With regard to the Codex Committee consultation on borate, antimony, copper, nitrite and manganese, it specifies as follows:

1. Borate

Codex sets 5 mg/l as the limit against the WHO limit of 0.5 mg/l. The maximum permitted value for B is 0.3 mg/l in accordance with the recommendation of the IBWA issued in 2000. The maximum level for borate would therefore be 1.5 mg/l, meaning that the Codex limit is too high. **We support the WHO proposal of 0.5 mg/l, or a resetting of 1.5 mg/l for borate or 0.3 mg/l for boron.**

2. Antimony

Codex has a limit of 0.005 mg/l against the WHO limit of 0.02 mg/l. The ICBWA has a maximum permitted value of 0.006 mg/l, **so we support the Codex proposal.**

3. Copper

Codex sets a limit of 1.0 mg/l against the WHO limit of 2.0 mg/l. The ICBWA has a maximum permitted value of 1 mg/l, **so we support the Codex proposal.**

#### 4. Manganese

Codex has a limit of 0.5 mg/l against the WHO limit of 0.4 mg/l. The ICBWA has a maximum permitted value of 0.05 mg/l, **so we request a revision of the analytical information underpinning the established values.**

#### 5. Nitrite

We consider that "short-term exposure" does not apply to drinking water, so reject the WHO proposal and **support the Codex proposal.**

### **EUROPEAN COMMUNITY**

The European Community (EC) appreciates the opportunity to address the Codex Alimentarius Commission's request for comments (CL 2006/13-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.**

The EC 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. The EC is in favour of ensuring a high level of consumer protection and has adopted upper limits for these substances in the EU legislation.

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 may lead to serious difficulties for market access for a significant number of E.U. NMW which have a boron content in the range of 0.5–2 mg/l.

As indicated in the WHO guidelines, it has to be recalled that this value of 0.5 mg/l is only provisional due to the technical difficulties to remove boron from drinking water.

The increase of the limits for nitrites, 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.

In conclusion, if a revision of section 3.2 would appear necessary then the EC considers that a direct reference to the WHO guidelines is not appropriate.

Therefore the EC is in favour of the second option (ii) laid down in paragraph 4 of CL 2006/13-NMW consisting of aligning, where necessary, the upper limits in section 3.2 with the values found in the 2004 edition of WHO guidelines, on a case by case approach for each substance of section 3.2. of Codex STAN 108-1981.

### **NORWAY**

The necessity to harmonise the CODEC STAN 108 with the WHO's guidelines is not considered crucial because the differences are small and can be handled nationally. The differences are not necessary a problem related to health even the intake of mineral water even in Norway has increased. However increased intake of



mineral water and increased trade may be an argument to harmonise the two standards. Different approaches related to limit values in the standard needs to be taken into account if harmonisation is the goal. Different substances, example Fluor, the CODEX STAN 108 has no limit value but has a labelled requirements about warning regarding children. The WHO guideline has a limit value but in a footnote it says national limits should be finally set when national intakes of Fluor from other sources are known. There are discrepancies regarding management of potential hazards between the two standards and this is clearly shown concerning Fluor. Norway has a policy that all foodstuffs should be safe and warning labelling should be avoided.

The EU commission recently ordered a risk assessment from EFSA regarding mineral water and its contents of Boron and Flour. The EFSA concluded that children between age of 1-14 are better protected if the limit value from the WHO guideline was implemented concerning Fluor. For Boron the protection for children were increased with a limit value between the CODEX STAN 108 and the WHO guideline.

The priority concerning the revision of CODEX STAN 108 should be to adjusted the limit values for Fluor and Boron. There are new risk assessments for these two substances and harmonisation would reduce the differences between the standard and the WHO guideline substantially.

## **PARAGUAY**

### **Background**

The Circular Letter invited a) comments on the need to proceed with an amendment to Section 3.2 of the Codex Standard on Natural Mineral Waters in the light of discrepancies between the Codex Standard and the WHO Guidelines and; b) an indication of the amendments considered necessary. Two possible options, among others, were i) and ii).

### **Reply to the two questions asked**

- a) PARAGUAY believes there is a need to amend Section 3.2 of Codex Standard STAN 108 -1981, Rev. 1-1997, in the light of the discrepancies that exist between this standard and the WHO Guidelines.
- b) It suggests option ii): "align, as necessary, the upper limits in Section 3.2 with those values found in the 3<sup>rd</sup> Edition of the WHO Guidelines".

### **Justification:**

PARAGUAY believes there is a need to amend Section 3.2 of Codex Standard STAN 108-1981, Rev. 1 – 1997, as stated above, because the related standards and limits need to be constantly updated, especially considering the recent revision of the WHO Guidelines following painstaking research on its part. We propose option ii) because we believe that aligning the values in the standard will facilitate the use of the standard and avoid recourse to a different document.

## **PERU**

### **COMPARISON BETWEEN THE SUBSTANCE LIMITS OF THE CODEX STANDARD FOR NATURAL MINERAL WATERS (CODEX STAN 108-1981, REV. 1 – 1997, AMENDED IN 2001) AND THE WHO GUIDELINES FOR DRINKING WATER QUALITY (3<sup>RD</sup> EDITION)**

**a. SUBSTANCE:** Antimony

**MAXIMUM PERMITTED LIMIT** 0.02 mg/l

**Peru** supports WHO's maximum permitted limit for the following reason: limit of detection.

**b. SUBSTANCE:** Borate

**MAXIMUM PERMITTED LIMIT:** 0.5 mg/l expressed as boron

**Peru** supports WHO's maximum permitted limit as this corresponds to the limit proposed in the draft Peruvian Health Standards.

c. **SUBSTANCE:** Copper

**MAXIMUM**

**PERMITTED LIMIT:** 2.0 mg/l

Peru supports WHO's maximum permitted limit as this corresponds to the limit proposed in the draft Peruvian Health Standards.

d. **SUBSTANCE:** Manganese

**MAXIMUM**

**PERMITTED LIMIT:** 0.4 mg/l

Peru supports WHO's maximum permitted limit as this corresponds to the limit proposed in the draft Peruvian Health Standards.

e. **SUBSTANCE:** Nitrite

**MAXIMUM**

**PERMITTED LIMIT:** 3 as NO<sub>2</sub> (short-term exposure)  
0.2 (P) (long-term exposure)

Peru lacks information and therefore abstains on technical grounds.

### **UNITED STATES**

The United States offers the following comments on CL 2006/13-NMW, Health Related Limits for Certain Substances in the Codex Standard for Natural Mineral Waters (CODEX STAN 108 -1981, Rev. 1 – 1997).

Document CL 2006/13-NMW proposes to update health-related guidelines in Section 3.2 of the Codex Standard on Natural Mineral Waters to bring them into agreement with revisions in the 3<sup>rd</sup> Edition of the World Health Organization (WHO) Drinking Water Guidelines. Options mentioned include (a) replacing Section 3.2 with language that directly references the WHO Drinking Water Guidelines, as in Section 3.2.1 of the Codex General Standard for Bottled/Packaged Drinking Waters, and (b) updating individual values that have become outdated since the 3<sup>rd</sup> Edition of the WHO Drinking Water Guidelines was published.

The United States supports the proposal to replace Section 3.2 with the language in Section 3.2.1 of the Codex General Standard for Bottled/Packaged Drinking Waters, thereby directly referencing the WHO Drinking Water Guidelines. The U.S. recommends that the replacement language be very specific in referencing "chemical and radiological standards," to avoid referencing microbiological standards.

The U.S. notes that its own health-related standards for bottled/package and mineral waters are not identical to the WHO standards, and that the U.S. may support different domestic standards to protect the health of U.S. consumers. However, referencing the WHO guidelines has the advantage of guaranteeing that health-related limits are not less protective for natural mineral water than for other types of bottled/package drinking water. Using a direct reference will also simplify the work of the Committee by obviating the need to debate individual standards. The U.S. notes that adoption of direct reference does not preclude the possibility of a country raising objections to a particular health-related limit, if issues arise with new limits in the future.

In case there is interest in updating individual values rather than using a direct reference, the U.S. notes that the mercury (0.001 mg/L) and nickel (0.02 mg/L) values cited in the Comparison table in CL 2006/13-NMW do not agree with the updated values found in the WHO Drinking Water Guidelines, 3<sup>rd</sup> Edition ([http://www.who.int/water\\_sanitation\\_health/dwq/gdwq0506\\_ann4.pdf](http://www.who.int/water_sanitation_health/dwq/gdwq0506_ann4.pdf)), namely 0.006 mg/L for mercury and 0.07 mg/L for nickel..

### **VIETNUM**

As a producer of bottled waters, including natural mineral waters, we would like to respond to the Codex Alimentarius CL 2006/13 – NMW requesting comments on the proposal to align the limits for certain substances in Codex Standard on Natural Mineral Waters (NMW), STAN 108 – 1981, Rev. 1 – 1997, with the guideline values listed in the WHO Guidelines for Drinking Water Quality.

We support changes based on advancements in scientific knowledge and food technology that can better ensure consumer safety. However, it is essential that revisions to the *Codex Standard for NMW* takes into account the specificity of natural mineral waters and the treatments that are technologically possible and currently permitted within this Standard.

For the following reasons, it is not feasible to directly align the limits for certain substances, i.e., boron and fluoride, in the *Standard for NMW* with those of the *WHO Guidelines* as it has been done for the *Codex General Standard for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters)*, *Codex STAN 227 – 2001*.

The limits established in the *WHO Guidelines*, and used by the *Standard for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters)* are possible to achieve due to treatments such as reverse osmosis which removes most chemical elements from water. Natural mineral waters can not be treated in such a manner and only the selective separation of certain substances, i.e., iron, manganese, sulphur and arsenic, is technologically possible and currently permitted within the *Standard for NMW*.

For boron, the Standard for NMW currently has a limit of 5 mg/litre while the WHO has established a Provisional guideline value of 0.5 mg/litre. A level of 0.5 mg/l is achieved for drinking waters by the use of reverse osmosis but even with this technology the WHO recognizes that in areas with naturally high levels of boron this limit will be difficult to achieve.

For natural mineral waters, reverse osmosis is not an allowed treatment and currently there is not a selective removal technology available for boron's removal. Thus a limit of 0.5 mg/l for NMWs originating in areas with high natural boron levels is impossible to achieve.

From a safety point of view, limits from several countries show that there is not a consensus on the level of boron in drinking water considered to be safe.<sup>15</sup>

Regarding fluoride, different approaches are taken within the *WHO Guidelines* which list a maximum limit of 1,5 mg/litre and the *Codex Standard for NMW* which imposes no content limit but an obligation to label above a 1 mg/litre content which better informs the consumer of the composition of the product.

As with boron, it is difficult to adopt a stricter limit for a chemical element in natural mineral water when no selective removal procedure is technologically available nor allowed with the *Codex Standard for NMW*.

While CL 2006/13-NMW has initiated discussion on one aspect of the *Standard for Natural Mineral Waters*, we would like to propose for consideration a revision and merging of the two Codex Standards on waters<sup>16</sup> which would result in only one Standard for all packaged waters. Some specificities for NMW would need to be included but having one Standard would be a rationalization of the current two-Standard system. This fusion would assist in ensuring consumer safety by taking into account advances in hygienic practices and available technologies for all bottled waters.

At the same time, the two Codes of Hygienic Practices<sup>17</sup> for waters would also need to be revised into one document.

## **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 carbonated soft drinks and noncarbonated beverages such as juice-drinks, bottled waters, and ready-to-drink coffees and teas. ICBA is pleased to provide the following comments in response to the request on

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<sup>15</sup> The limits set for boron in drinking water by several countries: European Union *Directive 98/83/EC* - 1.0 mg/l, Australia *Australian Drinking Water Guidelines*, 2004 - guideline concentration of 4 mg/l, USA *21 CFR 165.110* requirements for bottled water, and EPA Standards for drinking water do not include a limit for boron.

<sup>16</sup> Standard for Natural Mineral Waters, STAN 108-1981, Rev.1-1997, Standard for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters), STAN 227 – 2001

<sup>17</sup> Recommended International Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters, CAC/RCP 33-1985. Code of Hygienic Practice for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters), CAC/RCP 48-2001

information on Health Limits for Certain Substances in the Codex Standard for Natural Mineral Waters (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**

ICBA supports addressing the discrepancies that exist between the Codex Standard and the WHO Guidelines, especially when it relates to health-related parameters.

**b) What amendment is considered necessary**

- (i) Replace current Section 3.2 of the Codex Standard with the text that appears in Section 3.2.1 of the Codex General Standard for Bottled/Packaged Drinking Waters (i.e. direct reference to the WHO guidelines);

ICBA does not support this option due to the special nature of natural mineral waters.

- (ii) Align, as necessary, the upper limits in Section 3.2 with those values found in the 3<sup>rd</sup> Edition of the WHO Guidelines.

ICBA would support this option but believes that a careful consideration is necessary first to evaluate if the WHO guideline values for these parameters can be met in natural mineral waters. Levels of some elements may be naturally higher in these waters and derogations may be needed since no approved treatments exist for some, e.g., boron and fluoride. Approved and authorized treatments must be available to meet the aimed standard before it is adopted.

We also note that the WHO guideline level for nitrite (0.2 mg/L for long-term exposure) is ten times higher than the limit in the Codex standard (0.02 mg/L). Nitrite also can occur naturally. We suggest considering defining maximum limits that are health-related and separating them from quality indicators. The health-related limits should, in principle, be as close to the WHO guideline values as achievable but a due consideration should be given to the differences between intakes from drinking water and natural mineral water.

**ICBWA**

The International Council of Bottled Water Association is pleased to provide preliminary thoughts in response to the request of May 2006 for comments on the Health Related Limits of Certain Substances in the Codex Standard for Natural Mineral Waters.

The International Council of Bottled Water Association (ICBWA) is the worldwide federation of the bottled water industry trade associations. The Federation is composed today of six “Regional Associations”, each representing a geographical territory. ICBWA membership represents 1,567 companies throughout the world.

• ABWA	Asian and Middle East Bottled Water Associations (Asia)
• ABWI	Australasian Bottled Water Institute (Australia/New Zealand)
• EFBWA and EBWA jointly representing Europe	European Federation of Bottled Water Associations and European Bottled Water Association (Europe)
• IBWA	International Bottled Water Association (United States)
• LABWA	Latin America Bottled Water Association (Latin America)

The mission of the ICBWA is for its members to “further strengthen and promote the global bottled water industry by supporting and adhering to rigorous international product quality standards, by facilitating learning and providing a flow of information about the bottled water industry, among its members, international agencies and stakeholders.”

The ICBWA would like to commend the Secretary of the Codex Alimentarius Commission for seeking comments on this matter

1 – With regard to Health Related Limits, ICBWA favors a careful consideration of the types of special conditions and limits which may be applicable to Natural Mineral Waters.

While ICBWA agrees it is an opportune time to align *as necessary* the health related limits applicable to Natural Mineral Waters with the values of the WHO Drinking Water Guidelines, ICBWA believes that it is particularly important to carefully consider each substance on a case-by-case basis, due consideration being given to the fact, that the level of consumption of Natural Mineral Waters may not necessarily always be equivalent to that of Drinking Water. It is possible that in certain specific cases, the health related limit for a given substance may be higher for Natural Mineral Waters than for Drinking Water.

Furthermore, it is important to note the specificity of Natural Mineral Water, characterized by its constant and specific mineral composition, reflective of the natural specific geology of the aquifer from which the water is collected.

Therefore, it is important that in the newly updated standard, Natural Mineral Waters be eligible for specific waivers from the WHO Drinking Water Guidelines values, based on clearly and scientifically substantiated rationales, including, but not necessarily limited to, specific consumption patterns. The specific cases and types of waivers acceptable for Natural Mineral Waters will need to be discussed and agreed upon by the Codex Committee.

2 – The ICBWA suggests that it might be an opportune time to merge the Natural Mineral Codex into the General Standard for Bottled/Packaged Drinking Waters.

The Background section of the Circular Letter of May 2006 suggests that there is an apparent lack of coherence between the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981) and the General Standard for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) (CODEX STAN 227-2001), with regard to health related limits. In order to address this observation, the ICBWA suggests that the two standards be merged into a single General Standard for Bottled/Packaged Drinking Waters.

The ICBWA considers that inclusion of Natural Mineral Waters into the General Standard for Bottled / Packaged Drinking Waters would:

- a) Facilitate the use of the standards, and;
- b) Be in line with the goal to reduce the number of standards within Codex.

3 – Codes of Hygiene

In addition, on a separate but related subject, the merging of the standards offers the opportunity for the consideration of a consolidation of the current Codes of Hygienic Practices applicable to both Bottled/Packaged Drinking Water and Natural Mineral Water, namely:

- The Code Of Hygienic Practice For Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters) – *CAC/RCP 48-2001*
- The Recommended International Code Of Hygienic Practice For The Collecting, Processing And Marketing Of Natural Mineral Waters – *CAC/RCP 33-1985*

It is noteworthy that the 2001 Code of Hygienic Practice for Bottled/Packaged Drinking Waters incorporates the most recent developments in food safety management including the concept of Hazard Analysis Critical Control Points (HACCP). Meanwhile, the Natural Mineral Water Code of Hygiene was completed in 1985 and needs to be updated, a task easily performed by merging its remaining pertinent provisions into the Code of Hygienic Practice for Bottled/Packaged Drinking Waters.

The ICBWA appreciates the opportunity to provide comments on these important matters and would welcome any questions that you may have on the above.