codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/FH 99/3**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED /PACKAGED DRINKING WATERS (OTHER THAN NATURAL MINERAL WATERS) AT STEP 6

GOVERNMENT COMMENTS

Following Governments: Belgium, Brazil, Costa Rica, Denmark, Finland, Indonesia, Japan, Mexico, Paraguay, Peru, Poland, United Kingdom, and the United States of America; and International Organisations; Consumers International, International Soft Drink Council, and UNESEM-GISMES submitted comments in response to the CL 1999/9 - FH.

THE NECESSITY OF INCLUSION AND THE DEFINITION OF COMMERCIAL STERILITY IN THE DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED /PACKAGED DRINKING WATERS (OTHER THAN NATURAL MINERAL WATERS.

BELGIUM

- The rationale for this inclusion is not presented and is not clear.
- The inclusion of that concept may fundamentally modify the document which is already at a very advanced step.
- The signification of the term “sterility” is worldwide accepted and does not need any further clarification or definition.
- The application of the concept of “commercial sterility” can not be generalised to bottled/packaged waters because some of these packaged waters, like spring waters, contain naturally a very small amount of harmless microorganisms. The natural occurrence of these microorganisms is controlled through protective measures of the source and it’s monitored by microbiological testing. The safety and quality of these non-sterile waters are accepted and proved.

The conclusions are that this inclusion is not justified and is not necessary within the framework of this code.

BRAZIL

We agree with the inclusion of the definition on commercial sterility in this draft code.

FINLAND

Finland does not disagree the necessity for the definition of commercial sterility in general. If the definition is made and included in this Code, the appropriate treatment mentioned in this definition of commercial sterility also needs a referee to risk analysis

JAPAN

If the draft Code would include "commercial sterility", we think that the expert consultation ought to be held to discuss of what is the problems as viable micro-organisms (including spore) in bottled/packaged drinking water which is poor in nutriment, in view of the public health.

POLAND

We Suggest including the definition of commercial sterility in the Draft Code of Hygienic Practice for Bottled/packed drinking waters (other than natural mineral waters).

MEXICO

We have no comments on the definition of commercial sterility, however, it is considered important and the definition has an impact on this draft code, that is to say it should be used.

UNITED STATES OF AMERICA

The United States agrees with the incorporation into Section 2.3 of the Code, Definitions, of the definition of *Commercial Sterility* as presented in the Circular Letter with the understanding that the following sentence will be added to the end of the Introduction Section of the Code.

"Should the production of commercially sterile bottled waters covered under this code be deemed necessary for the preparation of infant formula, for the direct consumption by infants, or for other reasons, the definition of commercial sterility given in Section 2.3 of this Code should apply."

It is important to note that bottled water is normally not a sterile product. The addition of the above noted sentence to the Introduction section of the Code will provide clarification as to circumstances when commercial sterilisation ought to be considered.

INTERNATIONAL SOFT DRINK COUNCIL

Having studied the draft Code, we cannot find any indication of where the definition for "commercial sterility" would be placed in the Code. Would the definition be limited to water intended for use in infant feeding or for immuno-compromised persons? Or is the definition intended to apply to water in general.

If the definition is intended for labeling of bottled water for use in infant feeding and immuno-compromised individuals, then we have no comment except to point out that the definition as written contradicts the microbiological criteria included in Appendix 2, e.g. heterotropic bacteria would not be allowed under the proposed definition for commercial sterility. Furthermore, there is no criteria for commercial sterility in Appendix 2. Appendix 2 allows for a certain number of heterotropic bacteria.

If the definition is intended to apply to all bottled water, then we are opposed to the definition as written since it would be difficult to meet by most bottled waters. Complete sterility is neither easily achieved nor necessary for bottled water intended for the general consuming public. We would propose a modified definition for "commercial sterility" that could apply to all bottled waters (not intended for infant feeding or for immuno-compromised individuals) as follows: **"commercial sterility" means the condition achieved by the application of appropriate treatment to render the bottled water free of viable micro-organisms (including spores) of public health significance capable of growing in the product at normal non-refrigerated conditions at which the product is**

likely to be held during distribution and storage. Absence of microorganisms shall be determined with appropriate microbiological tests.

UNESEM – GISEMES

The need to include a definition of "commercially sterility" is not warranted, given that the microbiological criteria set out in Appendix II of the Code are sufficient to guarantee the quality of packed water and to preserve the health of the consumer.

In addition, any definition of "commercially sterility" anticipates that "the absence of viable micro-organisms must be determined with appropriate microbiological tests". Given that, to our knowledge, no appropriate microbiological tests for determining the absence of viable microorganisms in bottled water exists at present, this provision remains theoretical.

GENERAL COMMENTS

BELGIUM

1. The document should be more explicit or more clear about the existence of naturally-protected sources that produce drinking water naturally without requiring any treatment this is the case i.e. for spring water in Europe). It should emphasise more clearly that the safety of bottled water produced by these protected sources can be guaranteed by the appropriate combination of control measures (including the protection of natural resources) without necessarily having to resort to treatment.

2. There are some inconsistencies between the draft code and the draft standard for bottled/packaged waters and these should be suppressed, more particularly on the following points:

- The definitions should be identical, in particular the definition of bottled/packaged drinking waters.
- The Draft Standard on bottled waters contain-health-related limits for certain substances as well as some hygiene recommendations. Logically, these should be included in the present code and not in the Standard. The Standard should only deal with definitions and quality criteria of the end products

3. Except for the last sentence of section 5.4.1.1 that has been discussed during the last meeting no other part of the document should be put into brackets (i.e. in sections 3.3.2.2 and 5.1.1), because the Committee didn't convene on these new brackets.

BRAZIL

The text is lacking some numbers items (4.1; 5.2 and 5.3).

Spanish Version -There are some confusion about hazard (peligros, in Spanish) and risk (riesgos, in Spanish). Ingredient definition is very confuse in Spanish. In 2.1, the translation for "processing" has another meaning (elaborar= elaborating not processing).

COSTA RICA

The National Committee of Bottled Water of Costa Rica does not have any comments concerning these documents.

POLAND

We also suggest that demineralized water is not recommended for human consumption every day.

SOUTH AFRICA

We will abstain from comment for the moment.

UNITED STATES OF AMERICA

The United States supports the code as developed and recommends progressing it through the Codex Step Procedure.

INTERNATIONAL SOFT DRINK COUNCIL

Although we were not specifically asked to comment, we believe that this Code of Practice should be held at Step 7 or Step 6 until the draft Codex Standard for Bottled (Packaged) Waters Other Than Natural Mineral Waters is at the same step. It is difficult to comment on a Code of Practice when the corresponding standard is only at Step 3 in the Codex process.

SECTION 1. – INTRODUCTION

BELGIUM

1. It is not advisable to highlight parasitic protozoa because other microbiological contaminants (such as Pseudomonas) are equally important for immuno-compromised consumers.

The explicit references to specific microbiological organisms should be eliminated and paragraph 3 of the introduction should be simplified as follows:

"The information to consumers regarding the control measures the water has received, such as the protection of natural resources and treatments (i.e. boiling, pasteurization, distillation, reverse osmosis filtration, absolute and one micron or submicron filtration,…)"

2. The last paragraph should be suppressed to take into account the suggestion of the delegation of Argentina (point 38 ALINORM 99/13A), that is: the best place for the information regarding the use of water in infant formula is in the labelling of infant formula and not in the labelling of packaged waters.

BRAZIL

Second Paragraph:

Option 1 - to include the term "in all consuming points", as follows: " microbiological, chemical and physical safety of their product in all consuming points, to the extent previously thought possible..", or

Option 2 - Change the word "many" for "some"(' public and private waterworks may not be able, in some instances or under all circumstances to guarantee..")

Justification According to 5.11, waters intended for bottling should meet all public drinking water standard. The proposition aims at giving more coherence to the text, since the drinking water system may be in accordance with the Guidelines for Drinking Water Quality (WHO), we are asking to include "in all consuming points" in the Introduction or to change "many" for "some".

UNITED KINGDOM

Third Paragraph, sentence 3, typo should read "inactivate"

UNITED STATES OF AMERICA

Third paragraph, fifth line, the word Ainactive≅ should be changed to Ainactivate≅.

Additionally ii the fourth paragraph for purposes of better wording, delete the phrase Athe restrictions of their use of infant feeding≅, and replace it with Awhether or not they are suitable for infants and inclusion in infant formula.

Bottled drinking water products of particular chemical composition may need to provide information concerning their proper consumption and/or have directions regarding whether or not they are suitable for infants and inclusion in infant formula."

CONSUMERS INTERNATIONAL

Consumers International notes that the issue of protecting consumers from parasitic protozoa in drinking water is an important public health challenge, particularly since tests for these pathogens are often unreliable. While all consumers are at risk from these pathogens, immunocompromised consumers are at a greater risk. Many immunocompromised consumers are specifically directed by their physicians or other health authorities to consume only waters that have been collected or treated in such as way as to ensure that they are free from these pathogens. However, this is difficult to do when such information is not available to the consumer on the product label. The Committee has discussed this important public health issue at several sessions but has not yet come to resolution. As noted in the CL, earlier drafts of the Draft Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters) contained language in Section 9 of the Code, Product Information and Consumer Awareness", attempting to address this issue, but this information was moved to the introduction to accommodate the views of several delegations. The current draft in the Annex of CL 1999/9-FH further weakens this information.

Consumers International also notes that at the 31st session of the Committee, the Delegation of Argentina proposed that information regarding the appropriate/safe use of water to prepare infant formula should be a consideration for the labeling of infant formula.

Consumers International urges the Committee to:

(1) recognise the public health nature of these two issues and thus their appropriateness for inclusion in a Code of Hygienic Practice,

(2) refer the issues to the Committee for Food Labelling for advice on whether and how the labels for bottled/packaged waters and/or infant formula can address these issues, and

(3) advance this important document to step 8, after amending the last two paragraphs of the introduction, as follows (new wording IN CAPITALS):

"The contamination of water with parasitic protozoa is a serious concern all consumers, particularly the immunocompromised, ESPECIALLY SINCE TESTS FOR SOME PATHOGENS, PARTICULARLY PARASITIC PROTOZOA, ARE UNRELIABLE. It may be helpful to consumers to supply information ON THE LABEL regarding control measures the water has received, AND/OR WHETHER THE PRODUCT CAN BE SAFELY CONSUMED BY IMMUNOCOMPROMISED INDIVIDUALS. Protection of natural resources and treatments such as boiling, pasteurization, distillation, reverse osmosis filtration, absolute one micron or submicron filtration are treatments used to guard against, inactivate or remove possible water contaminants such as the oocysts of Cryptosporidium parvum, Cyclospora cayetanensis, and Toxooplasma gondii and cysts of other waterborne parasitic protozoa such as Giardia (lamblia) intestinalis, and Entamoeba histolytica.

Bottled drinking water products of particular chemical composition may need to provide information concerning their proper consumption and/or have directions regarding the restrictions of their use for infant feeding. SUCH INFORMATION CAN HELP TO ADDRESS THE CONCERN FOR INFANTS, PARTICULARLY 0 TO APPROXIMATELY 6 MONTHS OF AGE, THAT INGESTION OF WATER MAY CAUSE HYPONATREMIA. THE INFORMATION PROVIDED CAN ALSO ADDRESS THE POTENTIAL CONFUSION BY PARENTS REGARDING BOTTLED DRINKING WATERS INTENDED FOR INFANTS AND ELECTROLYTE SOLUTIONS INTENDED FOR THE MAINTENANCE OF AN ELECTROLYTE LEVEL DEPLETED BY DIARRHOEA OR VOMITING."

INTERNATIONAL SOFT DRINK COUNCIL

We recommend deletion of the entire second paragraph that begins "Aside from water shortages, real……" including the second sentence. In fact the second sentence tends to undermine the quality of public and private waterworks. This is unnecessary and untruthful and does not add to the Code in any way.

We also see no need for the sentence in the third paragraph that states that "It may be helpful to consumers to supply information regarding control measures the water has received;" nor for the sentence in the last fourth paragraph that states that "Bottled drinking water products of particular chemical composition may need to provide information concerning their proper consumption and/or have directions regarding the restrictions of their use for infant feeding." If there is a need for to supply this type of information, then the information should be incorporated at the appropriate place in the Code and not be mentioned in a general way in the Introduction.

Generally, the Introduction should be short and state the purpose of the Code. Extraneous information need not be included.

SECTION 2.1. – SCOPE

BELGIUM

A sentence has been added : "Mineral waters other than natural mineral water are covered by this Code." There is no need to mention or to focalise on one particular type of water since other types (spring water, artesian water, ...) are also covered by the Code. It would be more correct to state that this Code covers all the bottled waters other than natural mineral waters. The latter are, indeed, well defined.

UNITED STATES OF AMERICA

The last sentence can be omitted since this wording is redundant with wording in Section 2.2, Use of the Documents.

UNESEM-GISEMES

The scope of the Draft Code was expanded to include "mineral water". The extension of the scope must be eliminated.

During its Sixth Session, the Codex Committee on Natural Mineral Waters agreed to send a circular letter to the Governments requesting their comments before February 1, 2000 on the need to include a definition of mineral water in the Draft Standard for Packed Waters Other than Natural Mineral Waters. If a decision is not reached during the 7th Session of the Codex Committee on Natural Mineral Waters, which will be held in October 2000, the Draft Code can not cover mineral waters.

SECTION 2.2. - USE OF THE DOCUMENT

DENMARK

A reference can be included also to the document "Proposed Draft General Standard for Bottled/Packaged Waters other than natural mineral waters" being discussed in the Codex Committee on Natural Mineral Waters.

UNITED STATES OF AMERICA

This section can be reworded adding a reference to the HACCP Annex in the first sentence and deleting the current last sentence. This change removes redundant wording. However, a new last

sentence to this section should be added referencing the *Principles for the Establishment of and Application of Microbiological Criteria for Foods*. The revised section would then read as follows.

> AIt is emphasised that this document must be used in combination with the ***Recommended International Code of Practice: General Principles of Food Hygiene*** **(**CAC/RCP 1-1969, Rev. 3-1997) including the HACCP Annex, whose paragraph numbers and section headings it maintains, supplementing or specifically applying them to bottled/packaged drinking waters (other than natural mineral water). This Code should also be used in combination with the ***Principles for the Establishment of and Application of Microbiological Criteria for Foods*** (CAC/GL 21-1997).≅

SECTION 2.3. – DEFINITIONS

BRAZIL

We consider not necessary to include definition of FOOD.

In Food handling, we suggest to suppress "bottling" and "of bottles", remaining: "…processing, packing, storing ".

In Food Hygiene definition, changes as follows: "…the safety and suitability of food, including bottled drinking water…". It is interesting to discuss the necessity of including "ingredients". Perhaps it is sufficient to indicate CAC definitions.

Justification - These definitions are already existing in CAC definitions. We wonder if these definitions are only complementary to the existing ones or are new ones. As new ones, they do not add information to the existing ones in CAC.

BELGIUM

1. Delete The definition of "Food hygiene", because it is already included in the Code of Practice - General Principles of Food Hygiene.
2. the following words of the definition of ground water have been suppressed without any reasons: " and thus may be safe and suitable for direct consumption at the point of origin". This part of the definition should be reintroduced because it takes into account a fundamental characteristic of protected ground water.

PARAGUAY

In the definition for *Ground Water*, it should specify that the *Ground Water* may come from confined waters, which cannot be contaminated, or from partially confined waters, which may be contaminated.

PERU

There should be some uniformity in the use of the term "bottled/packaged water", which is used indiscriminately in the text.

POLAND

According to *definition of Food* we propose to declare the date of minimum durability for bottled/packed drinking water (on a basis of recommendations concerning *Food Labelling, point 4.7*).

UNITED KINGDOM

The definition for bottled/packaged drinking water(para2.3) differs to the definition for packaged waters in the General Draft Standard for Bottled/Packaged water Other Than Natural Mineral Water. The two definitions should be consistent.

INTERNATIONAL SOFT DRINK COUNCIL

The definitions used in the Code should be aligned with the definitions used in the Standard for Bottled Waters Other Than Natural Mineral Waters.

SECTION 3. - PRIMARY PRODUCTION

BELGIUM

Add to the second paragraph : "and to determine the possibilities and conditions for making the water safe and suitable for consumption". This sentence usefully completes and gives the rationale for that requirement.

UNITED KINGDOM

Second sentence, suggest modify to "…it's chemical composition, microbiological quality and physical and radiological characteristics should be established over a period "

UNITED STATES OF AMERICA

Second paragraph, first line, change Autilizing≅ to Ausing≅ as better word usage.

SECTION 3.1.1. - PRECAUTIONS IN SELECTING A RESOURCE SITE

BELGIUM

This new heading does not adequately reflect the contents of section 3.1.1, in particular the protective measures recommended within the protection zone. We suggest the following wording of the heading "Precautions and preventive measures for the resource site."

DENMARK

"Disposal of pollutants such as microorganisms, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic and inorganic substances should be controlled…". It should be added to the text: "…and avoided.."

UNITED KINGDOM

Sentence 4, suggest modify to "…be controlled. Drinking water resources should not be in "

UNITED STATES OF AMERICA

First paragraph, first sentence, add the word Afrom≅ after Awater≅ for purposes of correct grammar.

Second paragraph, second sentence, divide the sentence into two sentences as follows for purposes of better grammar.

> ADisposal of pollutants such as microorganisms Ψshould be controlled. Drinking water resources should not be in the path of potential sources of underground contamination Ψsolid waste disposal sites.≅

SECTION 3.2.1.1 – CONSIDERATION FOR GROUND WATER SUPPLIES

PARAGUAY

The parenthesis located in the middle of the sentence (including microbial) should be eliminated, resulting in the following sentence:

It is not easy to distinguish between protected and unprotected ground water. Ground water supplies should be tested regularly for the constancy of biological, chemical and radiological characteristics.

POLAND

We suggest that bottled/packed drinking water should be collected from protected ground supplies only.

BELGIUM

1. The first sentence ("It is not easy to distinguish between protected and unprotected ground water") should be deleted because it is confusing regarding the differences between protected safe ground water and unprotected ground water. It imparts no positive information and is rather pointless.

2. Inadequate exploitation of a source may disturb the aquifer and bring about contamination. The following sentence should be added: "The conditions of exploitation of a source (i.e. maximum volume of extracted water) should be determined in order to avoid disturbing the watershed."

MEXICO

We suggest the following modification: If any contamination is detected, bottled water production must be temporarily interrupted until the water quality is adjusted to the established parameters.

Justification: If contamination is detected, certainly corrective actions will be taken, however, these can be simple or complex, in the later case these could take more time, even to take effect. Complying with this (unmodified text), what may happen is production could continue, even if the safety measure has not taken effect and not necessarily due to ineffectiveness. With the suggested text there would not be a problem, since in case the measures are simple, the correction will be very quick.

SECTION 3.2.2 – PROTECTION OF SURFACE WATER SUPPLIES

BELGIUM

1. Treatments of the water are not part of the protective measures of the supplies. The second sentence about treatments should be moved to section 5.

2. The need for testing comes from the high variability in composition and quality of surface waters. That should be indicated for clarity, i.e. by the following words: "Surface waters may be highly variable in composition and quality. Supplies should thus be tested frequently.'

UNITED KINGDOM

Suggest modify to "…toxic, pathogenic, and aesthetic contaminants"

SECTION 3.3.1.1 – AT POINT OF ORIGIN

UNITED KINGDOM

Sentence 2,suggest modify to "The extraction or collection of water intended for bottling should be conducted in a hygienic manner to prevent any contamination or risk of pollution."

SECTION 3.3.1.3 – MAINTENANCE OF EXTRACTION OR COLLECTION FACILITIES

BRAZIL

We would like to know if "chamber" include "water case (bin, boxing)" If not we suggest to explicitate this in 3.3.2 (Storage and transport of water intended for bottling), since this will be the mean the industry may use for water pression and rate of flow.

UNITED KINGDOM

Line 4, suggest modify to "…maintenance activity. Wells should also be disinfected when testing shows the presence of indicator organisms…".

SECTION 3.3.2.1 – REQUIREMENTS

UNITED KINGDOM

Add "Such equipment should also be cleaned and disinfected before first use."

SECTION 3.3.2.2 - USE AND MAINTENANCE

BRAZIL

We indicate to take off the hooks and to include "chambers, water case (bin, boxing)".

INDONESIA

Proposes that containers and conveyances particularly in bulk transport should be used only for transporting water intended for bottling.

Therefore the draft should be written as follows:

Conveyances and bulk containers for transporting water intended for bottling should be kept in appropriate state of cleanliness, repair and condition. Containers and conveyances, particularly in bulk transport, should be used only for transporting water intended for bottling. When this cannot be achieved, conveyances and bulk containers should be used exclusively for food transportation and must be cleaned and disinfected as necessary to prevent contamination.

MEXICO

Mexico does not consider it advisable to allow the use of the bulk water conveyance to transport other foods, as pointed out in the item 3.3.2.2.

PARAGUAY

This country is in agreement with this item, but with the following clarification:

Conveyances and bulk containers for transporting water intended for bottling should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances, particularly in bulk transport, should preferably be used only for transporting water for bottling. When this cannot be achieved, *such as in cases of emergency or catastrophe*, conveyances and bulk containers should be used exclusively for food transportation and must be cleaned and disinfected….

UNITED STATES OF AMERICA

First sentence, change AΨcleanliness, repair and condition ≅ to AΨcleanliness and repair.≅ The former wording is redundant.

SECTION 4.1

UNITED KINGDOM

Has this been omitted?

SECTION 4.2 – PREMISES AND ROOMS

UNITED KINGDOM

Line 3, suggest delete “production of”.

SECTION 4.3.1 - WATER SUPPLY NOT INTENDED FOR BOTTLING

MEXICO

First paragraph; last sentence, "The standards of potability should not be less than those contained in the latest edition of the Guidelines for Drinking Water Quality (WHO)." We suggest: "The standards potability standards should not be inferior to those indicated in each country’s legislation", on the grounds that the WHO Guidelines include parameters for a large number of substances which depending on the conditions of each country may or may not produce contamination. In addition, many of these do not effect public health.

UNITED KINGDOM

To avoid confusion suggest this paragraph is re-drafted in two sections; one where potable water should be used; and another where non-potable water may be used.

INTERNATIONAL SOFT DRINK COUNCIL

In the second paragraph, the sentence “Water not intended for bottling should be carried in completely separate lines from water intended for bottling,” should be a requirement only if the water not intended for bottling does not originate from a drinking water system. This should be clarified in the Code. Water can enter the establishment from one source, and then be diverted into separate lines, one for bottling and the other for other purposes.

SECTION 5.1 -. CONTROL FOR FOOD HAZARD

BELGIUM

The word "steps" in the beginning of the second sentence is not appropriate in the context. Replace by i.e. "Measures".

INTERNATIONAL SOFT DRINK COUNCIL

The statement “Steps must be taken at all stages of processing to ensure that contamination of water intended for bottling does not occur, including the formation of toxic treatment by-products (particularly bromates) in accordance with relevant WHO guidelines,” is not realistic since use of certain treatments leads to the unavoidable formation of some toxic treatment by-products at very low levels. However, what should be stated is that “Steps must be taken ***to limit*** at all stages of processing the formation of toxic treatment by-products (particularly bromates) so as to comply with relevant WHO guidelines.

SECTION 5.1.1. - CONTROL MEASURES FOR WATERS INTENDED FOR BOTTLING

BELGIUM

1 A part of The second paragraph (after the words "toxic substances") has been omitted.

2 The first sentence of paragraph 4 should be made more explicit as follows: “A hazard analysis of the water for pathogenic micro-organisms or harmful substances, in the context of application of the HACCP principles, should be the basis for determining the appropriate combination of control measures for waters intended for bottling during processing in order to reduce, eliminate or prevent potential microbiological, chemical and radiological contamination.”

3. The last sentence of paragraph 7 appears to be too restrictive. It should be rewritten as follows: "... and there must be no formation of toxic by-products in a concentration of health concern according to WHO guidelines".

DENMARK

Denmark find it is a problem that there may be applied a number of chemical and physical processes like chemical disinfection and without any restrictions to bottled water or bottled drinking water. Denmark proposes that use of antimicrobial agents should be very restricted and follow the requirements for food additives.

FINLAND

In 5.1.1 control measures for waters intended for bottling is discussed. Finland suggest that in addition to mention the HACCP as a method to identify and control the hazards, also the risk analysis including option assessment and option implementation should be mentioned when application of chemical process to treat the water intended for bottling is discussed. Finland found this clarification to be important in order to courage the industry to consider more deeply the use of other measures than disinfection to reduce the microbiological hazards and also to emphasise that when the decision to use or not to use disinfection is made, both microbiological and chemical risk assessment is needed.

PARAGUAY

We are in favour of the removal of the brackets in the sentence that reads:

For documentation of an approved source, firms using water from drinking water systems….

In the second paragraph of Item 5.1.1 the following modifications are suggested in order to make the sentence clearer:

No waters intended for bottling or other ingredients should be accepted by an establishment if it is known to contain infective stages of human parasites, undesirable micro-organisms, excessive residues of pesticides, or toxic substances. *Waters intended for bottling should be of a quality such as treatment of that water during processing results in safe bottled drinking water….*

In the third paragraph of Item 5.1.1, we agree with the removal of the bracketed section in the hazard analysis sentence.

PERU

Last paragraph, line 1, It says “When necessary, treatment …” and the text continues. It is recommended that the phrase “When necessary, treatment” be modified by having the paragraph start from “The treatment …” and continuing with the text.

POLAND

We popose that treatment of waters intended for bottling may include such processes as ultraviolet radiation, ultrafiltration, aeration and bed filtration.

UNITED KINGDOM

Paragraph 2 modify to "…stages of human parasites, pathogenic and undesirable micro-organisms, excessive residues of pesticides or other toxic substances".

Paragraph 4: suggest modify to " Analyses of the water supply over a sufficient period for pathogenic micro-organisms, harmful substances and substances affecting aesthetic quality should be..".

Paragraph 5: include "coagulation" in both lists of treatments and suggest modify end of last sentence to " , and concentration of toxic by-products of health concern must be kept below the relevant WHO guideline values".

UNITED STATES OF AMERICA

Second paragraph, a significant portion of this paragraph was omitted in the process of preparing the CL document. The full paragraph should be the following:

> A**No waters intended for bottling or other ingredients should be accepted by an establishment if it is known to contain parasite stages infective for humans, undesirable micro-organisms, pesticides, toxic substances or matter that is decomposed or extraneous which would not be eliminated or reduced to an acceptable level by normal treatment and/or processing. Where appropriate, specifications for ingredients should be identified and applied. Ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory testing should be done to establish fitness for use. Only ingredients, which meet the above parameters, should be used.**@

INTERNATIONAL SOFT DRINK COUNCIL

The final statement "All treatments of water intended for bottling should be carried out under controlled conditions to avoid any type of contamination, and there must be no formation of toxic by-products of health concern in accordance with relevant WHO guidelines," is again unrealistic. We recommend rewording this sentence as follows: "All treatments of water intended for bottling should be carried out under controlled conditions to avoid any type of contamination, and the formation of toxic by-products of health concern should be limited so as to comply with relevant WHO guidelines."

SECTION 5.4 - PACKAGING

UNITED KINGDOM

Replace "sanitizing" with "disinfecting" throughout.

SECTION 5.4.1.1 - WASHING AND SANITIZING OF CONTAINERS

BELGIUM

The third sentence is unclear. It could be improved as follows: "When necessary, disposable containers must be washed and sanitized".

PARAGUAY

We suggest the following reading:

Reusable containers, *not including recycled containers*, should be washed and sanitized in an enclosed system and positioned within the processing plant so as o minimize post-sanitizing contamination prior to filling and sealing. Disposable containers may be ready for use without prior washing and sanitizing. Determine if this is the case; if not, treat as carefully as reusable containers.

PERU

First sentence states that “Reusable containers should be washed and sanitized in an enclosed system and positioned within the processing plant so as to minimize post-sanitizing contamination prior to filling and sealing.” It should say: “Reusable containers should be washed and sanitized in an enclosed system and positioned within the processing system with the intention of minimizing post-sanitizing contamination prior to filling and sealing.”

Second line after period it is suggested that the following sentence be substituted:

It says, “Disposable containers may be ready for use without prior washing and sanitizing. Determine if this is the case; if not, treat as carefully as reusable containers.”

It should say, “It is recommendable to rinse the inside and outside of all disposable containers with the same potable water used for bottling, in order to ensure their safety.”

This proposal is justified due to the fact that previously unused disposable containers may contain material residues and undesirable odors, which is why it is a common practice to rinse them prior to their use.

UNITED STATES OF AMERICA

Second sentence, insert the following words between Acontainers≅ and Amay≅, if produced on site immediately prior to filling,". The second sentence would then read as follows.

> ADisposable containers, if produced on site immediately prior to filling, may be ready for use without prior washing and sanitizing.≅

This change helps to ensure the hygienic nature of disposable containers.

SECTION 5.4.1.2 FILLING AND SEALING OF CONTAINERS

PARAGUAY

In addition to controlling and monitoring the presence of dust, dirt, micro-organisms and excessive moisture in the air, we suggest including *other live organisms*, referring to insects.

SECTION 5.4.1.3. - PRODUCT CONTAINERS AND CLOSURES

POLAND

We suggest that the reusable containers should be made of glass only.

UNITED STATES OF AMERICA

Insert the following sentence between current sentences one and two.

> AThe integrity of the closure (container seal) should be such that recontamination of the water during distribution and storage does not occur.≅

This provision is important to ensure the safety of the product during distribution and storage.

APPENDIX 1.

UNITED STATES OF AMERICA

We recommend deleting this Appendix. Section 2.2 already refers to the use of the *Recommended International Code of Practice: General Principles of Food Hygiene* including the HACCP Annex. Since this Appendix merely asks the user of this Codex to refer to the document, this Appendix is redundant and should be deleted. There would be a consequential change to renumbering Appendix 2 as Appendix 1.

APPENDIX 2.

BELGIUM

1. The text should make it clear whether the E-.coli criteria and the HPC and turbidity parameters are applicable for control by the authorities or by the producers or by both. E. Coli may be used for regulatory purposes. HPC and turbidity parameters must be considered as indicators in routine control by the producer only.

2. The limit for E. coli should be: 0 in a 250 ml portion. This criterion is included in the European Legislation.

3. It should be added that the E. coli criterion has to be established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods.

4- Health-related criteria should be those issued by the WHO in its guidelines for drinking water quality. In the last sentence, the document refers to quality criteria of the draft standard that are in fact no quality criteria but health-related criteria.

BRAZIL

We consider that the natural mineral water criteria are more appropriate than the proposed one. Considering that it will include commercial sterility in the definitions and this means that the bottled/packaged drinking waters may be processed for sterility, in this appendix may be included : "In the case of commercial sterility water, the parameters to verify this condition must be fulfilled" or another wording, with these meaning.

PERU

In the third paragraph, the following is proposed:

That the Heterotropic Plate Count (HPC) should have 100 CFU/ml as the limit for non- carbonated bottled drinking water and 50 CFU/ml for carbonated bottled drinking water."

Limits should also be established on the presence of UFC for molds and yeasts both for non-carbonated bottled drinking water and for carbonated drinking water. For non- carbonated bottled drinking water, 50 UFC/ml is recommended for yeasts, 10 UFC/ml for molds, and for carbonated bottled drinking water, 30 UFC/ml for yeasts and 5 UFC/ml for molds.

UNITED KINGDOM

Modify the sentence beginning "Not intended as criteria" since these are criteria and the qualification is inadequate. Suggested text:

"Therefore additional criteria which would indicate a potential cause for concern and warrant further investigation are:

(a) dilution of heterotrophic bacteria greater than 100 per 1 ml at 22^0C a sample taken at the time of bottling or within 12 hours following bottling if the bottle is kept at $5^{0c;}$

(b) any significant increase in heterotrophic bacteria counts over historical levels; and

(c) any significant increases in turbidity over historical levels."

UNITED STATES OF AMERICA

In the third paragraph, line 1, change Acauses≅ to Areasons≅ for the purposes of better word usage. Also in this paragraph, line 3, change Athey≅ to AHPC counts≅ for purposes of clarity.