

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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TO: Codex Contact Points  
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Italy

SUBJECT: **REQUEST FOR COMMENTS AND INFORMATION ON:**

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

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

DEADLINE: **15 September 1999**

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## BACKGROUND

The 21<sup>st</sup> Session of the Commission, ALINORM 95/37, approved the elaboration of the Proposed Draft International Code of Hygienic Practice for Bottled (Packaged) Drinking Waters (Other than Natural Mineral Water). At the 28<sup>th</sup> Session of the Codex Committee on Food Hygiene the delegate of the United States presented a discussion paper and the Committee agreed that the United States assisted by France, Indonesia, Japan, Spain, and Switzerland would draft the proposed code.

At the 29<sup>th</sup> Session of the Committee, the Delegation of United States presented a preliminary draft of the proposed code of practice for discussion. The Committee advised the Working Group to refer to "bottled water" and "packaged water" in the Title and Definition, but refer only to "bottled water" in the body of the Code. The Committee also recommended that a clear distinction be established between relatively safe protected underground water and other sources of water. With regard to the provisions concerning treatment, the Committee agreed that the need for treatment should be determined on the basis of an appropriate risk analysis and should consider chemical contamination of the water. Finally, the Committee returned the proposed draft to Step 2 and added the delegation of Belgium to the working Group and charged it to redraft the proposed code.

At the 30<sup>th</sup> Session of the Committee, the Committee agreed upon several changes to the document. The Committee agreed to solicit further comments on text in square brackets contained in several sections including sections 2.1, 5.4 and 9.3. The Committee recommended that two new sections should be developed; 3.2.2, Protection of Surface Water Supplies; and 3.2.2.1, Criteria for Surface Water Supplies. Finally, the Committee agreed that the Appendix on HACCP should not include HACCP examples but provide general guidelines on use of HACCP.

CL 1997/41 – FH was issued prior to the 31<sup>st</sup> Session of the Committee and comments were solicited on this modified document. . Responses were received from the governments of Canada, Denmark, and the United States of America and from Consumers International. The code was revised to accommodate the comments from Canada, Denmark, and the USA. However, Canadian comments on Appendix 2 were not included in the code because further information and a plenary discussion were found to be necessary. The concerns of Consumers International were met, it was felt, by the USA's suggestion of placing in the introduction the information previously contained in Section 9.1. The revised document was circulated at Step 6 of the Codex Procedure.

At the 31<sup>st</sup> Session of the Committee, an *ad hoc* Working Group met to consider the code and comments received in response to CL 1997/41 – FH. The *ad hoc* Working Group further amended the code that was presented to the Committee. Following a plenary discussion during which further changes in the Code were made, the Committee requested the Delegation of the United States to redraft the Code and solicit further comments on the redrafted code.

The present draft of the Code is in accord with decisions made during the plenary discussion at the 31<sup>st</sup> Session of the Committee and recommendations by the *ad hoc* Working Group. The mention of labeling provisions in reference to information for the immunocompromised and infant feeding were deleted from the Introduction on the recommendation of some, but not all, countries. Microbiological, chemical and physical criteria were developed as Appendix 2. Several passages were placed in square brackets for further deliberation and/or future removal (see Sections 3.3.2.2, 5.1.1 paragraph 4 and 5.4.1.1). Some paragraphs were combined or streamlined. Finally, numerous words and phrases were rewritten to facilitate a more accurate translation of the Code from the English into the French and Spanish languages.

In accordance with the Committee discussions and *ad hoc* Working Group deliberations extensive changes were made to Section 1, and Appendix 2 of the code. For example, labeling statements were deleted from the Introduction Section and in Appendix 2 microbiological physical, and chemical criteria were added. The revised code also includes some text in square brackets. Section 5.1.1 paragraph 4, and Section 5.4.1.1 include the text that was placed in square brackets. Additionally, some paragraphs were combined or eliminated from the revised code. Finally, throughout the revised code several words and phrases were changed to facilitate accurate translations of the code into the French and Spanish Languages.

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

The Sixth Session of the Codex Committee on Natural Mineral Waters while considering the Proposed Draft General Standard for Packaged (Bottled) Waters Other Than Natural Mineral Waters on the request to include the definition on *Commercial sterility*, agreed that it would more properly developed by the Codex Committee on Food Hygiene within the framework of the Code of Hygienic Practice and therefore decided to forward the following text to that Committee for consideration for inclusion in the Code.

*“Commercial Sterility means the condition achieved by the application of appropriate treatment to render the bottled water free from microorganisms capable of growing in the product at normal non-refrigerated conditions at which the product is likely to be held during distribution and storage and free of viable microorganisms (including spores) of public health significance. The absence of viable microorganisms shall be determined with appropriate microbiological tests.*

Member governments and interested International Organizations are therefore invited to provide comments on the Draft Code at Step 6 of the Procedure and on the necessity of inclusion in the Draft Code and the definition of Commercial Sterility (see Annex).

## ANNEX

**DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED/PACKAGED DRINKING  
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## 1. INTRODUCTION

International trade in bottled water has increased in recent years, both in quantity and diversity. Because of greater transport capacity, it is now possible to distribute bottled water not just as ship, rail, and road cargo but also as air freight, the latter being used mainly in crisis situations due to the higher cost. By all these means of transport, a remedy for water shortages has become available when local water supply systems fail due to natural causes (such as droughts and earthquakes) or societal disasters (such as sieges or sabotage) and bottled water, both natural mineral water and diverse other sorts, has been brought in to meet such emergencies.

Aside from water shortages, real and perceived needs to improve health also have contributed to an escalating trade in bottled water. Increasingly it has been recognized that traditional suppliers of drinking water such as public and private waterworks may not be able in many instances or under all circumstances to guarantee the microbiological, chemical and physical safety of their product to the extent previously thought possible.

The contamination of water with parasitic protozoa is a serious concern to all consumers, particularly the immunocompromised. It may be helpful to consumers to supply information regarding control measures the water has received. Protection of natural resources and such treatments as boiling, pasteurization, distillation, reverse osmosis filtration, absolute one micron or submicron filtration are some of the control measures used to guard against, inactivate or remove possible water contaminants such as oocysts of *Cryptosporidium parvum*, *Cyclospora cayentanensis*, and *Toxoplasma 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.

## 2. SCOPE AND USE OF THE DOCUMENT

### 2.1 SCOPE

This Code recommends general techniques for collecting, processing, packaging, storing, transporting, distributing, and offering for sale a variety of drinking waters (other than natural mineral water) for direct consumption. Recommendations concerning natural mineral water are provided in a separate Code (Recommended International Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters, CAC/RCP 33-1985). Mineral waters other than natural mineral water are covered by this Code. Underlying in this Code are the principles contained in *Application of the Hazard Analysis Critical Control Point (HACCP) System and Guidelines* needed to ensure the production of safe and suitable bottled drinking water.

### 2.2 USE OF THE DOCUMENT

It is emphasized 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, whose paragraph numbers and section headings it maintains, supplementing or specifically applying them to bottled/packageged drinking waters (other than natural mineral water). Other relevant document is: *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application* (Annex to CAC/RCP 1-1969, Rev.3 (1997)).

### 2.3 DEFINITIONS

These definitions are supplemental to the definitions in section 2.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997. The Food, Food Hygiene, and Food Handling definitions apply only to this Draft Code.

Bottled/packageged drinking water - Water filled into hermetically sealed containers of various compositions, forms, and capacities that is safe and suitable for direct consumption without necessary further treatment. Bottled drinking water is considered a food. The terms "drinking" and "potable" are used interchangeably in relation to water.

Drinking water systems - Public or private systems providing the consumer with tap water safe and suitable for direct consumption.

Establishment - Any suitable building(s), area(s) or surroundings in which water intended for bottling is collected, processed and bottled.

[Food - For the purposes of this Code, the term includes bottled drinking water.]

Food handling - Any operation pertaining to collecting, processing, bottling, packing of bottles, storing, transporting, distributing and marketing of bottled drinking water.

Food hygiene - All conditions and measures necessary to ensure the safety and suitability of bottled drinking water at all stages of its production.

Ground water - Waters such as spring water, artesian water, and well water originating from subsurface aquifers. Ground waters may be classified broadly as protected or unprotected water. Protected ground waters are not directly influenced by surface water or the surface environment.

Ingredient - Any substance, including food additives, used to manufacture or prepare foods, intentionally added to a finished product, sometimes in a modified form (it may or may not be safe and suitable for human consumption without further treatment).

Surface water - Waters open to the atmosphere such as streams, rivers, lakes, ponds and reservoirs.

### **3. PRIMARY PRODUCTION**

These guidelines are supplemental to those set forth in Section 3 of the *Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997.

Prior to utilizing a water resource for bottling purposes, its chemical composition and microbiological quality should be established over an appropriate period to allow for variations.

#### **3.1 ENVIRONMENTAL HYGIENE**

##### **3.1.1 Precautions in selecting a resource site**

A hydrogeologist should determine the watershed and the perimeter (area surrounding the body of water which supplies are drawn or the water's point of origin in the ground) that can be sources of contamination. These critical areas should be protected as much as possible.

All possible precautions should be taken within the protected perimeter (zone of protection) to avoid any pollution of, or external influence on, the quality of the ground or surface water. Preventive measures should be taken for disposal of liquid, solid or gaseous waste that could pollute the ground or surface water. 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 nor should drinking water resources be in the path of potential sources of underground contamination, such as sewers, septic tanks, industrial waste ponds, gas or chemical tanks, pipelines and solid waste disposal sites.

#### **3.2 HYGIENIC PRODUCTION OF WATER SUPPLIES**

##### **3.2.1 Protection of ground water supplies**

###### **3.2.1.1 Considerations for ground water supplies**

It is not easy to distinguish between protected and unprotected ground water. Ground water supplies should be tested regularly for constancy of biological (including microbial), chemical, physical and radiological characteristics. The frequency of testing is determined by the hydrogeological evaluation and historical constancy pattern of a particular water supply. If contamination is detected, and the chosen corrective action is ineffective, production of bottled water should cease until the water quality has returned to established parameters. Any underground supply from which water is collected, should be approved by an official authority having jurisdiction or by a third party with expertise for approving such underground supplies.

### **3.2.2 Protection of surface water supplies**

Surface waters intended for bottling should be protected from contamination to the fullest extent possible. Treatment(s) must be adequate to eliminate toxic or pathogenic contaminants. Supplies should be tested frequently.

#### **3.2.2.1 Considerations for surface water supplies**

Stringency in determining which surface waters are suitable for bottling should be the rule, even when treatment(s) is foreseen.

## **3.3 HANDLING, STORAGE AND TRANSPORT OF WATER INTENDED FOR BOTTLING**

### **3.3.1 Hygienic extraction or collection of water**

#### **3.3.1.1 At point of origin**

The extraction or collection of water intended for bottling should be conducted in such a manner as to prevent other than the intended water from entering the extraction or collection device. The extraction or collection of water intended for bottling should also be conducted in a hygienic manner to prevent any contamination. Where sampling points are necessary, they should be designed and operated to prevent any contamination of the water.

#### **3.3.1.2 Protection of the area of origin**

The immediate surroundings of the extraction or collection area should be protected by limiting access to only authorized persons. Wellheads and spring outflows should be protected by a suitable structure to prevent entry by unauthorized individuals, pests, dust and other sources of contamination such as extraneous matter, drainage, flood waters, and infiltration water.

#### **3.3.1.3 Maintenance of extraction or collection facilities**

Methods and procedures for maintaining the extraction facilities should be hygienic. They should not be a potential hazard to humans or a source of contamination for the water. Wells should be disinfected following construction and development of new wells nearby, after pump repair or replacement, or any well maintenance activity such as testing for and finding indicator organisms, pathogens, or abnormal plate counts in the water, and whenever biological growth inhibits proper operation. Water collection chambers should be disinfected within a reasonable time before use. Extraction devices such as those used for bore holes should be constructed and maintained in a manner that avoids contamination of the water and minimizes hazards to human health.

### **3.3.2 Storage and transport of water intended for bottling**

When storage and transport of the water intended for bottling from the point of origin to the processing plant is necessary, these operations must be conducted in a hygienic manner to prevent any contamination.

In addition, see 3.3.2.1 and 3.3.2.2 below. Guidelines that are supplemental to those set forth in Section 3 of the *Recommended International Code of Practice - General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3-1997* are found in the *Codex Code of Hygienic Practice for Bulk Transport of Food and Food Ingredients*, [which is being developed parallel to this Code]. Directing the supply of water through piping from the point of origin wherever possible is one of the preferred means of avoiding risks of contamination from bulk transport.

#### **3.3.2.1 Requirements**

Where or when they are necessary, bulk containers and conveyances such as tanks, pipings and tanker trucks should be designed and constructed so that they:

- do not contaminate the water intended for bottling;
- can be effectively cleaned and disinfected;
- provide effective protection from contamination, including dust and fumes; and
- allow any situation that arises to be checked easily.

### **3.3.2.2 Use and maintenance**

[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 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. See also [*Proposed Draft*] *Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs.*]

## **4. ESTABLISHMENT: DESIGN AND FACILITIES**

These guidelines are supplemental to those set forth in Section 4 of *the Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997.

### **4.2 PREMISES AND ROOMS**

In those areas of the processing establishment where containers are exposed to the external environment (i.e., on the loading dock), especially prior to filling and sealing, specific preventive measures should be incorporated into the facility's design to avoid contamination of the containers used for production of bottled water.

### **4.3 FACILITIES**

#### **4.3.1 Water supply not intended for bottling**

This section pertains to water used for cleaning and disinfection purposes; not for water to be bottled. For cleaning and disinfection purposes an ample supply of potable water distinct from that intended for bottling and in compliance with Section 4.4.1 of the *Codex Alimentarius Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination. The standards of potability should not be less than those contained in the latest edition of *Guidelines for Drinking Water Quality* (WHO).

Water not intended for bottling should be carried in completely separate lines from water intended for bottling. These lines should be identified, preferably by different colors. There must be no cross connections. Water not intended for bottling should be potable if there is a chance that it comes into direct or indirect contact with water that is intended for bottling; otherwise it may be non-potable (if used for such operations as steam production or refrigeration where there is no direct or indirect contact with water for bottling). For storage the provisions in the *Recommended International Code of Practice: General Principles of Food Hygiene* amply apply.

## **5. ESTABLISHMENT: CONTROL OF OPERATION**

These guidelines are supplemental to those set forth in Section 5 of *the Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997.

### **5.1 CONTROL OF FOOD HAZARDS**

Water is an excellent vehicle for carrying substances in soluble, dispersed, or emulsified form. 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.

#### **5.1.1 Control measures for waters intended for bottling**

Waters, from drinking water systems, intended for bottling should meet all public drinking water standards (i.e., chemical, microbiological, physical, radiological) established by the official authority having jurisdiction. [For documentation of an approved source, firms using waters from drinking water systems may use drinking water system testing results showing full compliance with drinking water standards established by the official authority having jurisdiction in accordance with the *Guidelines for Drinking Water Quality* (WHO)].

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 microorganisms, excessive residues of pesticides, toxic substances

Water intended for bottling should be of a quality (i.e., microbiological, chemical, physical, radiological), such that treatment (including multiple barrier treatments such as combination of filtration, chemical disinfection, etc.) of that water during processing results in finished bottled drinking water products that are safe and of suitable quality for consumption. Generally, the higher the quality of the water intended for bottling, the less treatment is required to produce safe bottled drinking water products. Surface waters should be tested for safety frequently and treated as necessary.

A [hazard] analysis of the water supply for pathogenic microorganisms or harmful substances should be the basis for treating waters intended for bottling during processing to reduce, remove or prevent growth of microorganisms or to reduce or remove chemical or radiological substances. A [hazard] analysis according to HACCP principles should be conducted to determine if there is a need for treatment(s) and, if so, the type and degree of treatment(s). Waters originating from protected underground supplies are less likely to require treatment than waters originating from surface supplies or unprotected underground supplies.

When necessary, treatment of waters intended for bottling, to reduce, remove or prevent growth of microorganisms, may include the application of chemical processes (such as chlorination, ozonation, carbonation) and physical agents or processes (such as high heat, ultraviolet radiation, filtration). These treatments can be used singly or in combination as multiple barriers. Treatments vary in their effectiveness against specific organisms. Bottled waters produced with the use of an adequate multiple barrier treatment technique will be less likely to contain microorganisms of public health concern.

When necessary, treatments to remove or reduce chemical substances may include chemical and particulate (mechanical) filtration such as achieved with surface filters (e.g., pleated membrane filters) or depth filters (e.g., sand or compressed fiber (cartridge) filters), activated carbon filtration, demineralization (deionization, water softening, reverse osmosis, nano-filtration), and aeration. These treatments for chemicals may not adequately reduce or remove microorganisms and, likewise, treatments for microorganisms may not adequately reduce or remove chemicals and particulate matters.

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.

## **5.4 PACKAGING**

### **5.4.1 Washing and sanitizing containers**

#### **5.4.1.1 Washing and sanitizing of containers**

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. 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. [Recycling of containers is not covered by this paragraph.]

#### **5.4.1.2 Filling and sealing of containers**

Bottling operations (i.e., filling and sealing of containers) should be conducted in a manner that protects against contamination. Control measures include the use of an enclosed area under positive air pressure and a containment enclosed system separate from other operations of the processing plant to protect against contamination. Dust, dirt, microorganisms and excessive moisture in the air should be controlled and monitored.

#### **5.4.1.3 Product containers and closures**

The containers and closures intended for bottling of drinking waters should be non-toxic and used exclusively for that purpose. Reusable containers should not have been used for any purpose that may lead to contamination of the product and should be individually inspected for suitability. New containers should be inspected if and as appropriate.

#### **5.4.1.4 Use of Closures**

Closures are generally supplied in a ready to use state and are not reusable.

**6. ESTABLISHMENT: MAINTENANCE AND SANITATION**

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 amply cover these topics.

**7. ESTABLISHMENT: PERSONAL HYGIENE**

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 amply cover this topic.

**8. TRANSPORTATION AND STORAGE OF BOTTLED WATER**

Guidelines that are supplemental to those set forth in Section 8 of the *Recommended International Code of Practice- General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 are found in the *Codex Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs*, [which is being developed in parallel to this Code]. For storage, the provisions in the *Recommended International Code of Practice: General Principles of Food Hygiene* amply apply.

**9. PRODUCT INFORMATION AND CONSUMER AWARENESS**

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 amply cover this topic.

**10. TRAINING**

The requirements made in the *International Recommended Code of Practice - General Principles of Food Hygiene*, CAC/RCP 1-1969, Rev. 3-1997 amply cover this topic.

**[APPENDIX 1: HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION - CONSIDERATIONS FOR BOTTLED WATERS (OTHER THAN NATURAL MINERAL WATER)]**

See the document The HACCP System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3-1997) which amply covers this topic.

## APPENDIX 2: MICROBIOLOGICAL, CHEMICAL, AND PHYSICAL CRITERIA

The occurrence of pathogens in drinking water is usually the result of faecal contamination. For assurance that such contamination has not occurred, the most suitable criterion is:

- No *Escherichia coli* detectable in a 100 mL portion.

Testing for this criterion should be done using internationally recognized or validated methods (e.g., ISO methods, AOAC methods, APHA/AWWA/WEF Standard Methods for the Examination of Water and Wastewater). Procedures that detect coliforms and those that detect *E. coli* are appropriate. However, in some instances such bacteriological tests do not give assurance that the product is free of all pathogens or their products in amounts harmful to health because parasitic protozoa and pathogenic viruses may be present in the absence of bacterial indicators of faecal contamination.

Not intended as criteria but only as causes of concern that may warrant further investigation are two factors: a) plate counts of heterotropic bacteria (HPC) if they are  $\geq 100$  HPC at time of bottling (or within twelve hours following bottling if the sample is kept at 5°C) or if they represent an increase over historical levels; b) increases in turbidity over historical levels are considered warnings of potential microbial problems.

Chemical and physical safety criteria for bottled water should be [those issued by the World Health Organization in its Guidelines for Drinking Water Quality].

For quality criteria see the *Draft General Standard for Bottled/Packaged Waters Other Than Natural Mineral Waters* (CX/NMW 98/2).