

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

CXC48-2001

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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 airfreight, 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 always be able to guarantee the microbiological, chemical and physical safety of their product to the extent previously thought possible.

The contamination of water with viruses and parasitic protozoa is a serious concern to all consumers, particularly the immunocompromised. These pathogens are difficult to detect and bacterial indicators of their potential presence are not always reliable. Therefore 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*.

It may be necessary that bottled drinking water products of particular chemical composition provide information concerning their proper consumption and/or have directions regarding whether or not they are suitable for infants and for the rehydration of infant formula.

SECTION 1. SCOPE, USE AND DEFINITIONS

1.1 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* (CXC 33-1985)). All bottled/packageged drinking waters other than natural mineral water are covered by this Code.

1.2 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*, (CXC 1-1969, Rev. 3-1997), including the HACCP Annex, whose paragraph numbers and section headings it maintains, supplementing or specifically applying them to bottled drinking waters (other than natural mineral waters). This Code should also be used in combination with the *Principles for the Establishment of and Application of Microbiological Criteria for Foods* (CXG 21-1997).

1.3 DEFINITIONS

These definitions are supplemental to the definitions in section 2.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CXC 1-1969, Rev. 3-1997). The *Food*, and *Food handling* definitions apply only to this Code.

Bottled/packaged 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/packaged drinking water.

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

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.

SECTION 2. PRIMARY PRODUCTION

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

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

2.1 ENVIRONMENTAL HYGIENE

2.1.1 *Precautions in selecting a resource site*

Hydrogeological data should determine the watershed and the perimeter (area surrounding the body of water from 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. Disposal of liquid, solid or gaseous waste that could pollute the ground or surface water should be controlled. Disposal of pollutants such as microorganisms, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic and inorganic substances in the watershed should be avoided. 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.

2.2 HYGIENIC PRODUCTION OF WATER SUPPLIES

2.2.1 Protection of ground water supplies

2.2.1.1. 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, where necessary, radiological characteristics. The frequency of testing is determined by the hydrogeological evaluation, the amount of water collected, and the historical constancy pattern of a particular water supply. If contamination is detected, production of bottled water should cease until the water characteristics have 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.

2.2.2 Protection of surface water supplies

Surface waters intended for bottling should be protected from contamination to the fullest extent possible even when treatments follow. Surface waters may be highly variable, so supplies should be tested frequently.

2.2.2.1. 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.

2.3 HANDLING, STORAGE AND TRANSPORT OF WATER INTENDED FOR BOTTLING

2.3.1 Hygienic extraction or collection of water

2.3.1.1. 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.

2.3.1.2. 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, floodwaters, and infiltration water.

2.3.1.3. 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 properly 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.

2.3.2 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 2.3.2.1 and 2.3.2.2 below. Guidelines that are supplemental to those set forth in Section 3 of the *Recommended International Code of Practice - General Principles of Food Hygiene*, (CXC 1-1969, Rev. 3-1997) are found in the *Code of Hygienic Practice for Bulk Transport of Food and Semi-Packaged Foodstuffs* (CXC 47-2001). Directing the supply of water through piping from the point of origin wherever possible is one of the means of avoiding risks of contamination from bulk transport.

2.3.2.1. 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.

2.3.2.2. Use and maintenance

Means of transport of 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 *Code of Hygienic Practice for the Transport of Bulk and Semi-Packed Food* (CXC 47-2001).

SECTION 3. 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*, (CXC 1-1969, Rev. 3-1997).

3.1 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 bottled water.

3.2 FACILITIES

3.2.1 Water supply not intended for bottling

This section pertains to water for cleaning and disinfection purposes; not to water for bottling.

Water intended for bottling should be carried in completely separate lines from water not intended for bottling. These lines should be identified, preferably by different colours. There must be no cross-connections. Water used for cleaning and disinfection, should be potable (the standards of potability should not be less than those contained in the latest edition of the WHO *Guidelines for Drinking Water Quality*) 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 where there is no direct or

indirect contact with water for bottling). For storage, the provision in the Recommended International Code of Practice: General Principles of Food Hygiene (CXC 1-1969, Rev. 3-1997) apply.

SECTION 4. ESTABLISHMENT: CONTROL OF OPERATION

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

Water is an excellent vehicle for carrying substances in soluble, dispersed or emulsified form. Control measures must be taken at all steps of processing to ensure that food safety and suitability are not compromised by hazards or other contaminants during operations.

4.1 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

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 should be accepted by an establishment if it is known to contain pathogens or excessive residues of pesticides or other toxic substances.

Water intended for bottling should be such (*i.e.* microbiologically, chemically, physically, and radiologically), that treatment if necessary (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 suitable 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 which takes into consideration pathogens and toxic substances should be undertaken in the overall context of the application of principles such as HACCP to the production of bottled water. This should provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, hazards (microbiological, chemical and radiological) for the production of safe bottled water. 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 pathogens, 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 pathogens 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 fibre (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, including the formation of toxic by-products (particularly bromates) and the presence of residues of water treatment chemicals in amounts that raise health concerns in accordance with relevant WHO guidelines.

4.2 PACKAGING

The requirements in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CXC 1-1969, Rev. 3-1997) cover these topics.

4.2.1 Washing and disinfecting of containers

Reused containers and where necessary other containers should be washed and disinfected in an appropriate 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 disinfecting. Determine if this is the case; if not, treat as carefully as reusable containers.

4.3 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 and a containment enclosed system separate from other operations of the processing plant to protect against contamination. Dust, dirt, microorganisms in the air, and condensation should be controlled and monitored.

4.3.1 Product containers and closures

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 and, if necessary, cleaned and disinfected.

4.3.2 Use of closures

Closures are generally supplied in a ready to use state and should be tamper resistant; they are not reusable.

SECTION 5. ESTABLISHMENT: MAINTENANCE AND SANITATION

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CXC 1-1969, Rev. 3-1997) cover these topics.

SECTION 6. ESTABLISHMENT: PERSONAL HYGIENE

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CXC 1-1969, Rev. 3-1997) cover this topic.

SECTION 7. 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* (CXC 1-1969, Rev. 3-1997) are found in the *Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Food* (CXC 47-2001). For storage, the provisions in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CXC 1-1969, Rev. 3-1997) apply.

SECTION 8. PRODUCT INFORMATION AND CONSUMER AWARENESS

These requirements are covered in the *Recommended International Code of Practice - General Principles of Food Hygiene*, (CXC 1-1969, Rev. 3-1997). See also the text in the Introduction of this document.

SECTION 9. TRAINING

The requirements made in the *International Recommended Code of Practice - General Principles of Food Hygiene*, (CXC 1-1969, Rev. 3-1997) cover this topic.

APPENDIX 1-MICROBIOLOGICAL AND OTHER SPECIFICATIONS

Section 5.2.3 Microbiological and Other Specifications of the *International Recommended Code of Practice - General Principles of Food Hygiene*, (CXC 1-1969, Rev. 3-1997) applies.

The provisions of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXG 21-1997) apply.

Microbiological and additional specifications for bottled drinking waters (other than natural mineral waters) are those of the World Health Organization *Guidelines for Drinking Water Quality*.