CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 6

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fifty-sixth Session

Scottsdale, Arizona, United States of America

16–20 November 2026

ALIGNMENT OF CODEX TEXTS DEVELOPED BY CCFH WITH THE REVISED *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969)

(Prepared by the Electronic Working Group chaired by China and co-chaired by the United Kingdom and Kenya)

This version was prepared by the EWG chair and co-chairs taking into consideration the comments received in response to CL 2026/69-FH. All changes compared to the working document (CX/FH 26/56/6) are marked as tracked changes. This document will be used as the basis for discussion at the PWG on Sunday 15th November.

BACKGROUND

1. At its 54th Session, the Codex Committee on Food Hygiene (CCFH54) agreed to prioritize the alignment of existing CCFH texts with the *General principles of food hygiene* (CXC 1-1969) and to integrate this activity into its forward workplan. CCFH54 established an Electronic Working Group (EWG) on alignment, chaired by China and co-chaired by the United Kingdom and the European Union, to initiate the structural alignment work and identify challenges arising from the exercise.

2. CCFH55 considered the first set of structurally aligned texts and the approach developed by the EWG. The follow-up document prepared during CCFH55 clarified the use of parent-section cross-references, the treatment of numbering, and the principle that structural alignment should preserve the technical content and intent of existing adopted texts. A decision tree was also introduced as a working tool to support a consistent and transparent approach to future alignment.

3. The EWG established at CCFH55 chaired by China and co-chaired by the United Kingdom and Kenya continued the alignment exercise with the next prioritized texts: the *Code of hygienic practice for the transport of food in bulk and semi-packed food* (CXC 47-2001), the *Code of hygienic practice for bottled/packaged drinking waters (other than natural mineral waters)* (CXC 48-2001), and the *Code of hygienic practice for collecting, processing and marketing of natural mineral waters* (CXC 33-1985).[1]

SCOPE AND OBJECTIVE

4. The scope of the current work remains limited to structural alignment with CXC 1-1969. The objective is to improve structural consistency, readability and usability while maintaining the integrity, scope and technical intent of the adopted texts. The exercise is not intended to reopen the technical provisions of the three codes.

5. In reviewing comments, the EWG therefore distinguished between: (i) structural changes needed to map existing provisions to the current structure of CXC 1-1969; (ii) editorial corrections consequential to that alignment; and (iii) proposals that would substantively revise, modernize or otherwise alter the technical content. Proposals in the third category were generally not incorporated and may be considered in a future technical revision, as appropriate.

WORK UNDERTAKEN BY THE EWG

6. Draft aligned versions of CXC 47-2001, CXC 48-2001 and CXC 33-1985 were circulated for comments. Comments were received from Members and were reviewed against the agreed structural-alignment principles. Revised clean texts were subsequently prepared, together with a consolidated record of comments and proposed actions.

[1] REP26/FH, para. 72

7. The review applied, in particular, the following approaches established during the previous round of work:

    - cross-references to CXC 1-1969 are normally placed at the parent-section level rather than repeated in each subsection;
    - where no additional commodity-specific text follows, the formulation “Refer to Section X of the *General principles of food hygiene* (CXC 1-1969).” is used;
    - where existing commodity-specific provisions follow, the formulation “Refer to Section X of the *General principles of food hygiene* (CXC 1-1969), together with the following:” is used;
    - subsection numbering may be introduced or adjusted for structural purposes, including jumps in numbering where necessary to preserve correspondence with CXC 1-1969; and
    - existing provisions are mapped according to their substantive function rather than solely according to their legacy heading or numbering.

8. Editorial corrections that do not affect technical meaning, such as updating Codex text identifiers and titles, correcting punctuation, capitalization, unit presentation and scientific name abbreviations, were incorporated where appropriate. Proposals that would change terminology, scope or substantive requirements were retained for later technical revision unless they were necessary to achieve structural alignment.

APPLICATION AND REFINEMENT OF THE DECISION TREE

9. The decision tree[2] for structural alignment, presented in Appendix IV of CRD22 at CCFH55, was used by the EWG as a working tool in the alignment of CXC 47-2001, CXC 48-2001 and CXC 33-1985. The decision tree provided a useful overall framework for determining whether provisions in the original texts corresponded directly to the structure of the GPFH, identifying the most relevant GPFH section where no direct correspondence existed, determining whether additional subdivisions were needed, and verifying cross references. This practical application confirmed the general utility of the decision tree in promoting a consistent and transparent approach to structural alignment.

10. Experience from the current alignment exercise, particularly with older texts whose structure differs substantially from that of the current GPFH, also identified areas where the decision tree could be further refined. In some cases, the title or location of a provision in the original text did not accurately indicate its substantive function. In other cases, provisions grouped under a single heading in the original text addressed different subjects corresponding to different sections or subsections of the GPFH. The EWG therefore considered that alignment should be based primarily on the substantive function and intent of individual provisions, rather than solely on their original headings, numbering or location.

11. The EWG also considered it useful to make explicit in the decision tree the boundary between structural alignment and technical revision. Where placement of a provision within the GPFH structure can be achieved without changing its technical content, scope, meaning or intent, the provision may be relocated and, where necessary, assigned new numbering for structural purposes. Where alignment would require a substantive change, the change should not be made as part of the structural alignment exercise and the issue should instead be identified for possible future technical revision. This gives operational effect to the principle established in FH55/CRD22 that the structure should follow the GPFH while the technical content of the original text remains unchanged.

12. Based on this experience, the decision tree has been revised to:

    - clarify that the substantive function of a provision should be identified before determining its placement in the GPFH structure;
    - allow provisions grouped under one original section or subsection to be considered separately where they perform different substantive functions;
    - distinguish between provisions that correspond directly to an existing GPFH section or subsection and commodity-specific provisions that need to be accommodated under the most relevant parent section;
    - clarify the approach to subsection numbering, including the introduction of commodity-specific subdivisions where necessary without using a GPFH subsection number that relates to a different subject;

[2] fh55_crd22x, Appendix IV

- include an explicit check that the proposed alignment does not change the technical content, scope, meaning or intent of the original provision; and
- retain the final verification of cross-references to the GPFH and other relevant Codex texts.

13. The revised decision tree is presented in Appendix IV. It is intended to remain a practical working tool rather than a rigid classification system. The experience gained from its application to CXC 47-2001, CXC 48-2001 and CXC 33-1985 indicates that judgement may still be required where an older provision does not have a direct counterpart in the GPFH. In such cases, the objective should be to identify the closest substantive correspondence while preserving the technical integrity and traceability of the original text.

OUTCOME OF THE REVIEW

CXC 47-2001

14. For CXC 47-2001, the revised draft retains the commodity-specific provisions under the corresponding sections of CXC 1-1969 and incorporates agreed editorial and structural corrections. The parent-section reference approach has been maintained. The subsection on documentation and records has been mapped to Section 13.4, and the transport specific provisions remain under Section 15, with commodity specific subsection numbering used where needed.

15. A number of comments proposed modernization of wording by reference to other recently revised Codex texts, including changes to the Objectives, Scope and terminology. These were not incorporated where they went beyond structural alignment. Editorial corrections, including the correction of “unit’s” to “units”, punctuation and the use of “cross-contamination”, were accepted.

CXC 48-2001

16. For CXC 48-2001, the revised draft aligns the main structure with CXC 1-1969 while retaining the water-specific organization needed to preserve the meaning of the original code. Under Section 8, provisions are organized under environmental control, hygienic production, and handling, storage and transport. Under Section 13, existing operational provisions are mapped to the relevant aspects of GHPs, including packaging and filling/sealing of containers.

17. Comments highlighted the difficulty of aligning older commodity-specific subsection headings directly with the current headings of CXC 1-1969. The EWG considered that a heading should not be replaced merely because a similarly numbered heading exists in CXC 1-1969 where the substantive meaning is different. The revised draft therefore uses direct CXC 1 headings where there is a genuine correspondence and retains or introduces commodity specific subheadings where necessary.

18. Further attention is required to the treatment of water-supply provisions not intended for bottling and to the relationship between the code’s existing definitions and more recent horizontal Codex texts. These issues are identified below for further discussion.

CXC 33-1985

19. CXC 33-1985 required the most extensive restructuring because its legacy organization differs substantially from the current structure of CXC 1-1969. The revised draft reorganizes source-protection and primary-production provisions under Section 8; establishment design, facilities and equipment under Section 9; maintenance, cleaning and pest control under Section 11; operational controls under Section 13; product information under Section 14; transportation under Section 15; and adds the CXC 1-1969 HACCP framework under Sections 16-19.

20. In Section 8, provisions on authorization, genesis of the natural mineral water, perimeter of protection and protective measures are grouped under environmental control; extraction, protection of the extraction area, equipment or reservoirs and monitoring are grouped under hygienic production; and handling, storage and transport are grouped under a separate subsection. Primary production cleaning, maintenance and personnel hygiene provisions have been moved to Section 8.4 based on their substantive function.

21. In Section 9, the former provisions on premises and rooms and other facilities have been mapped according to their substantive function. In particular, the provision formerly headed “Water supply” concerns the separation and identification of supply lines and the safety of steam used on product contact surfaces. It is therefore treated as a facility related provision rather than being moved automatically to Section 13.3 solely because its legacy heading refers to water.

22. In Section 13, the former provisions on control of operation have been mapped to the relevant CXC 1-1969 subsections. The former combined heading “Physical and Chemical Contamination” has been treated as physical

contamination because the retained provisions address glass breakage and glass fragments; no separate chemical-contamination provision is created where the source text contains no corresponding requirement.

23. The microbiological criteria annex has also been reviewed for editorial presentation. Agreed corrections include use of "*P. aeruginosa*", capitalization of "CFU", "mL" for millilitres, and "sulphite-reducing". A question remains on whether the expression "n.d." and its definition should be retained or updated, as this may extend beyond a purely structural or editorial change.

KEY ISSUES REQUIRING FURTHER CONSIDERATION

24. The comments on the three codes confirm several horizontal questions that would benefit from a common approach rather than code-by-code decisions.

- Boundary between structural alignment and technical revision. References to newer Codex texts or proposals to modernize terminology may improve consistency but should not be incorporated through this exercise where they alter substantive meaning, scope or requirements.
- Substantive mapping versus title matching. Legacy headings should not determine placement by themselves. Existing provisions should be mapped according to the function of the requirement and its closest substantive correspondence with CXC 1-1969.
- Use of CXC 1-1969 subsection numbering. Where a commodity specific provision corresponds directly to an existing CXC 1 subsection, the corresponding number and heading should be used. Where no direct correspondence exists, an additional commodity specific subsection may be introduced without occupying a CXC 1 number that has a different meaning.
- Numbering jumps. Numbering may intentionally jump in order to maintain visible correspondence with CXC 1-1969. Such jumps are structural and do not imply omitted commodity specific requirements.
- Parent section references. Repetition of the same CXC 1-1969 reference at subsection level should generally be avoided unless a specific cross-reference is necessary for understanding.
- Horizontal terminology and drafting conventions. Issues such as "Code" versus "code of practice", and whether definitions should be updated against newer horizontal texts, should be addressed consistently across the aligned codes rather than through isolated changes.
- Treatment of outdated or potentially obsolete references. Where an old cross reference no longer maps cleanly to the current CXC 1-1969 structure, the EWG should determine whether a current section can be identified without changing technical intent, whether a generic reference is sufficient, or whether the issue should be deferred to technical revision.
- Microbiological criteria presentation in CXC 33-1985. Purely editorial corrections can be made during alignment; changes to the substance or interpretation of criteria, including terminology such as "not detectable", should be considered separately if they may have technical implications.

PROPOSED APPROACH FOR THE PHYSICAL WORKING GROUP

25. To facilitate completion of the three texts, the physical working group (PWG) may wish to focus on comments received in response to the Circular Letter, rather than reopening comments already resolved as editorial or clearly outside the structural alignment mandate.

26. To address these comments received, the PWG could apply the following approach:

1) identify the substantive function of the original provision;
2) identify whether CXC 1-1969 contains a direct structural counterpart;
3) retain the original technical content and wording to the greatest extent possible;
4) introduce only the minimum heading, numbering, cross-reference or editorial adjustment necessary for alignment; and,
5) where this cannot be achieved without a substantive change, flag the matter for future technical revision rather than resolving it through structural alignment.

27. Particular attention may be given to other areas, including the placement and numbering of selected CXC 33 and CXC 48 provisions, treatment of legacy cross-references, and horizontal drafting conventions.

RECOMMENDATIONS

28. CCFH56 is invited to:

i. note the progress made by the EWG in structurally aligning CXC 47-2001, CXC 48-2001 and CXC 33-1985 with the revised *General principles of food hygiene* (CXC 1-1969);

ii. consider the revised aligned texts in Appendices I-III;

iii. endorse the revised decision tree in Appendix IV as a working tool for the structural alignment of CCFH texts with the GPFH, taking into account the experience gained from its application to CXC 47-2001, CXC 48-2001 and CXC 33-1985, and agree that it may be further refined, as necessary, based on experience from future alignment work;

iv. confirm that structural alignment should preserve the scope, intent and technical content of existing adopted texts, and that issues requiring substantive revision should be identified separately for possible future consideration; and

v. consider continuation of the alignment work for the remaining prioritized texts in the CCFH Forward workplan.

APPENDIX I

Revised Draft Aligned *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001)

1. INTRODUCTION

Food may become contaminated or reach ~~their~~ its destination in an unsuitable condition for consumption unless control measures are ~~taken~~ applied during transport. Such condition may occur even where adequate hygiene measures have been ~~taken~~ applied earlier in the food chain. Adequate transportation systems should be in place which will ensure that foods remain safe and suitable for consumption upon delivery and assist countries to assure continued trade.

Effective~~Good~~ communication between shipper/manufacturer, transporter and receiver of foods is essential. They share responsibility for food safety for~~on~~ this part of the food chain. Food manufacturers or receivers are responsible for communicating to transporters specific food safety control measures~~procedures~~ required during transportation.

This document is formatted in accordance with *General Principles of Food Hygiene* (CXC 1-1969), which must be ~~consulted in the use of this~~ used alongside this Code. Those sections of this Code that require specific food safety requirements beyond those of the~~contained in~~ *General Principles of Food Hygiene* (CXC 1-1969), due to specific transportation characteristics, are noted and the specific requirements are detailed.

This code is not applicable to, and does not take precedence over, other Codex commodity ~~-~~ specific codes already in existence for such commodities in bulk, for example *Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk* (CXC 36-1987).

2. OBJECTIVES

The code of hygienic practice for the transport of bulk and semi-packed foods is intended to describe;

- identifies ~~additional~~ requirements for~~of~~ food hygiene ~~applicable~~ to *General Principles of Food Hygiene* (CXC 1-1969) ~~applicable~~ for~~to~~ the ~~condition of the~~ food transportation unit and the loading, transport, in-transit storage and unloading of bulk and semi-packed foods to ensure that food remains safe and suitable for human consumption;
- ~~indicates~~ how to implement these requirements~~controls~~; and
- ~~provides~~ ways to verify that these requirements~~controls~~ have been applied.

3. SCOPE

This code of practice covers the condition of the food transportation unit, loading, transport, in-transit storage and unloading of bulk, semi-packed foods and fresh produce. ~~This code covers food transportation unit and product~~ from the points of shipment to the points of receipt. Examples of foods included in this code include:

- food transported from the packaging or processing facility to a retail/distribution establishment,
- food transported from one process/distribution facility to another or from a process/distribution facility to another or from a process/distribution facility to a retail establishment, and
- food transported from collection points, elevators, storage facilities, etc., to processing plants/distribution sites, or retail markets.

This code does not cover ~~growing and gathering~~ growing, harvesting or fishing operations that occur prior to loading product into the food transportation unit for shipment, nor does it cover in-plant conveyance of product that occurs after unloading or after off-loading and emptying. Examples of foods excluded from this code are the following:

- on farm movement of a product; and~~,~~
- movement from the field to collection facility, packaging facility, or storage facility.

4. USE

Together with the *General Principles of Food Hygiene* (CXC 1-1969), this code of practice, including Section 15 that specifically addresses transportation, is complementary to and should be used in conjunction with any relevant Codex texts.

5. GENERAL PRINCIPLES

Refer to Section 5 of the *General Principles of Food Hygiene* (CXC 1-1969).

6. DEFINITIONS

Refer to Section 6 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

Food transportation unit: Includes food transport vehicles or contact receptacles (such as containers, boxes, bins, bulk tanks) in vehicles, aircraft, railcars, trailers and ships and any other transport receptacles in which food is transported.

Bulk: Means unpacked food in direct contact with the contact surface of the food transportation unit and the atmosphere (for example, powdered, granulated or liquid form).

Semi-packed food: Semi-packed food is a food which might come in direct contact with the food transportation unit or the atmosphere (e.g. vegetables and food in crates and bags).~~.~~

GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

Refer to Section 7 of the *General Principles of Food Hygiene* (CXC 1-1969) and as appropriate, provisions of other Codex Codes of Hygienic Practice, together with the following:

7.1 Identification of potential hazards

It may be useful to refer to the listed questions (see Table 1) to identify and manage hazards during transport of bulk and semi-packed foods. Reference is made also to the HACCP approach.

Table 1

Is the food "ready for direct consumption"?
Are the conditions of the food transportation unit likely to introduce or ~~support the~~ increase the level of a hazard?
Is it ~~likely,~~likely that a hazard is introduced or increased during loading?
Is it ~~likely,~~likely that a hazard may increase during transport or storage in the food transportation unit?
Is it ~~likely,~~likely that a hazard is introduced or increased during unloading?

7.2 Records of prior cargoes and prior cleaning

The transporter should maintain records, readily available at the food transportation unit or as prescribed by the official agency having jurisdiction, of the three most recent prior cargoes and cleaning and disinfection, where necessary, method employed of the food transportation unit including volumes transported and make this information, on request, available to the food shipper, official control authorities and/or receiver/food manufacturers, for evaluation of potential hazards.

A complete record of previous cargoes should be kept over a period of six months by the ~~transporter.~~FBO

7.3 Sources of Hazards

The possibility of a hazard should be considered from the following sources, cited as examples:

7.3.1 Hazards related to the food transportation unit

Unsuitability of the construction material and coating, lack of sealing/locking device, residues of previous cargoes, residues from cleaning and sanitizing materials.

Where appropriate, consideration should be given to food transportation ~~unit's~~units dedicated to single commodity use.

7.3.2 Hazards related to loading and unloading

Increase/decrease of temperature of the food. Undesirable introduction of microbes, dust, moisture, or other physical contamination.

7.3.3 Hazards related to transport

Leakage of heating/cooling ~~fluid~~fluids. ~~Break down~~Breakdown of temperature control.

8. PRIMARY PRODUCTION

Refer to Section 8 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice.

9. ESTABLISHMENT – DESIGN OF FACILITIES AND EQUIPMENT

Refer to Section 9 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice.

10. TRAINING AND COMPETENCE

Refer to Section 10 of the General Principles of Food Hygiene (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice, together with the following:

It is important that personnel responsible for the transport are well aware of the nature of the foods that are being handled/transported and anythe possible extra precautionary measures that may be required for that food. Personnel should be trained on food transportation unit inspection procedures for food safety.

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice, together with the following:

Food transportation units, accessories, and connections should be cleaned, disinfected, where appropriate and maintained to avoid or at least reduce the risk of contamination. It should be noted that depending on the commodity concerned,~~relevant~~, different cleaning procedures may~~are~~ applicable, which should be recorded (refer 7.2). Where necessary, there should be disinfection with subsequent rinsing unless manufacturer's instruction indicates, on a scientific basis, that rinsing is not required.

12. PERSONAL HYGIENE

Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice.

13. CONTROL OF OPERATION

Refer to Section 13 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice, together with the following:

13.4 Documentation and Records

~~Suitable controls can be formulated~~Specific measures required by FBOs to ~~by shippers or receivers to~~ ensure food safety during transport ~~in particular cases (see questions in Table 1). Such controls~~ should be communicated in writing. and ~~Documentation is an important tool for validation and for verification that the principles have been adhered to. This documentation~~ may include food transportation unit number, registration of previous loads, temperature/time recordings and cleaning ~~certificates.~~certificates. (It should be noted that some food transportation units are intended for single use only). To facilitate validation of the transport regime and for verifiaction, documentation ~~Such documentation~~ should be available to the official agencies having jurisdiction. ~~It should be noted that some food transportation units are intended for single use only.~~

14. PRODUCT INFORMATION AND CONSUMERS AWARENESS

Refer to Section 14 of the *General Principles of Food Hygiene* (CXC 1-1969) and, as appropriate, provisions of other Codex Codes of Hygienic Practice.

15. TRANSPORTATION

Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

15.4 Dedicated transport

Where appropriate, ~~particularly~~ bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

Bulk food in liquid, granulated or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of food unless the application of principles such as HACCP demonstrates that dedicated transport for these products is not necessary to achieve the same level of food safety.

15.5 Food transportation units

The design of the food transportation unit should be such as to avoid cross-contamination due to simultaneous or consecutive transport. Important aspects are cleanability and appropriate coatings.

Construction and design of the food transportation unit should facilitate inspection, cleaning, disinfection and, when appropriate, enable temperature control.

Use of means for cooling or heating should by design and construction be such as to avoid contamination. Although hot water and steam are preferred means of heating, other substances may be used on the basis of safety and risk evaluation and inspection procedures. Upon request by the competent authority, evidence may be required to demonstrate that the heating media employed have been properly evaluated and safely used.

Inner surface materials suitable for direct food contact should be used. These should be non-toxic, inert, or at least compatible with the transported food, and which do not transfer substances to the food or adversely affect the food. Stainless steel or surface coated with food-grade epoxy resins are most suitable. The interior design should eliminate areas that are difficult to access and clean.

~~The appropriate~~ Dd~~e~~sign of the food transportation unit should assist in preventing access of insects, vermin, and contaminants ~~etc., contamination~~ from the environment, and when necessary, provid~~e~~~~ing~~ insulation against loss or gain of heat, adequate cooling or heating capacity, and facilitate security by~~ion of~~ locking or sealing.

~~There should be~~ A~~a~~ppropriate facilities ~~conveniently available~~ for cleaning and, where appropriate disinfecting of the food transportation unit should be available and convenient ~~.~~

Auxiliary equipment should be, where appropriate, subjected to the above stated requirements.

To maintain sanitary conditions, facilities should be provided for the storage of pipes, hoses and other equipment used in the transfer of foods.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

16. INTRODUCTION TO HACCP

Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

17. PRINCIPLES OF THE HACCP SYSTEM

Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

19. APPLICATION

Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

APPENDIX II

Revised Draft Aligned *Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters)* (CXC 48-2001)

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 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 products 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~~ immunocompromised. These pathogens are difficult to ~~detect~~detect, and bacterial indicators of their potential presence are not always reliable. ~~Therefore~~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.

2. OBJECTIVES

Refer to Section 2 of the *General Principles of Food Hygiene* (CXC 1-1969).

3. SCOPE

This Code recommends general ~~techniques~~procedures 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 (*Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CXC 33-1985)). All bottled/packaged drinking waters other than natural mineral water are covered by this Code.

4. USE

~~It is emphasized that~~ This document must be used in combination with the *General Principles of Food Hygiene*, (CXC 1~~-1~~1969), 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).

5. GENERAL PRINCIPLES

Refer to Section 5 of the *General Principles of Food Hygiene* (CXC 1-1969).

6. DEFINITIONS

Refer to Section 6 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

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 necessarily 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.

GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

Refer to Section 7 of the *General Principles of Food Hygiene* (CXC 1-1969).

8. PRIMARY PRODUCTION

Refer to Section 8 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

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 variability~~ations~~.

8.1 Environmental control

8.1.1 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.~~ All possible precautions should be taken within the protected perimeter (zone of protection) to avoid any contamination of, or external influence on, the quality of the ground or surface water. Disposal of liquid, solid or gaseous waste that could contaminate the ground or surface water should be controlled. Disposal of contaminants 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. Drinking water resources should not 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.

8.2 Hygienic production

8.2.1 Protection of ground water supplies

8.2.1.1 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.~~

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. Testing can be used to assure source suitability and the frequency 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 safety parameters. Any underground supply from which water is collected, should be approved by the competent authority or by a third party with expertise for approving such underground supplies.

8.2.2 Protection of surface water supplies

Surface waters intended for bottling should be protected from contamination to the fullest extent possible, even when treatment(s) follow, and tested to provide assurance of safety. ~~–~~Surface waters may be highly variable, so supplies should be tested frequently.

8.2.2.1 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.

8.3 Handling, storage and transport

8.3.1 Hygienic extraction or collection of water

8.3.1.1 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.

8.3.1.2 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.

8.3.1.3 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.

8.3.2 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 8.3.2.1 and 8.3.2.2 below. Guidelines that are supplemental to those set forth in the *General Principles of Food Hygiene*, (CXC 1-1969) are found in the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (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.

8.3.2.1 Requirements

When used~~ere or when they are necessary~~, bulk containers and conveyances such as tanks, piping~~s~~ 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.

8.3.2.2 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 Food in Bulk and Semi-Packed Food* (CXC 47-2001).

9. ESTABLISHMENT – DESIGN OF FACILITIES AND EQUIPMENT

Refer to Section 9 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

9.1 Location and structure

9.1.2 Design and layout of food establishment

In those areas of the processing establishment where containers are exposed to the external environment (i.e~~.,~~ on the loading dock ~~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.

~~9.2 Facilities~~

10. TRAINING AND COMPETENCE

Refer to Section 10 of the *General Principles of Food Hygiene* (CXC 1-1969).

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969).

12. PERSONAL HYGIENE

Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969).

13. CONTROL OF OPERATION

Refer to Section 13 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

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.

13.2 Key aspects of GHPs

Water~~s,~~ 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~~competent authority. 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~~ W~~w~~aters intended for bottling should not 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. Water~~s~~

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, treatmentsControl measures to remove or reduce chemical contaminantssubstances 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, control measures treatments for microorganisms may not adequately reduce or remove chemicals and particulate matters.

All control measures treatments forof 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.

13.2.9 Packaging

13.2.9.1 Washing and disinfecting of containers

Reused containers and, where necessarynecessary, other containers should be washed and disinfected in an appropriate system and positioned within the processing plant so as to minimize post-sanitationnitizing 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 although if unsure, treat foras carefully as reusable containers.

13.2.10 Filling and sealing of containers

Bottling operations (i.e. filling and sealing of containers) should be conducted in a manner that preventsprotects 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.

13.2.10.1 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.

13.2.10.2 Use of closures

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

13.3 Water

13.3.1 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).

14. PRODUCT INFORMATION AND CONSUMERS AWARENESS

Refer to Section 14 of the *General Principles of Food Hygiene* (CXC 1-1969). See also the text in the Introduction of this document.

15. TRANSPORTATION

Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969).

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

16. INTRODUCTION TO HACCP

Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

17. PRINCIPLES OF THE HACCP SYSTEM

Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

19. APPLICATION

Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

APPENDIX III

Revised Draft Aligned *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CXC 33-1985)

1. INTRODUCTION

This Code describesrecommends appropriate hygienic practices for collecting natural mineral waters, their treatment, bottling, packaging, storage, transport, distribution and sale for direct consumption that , so as to guarantee a if implamented provide assurances that mineral water is safe, healthy and wholesome product. These hygienic practices are particularly important, because some hygiene control measures usually applied to bottled waters cannot be used for natural mineral waters.

2. OBJECTIVES

The Code of hygienic practice for collecting, processing and marketing of natural mineral waters is intended to;

- iIdentifiyes the necessary requirements that have to be fulfilled in order to ensure the distribution of natural mineral waters that are safe and suitable for human consumption;
- Recommends an approachdescribe measures specifically for natural mineral waters augment those in the based on the principles of the *General Principles of Food Hygiene* (CXC 1-1969);
- Recommends conducting a specificdescribe the use of hazard analysis in the overall context of the application of principles such as HACCP to the production of natural mineral waters;
- pProvides guidance containing conditions specifically linked to natural mineral waters.

3. SCOPE

This Code applies to all packaged natural mineral waters offered for sale as food. It does not apply to natural mineral waters sold or used for other purposes.

4. USE

This Code is supplemental to and should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969)

In many instances, the control measures are articulated in a general manner in the *General Principles of Food Hygiene* (CXC 1-1969) as part of the general strategy for food safety. In providing this Code, it is assumed that the *General Principles of Food Hygiene* are implemented.

The use of this Code may require modifications and amendments that take into account such factors as regional differences due to specific environmental and hydro-geological conditions.

5. GENERAL PRINCIPLES

Refer to Section 5 of the *General Principles of Food Hygiene* (CXC 1-1969).

6. DEFINITIONS

For the purpose of this Code, definitions contained in the *General Principles of Food Hygiene* (CXC 1-1969) apply.

In addition, the following definitions also apply:

Natural mineral water: all waters meeting the definitions in Section 2 of the *Standard for Natural Mineral Waters* (CXS 108 - 1981).

Adequate: sufficient to accomplish the intended purpose of this Code.

Aquifer: a saturated geological unit below the surface that yields water in sufficient quantities under normal hydraulic conditions.

Watershed: the surface area upstream of the ground water resource within which precipitations can either directly or indirectly enter the ground water system and which can contribute to recharge the aquifer.

Containers: any vessels made from food-grade packaging material intended to be filled with natural mineral waters.

~~**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 ground water. Protected ground waters are not directly influenced by surface water or the surface environment.~~

~~**Handling of natural mineral waters**: any manipulation with regard to collecting, treating, filling, packaging, storing, distribution and sale of natural mineral waters.~~

~~**Packaging material**: any materials, food grade or not, e.g. foil, film, metal, paper, wax-paper, etc.~~

~~**Perimeter of protection / protection zone**: area where human and animal activities need to be monitored and managed to protect the water from contamination.~~

~~**Pests:** any animals capable of directly or indirectly contaminating natural mineral waters.~~

~~**Recharge:** The process by which water enters an underground aquifer through faults, fractures or direct absorption.~~

~~**Recharge rate:** The quantity of water per unit of time that replenishes or refills an aquifer.~~

~~**Reservoir:** For the purposes of this document a reservoir is a holding tank.~~

~~**Safe yield:** Sustainable quantity of water per unit of time that may flow from a spring or be pumped continuously from a well or a borehole without depleting that resource beyond its ability to be replenished naturally.~~

~~**Spring**: An underground formation from which natural mineral waters discharge naturally from the ground.~~

Adequate: Sufficient to accomplish the intended purpose of this Code.

Aquifer: A saturated geological unit below the surface that yields water in sufficient quantities under normal hydraulic conditions.

Containers: Any vessels made from food-grade packaging material intended to be filled with natural mineral waters.

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 ground water. Protected ground waters are not directly influenced by surface water or the surface environment.

Handling of natural mineral waters: Any manipulation with regard to collecting, treating, filling, packaging, storing, distribution and sale of natural mineral waters.

Natural mineral water: All waters meeting the definitions in Section 2 of the Standard for Natural Mineral Waters (CXS 108-1981).

Packaging material: Any materials, food grade or not, e.g. foil, film, metal, paper, wax-paper, etc.

Perimeter of protection / protection zone: Area where human and animal activities need to be monitored and managed to protect the water from contamination.

Pests: Any animals capable of directly or indirectly contaminating natural mineral waters.

Recharge: The process by which water enters an underground aquifer through faults, fractures or direct absorption.

Recharge rate: The quantity of water per unit of time that replenishes or refills an aquifer.

Reservoir: A reservoir is a holding tank.

Safe yield: Sustainable quantity of water per unit of time that may flow from a spring or be pumped continuously from a well or a borehole without depleting that resource beyond its ability to be replenished naturally.

Spring: An underground formation from which natural mineral waters discharge naturally from the ground.

Watershed: The surface area upstream of the ground water resource within which precipitations can either directly or indirectly enter the ground water system and which can contribute to recharge the aquifer.

GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

Refer to Section 7 of the *General Principles of Food Hygiene* (CXC 1-1969).

8. PRIMARY PRODUCTION

Refer to Section 8 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

8.1 Environmental Control

8.1.1 Authorization

Any spring, well or drilling intended for the collection of natural mineral waters should be approved by the official authority having jurisdiction.

8.1.2 Determination of the source, origin and qualitygenesis of the natural mineral waters

As far as it is methodologically possible in each case, a precise analysis should be carried out on the origin of natural mineral waters, the period of their residence in the ground before being collected and their chemical and physical qualities.

8.1.3 Perimeter of protection

Areas, wherein natural mineral waters might be contaminated or their chemical, physical, radiological and microbiological qualities otherwise deteriorated, should be determined. Where indicated by hydrogeological conditions and considering the risks of contaminationcontamination, several perimeters with separate dimensions may be established provided for.

Hydro-geological studies by qualified experts should be carried out to determine and to describe the watershed.

Hydro-geological studies should include:

- location of the extraction points;
- determination of the extent and properties of the aquifer containing the ground water resource;
- location and extent of the watershed;
- degree and nature of natural protection against contamination;
- surface water features, identifying those interacting with the ground water resource;
- other water abstractors, identifying those exploiting the same ground water resource;
- chemistry and quality of the ground water resource;
- determination of the ground water recharge rate and safe yield; and
- travel times for ground water between recharge zone and extraction point(s).

8.1.4 Protective measures

All possible precautions should be taken within the perimeter of protection to preventavoid any contamination of, or external influence on, the chemical, physical, radiological and microbiological qualities of natural mineral waters. It is recommended that regulations Measures, including regulatory measures should be implemented be established for the disposal of liquid, solid or gaseous waste, the use of substances that might deteriorate natural mineral waters (e.g. by agriculture) as well as for any possibility of accidental deterioration of natural mineral waters by natural occurrences such as a change in the hydro-geological conditions. Consideration should be given to the following potential contaminants: bacteria, viruses, protozoa, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic or inorganic substances. Even where nature provides apparently sufficient protection against surface contamination, activities particularly likely to result in contamination, e.gsuch as mining, construction, etc., should be taken into consideration.

An evaluation of the adverse impacts of potential threats to the quantity and quality of the water supply should be performed. The evaluation should ~~normally~~ include:

- A review of land ownership and land use (current and historic) for the perimeter of protection;
- A collection of data on contaminants, contamination incidents and legal controls applicable to protecting waters from contamination; and
- An evaluation for each land use or activity;~~.~~

Protection zones and monitoring programmes should be defined using the ~~finding~~findings of the evaluation. At a minimum, the protection zone should encompass property owned by the producer, but as much as reasonably possible extend to other areas not under their control. Different levels of protection are required depending on proximity to the water source and potential risks.

8.2 Hygienic Protection

8.2.1 Hygienic extraction and collection of natural mineral waters

The extraction of natural mineral waters (from springs, natural or drilled wells) should be performed as appropiate ~~in conformity~~ with the hydro-geological conditions ~~in such a manner as~~ to prevent any water other than the natural mineral waters from entering or, should there be pumping facilities, prevent any extraneous water from entering by reducing the supply. The natural mineral waters thus collected or pumped should be protected ~~in such a way that they will be safe from~~ to prevent contamination whether caused by natural occurrence or actions or neglect or ill will.

The extraction facilities should be managed to prevent any other water, such as flood water or shallow seepage, from entering. They~~It~~ should also be managed in a hygienic manner to prevent any natural or manmade contamination.

8.2.2 Protection of the extraction area

In the immediate surroundings of springs and wells, precautionary measures should be taken to ensure that contaminants cannot enter the extraction area. The extraction area should be inaccessible to non-authorized persons by providing adequate devices (e.g. enclosure). Any activity not aiming at the collection of natural mineral waters should not be allowed in this area.

Roadways, areas used by wheeled traffic and areas serving the establishment which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage and provision should be made for the protection of the extraction area, where appropriate. Adequate road signage may be provided to call the attention of road users to the existence of a natural mineral waters extraction area.

8.2.3 Equipment and reservoirs

Equipment used for extraction of natural mineral waters and reservoirs should be designed and constructed in order to avoid contamination of natural mineral waters and to maintain their original characteristics.

The pipes, pumps or other possible devices coming into contact with natural mineral waters and used for its collection should be made of inert material as to ensure that the original characteristics and qualities of natural mineral waters will not be changed.

8.2.4 Exploitation of natural mineral waters, monitoring

The condition of the extraction facilities, areas of extraction and perimeters of protection as well as the quality of the natural mineral waters should periodically be examined. Automatic or manual measurements of the typical ~~To monitor the stability of the~~ chemical and physical parameters of the natural mineral waters, ~~allowing for natural variations, automatic or manual measurements of the typical characteristics~~ should be carried out resultsand documented.

Periodic monitoring should include the following basic parameters:

- appearance, odour and taste;
- physical: flow rate, temperature, electrical conductivity, piezometric level;
- physico-chemical: pH; and

- chemical: according to water characteristics, content of carbon dioxide.

Microbiological monitoring at the source should meet the criteria outlined in the ~~of the~~ Table in Annex I of this document and should be performed at a frequency that enables timely hygienic management ~~the appropriate hygienic management.~~

Should there be a failure to meet the limits of the established criteria, the necessary corrective measures are immediately to be taken and recorded.

8.3 Handling, storage and transport

8.3.1 Technical aspects

Methods and procedures for maintaining the handling and storage facilities should be hygienic and not be a potential health hazard to humans or a source of contamination to natural mineral waters. From the hygiene standpoint, servicing of the handling and storage installations should meet the same standards as those required for the packaging or treatment.

8.3.2 Storage at the point of extraction

The quantity of natural mineral waters stored at the point of extraction should be as low as possible. Storage conditions should prevent~~The storing should furthermore ensure protection against~~ contamination or deterioration.

Water should be stored for ~~a time as short as possible, in order to~~the shortest time possible to minimise potential for contamination and to avoid stagnant water. The design and operation of the reservoirs should minimise~~restrict~~ the time from point of extraction to packaging ~~to a minimum~~. The reservoir should be enclosed to ~~protect water from environmental contamination. Air~~ and air entering the headspace of reservoirs should be filtered or treated to prevent contamination of the water from the enviroment ~~to prevent contamination of the water~~. Air filters should have a pore size of 0.45 µm or less.

8.3.3 Piping and reservoirs

Any piping or reservoir used in the processing of natural mineral waters from its source to the packaging ~~facilities, the latter included~~, facilities should comply with the ~~necessary~~ requirements set by the competent authority~~official authority~~ having jurisdiction and be made of inert material approved for food contact such as ceramic and stainless steel that prevents any deterioration, be it by water, handling, servicing or disinfection.

8.4 Cleaning, maintenance and personnel hygiene

The water extraction and supply network should be properly managed and maintained, and cleaned or disinfected to prevent ~~protect all components from risk of~~ chemical, physical and microbiological contamination. For the extraction facilities itself, the disinfection regime should be designed to take account of the risks and its operational regime. For example, a constantly flowing spring may require sanitation only at times of intervention.

A detailed contingency plan should ~~also~~ be developed in collaboration with appropriate experts and authorities in order to react as quickly as possible to exceptional events (e.g. contamination of the groundwater resource, earthquake, forest fires, as appropriate for the specific location) so that consequences can be minimised. This plan should be part of the global crisis management system of the operating company.

Any reservoir should be properly cleaned and if necessary disinfected and kept in good condition so as to not present any potential for contamination to natural mineral waters and of modification of the original characteristics of natural mineral waters.

9. ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

Refer to Section 9 of the *General Principles of Food Hygiene*~~.~~ (CXC 1-1969), together with the following:

9.1 Location and structure

9.1.5 Premises and rooms

The filling equipment (e.g rinser, filler, capper) should be protected by a cabinet under positive pressure filtered air or in a room under sterile air filtration with positive pressure. It is advised to restrict operations in this particular area to a minimum by confining it to the open container activities of rinsing, filling and capping.

Operations such as labelling, coding, shrink wrapping, etc. can generate considerable suspended particles therefore it is preferable to exclude these activities from the rinsing, filling and capping areas. The use of hot glues

and ink jet equipment may result in change in taste and odour if used inside filling rooms, and this is why labelling machines inside filling rooms should have effective exhaust systems.

9.2 Facilities

9.2.1 Drainage and waste disposal facilities

Pipes or drain systems and sewage waters, as well as waste disposal bins located in the perimeter of protection, should be constructed and maintained ~~so as not~~ to prevent~~present a risk of~~ contamination of aquifers. Effective measures should be taken to prevent the unauthorized reuse of rejected containers – particularly those bearing company logos and other identification. Rejected containers ~~waiting~~waiting for disfigurement, destruction or authorized collection should be stored securely.

9.2.2 Cleaning facilities

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be constructed with corrosion resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying hot and cold water in sufficient quantities.

9.2.7 Storage

Materials storage should be separated into allocated areas for packaging materials, closures and bottles and, where possible also different types of bottles such as glass, PET, PE, PC and PVC.

~~It is advised to store p~~Packaging materials in a clean and dry area, away from any chemical vapours and under an effective pest control program.

Seperate f~~F~~acilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material ~~by pests~~ and to avoid contamination of natural mineral water, potable water, equipment, buildings or roadways on the premises.

9.2.8 Water supply

Natural mineral waters, potable water, and other water fit for purpose for~~non-potable water for~~ steam production or for refrigeration or any other use should be carried in completely separated lines. ~~It would be desirable that these~~These lines shoul~~d are~~ differentiated, e.g. by different colours. Steam used on surfaces in direct contact with natural mineral waters should not contain~~contain no~~ substances which may be hazardous to health or may contaminate the natural mineral water.

9.3 Equipment

9.3.1 General

As water is one of nature's most effective solvents, care should be taken when selecting water contact materials. This should include the materials used in the manufacture of pumps, pipes, filling equipment, etc.

Food-grade stainless steel is the most appropriate material for equipment in contact with water. Alternative materials should be inert materials approved for food contact that do not impart an odour or taste to the water or alter its composition.

It is essential to verify that lubricants used are suitable for food use. However, care should be taken to avoid lubricants from coming into contact with natural mineral water.

10. TRAINING AND COMPETENCE

Refer to Section 10 of the *General Principles of Food Hygiene* (CXC 1-1969).

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

Refer to Section 11 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

11.1 Maintenance and cleaning

Adequate precaution~~s~~ should be taken to prevent contamination of natural mineral waters ~~from being contaminated~~ during cleaning or disinfection of rooms, equipment or utensils, by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the ~~official authority having jurisdiction~~competent authority. Residues of these agents on a surface which may come in contact with natural mineral waters should be removed by thorough rinsing with potable water or preferably with natural mineral water.

~~The c~~Cleaning products should be odour-free.

If a packaging line is exclusively used for the packaging of natural mineral waters, a cold cleaning and disinfecting process should be considered as a minimum. CIP/COP (cleaning in place/cleaning out place) operations should be carried out on a regular basis. The cleaning and disinfecting agents should penetrate all areas of product flow (CIP) and should cover the operational surfaces (COP).

Painting works should not be undertaken during production time. Care should be taken in the selection of paint used. It is advisable to select paint specifically for use in a food manufacturing environment and with minimum odour. It cannot be emphasized enough that the odour of paint will be absorbed by water and may give a taste taint. It may be advisable to select a paint, which includes a mould inhibitor.

11.2 Pest control systems

Toxic baits should not be used for internal pest control.

Insect stunning devices, if and where used, should be carefully located so that stunned insects and fragments of them do not fall into open containers or closures. Use of glue boards' type insect monitor devices is recommended. Trays should be large enough to catch falling insects. ~~The l~~Instruments should be regularly maintained and cleaned out.

12. PERSONAL HYGIENE

Refer to Section 12 of the *General Principles of Food Hygiene* (CXC 1-1969).

13. CONTROL OF OPERATION

Refer to Section 13 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

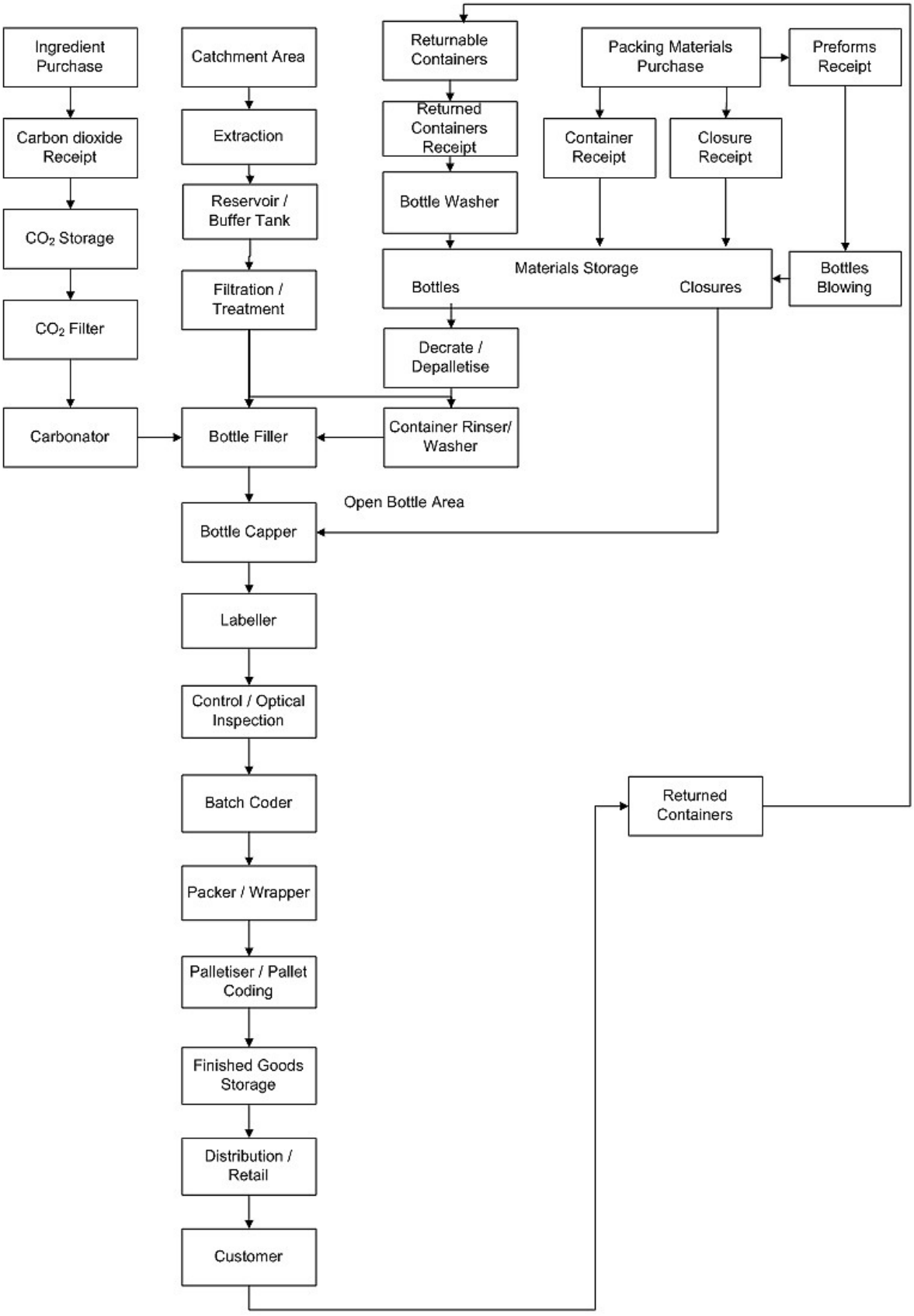
13.2 Key aspects of GHPs

Natural mineral waters intended for packaging should meet all standards (i.e. chemical, microbiological, physical, radiological) established by the competent authority ~~official authority having jurisdiction.~~

A hazard analysis, from catchment through distribution, which takes into consideration microbiological, physical, chemical and radiological hazards, should be undertaken according to HACCP principles. This should provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, these hazards to the production of safe natural mineral waters.

13.2.2 Specific process steps

Example of a Process Flow for Natural Mineral Waters



13.2.2.1 Buffer tank

Product is best kept in constant flow from source to packaging. The design and operation of the buffer tanks should restrict the time from storage to packaging to a minimum as determined based on the hazard analysis. Air entering the headspace of tanks should be filtered or treated to prevent contamination of product water.

13.2.2.2 Treatment

Natural mineral waters may not be subjected to any treatments other than those permitted by the *Standard for Natural Mineral Waters* (CXS 108-1981).

When necessary and subject to the approval of the competent authority ~~having jurisdiction~~, treatments to remove or reduce unstable constituents and health-related substances may include ~~—~~adsorption 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), oxygenation (O_2) and aeration.

All treatments of natural mineral waters should be carried out under controlled conditions to avoid any type of contamination.

Any treatment of natural mineral waters may introduce the possibility of contamination. Therefore, approved treatments, which are part of the process, should be subjected to HACCP principles.

13.2.2.3 Container rinser / washer

The design for refillable containers should enable easy multiple cleaning and disinfection. Effective washers should be in place.

Rejected containers (contaminated or non-cleanable) should be segregated and then managed in a way to avoid the potential for putting the container back on the line by mistake.

The outlet of the washer should be adequately protected. Conveyors from the outlet of the washing machine to the filling machine should be covered to protect the containers from contamination. Cleaned and disinfected containers should be ~~all the time~~ protected by covers ~~when~~ at all times while on conveyors, loading tables etc. Conveyor covers should be so designed as to protect containers from above and laterally from dust and other airborne particles.

13.2.2.4 Labeller

Labelling should not be caried out inside the filling room to prevent aerosol contamination, ~~is not recommended~~. If engineering or personnel organization constraints require the labellers to be in the filling room, they should be separated from the filler as far as possible and a hooded vent should be installed (except where cold glue is used) to adequately remove any fumes from the labellers, solvents and glue. In such cases the air circulation systems should be designed in order to avoid cross-contamination from the fumes.

13.2.3 Microbiological physical, chemical and allergen specifications

Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

Microbiological monitoring of natural mineral waters should meet the specifications of the Table in Annex I of this document and should be performed at a frequency that enables timely hygenic management.~~the appropriate hygienic management~~.

13.2.5 Physical contamination

Where glass bottles are used, periodic inspection requirements and defined procedures in case of breakage should be put in place in particular during the washing and filling steps of the glass bottles.

Special measures should be taken when filling glass bottles with carbonated water to avoid explosion and to protect the product from glass fragment.

Dedicated optical device should be installed to monitor the neck finish of glass bottles as well as the presence of glass fragments inside. Defective bottles should be automatically discarded from the line (detection/rejection device). Any packaged natural mineral water containing glass fragments should be considered unacceptable.

13.2.8 Incoming material requirements

Raw materials (i.e. CO_2) and processing materials (e.g. filtration media) should be purchased from approved suppliers and conform to mutually agreed specifications.

Consideration should be given to ensuring that no sensorial and microbiological contaminants arise from contact of CO_2, either with the final product or with containers and closures used for the packaging of natural mineral water.

13.2.9 Packaging

Containers should be stored in a way that prevents contamination from volatile compounds, airborne contaminants, pests and malicious acts.

Packaging materials should be stored in a dry place and be protected against heat, dust, pests and chemicals.

The use of recycled plastic packaging materials should be authorised by the official authority having jurisdiction.

14. PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to Section 14 of the *General Principles of Food Hygiene.* (CXC 1-1969) and Section 7 of the ~~*Codex*~~ *Standard for Natural Mineral Waters* (CXS 108-1981).

15. TRANSPORTATION

Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

Care should be taken to ensure a minimum temperature to prevent freezing of natural mineral waters which, due to expansion, is liable to cause breakage and/or explosion of containers and/or increase the potential for failure during distribution and consequent risk to the safety of the consumer. It should also be noted that following a severe cold spell there is an increased potential for condensation developing on containers which can give rise to damaged/mouldy labels and damp secondary packaging.

Storage and transportation of packaged natural mineral waters at excessive high or low temperatures should be avoided as it may result in quality reduction (e.g. risk of compound migration from primary packaging materials).

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

16. INTRODUCTION TO HACCP

Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

17. PRINCIPLES OF THE HACCP SYSTEM

Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

19. APPLICATION

Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

ANNEX I

MICROBIOLOGICAL CRITERIA

Natural mineral waters should be of such a microbiological quality that they will not present a risk to the health of the consumer (in particular regarding pathogenic microorganisms including parasites).

The production of microbiologically safe packaged natural mineral waters is dependent on maintaining a high level of hygienic control – from the protection of the aquifer, the extraction and up to the packaging and capping.

The following microbiological criteria (see Table) are intended to be used by manufacturers to verify the effectiveness of the implemented hygiene control measures as outlined in this Code of Hygienic Practice. Manufacturers may choose to perform all or a subset of the faecal indicator tests in the Table, as appropriate, in accordance with any requirements set by the competent authority.

Competent authorities can use all or a subset of the following microbiological criteria, as appropriate, to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

Table: Microbiological Criteria, Point of application: at source, during production and end-product

Parameters	**n**	**c**	**m**	**Class Plan**	**Method[1]**
Escherichia coli[3]	5	0	n.d. in 250 mL	2 [a]	ISO 9308-1
Total coliforms[3]	5	0	n.d. in 250 mL	2 [a]	ISO 9308-1
Enterococci[3]	5	0	n.d. in 250 mL	2 [a]	ISO 7899/-2
spore-forming sulphite-reducing anaerobes[3]	5	0	n.d. in 50 mL	2 [b]	ISO 6461/2
Pseudomonas aeruginosa[4]	5	0	n.d. in 250 mL	2 [a]	ISO 16266-2006
Aerobic mesophilic count / heterotrophic plate count[2, 4]	5	0	100 CFU/mL	2 [c]	ISO 6222-1999

1. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g. based on ISO/TR/13843).

2. Point of application: only at source, during production and within 12 hours following packaging.

3. Faecal indicator

4. Process control indicator

Where n = number of samples that must conform to the criteria: c = the maximum allowable number of defective sample units in a 2-class plan: m = a microbiological limit which, in a 2-class plan separates good quality from defective quality.

n.d. = not detectable

Performance of the sampling plan:

a. Assuming a log normal distribution and an analytical standard deviation of 0.25 log CFU/mL, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 2.3 CFU/L, corresponding to 1 CFU per 422 mL, would be detected and rejected based on any of the five samples testing positive.

b. Assuming a log normal distribution and an analytical standard deviation of 0.25 log CFU/mL, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 11.3 CFU/L, corresponding to 1CFU per 88 mL, would be detected and rejected based on any of the five samples testing positive.

c. Assuming a log normal distribution and an analytical standard deviation of 0.25 log CFU/mL, this sampling plan would provide 95% confidence that a lot of water containing a geometric mean concentration of 93 CFU/mL would be detected and rejected based on any of the five samples exceeding 100 CFU/mL.

Corrective actions:

The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected natural mineral water from being released for human consumption and (2) determine and correct the root cause of the failure and (3), as appropriate, review monitoring procedures and prerequisite programs.

Rationale for the parameters chosen:

Escherichia. coli

Escherichia coli is considered one of the most suitable indicators of faecal contamination.

Total coliforms

Coliforms can originate from faecal contamination or from the environment. Coliforms which can occur naturally in soil, water and vegetation, indicate possible contamination from airborne sources or from product contact surfaces that have not been effectively disinfected. Coliforms are normally not present in natural mineral water sources. Therefore, they are considered as an indicator of contamination of the water at source or during the packaging process.

Enterococci

Enterococci are a sub-group of faecal streptococci. Compared to *E. coli* and coliforms they tend to survive longer in the water environment and are therefore used as an additional indicator of faecal contamination.

Spore-forming sulphite-reducing anaerobes

The spores of this group of bacteria are very resistant towards various kinds of environmental stresses. Spore-forming sulphite-reducing anaerobes can originate from faecal contamination and due to the length of their survival in unfavourable environments, they are usually used as an indicator of faecal contamination.

Pseudomonas aeruginosa

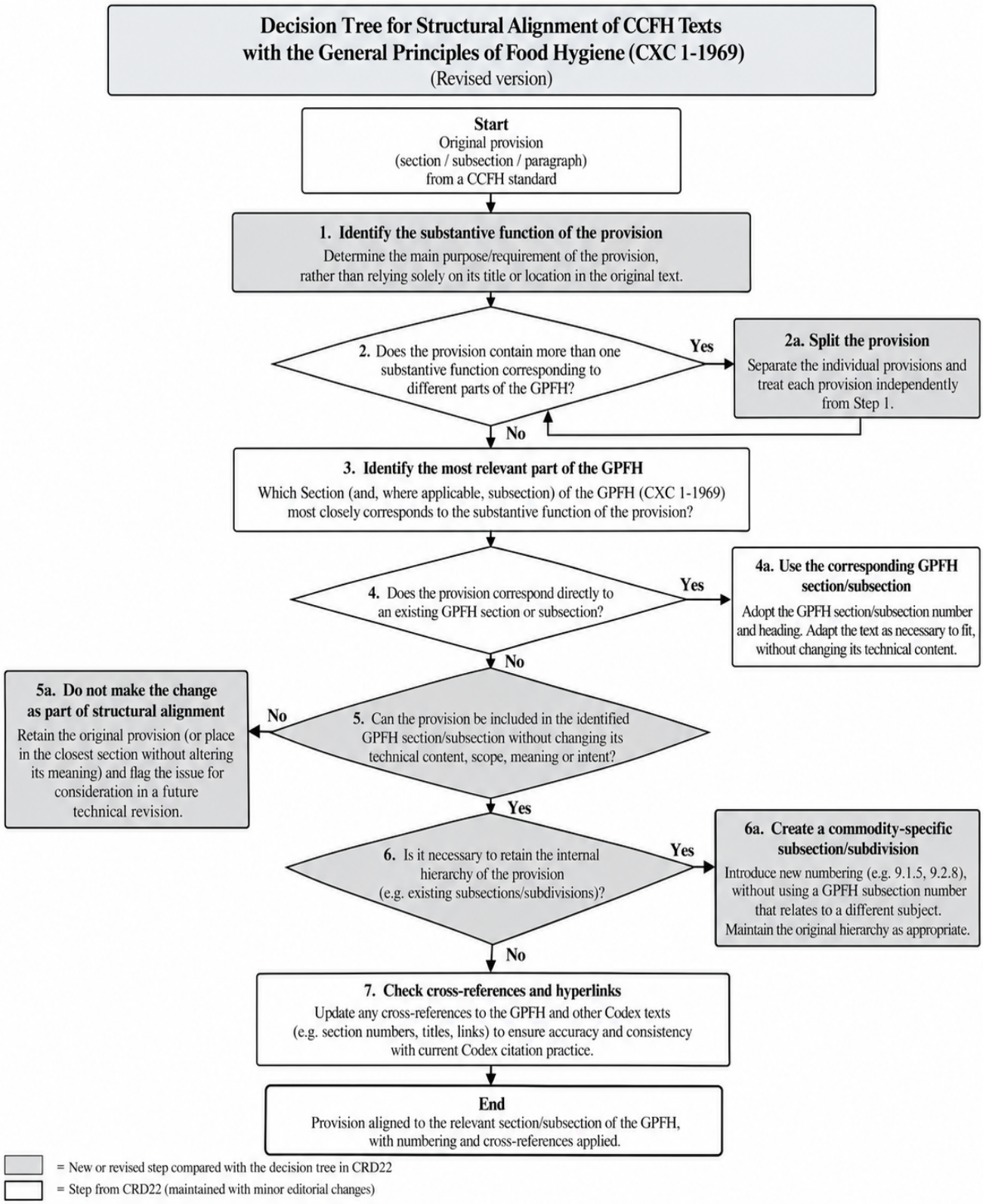
Pseudomonas aeruginosa is not a normal component of the natural flora of natural mineral waters. When detected, it is usually in low numbers but *P. aeruginosa* can survive and grow in natural mineral waters. Therefore, its presence is considered as an indicator of contamination of the water at source or during the packaging process.

Aerobic mesophilic count / heterotrophic plate count

The aerobic mesophilic count / heterotrophic plate count is part of the natural flora of natural mineral waters and is used as a process management indicator. A limited increase in the counts is normal from source to the packaging. Numbers increasing over a certain level can indicate deterioration in cleanliness, stagnation or development of biofilms.

APPENDIX IV

Revised Decision Tree for Structural Alignment of CCFH Texts with the GPFH (CXC 1-1969)



Appendix V

List of participants of the EWG

Chair

China

Co-Chairs

United Kingdom

Kenya

MEMBERS

Argentina

Brazil

Canada

China

Ecuador

Egypt

European Union

Honduras

India

Indonesia

Ireland

Japan

Jordan

Morocco

New Zealand

North Macedonia

Portugal

Republic of Korea

Saudi Arabia

Spain

Thailand

Türkİye

United Kingdom

OBSERVERS

AOECS

ICBA