CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/FH 10/42/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-second Session
Kampala, Uganda, 29 November – 3 December 2010

PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS
(At Step 3)

Prepared by the physical working group led by Switzerland.

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Revision at Step 3 (see Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720 3157, or email Barbara.McNiff@fsis.usda.gov with a copy **to**: Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 20 October 2010.**

BACKGROUND

The 41st Session of the Committee on Food Hygiene agreed to request the 33rd Session of the Commission to approve new work on the revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985). The 33rd Session of the Commission approved this new work (N05-2010).

The Committee further agreed that a physical working group, led by Switzerland, would revise the recommended code of hygienic practice for circulation for comments at Step 3 and consideration by the next session of the Committee.

The physical working group met in Lucerne, Switzerland on 7 – 9 June 2010 and prepared the revised Code (see Appendix I) for circulation at Step 3 for comments. The report of the working group is presented below.

REQUEST FOR COMMENTS

Governments and interested international organizations are invited to submit comments at Step 3, as directed above, on the proposed draft revision of the *Recommended International Code of Hygienic Practice for Collecting, processing and Marketing of Natural Mineral Water* (CAC/RCP 33-1985), attached as Appendix I to this document.

Report of the Physical Working Group

1. The CCFH-WG NMW (WG) held its meeting in Lucerne, Switzerland, from 7th to 9th June 2010 at the invitation of the Government of Switzerland. The WG meeting was opened by Dr. Roland Charrière, Deputy Director of the Swiss Federal Office of Public Health and head of the Consumer Protection Directorate. Ms Awilo Ochieng Pernet, Swiss Federal Office of Public Health chaired the meeting which was attended by 42 delegates from Brazil, the European Union, France, Germany, Hungary, Ireland, Iraq, Italy, Japan, Poland, Suriname, Switzerland, the United States of America, FAO, WHO, ICBA, ICBWA and ICMSF. A complete list of participants is given in Appendix II to this report.

2. In her introductory remarks, the chairperson recalled that the CCFH had agreed at its 41st session which took place in San Diego, United States of America from 16th to 20th November 2009, to establish a Physical Working Group on the Code of Hygienic Practice for Natural Mineral Waters chaired by Switzerland (also refer to ALINORM 10/33/13, paragraph 132). The mandate of the WG was to revise the *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985)*, in line with the Project Document in Appendix V of ALINORM 10/33/13, in order to bring the revised Code of Hygienic Practice in line with HACCP principles and the requirements of the *Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969)*, for circulation in view of comments at Step 3.

3. She further recalled that participation in the WG was open to all interested Codex Members and Observers and that on 21st December 2009, the Codex Secretariat had distributed, via the Codex mailing lists, the preliminary information including the tentative dates for the CCFH-WG Meeting. The official invitation to participate in the WG Meeting had later been distributed by the Codex Secretariat to all Codex Members and Observers on 5th March 2010.

4. The meeting was conducted in English, French and Spanish and simultaneous interpretation facilities were provided in all three Codex languages.

5. In her capacity as Chair of the WG, Switzerland had prepared a Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters based on the structure and principles contained in the *Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2003))*. This Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters had been distributed in all three Codex languages to all WG members prior to the meeting held in Lucerne.

6. Two WG members (Canada and Kenya) submitted written comments on the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters prior to the WG Meeting. These comments were distributed to all participants and they were given careful consideration during the WG discussions.

7. The WG discussed the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters and agreed on the following key points:

Introduction:

8. It was agreed to highlight that appropriate hygienic practices from the protection of aquifers up to the collection and sale of natural mineral waters (NMW) are of particular importance as certain hygiene control measures (e.g. treatments) which are usually applied to bottled waters cannot be used for NMW.

Section 2:

9. The WG agreed to keep the definition for NMW as stated in Section 2 of the *Codex Standard for Natural Mineral Waters (CODEX STAN 108 - 1981)*. In addition, all other relevant terms used in the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters have been listed with their respective definition.

Sections 3 and 4:

10. The WG revised the proposed Sections 3 and 4 in order: to follow the sequence of primary production activities; to fit into the existing subsection of 3.1- 3.4 format as much as possible; and clearly separate the operations which belong to primary production such as the protection of the source and the hygienic extraction and collection of NMW from operations within the establishment.

Sections 5 and 6:

11. In these sections, the WG addressed key aspects of hygiene control measures which are necessary during the "production" of NMW.

Annex I, Microbiological criteria:

12. The proposed Annex I as given in the draft document prepared by Switzerland was a major issue of discussion during the WG meeting.

13. There was unanimous agreement within the WG regarding the fact that the existing microbiological criteria for NMW as given both in the Codex Standard for NMW as well as in the Code of Hygienic Practice for NMW should take into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)*. Furthermore, there was general agreement that microbiological criteria for NMW should only be set in one document, preferably in the Code of Hygienic Practice for NMW.

14. However, the WG had some discussion on the parameters to be chosen, on the scientific justification for the chosen parameters and on the lack of statistical performances for the proposed sampling plans.

15. The WG decided to base its discussions on the microbiological requirements as outlined in section 4.4 of the *Codex Standard for Natural Mineral Waters (Codex STAN 108-1981)*. The following amendments were given due consideration by the WG and were thus included in the proposed Annex I:

    (a) The fact that the absence of pathogenic microorganisms is currently included in the requirements under 4.4a. The WG agreed to delete this absence of pathogenic microorganisms and proposed paragraphs 97 - 99. The rationale for this deletion was that according to CAC/GL 21-1997, only relevant parameters should be included in the microbiological criteria. Based on a long history of safe use, it could be concluded that no such food safety criterion is needed and that effectiveness of control measures is demonstrated by the compliance to process hygiene criteria as outlined in Tables 1 and 2 of the proposed Annex I.
    (b) This approach of establishing process hygiene criteria required an amendment regarding the point of the food chain at which the chosen process hygiene criteria would apply. Therefore, Tables 1 and 2 are proposed, taking into account different points of the NMW chain and stating the necessary actions to be taken when a criterion is not met.
    (c) A rationale for the parameters chosen in Tables 1 and 2 was included in the proposed Annex I based on the WHO Guidelines for Drinking Water Quality and the expert opinions given by the members of the WG.
    (d) The WG agreed on the fact that a statistical performance of the proposed sampling plans was needed. The representative from ICMSF kindly offered to establish the statistical performances of the proposed sampling plans in collaboration with FAO/WHO. The outcome of this work should be included in the proposed Annex I. The WG agreed that until the statistical performances of the proposed sampling plans would be available, square brackets were put around the criteria for aerobic mesophilic count/ heterotrophic plate count in Table 1 of Annex I.
    (e) In line with the WG agreement, ICMSF and FAO/WHO have in the meantime provided the necessary statistical performance for the sampling plan proposed in Table 1 and 2 of Annex I. Consequently, the square brackets concerning the criteria for aerobic mesophilic count/ heterotrophic plate count have been removed in Table 1.

16. The WG **agreed** to submit the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (Appendix II) for comments at Step 3 and discussion at Step 4 during the 42nd session of the CCFH due to take place from 29th November to 3rd December 2010.

17. The WG **recommends** that once there is agreement on Annex I of the Proposed Draft Revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters, the Codex Committee on Food Hygiene should discuss the proposal to delete section 4.4 of the *Codex Standard for Natural Mineral Waters (Codex STAN 108-1981).*

APPENDIX I

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (CAC/RCP 33-1985)

(N05-2010)

INTRODUCTION

1. This Code recommends appropriate hygienic practices for collecting natural mineral waters, their treatment, bottling, packaging, storage, transport, distribution and sale for direct consumption, so as to guarantee a 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.

SECTION I – OBJECTIVES

2. The Code of hygienic practice for collecting, processing and marketing of natural mineral waters

- Identifies the necessary requirements that have to be fulfilled in order to guarantee the distribution of natural mineral waters that are safe and suitable for human consumption.
- Recommends an approach based on the principles of the *Recommended International Code of Practice - General Principles of Food Hygiene* (abbreviated in this document as General Principles of Food Hygiene)
- Recommends conducting a specific hazard analysis in the overall context of the application of principles such as HACCP to the production of natural mineral waters.
- Provides guidance containing conditions specifically linked to natural mineral waters.

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

3. 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.

2.2 USE OF THE DOCUMENT

4. This Code is supplemental to and should be used in conjunction with the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5. In many instances, the control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* 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.

6. 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.

2.3 DEFINITIONS

7. Definitions contained in the *Recommended International Code of Practice - General Principles of Food Hygiene*

8. For the purpose of this Code, the following definitions apply:

Natural mineral waters - all waters meeting the definitions in Section 2 of the *Codex Standard for Natural Mineral Waters (CODEX STAN 108 - 1981)*

Adequate - sufficient to accomplish the intended purpose of this Code

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

Catchment area - the surface area within which precipitations can either directly or indirectly enter the ground water system into which the well is tapped, and which can contribute to replenish the aquifer.

Containers - any bottle, carton, can or other container to be filled with natural mineral waters.

Groundwater - all water below the surface of the ground in the saturated zone and in direct contact with the ground or subsoil. It is normally tapped by means of a borehole, dug well, spring or near horizontal shaft or gallery.

Handling of natural mineral waters - any manipulation with regard to collecting, treating, bottling, packaging, storing, transport, distribution and sale of natural mineral waters.

Packaging material – any containers such as cans, bottles, cartons, boxes, cases or wrapping and covering material such as foil, film, metal paper and wax-paper.

Perimeter of protection / protection zone - area where human 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

Reservoir - For the purposes of this document a reservoir is a holding tank

Spring - any natural mineral waters discharging naturally from the ground.

Water basin - area defining the body of water from which supplies are drawn, including the extraction point

SECTION III - PRIMARY PRODUCTION

9. Refer to Section III of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

3.1 ENVIRONMENTAL HYGIENE - PROTECTION OF AQUIFERS

3.1.1 Authorization

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

3.1.2 Determination of the genesis of the natural mineral waters

11. 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.

3.1.3 Perimeter of protection

12. Areas, wherein natural mineral waters might be contaminated or its chemical, physical and microbiological qualities otherwise deteriorated, should be determined. Where indicated by hydro-geological conditions and considering the risks of contamination several perimeters with separate dimensions may be provided for.

13. Hydro-geological studies by qualified experts should be carried out to determine the water basin and to describe the recharge zone and catchment area.

14. Hydro-geological studies should include:

- location of the extraction points
- the geological unit(s) (the aquifer) containing the groundwater resource
- location and extent of the catchment area
- degree and nature of natural protection against contamination
- surface water features, identifying those interacting with the groundwater resource
- other water abstractors, identifying those exploiting the same groundwater resource

- chemistry and quality of the groundwater resource
- water balance and capacity
- travel times for groundwater between recharge zone and extraction point(s)
- studies to justify the extraction licence and to demonstrate the sustainability of the groundwater yield.

3.1.4 Protective measures

15. All possible precautions should be taken within the perimeter of protection to avoid any contamination of, or external influence on, the chemical, physical and microbiological qualities of natural mineral waters. It is recommended that regulations 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. Particular 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, potential hazards should be taken into consideration, such as mining, hydraulic and engineering facilities, etc.
16. 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:
    - Review of land ownership and land use (current and historic) for the water basin
    - Collection of data on contaminants, contamination incidents and legal controls applicable to protecting waters from contamination
    - Evaluation for each land use or activity.
17. Protection zones and monitoring programmes should be defined using the finding 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. Different levels of protection are required depending on proximity to the water source and potential risks.

3.2 HYGIENE EXTRACTION AND COLLECTION OF NATURAL MINERAL WATERS

3.2.1 Extraction

18. The withdrawal of natural mineral waters (from springs, galleries, natural or drilled wells) should be performed 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 contamination whether caused by natural occurrence or actions or neglect or ill will.
19. The water source should be managed to prevent any other water, such as flood water or shallow seepage, from entering. It should also be managed in a hygienic manner to prevent any natural or manmade contamination.

3.2.2 Protection of the extraction area

20. In the immediate surroundings of springs and wells, precautionary measures should be taken to guarantee that no contaminant whatsoever can 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 be forbidden in this area.

3.2.3 Materials

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

3.2.4 Equipment and reservoirs

22. Equipment and reservoirs used for extraction of natural mineral waters should be designed and constructed in order to minimize all hazards to human health, to avoid contamination of natural mineral waters and to maintain their original characteristics.

3.2.5 Exploitation of natural mineral waters, monitoring

23. 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 checked. 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 and notified.

24. Periodic monitoring should include the following basic parameters:

- Appearance, odour and taste
- Physical: flow rate, temperature, electrical conductivity, piezometric level
- Physico-chemical: pH
- Chemical: according to water characteristics, content of carbon dioxide

25. Microbiological monitoring at the source shall meet the criteria of Table 1 in Annex I of this document and should be performed at a frequency that enables the appropriate hygienic management.

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

3.3 HANDLING, STORAGE AND TRANSPORT OF NATURAL MINERAL WATERS INTENDED FOR BOTTLING

3.3.1 Technical aspects

27. Methods and procedures for maintaining the extraction 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 extraction installations should meet the same standards as those required for the bottling or treatment.

3.3.2 Storage at the point of extraction

28. The quantity of natural mineral waters stored at the point of extraction should be as low as possible. The storing should furthermore guarantee protection against contamination or deterioration.

29. Water should not be retained excessively in reservoirs. The design and operation of the reservoirs should restrict the time from point of extraction to bottling to a minimum. Air entering the headspace of reservoirs should be filtered or treated to prevent contamination of the water. In addition, the following requirements should be applied:

- The reservoirs should be protected from environmental contamination (be enclosed, and with air filters (pore size of 0.45 µm or less recommended), etc.)
- Water should be stored for a time as short as possible, in order to minimise potential for contamination and to avoid stagnant water.

3.3.3 Transport, piping and reservoirs

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

31. 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.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

32. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

33. The water extraction and supply network should be properly managed and maintained, and cleaned or disinfected to 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.

34. 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.

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

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

36. Refer to Section IV of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.1 LOCATION

37. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.2 PREMISES AND ROOMS

38. The filling equipment (rinser, filler, capper) should be protected by a cabinet under air filtered positive pressure 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 bottle activities of bottle rinsing, filling and capping areas.

39. Operations such as labelling, coding, shrink wrapping, etc. can generate considerable aerial debris, therefore it is preferable to exclude these activities from the filling and capping areas. The use of hot glues and ink jet equipment can result in taste and odour problems if used inside filling rooms. Labelling machines inside filling rooms should have effective exhaust systems.

4.3 EQUIPMENT

40. 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.

41. Food-grade stainless steel is the most appropriate material for equipment in contact with water. If alternative materials are used, it is vitally important to ensure that they do not impart an odour or taste to the water or alter its composition in any way.

42. It is essential to verify that any lubricants used are not only suitable for food use, but that they specifically have no adverse effect on water or its containers.

4.4 FACILITIES

4.4.1 Water supply

43. Natural mineral waters, potable water, non potable water for steam production or for refrigeration or any other use should be carried in completely separate lines with no cross connection between them and without back siphonage. It would be desirable that these lines be identified by different colours. Steam used on surfaces in direct contact with natural mineral waters should contain no substances which may be hazardous to health or may contaminate the water.

4.4.2 Drainage and waste disposal

44. Effective measures should be taken to prevent the unauthorized reuse of rejected bottles – particularly those bearing company logos and other identification. Rejected bottles waiting disfigurement, destruction or authorized collection should be stored securely.

4.4.3 Cleaning

45. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.4.4 Personal hygiene facilities and toilets

46. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.4.5 Temperature control

47. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.4.6 Air quality and ventilation

48. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.4.7 Lighting

49. Refer to *Recommended International Code of Practice - General Principles of Food Hygiene.*

4.4.8 Storage

50. 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.

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

SECTION V - ESTABLISHMENT: CONTROL OF OPERATION

52. Refer to Section V of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5.1 CONTROL OF FOOD HAZARDS

53. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

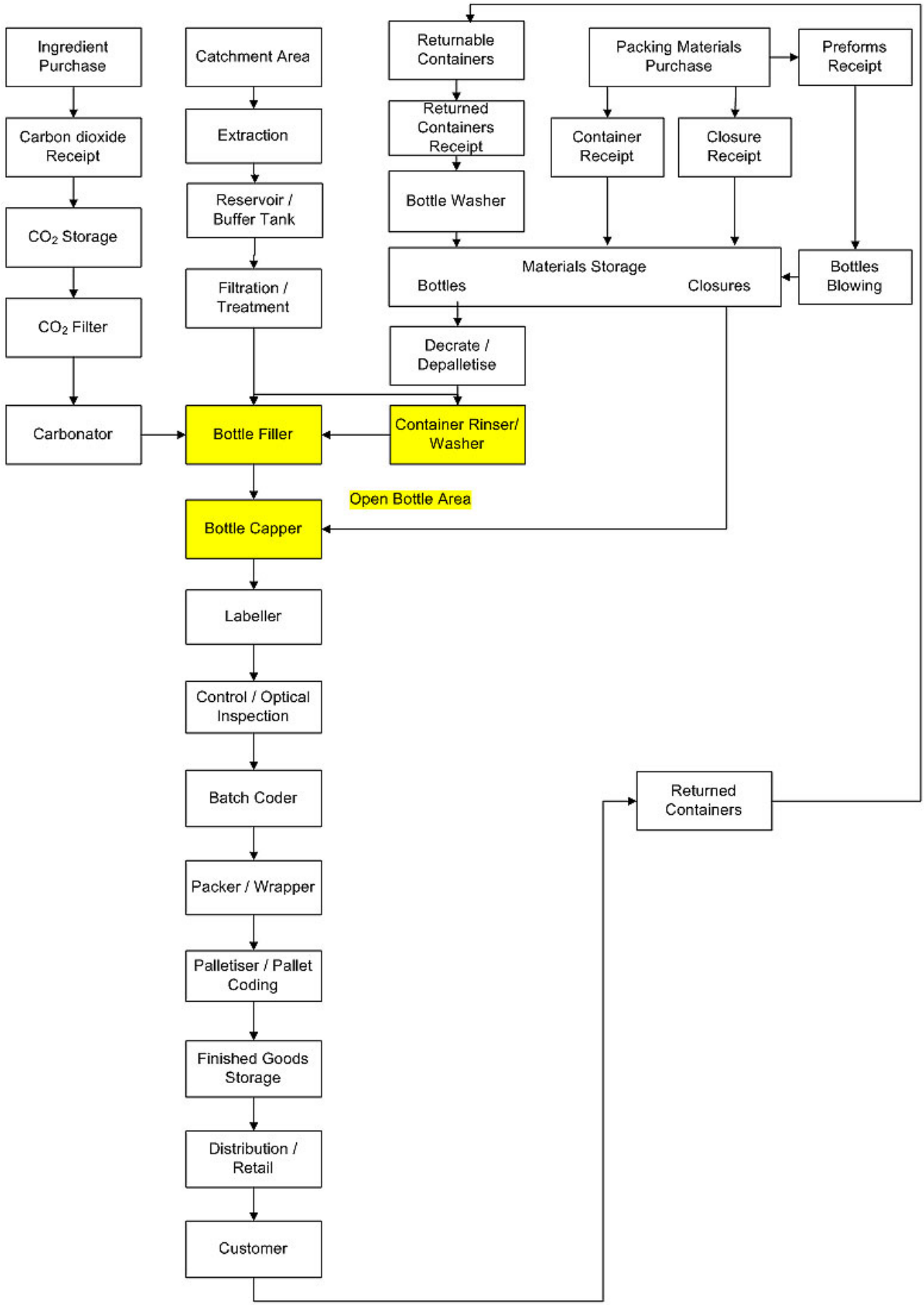
5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

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

55. 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.

5.2.2 Specific process steps

Example of a Process Flow for Natural Mineral Waters



5.2.2.1 Buffer tank

56. Product is best kept in constant flow from source to bottling. The design and operation of the buffer tanks should restrict the time from storage to bottling 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.

5.2.2.2 ***Treatment***

57. Natural mineral waters may not be subjected to any treatments other than those permitted by the *Codex Standard for Natural Mineral Waters.*

58. 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 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), and aeration.

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

60. 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. A monitoring program for treatment risks should be put in place.

5.2.2.3 ***Container rinser / washer***

61. The bottle design for refillable bottles should enable easy multiple cleaning and disinfecting through washer. Effective bottle washers should be in place.

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

63. 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 bottles should be all the time protected by covers when on conveyors, loading tables etc. Conveyor covers should be so designed as to protect bottles from above and laterally from dust, sneezes etc.

5.2.2.4 ***Labeller***

64. Labelling inside the filling room 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 labeller, solvents and glue. In such cases the air circulation systems should be designed in order to avoid cross-contamination from the fumes.

5.2.3 Microbiological and other specifications

65. Refer to the *Principles for the Establishment and Applications of Microbiological Criteria* (CAC/GL 21-1997).

66. Microbiological monitoring of natural mineral waters shall meet the specifications of Tables 1 and 2 in Annex I of this document and should be performed at a frequency that enables the appropriate hygienic management.

5.2.4 Microbiological cross-contamination

67. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5.2.5 Physical and chemical contamination

68. 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.

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

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

5.3 INCOMING MATERIAL REQUIREMENTS

71. 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.

72. 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 the primary packaging materials used for the bottling of water.

5.4 PACKAGING

73. The primary packaging materials (e.g. pre-forms, blown plastic bottles, cleaned glass bottles, caps and closures) should be stored in a way that prevents contamination from volatile compounds, airborne contaminants, pests and malicious acts.

74. Caps and closures should be stored in a dry place and be protected against heat, dust, pests and chemicals.

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

5.5 WATER

76. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5.6 MANAGEMENT AND SUPERVISION

77. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5.7 DOCUMENTATION AND RECORDS

78. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

5.8 RECALL PROCEDURES

79. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

80. *Refer to Section VI of the Recommended International Code of Practice - General Principles of Food Hygiene.*

6.1 MAINTENANCE AND CLEANING

81. Adequate precautions should be taken to prevent 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. Residues of these agents on a surface which may come in contact with natural mineral waters should, unless otherwise authorized by the official authority having jurisdiction, be removed by thorough rinsing with potable water or preferably with natural mineral water.

82. The cleaning products should be odour-free.

83. If a bottling line is exclusively used for the bottling 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).

84. 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.

6.2 CLEANING PROGRAMS

85. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

6.3 PEST CONTROL SYSTEMS

86. Poisonous pest control systems should not be used inside the manufacturing area.

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

6.4 WASTE MANAGEMENT

88. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

6.5 MONITORING EFFECTIVENESS

89. Refer to the *Recommended International Code of Practice - General Principles of Food Hygiene.*

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

90. Refer to Section VII of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

SECTION VIII – TRANSPORTATION AND STORAGE OF BOTTLED NATURAL MINERAL WATERS

91. Refer to Section VIII of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

92. 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 bottles 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 bottles which can give rise to damaged/mouldy labels and damp secondary packaging.

93. Transportation of 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).

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

94. Refer to Section IX of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

95. Refer to Section VI of the *Codex Standard for Natural Mineral Waters.*

SECTION X - TRAINING

96. Refer to Section X of the *Recommended International Code of Practice - General Principles of Food Hygiene.*

ANNEX I: MICROBIOLOGICAL CRITERIA

97. Natural mineral waters shall be of such a microbiological quality that they will not present a risk to the health of the consumer.

98. The production of microbiologically safe bottled 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 bottling and capping.

99. The following process hygiene criteria (see Tables 1 and 2) 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.

Table 1: Process Hygiene Criteria, Point of application: at source and during production

Parameters	**n**	**c**	**m**	**M**	**Class Plan**	**Method**[1]
E. coli	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 9308-1
Total coliforms	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 9308-1
Enterococci	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 7899/2
spore-forming sulfite-reducing anaerobes	5	0	n.d. in 50 ml	not applicable	2 [b]	ISO 6461/2
Ps. aeruginosa	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 16266
Aerobic mesophilic count / heterotrophic plate count[2]	5	0	100 cfu/ml	not applicable	2 [c]	ISO 4833

[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: at source, during production and within 12 hours following bottling.

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 or marginally acceptable sample units in a 3-class plan: m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality: M = a microbiological limit which, in a 3-class plan, separates marginally acceptable 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 detecting 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 1 cfu per 88 ml, would be detected and rejected based on any of the five samples detecting 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:

E. coli

E. 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 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 bottling 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 sulfite-reducing anaerobes

The spores of this group of bacteria are very resistant towards various kinds of environmental stresses. Due to their survival time 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 *Pseudomonas 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 bottling 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 bottling. Numbers increasing over a certain level can indicate deterioration in cleanliness, stagnation or development of biofilms.

Table 2: Process Hygiene Criteria, Point of application: end-product specifications

Parameters	**n**	**c**	**m**	**M**	**Class Plan**	**Method[1]**
E. coli	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 9308-1
Total coliforms	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 9308-1
Enterococci	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 7899/2
spore-forming sulfite-reducing anaerobes	5	0	n.d. in 50 ml	not applicable	2 [b]	ISO 6461/2
Ps. aeruginosa	5	0	n.d. in 250 ml	not applicable	2 [a]	ISO 16266

[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).

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 or marginally acceptable sample units in a 3-class plan: m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality: M = a microbiological limit which, in a 3-class plan, separates marginally acceptable 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 detecting 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 1 cfu per 88 ml, would be detected and rejected based on any of the five samples detecting positive.

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 lots 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:

E. coli

E. 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 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 bottling 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 sulfite-reducing anaerobes

The spores of this group of bacteria are very resistant towards various kinds of environmental stresses. Due to their survival time 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 *Pseudomonas 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 bottling process.

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