

## CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS

(CXC 33-1985)

### 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.

### 1. 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 ensure 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.

### 2. 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 General Principles of Food Hygiene.*

5. In many instances, the control measures are articulated in a general manner in the *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. For the purpose of this Code, definitions contained in the *General Principles of Food Hygiene* apply.

8. In addition, the following definitions also 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.

**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.

### **3. SECTION III - PRIMARY PRODUCTION**

9. Refer to Section III of the *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 their chemical, physical, radiological 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 and to describe the watershed.

14. 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
- Travel times for ground water between recharge zone and extraction point(s)

### **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, radiological 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. 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, such as mining, construction, etc., should be taken into consideration.

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 perimeter of protection;
- 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 not under their control. Different levels of protection are required depending on proximity to the water source and potential risks.

## **3.2 HYGIENIC EXTRACTION AND COLLECTION OF NATURAL MINERAL WATERS**

### **3.2.1 EXTRACTION**

18. The extraction of natural mineral waters (from springs, 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 extraction facilities 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 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.

21. 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.

### **3.2.3 EQUIPMENT AND RESERVOIRS**

22. 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.

23. 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.

### **3.2.4 EXPLOITATION OF NATURAL MINERAL WATERS, MONITORING**

24. 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. 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 documented.

25. 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

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

27. 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 AND STORAGE OF NATURAL MINERAL WATERS INTENDED FOR PACKAGING**

### **3.3.1 TECHNICAL ASPECTS**

28. 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.

### **3.3.2 STORAGE AT THE POINT OF EXTRACTION**

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

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

### **3.3.3 PIPING AND RESERVOIRS**

31. Any piping or reservoir used in the processing of natural mineral waters from its source to the packaging 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 that prevents any deterioration, be it by water, handling, servicing or disinfection.

## **3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION**

32. 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.

33. 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.

34. 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.

#### **4. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES**

35. Refer to Section IV of the *General Principles of Food Hygiene*.

##### **4.1 LOCATION**

36. Refer to *General Principles of Food Hygiene*.

##### **4.2 PREMISES AND ROOMS**

37. The filling equipment (rinsing, 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.

38. 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.

##### **4.3 EQUIPMENT**

39. 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.

40. 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.

41. 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.

##### **4.4 FACILITIES**

###### **4.4.1 WATER SUPPLY**

42. Natural mineral waters, potable water, 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 lines are differentiated, e.g. 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 natural mineral water.

###### **4.4.2 DRAINAGE AND WASTE DISPOSAL**

43. 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 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 disfigurement, destruction or authorized collection should be stored securely.

###### **4.4.3 CLEANING**

44. Refer to *General Principles of Food Hygiene*.

45. 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.

#### **4.4.4 PERSONAL HYGIENE FACILITIES AND TOILETS**

46. Refer to *General Principles of Food Hygiene*.

#### **4.4.5 TEMPERATURE CONTROL**

47. Refer to *General Principles of Food Hygiene*.

#### **4.4.6 AIR QUALITY AND VENTILATION**

48. Refer to *General Principles of Food Hygiene*.

#### **4.4.7 LIGHTING**

49. Refer to *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.

52. Facilities 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.

### **5. SECTION V - ESTABLISHMENT: CONTROL OF OPERATION**

53. Refer to Section V of the *General Principles of Food Hygiene*.

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

54. Refer to the *General Principles of Food Hygiene*.

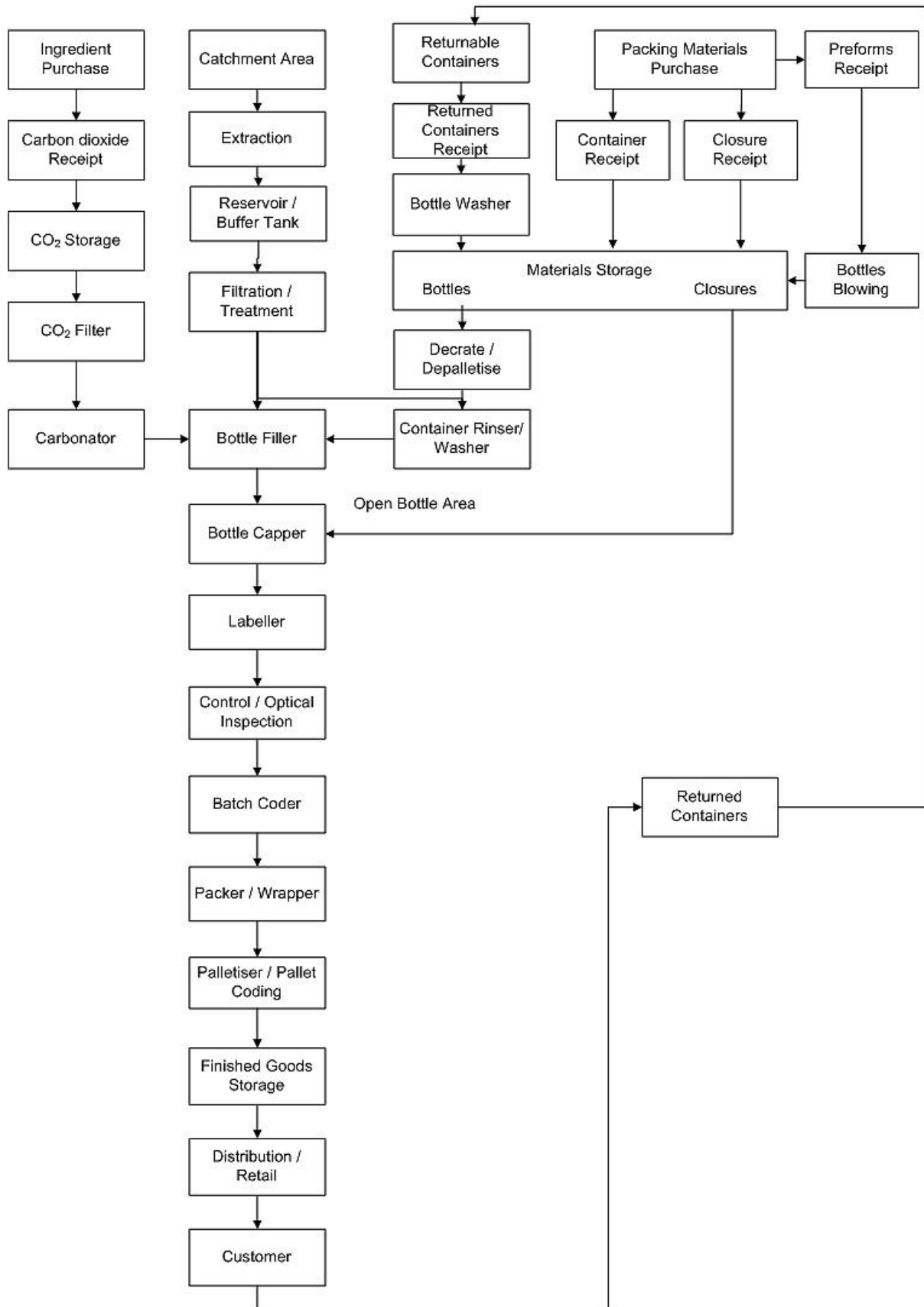
#### **5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS**

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

56. 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

57. 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.

### 5.2.2.2 TREATMENT

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

59. 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<sub>2</sub>) and aeration.

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

61. 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.

### 5.2.2.3 CONTAINER RINSER / WASHER

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

63. 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.

64. 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 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.

### 5.2.2.4 LABELLER

65. 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

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

67. 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 the appropriate hygienic management.

### 5.2.4 MICROBIOLOGICAL CROSS-CONTAMINATION

68. Refer to the *General Principles of Food Hygiene*.

### 5.2.5 PHYSICAL AND CHEMICAL CONTAMINATION

69. 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.

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

71. 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.

### **5.3 INCOMING MATERIAL REQUIREMENTS**

72. Raw materials (i.e. CO<sub>2</sub>) and processing materials (e.g. filtration media) should be purchased from approved suppliers and conform to mutually agreed specifications.

73. Consideration should be given to ensuring that no sensorial and microbiological contaminants arise from contact of CO<sub>2</sub>, either with the final product or with containers and closures used for the packaging of natural mineral water.

### **5.4 PACKAGING**

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

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

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

### **5.5 WATER**

77. Refer to Section 5.5.1 of the *General Principles of Food Hygiene*.

### **5.6 MANAGEMENT AND SUPERVISION**

78. Refer to the *General Principles of Food Hygiene*.

### **5.7 DOCUMENTATION AND RECORDS**

79. Refer to the *General Principles of Food Hygiene*.

### **5.8 RECALL PROCEDURES**

80. Refer to the *General Principles of Food Hygiene*.

## **6. SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION**

81. Refer to Section VI of the *General Principles of Food Hygiene*.

### **6.1 MAINTENANCE AND CLEANING**

82. 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 be removed by thorough rinsing with potable water or preferably with natural mineral water.

83. The cleaning products should be odour-free.

84. 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).

85. 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**

86. Refer to the *General Principles of Food Hygiene*.

### **6.3 PEST CONTROL SYSTEMS**

87. Refer to the *General Principles of Food Hygiene*.
88. Toxic baits should not be used for internal pest control.
89. 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 instruments should be regularly maintained and cleaned out.

### **6.4 WASTE MANAGEMENT**

90. Refer to the *General Principles of Food Hygiene*.

### **6.5 MONITORING EFFECTIVENESS**

91. Refer to the *General Principles of Food Hygiene*.

## **7 SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE**

92. Refer to Section VII of the *General Principles of Food Hygiene*.

## **8. SECTION VIII – TRANSPORTATION AND STORAGE OF PACKAGED NATURAL MINERAL WATERS**

93. Refer to Section VIII of the *General Principles of Food Hygiene*.
94. 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.
95. 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).

## **9. SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS**

96. Refer to Section IX of the *General Principles of Food Hygiene* and Section VI of the *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981).

## **10 SECTION X - TRAINING**

97. Refer to Section X of the *General Principles of Food Hygiene*.

## ANNEX I: MICROBIOLOGICAL CRITERIA

98. 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).

99. 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.

100. 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.

101. 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, and during production and end-product**

Parameters	n	c	m	Class Plan	Method <sup>1</sup>
<i>E. coli</i> <sup>3</sup>	5	0	n.d. in 250 ml	2 <sup>a</sup>	ISO 9308-1
Total coliforms <sup>3</sup>	5	0	n.d. in 250 ml	2 <sup>a</sup>	ISO 9308-1
Enterococci <sup>3</sup>	5	0	n.d. in 250 ml	2 <sup>a</sup>	ISO 7899-2
spore-forming sulphite-reducing anaerobes <sup>3</sup>	5	0	n.d. in 50 ml	2 <sup>b</sup>	ISO 6461/2
<i>Ps. aeruginosa</i> <sup>4</sup>	5	0	n.d. in 250 ml	2 <sup>a</sup>	ISO 16266-2006
Aerobic mesophilic count / heterotrophic plate count <sup>2, 4</sup>	5	0	100 cfu/ml	2 <sup>c</sup>	ISO 6222-1999

<sup>1</sup> 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).

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

<sup>3</sup> Faecal indicator

<sup>4</sup> 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:

<sup>a</sup>. 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.

<sup>b</sup>. 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 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:***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 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 *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 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.