



Guide to Good Hygienic Practices for Packaged Water In Europe



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INTRODUCTION

Regulation EC 853/2004 of 29 April 2004 on the Hygiene of Foodstuffs lists a set of obligations for food business operators, including compliance with the general hygiene provisions laid down in Annex I, and the requirement to establish implement and maintain a permanent procedure or procedures based on the seven HACCP principles.

With regards to the "Guides of Good Hygiene Practice", the regulation supports the development of national guides to good practices (Article 8) and of "Community Guides" (Article 9).

The European Federation of Bottled Waters⁽¹⁾, representing the interests of all types of packaged waters across Europe, decided in July 2007 to develop a *Guide to Good Hygienic*

Practices for Packaged Water in Europe. This document was developed in accordance with Article 9 of Regulation EC 853/2004 and the EC Guidelines for the development of community guides to good practice of hygiene. The document also integrates the requirements described in the publicly available specification (ISO/TS 22002-1:2009) published by the British Standard Institution (BSI). This document specifies requirements for prerequisite programmes to assist in controlling food safety hazards.

This Guide does not preclude from preparing guides by national food and beverage associations.

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(1) The European Federation of Bottled Waters (EFBW) is a non profit trade association, based in Brussels and founded in 2003 in order to represent the interests of all types of packaged waters across Europe. EFBW's members are national associations which together represent over six hundred bottlers across Europe. (<http://www.efbw.eu>)



SCOPE OF THE GUIDE

This guide recommends general and specific hygiene requirements for collecting, processing, packaging, storing, transporting, distributing and selling packaged water. It also illustrates the HACCP methodology at specific steps of the processing.

European and national legislation distinguish three categories of waters, still or sparkling: natural mineral water (NMW), spring water (SW) and bottled drinking water (BDW), also known as table water or processed water. This guide covers all three categories.

NATURAL MINERAL WATER

In accordance with Annex I.1.1 of Directive 2009/54/EC, NMW comes from a specified underground source which must be protected from all types of pollution.

NMW is characterised by its original purity, its microbiological wholesomeness, its stable composition (as indicated on the label) and, in some cases, its beneficial health effects. NMW may not be disinfected.

Regular and comprehensive analyses are conducted to ensure that these standards are maintained.

NMW shall be bottled at source and fitted with a tamper evident seal.

NMW shall be officially recognised by national authorities. An updated list of all recognised NMW is published by the European Commission in the Official Journal and on its website: http://ec.europa.eu/food/food/labellingnutrition/water/mw_eulist_en.pdf

SPRING WATER

In accordance with Article 9.4. of Directive 2009/54/EC, SW shall also comply with high quality standards. It shall be safe to drink at source and may not be disinfected. However, SW does not need to have the same mineral consistency as NMW and its chemical composition need not be stated on the label.

BOTTLED DRINKING WATER

BDW, sometimes called 'table water', is the description given to water that may come from various origins including surface waters or from a municipal supply. BDW is generally treated and disinfected and demineralised and remineralised as appropriate.

BDW is regulated by Directive 98/83/EC of 3 November 1998 on the Quality of water intended for human consumption.

This Guide does not advise on fortified waters, flavoured waters or other soft drinks, nor does this document provide guidance in relation to the distribution and servicing of bottled watercoolers. However the Guide is applicable to the filling of returnable containers.

RELEVANT LEGISLATION

In the preparation of the Guide, consideration has been given to the following relevant legislation :

Regulation (EC) N° **178/2002** laying down the general principle and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) N° **852/2004** on the hygiene of foodstuffs

Council Directive **2009/54/EC** relating to the exploitation and marketing of natural mineral waters

Commission Directive **2003/40** establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters

Commission Regulation (EU) N° **115/2010** of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Council Directive **98/83/EEC** relating to the quality of water intended for human consumption

Directive **2000/60/EC** of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

Regulation (EC) N° **882/2004** on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare

Other useful information –books, legislation and reference documents – is listed in section 4.

STRUCTURE OF THE GUIDE

The main objective of this document is to help EFBW national trade associations develop their own guides and to help water bottlers meet applicable requirements on the hygiene of foodstuffs. It also aims to encourage the bottled water industry to develop its own quality and food safety management systems.

The guide is structured into three major sections :

1. General aspects of quality and food safety management
2. Prerequisite programmes (PRPs)
3. HACCP (Hazard Analysis and Critical Control Points)

SECTION 1 addresses the main features of the management of quality and food safety that should be combined with the HACCP approach of Section 3.

SECTION 2 covers standard good hygienic practices and good manufacturing practices. Section 2 takes into account all provisions of regulation 852/2004 on the hygiene of foodstuffs as well as the requirements described in the Publicly Available Specification (ISO/TS 22002-1:2009) recently issued by the British Standards Institution (BSI).

This detailed section outlines the industrial processes (from water catchments to warehousing and transport of the finished products: sections 2.1. to 2.13). Sections 2.14 to 2.20 cover a large range of specific hygienic and quality topics: foreign bodies, cleaning and sanitising, pest control, personal hygiene and employee facilities, as well as training, process and product specifications, product monitoring, traceability, complaint and crisis management, product withdrawal and recall procedures. The last subsection (2.21) is dedicated to emerging topics such as food defense, bio-vigilance and bioterrorism.

For all items of each subsection, the document is divided in **two parts**:



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Part 1 states the requirements to satisfy Regulation 852/2004. The word "shall" is used to indicate that those items are essential requirements.



SHOULD

Part 2 presents additional "guidelines" on best practices within the bottled water industry.

SECTION 3 is dedicated to HACCP.

After an overview of the preliminary steps and the seven principles, the guide gives three examples of the methodology, notably microbiological, chemical and physical hazards.





General aspects of quality & food safety management

1.1. QUALITY AND FOOD SAFETY MANAGEMENT SYSTEMS

1.1.1. BASIC PRINCIPLES

The quality and food safety management systems should be based on continuous improvement principles and developed on the basis of ISO 9001 and 22000 standards.

To be effective, the system should :

- Identify the processes required
- Determine the sequence and interaction of these processes
- Establish the appropriate measurements needed to demonstrate the effectiveness of both the operation and control of these processes
- Ensure adequate resources and information are available to support the operation
- Monitor, measure and analyze its processes
- Ensure control over any outsourced process that affects conformity with requirements
- Take all necessary actions to deliver products that meet consumer requirements as well as comply with all applicable laws and regulations
- Set actions to achieve planned results ensure continuous product quality and food safety improvement.

1.1.2. DOCUMENTATION

The quality and food safety management systems documentation maintained by the organization should include:

- Documented statements of quality and food safety policy and objectives
- A quality manual with (or reference to them) written procedures and methods which include those required by customers and by applicable laws and regulations
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Any records required by customers and by applicable laws and regulations

Documents constituting the quality and food safety management systems should be controlled.

Procedures should be established to define the appropriate controls needed: documents approval, documents identification, rules of distribution, update and review, records keeping...

Records should be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality and food safety management systems.



1.2. MANAGEMENT RESPONSIBILITY

1.2.1. MANAGEMENT COMMITMENT AND OBJECTIVES

The organization's (top) management should provide evidence of its commitment to the development and implementation of the quality and food safety management systems and continually improving its effectiveness by:

- Communicating to all employees the importance of meeting customer as well as legal requirements
- Showing food safety is supported by the objectives of the organization
- Ensuring that customer requirements are understood and consistently met with the aim of enhancing customer satisfaction
- Establishing quality and food safety policy
- Establishing measurable quality and food safety objectives at relevant functions and levels within the organization
- Conducting management reviews, and
- Ensuring the availability of resources.

1.2.2. QUALITY AND FOOD SAFETY POLICY

The organisation's (top) management should establish and document its quality and food safety policy and should ensure that the quality and food safety policy:

- Is appropriate to the role of the organization in the food chain
- Includes a commitment to comply with legal requirements and with mutually agreed quality and food safety customer requirements and to continually improve the effectiveness of the quality management system
- Includes a commitment to food safety
- Provides a framework for establishing and reviewing quality and food safety objectives
- Is communicated, implemented and maintained at all levels of the organization and understood within the organisation
- Is reviewed regularly for continuing suitability
- Adequately addresses internal and external communication.

1.2.3. QUALITY AND FOOD SAFETY MANAGEMENT SYSTEMS PLANNING

The organisation's management should ensure that:

- The planning of the quality and food safety management systems is carried out in order to meet the requirements given in 3.1.1, as well as the quality and food safety objectives
- The integrity of the quality and food safety management systems is maintained when changes are planned and implemented within the organisation.

1.2.4. RESPONSIBILITY, AUTHORITY AND INTERNAL AND EXTERNAL COMMUNICATION

The organisation's management should ensure that responsibilities and authorities are defined and communicated within the organization.



The organisation's management should appoint (a) member(s) of management as quality and food safety management representative(s) having the responsibility and authority to:

- Manage the HACCP team and organize its work
 - Ensure relevant training and education of the HACCP team members
 - Ensure that processes needed for the quality and food safety management systems are established, implemented, maintained and updated
 - Report to the organisation's management on the effectiveness and suitability of the quality and food safety management systems, its performance of the quality management system and any need for improvement
 - Ensure the promotion of awareness of customer and applicable legal requirements throughout the organisation
- The organisation's management should ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality and food safety management systems.

To ensure that sufficient information on issues concerning quality and food safety is available throughout the food chain, the organisation should establish, implement and maintain effective arrangements for communicating with:

- Suppliers and contractors
- Customers or consumers, in particular in relation to product information, enquiries, contracts or order-handling including amendments, and customer feedback including customer complaints
- Legal authorities
- Other organisations that have an impact on, or will be affected by, the effectiveness or updating of the quality and food safety management systems

Records of communications should be maintained.

1.2.5. MANAGEMENT REVIEW

The organisation's management should review the quality and food safety management systems at planned intervals to ensure its continuing implementation, suitability, adequacy and effectiveness.

The management review should include, at minimum, a review and analysis of the following inputs:

- Results of internal audits, external audits or inspections
- Customer and consumer feedback
- Process performance and product conformity data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the quality and food safety management systems performance
- Recommendations for improvement
- Analysis of results of verification activities
- Reviewing results of systems-updating activities,
- Changing circumstances that can affect quality and food safety
- Review of communication activities

The output from the management review should include decisions and actions related to:

- Improvement of the effectiveness of the quality and food safety management systems and its processes
- Adequacy or revision, suitability and effectiveness of quality and food safety objectives and quality and food safety policy



- Improvement of product or service related to customer requirements
- Allocation of resources
- Establishment of priorities for improvement opportunities

Records from management reviews should be maintained.

1.3. RESOURCE MANAGEMENT

1.3.1. PROVISION OF RESOURCES

The organisation's management should determine and provide adequate resources for the establishment, implementation, maintenance and updating of the quality and food safety management systems needed to:

- Effectively achieve the organization's objectives
- Implement and maintain the quality and food safety management systems and continually improve their effectiveness
- Ensure and improve customer satisfaction by meeting customer and applicable legal requirements.

1.3.2. HUMAN RESOURCES

The organization should:

- Determine the necessary competence for personnel performing work affecting product quality and food safety
- Provide training or take other actions to satisfy these needs
- Evaluate the effectiveness of the actions taken
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality and food safety objectives
- Maintain appropriate records of education, training, skills and experience

1.3.3. INFRASTRUCTURE AND WORK ENVIRONMENT

The organisation should determine, provide, and maintain the infrastructure needed to achieve conformity to product and service requirements.

Infrastructure includes, as applicable :

- Buildings, workspace, and associated utilities
- Process equipment (including hardware and software)
- Supporting services (such as transport or communication).

The organisation should determine and manage the work environment needed to achieve conformity to product requirements.

1.4. CONTROL OF PRODUCT QUALITY AND SAFETY

The organisation should plan, develop and implement the processes needed for delivering safe and quality products to their customers and consumers. By doing so and keeping the related records, the organisation should be able to demonstrate that it is:

- Meeting the applicable legal requirements
- Meeting the mutually agreed customer requirements related to quality and food safety

This should include, as appropriate:

- Determination of quality and food safety objectives and requirements for the product; required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
- Determination of the food safety prerequisites (PRPs) and HACCP programmes(s)
- Determination of requirements related to the product
- Review of requirements related to the product
- Communication with customers
- Design and development
- Purchasing process, information and verification of purchased product
- Control of production and validation of processes for production
- Identification and traceability
- Customer property
- Preservation of product
- Control of monitoring and measuring devices

The organisation should also have procedures and controls in place to prevent the unintended use or distribution of non-conforming products.

These documented procedures that include related responsibilities and authorities, should be established to ensure that any non-conforming product is segregated from the acceptable product and not distributed.

The organisation should deal with non-conforming product(s) by one or more of the following ways:

- By taking action to eliminate the detected non-conformity, including actions necessary to ensure compliance with applicable regulatory requirements
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- By taking action to preclude its original intended use or application

When non-conforming product is detected after delivery or use has started, the organisation should take action appropriate to the effects, or potential effects, of the non-conformity.

Records of the control of non-conforming product(s), including descriptions of the non-conformity and disposition (including concessions, as applicable) should be maintained.



1.5. MEASUREMENT, ANALYSIS AND IMPROVEMENT

The organisation should plan and implement monitoring, measurement, analysis and improvement processes.

1.5.1. MONITORING AND MEASUREMENT

The following should be considered:

- Monitoring information relating to customer perception
- Conducting internal audits at planned interval to determine whether the quality and food safety management systems is in conformance with all the planned arrangements and is effectively implemented and maintained
- Applying suitable methods for monitoring and measurement of the quality and food safety management systems to demonstrate the ability of the processes to achieve planned results
- Monitoring and measuring the characteristics of the product to verify that product requirements have been met. Evidence of conformity with the acceptance criteria should be maintained.

1.5.2. ANALYSIS OF DATA

The organisation should determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality and food safety management systems and to evaluate where improvement can be made.

1.5.3. CONTINUAL IMPROVEMENT

The organisation should continually improve the effectiveness of its quality and food safety management systems through the use of the quality and food safety policy, quality and food safety objectives, audit results, analysis of data, corrective and preventive actions and management review.

1.6. PRODUCT INFORMATION AND CONSUMER AWARENESS

Consumers have a right to know what is in the bottled water they drink.

In addition to labelling its products according to applicable laws, the organisation should, upon request, provide to consumers meaningful information about its bottled water brands. This includes, but not limited to, information that demonstrates compliance with applicable legal laws and analytical testing data results.

The organisation should determine how information is provided to consumers (e.g., via mail, web site, phone...) but should provide the information in written form upon request.





Prerequisite Programmes - PRPs

2.1. WATER RESOURCES / WATER TREATMENT

This section examines all components of the abstraction system and management of water. This includes the catchment area, the abstraction point, transport, treatment and storage, up to the point at which water is delivered for filling or process use.

All the requirements and guidelines outlined in this section apply to natural mineral water and spring water with respect to their underground origin, the necessity of protecting the water from all risk of pollution and for natural mineral water, the specific procedure of recognition. For natural mineral water, the requirements are to protect its original purity. For spring water, they are to protect its natural compliance with drinking water quality. For bottled drinking waters derived from private groundwater sources, a similar level of monitoring and protection is a guideline.

2.1.1. RESOURCE DEVELOPMENT

2.1.1.1 General Requirements



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Technical analysis to fully understand the nature and origin of the water resource shall be conducted.

Hydrogeological studies shall determine the location of the water basin, (area defining the body of water from which supplies are drawn, including the abstraction point). The basin shall be managed to protect it from all risks of pollution.

A hydrogeological study (by qualified experts) shall be carried out to identify and describe the recharge zone and groundwater catchment(s).

This hydrogeological study shall include:

- location of the abstraction points
- the geological unit(s) (the aquifer) containing the groundwater resource
- location and extent of the groundwater catchment
- degree and nature of natural protection against pollution
- surface water features, identifying those interacting with the groundwater reservoir
- other water abstractors, identifying those exploiting the same groundwater reservoir
- chemistry and quality of the groundwater reservoir
- water balance and capacity
- travel times for groundwater between recharge zone and abstraction point(s)
- studies to justify the abstraction licence and to demonstrate the sustainability of the groundwater yield





SHOULD

In addition, an environmental impact assessment should be completed in order to define :

- *water balance and capacity of the aquifer*
- *land uses and evolution of anthropogenic (human) activities*
- *safe abstraction limits to preserve long-term exploitation of the aquifer and associated ecosystems*
- *a monitoring and management plan to protect the water resources and ecosystems.*

This environmental impact should be evaluated periodically, at least every 5 years.

2.1.1.2 Risk Assessment



SHALL

A risk assessment shall be carried out in relation to potential threats to quantity and quality of water supply.



SHOULD

The risk assessment should normally include:

- *Review of land ownership and land use (current and historic) for the water basin*
- *Collection of data on:*
 - *contaminants*
 - *pollution incidents*
 - *legal controls applicable to protecting water from pollution*
- *Evaluation of risk for each land use , activity or natural risk: low, medium or high.*

The output of this analysis is the basis for the design of the protection zones and monitoring programmes.



SHALL

2.1.2. RESOURCE PROTECTION

Protection zones shall be defined, using the findings of the risk assessment.

All activities which are able to impact or pollute the water basin area and threaten the source shall be prohibited or controlled as far as feasible.



SHOULD

As a minimum, this 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. Zones should be defined on the basis of hydrogeological studies (see Section 2.1.1.1). A common approach is to establish three zones of varying levels of protection and management, Zone 1 being closest to the source and with the highest level of protection.

Zone 1 (inner zone):



Example of protection zone 1 around the abstraction point

Immediate to the abstraction point and on property under full control of the bottler. The operator should maintain complete control of access and any activities, which should be limited to those directly linked to management of the water source. Any other non-essential and certainly any potentially polluting activities should be prohibited. Ideally, this area is securely fenced. Adequate measures should be taken to protect as much as possible against malicious or bioterrorism acts. For example, a secure radius around the source of 10 to 50 metres should be established.

Zone 2 (intermediate zone):

This zone will often extend beyond bottler-controlled property. Management will normally require cooperation and/or agreements with the authorities and neighbouring landowners.

Usually defined as the geographical area in which pollution could affect the quality of water at the abstraction point or the resource. Depending on the type of aquifer, it is often based on groundwater travel times (for example: several months). It should include prohibition and/or regulation of transport, storage of oils or hazardous substances, drainage, burying of potential contaminants, waste disposal and specified activities or developments. It is also important to monitor and control the use of fertilisers, detergents, pesticides, herbicides and any soluble organic or inorganic substances. Any possible underground sources of contamination such as sewers, septic tanks, industrial waste water, gas or chemical (fuel) tanks, pipelines, etc, should be removed if feasible, or otherwise monitored and controlled. In any case, pipelines and storage facilities should be designed to prevent leakage.

Zone 3 (outer zone):

Normally, most of this zone will not be under the control of the bottler. Management will require cooperation and agreements with the authorities and landowners. In many cases, the ability to influence land use will be limited, but it will remain important to monitor the risks.

It is represented by the complete drainage basin or large part of it, and could therefore include areas from which groundwater travel times are many years. Potential hazards are the same as those in other areas but less serious. Protective measures should therefore be adapted as appropriate, taking into account extended travel times and greater potential for dispersion, breakdown and dilution of pollutants.

2.1.3. EXPLOITATION OF THE RESOURCE**2.1.3.1 Technical requirements****SHALL**

All materials in contact with the water, during abstraction, transport, storage and filling, including the packaging, shall comply with food contact requirements. They shall not affect water characteristics, especially microbiological ones and shall not present a risk for consumer health.

**SHOULD**

Before installation, appropriate tests should be performed in order to verify that those materials are not likely to modify characteristics (sensorial, chemical, microbiological and physical) of the water.

**SHALL**

Inside view of the head of a borehole designed to avoid contamination and to allow sampling

2.1.3.2 Point of abstraction

The water source shall be managed to prevent any other waters, such as flood water or shallow seepage, from entering. It shall also be managed in a hygienic manner to prevent any natural or man-made contamination.

**SHOULD**

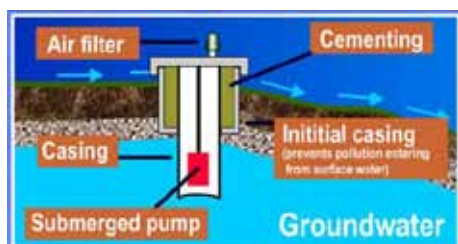
Sampling points should be designed and operated to prevent any reverse contamination of the water or flow pipe (eg. From backflow of water or unfiltered air). There should be a tap which allows technically correct sampling.

The following items should be considered for the abstraction point:

- Location: as far as practicable, site away from potential polluting activities (including historic ones which could have contaminated the ground)
- The design, construction and development of the water abstraction point should comply with state-of-the-art principles and be supervised by a competent expert



Example of protection zone 1 around the abstraction point



General design of a borehole for ground water abstraction

- Boreholes/wells
 - Construct to protect from surface and shallow groundwater pollution, normally with the upper casing penetrating at least 10 metres depth, and fully sealed around its annulus with a cement-grout seal
 - Avoid contamination of the groundwater during construction, especially that of microbial or hydrocarbon origin (e.g. oils, grease).
 - Construct wellhead to protect the groundwater from run-off and from air-borne pollutants (including dust and micro-organisms). Install sealed fittings and air-filter
 - Use all inert food-grade materials for piping and fittings in contact with the water
 - Non-return valve to avoid backflow of water into the borehole/well
- Springs (including gallery systems)
 - Install a spring capture over the spring (or gallery) exit to protect it from surface and air-borne pollution, and pests.
 - Where possible, the water should be tapped from a depth below the natural surface, where it is better protected
 - Avoid contamination of the water supply during construction, especially that of microbial or hydrocarbon origin (e.g. oils, grease)
- Construct the spring capture to protect the water supply from run-off and from air-borne pollutants (including dust and microbes)
- Use all inert food-grade materials for piping and fittings in contact with the water.
- Housing (for boreholes and springs)
 - Borehole or spring to be protected by a covered and secure enclosure
 - To be constructed to protect the abstraction point against: unauthorised access, pests and vermin, air-borne contaminants, surface water run-off and flooding
 - Lockable, and where 'off-site', with a security alarm and security fencing
 - Establish an inner protection zone (as zone 1, section 2.1.2).

2.1.3.3 Transfer/Piping to the filling operation

**SHALL**

Transfer of the water from the source to the filling operation shall be by pipeline only and, shall be conducted in a hygienic manner to prevent any contamination.



**SHOULD**

The system should be designed and constructed so that it:

- *does not contaminate the water intended for filling*
- *can be effectively cleaned and disinfected*
- *allows for easy access and inspection of the pipeline should any problems arise (as far as practicable).*

The transfer system should:

- *be constructed of food grade material*
- *avoid dead-ends, to avoid stagnant water, to ensure easy cleaning, disinfection and rinsing, and to maintain a smooth flow*
- *be operated to avoid negative pressure (which could cause the sucking in of water or airborne contaminants)*
- *be designed to:*
 - *avoid the risk of contamination of the water by chemical products*
 - *ensure that the piping and storage systems for water intended for filling be kept separate and clearly identified.*
 - *allow for easy inspection*
 - *sanitise after interventions*

2.1.3.4 Storage tanks

**SHALL**

Water holding tanks are sometimes used to act as a buffer. The quality of air entering such tanks shall be of a suitable hygienic standard. (2.9.3.)

Water storage shall be conducted hygienically to protect against contamination.

**SHOULD**

Water should not be retained excessively in water holding tanks. The design and operation of the holding tanks should restrict the time from catchment to filling to a minimum. Air entering the headspace of tanks should be filtered or treated to prevent contamination of product water. (cf 2.9.3.)



Water storage tank equipped with an air filter

In addition to the rules given above for transfer systems, the following requirements should be applied:

- *the storage tank should be protected from environmental contamination (be enclosed, and with air filters (0.45µ or less recommended), etc.)*
- *the maximum storage time should be optimised to minimise pollution risk and avoid stagnant water*

2.1.4. WATER TREATMENTS

**SHALL**

Natural mineral waters and spring waters shall not be subjected to any treatment other than those permitted according to Article 4 of Directive **2009/54/EC**.

Treatments introduce an element of risk which shall be properly monitored and addressed. These include a failure of treatment, insufficient maintenance and regeneration, contamination from treatment chemicals or bacterial growth, and residual taints.



Therefore, treatment processes shall be subject to hazard identification and the results incorporated into the HACCP analysis and managed in quality system documents.

In the case of bottled drinking water, there is no restriction on types of treatment.

Treatment processes shall be subject to hazard identification and the results incorporated into the HACCP analysis and managed in quality system documents.

2.1.5. MONITORING



A monitoring programme shall be put in place.

The food safety related parameters to be monitored, frequency of analysis and location of sampling points shall be defined based on HACCP methodology, including a combination of minimum criteria and risk assessment. Data loggers shall be used where possible and appropriate.



Basic parameters should include:

1. *micro-biological indicators*
2. *physical: flow rate, temperature, electrical conductivity, piezometric level*
3. *physico-chemical: pH, electrical conductivity, red-ox potential, ...*
4. *chemical: according to water characteristics.*

2.1.6. MAINTENANCE



The maintenance programme for water transfer, storage and filling systems shall include routine disinfection and cleaning to maintain the network in accordance with good hygienic conditions.

After any disinfection or maintenance works, it shall be verified that filling can be resumed without risk.



The water abstraction and supply network should be properly managed and maintained, and cleaned or disinfected to protect all components from risk of microbiological, chemical and physical pollution.

For the source itself, the disinfection regime should be designed to take account of the risks and its operational regime. For example, a constantly flowing source 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 (eg. source pollution, 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.

2.1.7. CORRECTIVE ACTION



In the event of pollution at source or contamination of product during filling, then filling shall be suspended until the origin of contamination is eradicated and the water complies again with quality requirements.



Monitoring data should be periodically reviewed and reported on, with corrective actions, as appropriate, on any results or trends of concern to food safety. If necessary, additional monitoring points should be installed, which may include new monitoring wells, sampling points, etc.

In the event of a breach of a quality standard, product recall may be required. Such actions are normally decided in agreement with the authorities.



2.2. CONSTRUCTION AND LAYOUT OF BUILDINGS

2.2.1. GENERAL REQUIREMENTS



SHALL

Buildings shall be located, designed, constructed and maintained in a manner appropriate to the nature of the processing operations to be carried out, the food safety hazards associated with those operations, and potential sources of contamination from the plant environs.

The outer fabric of the buildings including the roof shall be structurally maintained in sound condition.

Construction shall be designed to avoid build up of dirt and condensation. Toxic materials shall not be used for food contact used.

The building shall be of durable construction which presents no hazard to the product

The roof shall be self-draining and waterproof.



SHOULD

The number of wide doors allowing the entrance of contaminated air (combustion from trucks, air-borne contamination,...) should be limited, more specifically in the vicinity of open bottle areas or storage of packaging material. External doors should be self-closing and pest-proof when closed.

The design of the construction and of the ventilation system as well as the choice of the equipment and materials used should be adequate to limit dirt and condensation.

A particular area for the critical stage of bottle filling and capping should be allocated so that a controlled environment can be provided, i.e. positive pressure maintained at the point of filling – in cabinet or room.

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. Labelling and packaging can generate considerable aerial debris, which it is preferable to exclude from the filling and capping areas. The use of hot glues can result in taste and odour problems. Labelling machines inside filling rooms should have effective extraction systems.

Physical barriers around the bottle filling and capping area should be used. Filtering the air and imposing a positive pressure is an additional measure which should be considered.

2.2.2. ENVIRONMENT



SHALL

Consideration shall be given to potential sources of contamination from the local environment.

The effectiveness of measures taken to protect against potential contaminants shall be periodically reviewed.

Gasoline or diesel powered forklifts shall not be used.

The buildings shall be designed to minimize the ingress of pests. Outer doors shall be well fitted and shall prevent bird, rodent or insect entry. External doors shall not open directly into open bottle areas.



SHOULD

Food production should not be carried out in areas where potentially harmful substances could enter the product.

Trucks entering or leaving the plant should be limited and use specific routes.

Elevators (forklifts) should be powered by electricity or gas.

Outer doors should be kept closed whenever possible, only opening them for receipt of materials or for loading out finished products. Automatic doors are available and can assist in protection.

It is important to extend good housekeeping practice to the perimeter of the site, keeping grass cut and litter cleared. Maintaining a tidy exterior will enhance the image of the company, will maintain employee moral and reduce risk of rodent activity.

An external pest control service could advise on proofing requirements as well as the means of control.

2.2.3. LOCATIONS OF ESTABLISHMENTS



SHALL

The site boundaries shall be clearly identified.

Access to the site shall be controlled.

The site shall be maintained in good order. Vegetation shall be tended or removed. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

The filling sites boundaries should be closed by physical barriers to avoid external intrusion.

Signs should indicate that water for human consumption is bottled on the site. Remote buildings or cabinets containing drinking water sources should be unmarked.

2.3. LAYOUT OF PREMISES AND WORKSPACE

Reg° 852/2004, annex II:

refers to art. 2, 3, 4, 6 and 10 of chap. I and art. 1 of chap. II

2.3.1. GENERAL REQUIREMENTS



SHALL

The layout, design, construction, sitting and size of food premises shall:

- a) - permit adequate maintenance, repair, cleaning and disinfection; avoid or minimize air-borne contamination, and provide adequate working space to allow for the safe and hygienic performance of all operations;
- b) - be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or mould on surfaces;
- c) - permit good food hygiene practices including protection against contamination and, in particular, pest control;

The movement patterns of materials, products and people and the layout of equipment shall protect against potential contamination sources.



SHOULD

Areas should be defined for designated use to prevent cross contamination.

The building should be able to accommodate a continuous process flow with materials receipt and storage at one end and finished goods and dispatch at the other end and the processing stages in order of procedures in between.

Where necessary, the layout, design, construction, sitting and size of food premises should provide suitable

temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

2.3.2. INTERNAL DESIGN, LAYOUT AND TRAFFIC PATTERNS



SHALL

The building shall provide adequate space, with a logical flow of materials, products and personnel, and physical separation of raw from processed areas.

The flow of materials, products and personnel shall be clearly defined and applied.



SHOULD

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

Maintenance storage, workshops and laboratories are required to provide engineering and technical services. These should be well separated from production areas.

2.3.3. INTERNAL STRUCTURES AND FITTINGS



SHALL

Process area floors, walls, ceilings, windows, doors, surfaces and sanitary conveniences shall be washable or cleanable, as appropriate for the process or product hazard.

Materials shall be resistant to the cleaning system applied.

Filling rooms shall be of food-grade standard with smooth, non-absorbent and easily-cleanable surfaces.



SHOULD

Filling rooms should have sealed joints and coved corners with floors and ceilings.

2.3.3.a. Floor surfaces



SHALL



Hygienic floor surface of a blowing and filling room



Detail of a hygienic floor with coved corners

Floor surfaces shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect.

This shall require the use of impervious, non-absorbent, washable and non-toxic materials.

Where appropriate, such as wet process areas, floors shall allow adequate surface drainage to avoid standing water.

All floors shall be sealed and easily cleanable.

Floor surfaces shall be maintained in good condition, any repairs necessary being carried out promptly.

A high standard of floor cleanliness shall be maintained particularly for gullies or drains.

Wall floor junctions and corners shall be designed to facilitate cleaning.



Floors in filling area should provide surface flow to drainage.

Floors should be such that they can withstand the use they are put to, including fork lift truck traffic where used.

Corners should be coved.

2.3.3.b. Wall surfaces



Wall surfaces of a filling room

Wall surfaces shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect.

This shall require the use of impervious, non-absorbent, washable and non-toxic materials, and require a smooth surface up to a height appropriate for the operations.

Walls shall be of a smooth impervious nature and easily cleanable.

They shall be kept in a good state of repair.

A high standard of cleanliness shall be maintained particularly in sensitive areas, e.g. blowing rooms, filling and capping areas and where water-contact materials are stored.

Wall floor junctions and corners shall be designed to facilitate cleaning.



Walls should be coved to junctions with ceilings and floors in sensitive areas.

In processing areas, walls should be light in colour to reflect as much light as possible and so that any soiling is easily visible for cleaning.

Wall floor junction should be rounded in processing areas, e.g. blowing, washing, rinsing and filling.

Corners should be coved.

2.3.3. c. Ceilings



Ceilings and overhead fixtures shall be designed to minimize build up of dirt and condensation.

Ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures shall be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of mould and the shedding of particles.

Ceilings and overhead fixtures shall be properly maintained and shall not represent a source of contamination. Where necessary, protection measures shall be taken i.e. protection against condensation and drip page.



Ceilings should be light in colour to reflect as much light as possible and so that any soiling is easily visible for cleaning.

Ceilings and overhead fixtures in open bottle areas should be of a smooth and impervious nature and easily cleanable.

If false or lowered ceilings are fitted, access to the space above should be available to facilitate servicing and maintenance.

Any roof windows should be shatterproof, listed as part of the plant glass register and designed out where possible.

2.3.3.d. Windows**SHALL**

Windows and other openings shall be constructed to prevent the accumulation of dirt.

Those which can be opened to the outside environment shall, where necessary, be fitted with insect-proof screens which can be easily removed for cleaning.

Windows in production to be closed at all times i.e. permanently sealed. Contamination can result from open windows during shut-down.

Windows shall be close-fitting and allow for effective cleaning.

External windows shall not open into open bottle areas.

Windows shall also be reinforced to prevent shattering or equipped with film protection, with preference for alternative to glass materials used in all process areas.

**SHOULD**

Windows in processing areas should be constructed of clear, shatterproof material

Window surrounds should be impervious and easily cleanable. Where possible in production areas, sills should be sloped to discourage their use as shelves.

Where external windows are used for ventilation, they should be fitted with easy cleanable insect-proof screens.

Where windows or viewing safety panels are fitted to doors, these should be of clear shatterproof material.

2.3.3.e. Doors**SHALL**

Doors shall be easy to clean by design and, where necessary, disinfect.

This will require the use of smooth and non absorbent surfaces.

A high standard of cleanliness shall be maintained. If wooden doors are used, these shall have a well maintained painted or sealed finish so that they are impervious and easily cleanable.

Exterior doors shall be closed when not in use and shall be pest-proof when closed.

**SHOULD**

Doors should be close fitting and ideally doors to high risk areas e.g. filling, capping and blowing areas should be self-closing.

Wooden doors should be avoided in high risk areas. Wood is acceptable in non-high risk areas if painted or otherwise treated.

2.3.3.f. Surfaces**SHALL**

Surfaces (including surfaces of equipment) in processing areas shall be maintained in a clean and sound condition, be easy to clean and, where necessary, to disinfect.

This shall require the use of smooth, washable corrosion-resistant and non toxic materials, unless bottled water producers can satisfy the competent authority that other materials used are appropriate.

2.3.3.g Sanitary conveniences**SHALL**

An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories shall not open directly into rooms in which food is handled or where food-contact materials are unprotected.

There shall be an adequate number of toilet/WC according to number and sex of employees. There shall be no direct access to toilets from processing areas. Toilets shall be well separated from production areas by a suitable intervening space such as corridors.

WCs shall have seats.

An adequate number of wash basins shall be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying.

An adequate number of washbasins shall be located close to toilet facilities and at strategic places within premises. Hand wash only basins shall not be used for washing foods or bottles.

Soap or detergent shall be provided.

Single use hand towels or warm air hand dryers shall be provided.

Sanitary conveniences shall have adequate natural or mechanical ventilation.

Natural or mechanical ventilation systems shall be designed to discharge air from sanitary conveniences away from production areas and shall be separated from any ventilation systems within the filling plant.

**SHOULD**

Notices such as "Wash Hands Now" should be located in toilet areas.

Wash hand basins should be located at all entry points to open bottle areas, in laboratories, maintenance workshops, and canteen.

Taps that are not operated by hand should be preferred.

In some cases mixer taps should be used.

Un-perfumed and bactericidal soap/detergent should be provided by dispensers. Solid soaps should not be used.

Nail brushes, maintained in hygienic condition by regular boiling or frequent replacement should be available.

If warm air hand dryers are used, they should be effective and efficient.

2.3.4. LOCATIONS OF EQUIPMENT**SHALL**

Equipment shall be designed and located so as to facilitate good hygiene practices and monitoring.

Equipment shall be located to permit access for operation, cleaning and maintenance.

2.3.5. TEST AND LABORATORY FACILITIES**SHALL**

In-line and on-line test facilities shall be controlled to minimize risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly onto a production area.



**SHALL**

2.3.6. STORAGE OF INGREDIENTS, PACKAGING MATERIALS, PRODUCTS AND CHEMICALS (see also section 2.12)

Facilities used to store ingredients (minerals, CO₂), packaging materials and products shall provide protection from dust, condensation, drains, waste and other sources of contamination.

Storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where specified.

All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.

The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

A separate dedicated area (locked or otherwise access controlled) shall be provided for storage of chemicals such as cleaning agents, disinfectants and other auxiliary chemicals. All chemicals shall be stored in holding tanks.

The dedicated storage area shall be adequately ventilated to the external air.

**SHOULD**

Cleaning agents, disinfectants and other auxiliary chemicals should be kept in a sealed unit away from the production areas.

Food-grade lubricants should be stored separately from non food-grade oils and greases.

Master Safety Data Sheets should be readily accessible to users of chemicals.

SECTION 2.4. UTILITIES : WATER, AIR, ENERGY, LIGHTING

Reg.852/2004, annex II:

refers to art. 2, 5 and 7 of chap. I and art. 1 and 3 of chap. VII

2.4.1. GENERAL REQUIREMENTS

**SHALL**

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination.

Utilities' quality shall be monitored to minimize product contamination risk.

2.4.2. WATER SUPPLIES

**SHALL**

Water used as a product ingredient, or in contact with packaging materials shall meet quality and microbiological requirements relevant to the product.

Water for applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application.

Water pipes shall be capable of being cleaned and/or disinfected.



2.4.2.a. Drinking water

The supply of drinking water shall be sufficient to meet the needs of the production process(es).

Facilities for storage, distribution and, where needed, temperature control of the water shall be designed to meet specified water quality requirements.

Drinking water (as defined in Directive EEC 98/83) shall be used for:

- cleaning of filling equipment
- washing/rinsing of product bottles
- hand washing

Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.



Potability compliance should be assessed on an appropriate frequency.

As good practice any water supply should be a drinking quality.

A recycling policy should be established in order to reduce the environmental footprint.

2.4.2.b. Non potable water

Non potable water may be used for fire control, steam production, refrigeration, and other purposes.

Non potable water shall have a separate system, labelled, not connected to, and prevented from, reflux into the drinking system and other water systems.



Hoses intended for use in the event of fire should be clearly marked for fire fighting and should not be used for general cleaning purposes.

2.4.2.c. Recycled water

The quality of recycled water shall be determined by its final use.

Recycled water used in processing shall not present a risk of contamination.

Recycled water, when used, shall circulate in a separate duly identified system.



If recycled water is used in processing quality compliance should be assessed on an appropriate frequency.

2.4.3. BOILER CHEMICALS

Boiler chemicals, if used, shall be either:

- a) approved food additives which meet relevant additive specifications; or
- b) additives which have been approved by the relevant regulatory authority as safe for use in water intended for human consumption.

Boiler chemicals shall be stored in a separate, secure (locked or otherwise access controlled) area when not in immediate use.

2.4.4. VENTILATION



Suitable and sufficient means of natural and/or mechanical ventilation shall be available.

The design of the construction and of the ventilation system as well as the choice of the equipment and materials used shall be adequate to limit dirt and condensation.

The organisation shall establish requirements for filtration, humidity and microbiology of air in contact with water and/or packaging materials.

Where temperature and/or humidity are deemed critical by the HACCP analysis, a control system shall be put in place and monitored.

Ventilation (natural and/or mechanical) shall be provided to remove excess or unwanted steam, dust and odours, and to facilitate drying after wet cleaning.

Room air supply quality shall be controlled to minimise air-borne microbiological and particulate contamination in processing areas.

Ventilation systems shall be designed and constructed such that air does not flow from contaminated or raw areas to clean areas. Specified positive air pressure differentials shall be maintained.

Systems shall be accessible for cleaning, filter changing and maintenance.

Ventilation systems shall be maintained and be suitably screened to prevent rodent and insect access.

Interior and exterior air intake ports shall be examined periodically for physical integrity.



Pressure measurement of a filling cabinet



Volumetric air sampling equipment



Schedules for regular maintenance of air filtration systems should be made which incorporate requirements for changing of cartridges/filter media at appropriate frequencies to ensure effective control. Indicators should be installed in appropriate locations to provide visual verification that air flows are in positive pressure, particularly in high risk areas such as filling rooms. Volumetric air sampling equipment should be used at regular intervals to monitor air quality in high risk areas.

2.4.5. COMPRESSED AIR AND OTHER GASES (CO₂, N₂)

**SHALL**

Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing shall be constructed and maintained so as to prevent contamination.

Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be:

- from an approved source
- filtered to remove dust, oil and water
- food grade
- compliant with requirements for technical gases.

Requirements for filtration, humidity and microbiology shall be specified.

Where oil is used for compressors it shall be food grade.

**SHOULD**

Oil-free compressors should be used.

Filtration of the air and other gases should be as close to the point of use as is practicable.

A Certificate of Analysis should accompany every shipment of purchased gas.

2.4.6. LIGHTING



Artificial lighting with unbreakable cover

**SHALL**

Food premises shall have adequate natural and/or artificial lighting.

Lighting shall be adequate to allow safe operations and verification of hygienic conditions of the working place and shall meet the minimum legal requirements under Health and Safety at Work legislation. 538 lux is required wherever there is exposed product or product contact surfaces to be able to determine the presence of physical contamination notably in the following areas: bottling, cooler refurbishing, processing equipment and areas where these items are repaired, handwashing, rest rooms and the kitchen or break room).

**SHOULD**

Light fittings should all have unbreakable diffusers or covers over (not glass), and where fluorescent tubes are fitted the diffusers

should have covered ends. Alternatively, tubes should be sleeved. Or safety (unbreakable) light bulbs should be used.

Plant management should have access to calibrated light meters to check lighting levels.

215 lux should be provided in other areas than the ones described under the requirements.

Where possible, light fittings should be flush with the ceilings.

2.5 WASTE MANAGEMENT AND SEWAGE DISPOSAL

Reg° 852/2004, annex II.

2.5.1. GENERAL REQUIREMENTS



Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

Waste materials shall be removed from processing rooms as quickly as possible so as to avoid contamination.



A waste reduction plan should be implemented in order to limit the production of all kinds of waste at origin (including waste waters and packaging debris)

2.5.2. CONTAINERS / BINS FOR WASTE MATERIALS AND HAZARDOUS SUBSTANCES



Containers / bins for waste materials and hazardous substances shall be:

- a) clearly identified for their intended purpose;
- b) located in a designated area;
- c) closed when not in immediate use and locked if hazardous;
- d) constructed of impervious material which can be readily cleaned and sanitized.
- e) equipped with a pedal-opening system in critical areas: filling rooms as well as hand washing areas.



Bins in a designated area



Clearly identified bins



Clearly identified bins



Particular bins should be designated for use in specific areas, particularly in the filling area.

Waste of a potentially contaminating nature e.g. glue, wet cardboard, debris from floor etc. should be placed in covered bins and/or removed promptly from sensitive areas.

Bins should be emptied at least daily, kept in good hygienic condition and cleaned on a regular basis.

Bins should be identified in order to allow the categorization of waste for further recycling.

Unless actively receiving additional content, bins containing dry recyclable materials or packaging waste (e.g. cardboard, plastic film) should be covered when stored outside the production area.

2.5.3. WASTE MANAGEMENT AND REMOVAL



Adequate provision shall be made for the segregation, storage and removal of waste.

Refuse stores shall be designed and managed in such a way as to enable them to be kept clean, and pest-free. (2.15)

A designated waste collection area shall provide well managed storage which will not have a detrimental effect in any way on product integrity.

Accumulation of waste shall not be allowed in processing and storage areas. Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal.

Labelled materials or products which are designated as waste shall be disfigured before leaving the premises or destroyed to ensure that trademarks cannot be re-used. Removal and destruction shall be carried out by approved disposal contractors. The organisation shall retain records of destruction.

Disposal of other refuse, e.g. bottles, labels, closures and other packaging shall be suitably controlled. Potentially contaminating wastes (e.g. debris, empty detergent containers) shall be disposed of in a hygienic manner.

All waste shall be removed at an appropriate frequency, in a hygienic and environmentally friendly way in accordance with applicable legislation to that effect

Electronic and electrical waste disposal shall comply with local Regulatory requirements.

Disposal of lubricants and oils for equipment shall comply with local Regulatory requirements.



Storage of waste should not be an attraction to or be accessible to pests.

Waste containers should be of the enclosed type, prevent pest access and should be emptied cleaned or replaced regularly.

Waste segregated and stored for recycling should be kept to a minimum and should be well secured.

The implementation of packaging waste recycling programs should be encouraged.

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

2.5.4. DRAINS AND DRAINAGE



High capacity drain in a bottling area

Drains shall be designed, constructed, located and maintained so that the risk of contamination of materials or products is avoided. Drains shall have sufficient capacity to remove expected flow loads. Drains shall not pass over processing lines. Drains shall be trapped and sealed. There shall be no direct connections between equipment and drain or sewage lines.

As a general rule, water facilities and equipment shall be constructed to prevent back siphonage or backflow, using anti-backflow valves.

Floors shall be sloped to allow effective drainage in wet areas.

Standing water shall be avoided and prevented.



Drainage system to avoid water accumulation on the floors

Water accumulation on the floors and drainage facilities shall not become a source of potential contamination. Waste waters shall be capable of running to a suitable drainage system.

Where drainage channels are fully or partially open, they shall be designed to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular in processing and storage areas.



SHOULD

Where possible, floors should be constructed so that any liquid spillages flow to a drain to prevent pooling of water.

Floor gullies should be in place to collect liquid spillages.

Drains should be fitted with perforated traps of easily cleanable material to retain extraneous matter, e.g. caps. Any external drain outlets should be covered to avoid ingress of rodent or other pests.

The cleaning and disinfection of drains on a routine basis should be provided for in the cleaning schedules.

2.6 EQUIPMENT SUITABILITY

Reg 852/2004, annex II.

2.6.1. GENERAL REQUIREMENTS



SHALL

Food contact equipment (e.g. piping, filling equipment, conveyor; etc.) shall be designed and constructed and installed to facilitate cleaning, disinfection and maintenance.

Food contact equipment shall be designed to be removable or able to be disassembled to allow cleaning or maintenance. It shall be constructed of durable materials able to resist repeated cleaning.

Where necessary, equipment shall be fitted with any appropriate control device to guarantee fulfilment of applicable food safety and quality regulations. The control devices are the ones determined by the organisation as necessary to ensure the food safety (HACCP) and the quality of the products.

Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

The product in process shall be in sealed piping system under pressure and free of leaks or other sources of contamination. Lids on storage tanks shall effect a tight seal when in place.

CIP and COP schedules shall be prepared and carried out to ensure that all filling equipment is maintained to a suitable hygienic standard. (See also section 2.14)

Any lubricants of conveyors shall be suitable for food use, and have no adverse affect on water and its containers.

**SHOULD**

All equipment coming into contact with product water should have a mechanism or procedure to determine cleanliness and state of repair.

A preventative maintenance schedule / system should be implemented. A high standard of maintenance should prevail and any damaged equipment should be promptly reported and attended to. There should be a system or procedure for releasing maintained equipment to production.

The use of string or tape to effect even temporary repairs should be discouraged.

Ensure that no small items such as nuts, bolts or washers are abandoned in open bottle areas.

Drawing pins and similar fixings should not be used to secure notices etc in production areas and where primary packaging is stored.

2.6.2. HYGIENIC DESIGN

**SHALL**

Equipment shall be able to meet established principles of hygienic design, including:

- a) smooth, accessible, cleanable surfaces, self draining in wet process areas;
- b) use of materials compatible with intended products and cleaning or flushing agents;
- c) framework not penetrated by holes or nuts and bolts.
- d) welding of product-contact materials shall be smooth

Piping, tanking and ductwork shall be cleanable, fully drainable, and with no dead ends.

Equipment shall be designed to minimize contact between the operator's hands and the products.

There shall be no direct connections between equipment and drain or sewage lines. Drain-outs from storage tanks shall not discharge below flood levels of floor drains.

**SHOULD**

There should not be duckboards in filling rooms.

Wooden processing equipment should not be permitted for exposed raw materials, work-in-progress, or unwrapped finished products.

2.6.3. PRODUCT CONTACT SURFACES

**SHALL**

Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust and corrosion free.

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.

Where chemical additives have to be used to prevent corrosion of equipment and containers, they shall be used in accordance with good practice.

All chemicals shall be assessed to comply with REACH Regulation.

Lubricants used where there is the potential for incidental contact with the product or product-contact surfaces shall be food-grade.

**SHOULD**

As regard chemicals in general, the manufacturer's instructions should be implemented and considered during the evaluation of the food safety hazards (HACCP)

There should be documents on file attesting to the product contact surface's approval for food use (e.g. Letter or Guarantee).

Chemicals should have a corresponding Material Safety Data Sheet (MSDS) on file.

2.6.4. TEMPERATURE CONTROL AND MONITORING EQUIPMENT

**SHALL**

Equipment used for thermal processes (e.g. for prepared water or cleaning / sanitizing waters) shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.

Equipment shall provide for the monitoring and control of the temperature.

**SHOULD**

Equipment should have audible and/or visual alarm systems in the event of systems failure.

2.7 WORKS AND MAINTENANCE

Reg° 852/2004, annex II:

2.7.1. GENERAL REQUIREMENTS

**SHALL**

Food premises shall be kept clean and maintained in good repair and condition.

A preventive maintenance programme shall be in place

**SHOULD**

Contractors, service engineers, temporary and other external workers should be adequately managed.

2.7.2. PLANT AND FOOD PREMISES

2.7.2.a Outer fabric

**SHALL**

The outer fabric of the buildings including the roof shall be structurally maintained in sound condition.

**SHOULD**

It is important to extend good housekeeping practice to the perimeter of the site, keeping grass cut and litter cleared. Maintaining a tidy exterior will enhance the image of the company, will maintain employee moral and reduce risk of rodent activity.

Dust around the building should be controlled.

2.7.2.b Inside fabrics and equipment**SHALL**

The inside of the buildings shall be maintained in a high state of repair and cleanliness. This relates to the structure of the buildings and also to fixtures such as lighting and ventilation.



Screening to protect a filling zone during repairs

Where more extensive structural alterations and repairs shall be undertaken, adequate screening shall be provided to enable production to continue without causing any contamination to product water from dust and debris. This shall be well controlled and monitored throughout and completed in as short a time as possible.

A high standard of cleanliness and hygiene shall be maintained throughout the premises and for production equipment.

Care shall be taken in the selection of cleaning products.

**SHOULD**

Where feasible, a shutdown for general routine repairs should be planned at an appropriate frequency.

Painting 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.

Detailed schedules and procedures for routine cleaning should be implemented. The frequency and type of cleaning for different areas should be related to their designated use.

The cleaning products should be odour-free and free rinsing whenever possible.

The cleaning equipment used should be maintained and cleaned on a scheduled basis. Wooden implements should not be in operation.

The cleaning team should be trained, including hygiene trained and supervised.

Cleanliness standards should be audited and monitored on an on-going basis by competent internal supervisory/managerial staff to ensure that schedules and procedures are appropriate and effectively applied.

2.7.3. USTENSILS AND EQUIPMENT: PREVENTIVE AND CORRECTIVE MAINTENANCE**SHALL**

The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards.

Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

Maintenance requests which impact product safety shall be given priority.

Temporary fixes shall not put product safety at risk, and shall be replaced by permanent repair in a timely manner.

String, tape, wire, rubber bands etc. shall not be used as temporary fixes.

Lubricants and heat transfer fluids shall be food grade where there is potential for direct or indirect contact with the product.

The procedure for releasing maintained equipment back to production shall include clean up, sanitising, where specified in process sanitation procedures, and pre-use inspection.

Local area prerequisite programs requirements shall apply to maintenance areas and maintenance activities in process areas.

Maintenance personnel shall be trained in the product hazards associated with their activities.

2.8 MANAGEMENT OF PURCHASED MATERIALS

Reg 852/2004, annex II

refers to art. 1 of chap. IX and art. 1 and 4 of chap. X.

2.8.1. GENERAL REQUIREMENTS



SHALL

Purchasing of materials which impact food safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements, both technical and regulatory.

The conformance of incoming materials to specified purchase requirements shall be verified.

2.8.2. INCOMING MATERIAL REQUIREMENTS (RAW /INGREDIENTS/PACKAGING)



SHALL

A packaged water producer shall not accept raw materials or ingredients, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms, or toxic, decomposed or foreign substances, to such an extent that even after the packaged water producer had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. seals are intact, free from infestation, integrity of packaging, etc.)

Incoming materials shall be inspected and/or covered by certificate of analysis to verify conformance to specified requirements prior to acceptance or use.

The inspection frequency and scope shall be based on the hazard presented by the material and the risk assessment of the specific suppliers.

Incoming materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use.

Access points to bulk material receiving lines (e.g. PET chips) shall be identified, capped and locked. Discharge into such systems shall take place only after approval and verification of the material to be received.



SHOULD

*Incoming materials should be tested to verify conformance to specified requirements prior to acceptance or use.
The method of verification should be documented.*



2.8.2.a. Water**SHALL**

Natural mineral and SW shall conform to Directive 2009/54/EC (as amended) and/or 98/83/EC (as amended) and 2003/40/EC.

BDW should comply with Directive 98/83/EC.

Water companies shall demonstrate compliance to these by regular testing for those parameters defined in the relevant sections of the regulations.

2.8.2.b. Other ingredients and processing materials**SHALL**

All other ingredients (minerals⁽²⁾ and CO₂) and processing materials (e.g. filtration media) shall be purchased from approved suppliers and conform to mutually agreed specifications and relevant food safety legislation.

Consideration shall be given to ensuring that no sensorial and microbiological contaminants arise from contact of CO₂, either with the final product or with the primary packaging materials used for the filling of water.

**SHOULD**

Testing, where applicable, should be carried out to demonstrate compliance of the ingredients and processing materials to food safety legislation.

(2) As may be added to drinking water only for remineralisation purposes

2.8.2.c. Primary packaging materials**SHALL**

Primary packaging materials (PET, PE, PC, PVC, glass, aluminium, card board,...) shall be purchased from suppliers approved by the producer. These materials shall conform to mutually agreed specifications and relevant food safety legislation. These materials shall be stored and used in such a manner that the integrity of products is not negatively impacted.

Supplier approval and monitoring systems for primary packaging materials shall be in place (e.g. audit supplier for compliance).

**SHOULD**

Testing, where applicable, should be carried out to demonstrate compliance of primary packaging materials to food safety legislation.

Incoming primary packaging materials (bottles, caps, pre-forms) should be manufactured from food-grade raw material. In addition, appropriate tests should be performed in order to verify that packaging materials are not likely to modify characteristics (sensorial, chemical and physical) of the finished product all over the shelf life, as well as mechanical properties of the packaging.

These tests should be repeated in case of significant change in packaging characteristics, such as the introduction of recycled PET.

2.8.2.d. Packaging (other than primary)**SHALL**

Materials used for packaging other than primary shall not be a source of contamination.

The crates design shall enable easy multiple cleaning through washer.

**SHOULD**

Materials used for packaging (other than primary packaging) should be purchased from approved suppliers and conform to mutually agreed specifications.

Supplier approval and monitoring systems for packaging other than primary materials should be in place (e.g. audit supplier for compliance)

Racks for storage and transport of packaged products should be maintained in good repair and should not pose a risk to the contents.



2.9 CONTAINERS, CAPS AND CLOSURES

Reg 852/2004, annex II refers to art. 3 of chap. IX and art. 1-4 of chap. X.

Guidelines specific to the bottled water industry.

2.9.1. GENERAL REQUIREMENTS



At all stages of production, processing and distribution, food shall be protected against any contamination likely to render the product unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

Anything which has a direct contact with the water may have an impact on the food safety and quality of the final product.

By design, the primary packaging materials such as containers, caps and closures shall not be a source of contamination.

The wrapping process shall ensure no contamination of the product occurs by appropriate location, hygienic design and/or choice of appropriate hygienic equipment, maintenance of equipment and control of the filling operations.

The primary packaging materials are to be stored in such a manner that they are not exposed to a risk of contamination.

All primary packaging materials shall be selected, purchased and approved as described in section 2.8.2.

2.9.2. CONTAINERS, CAPS AND CLOSURES STORAGE



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

The design of the glass bottles and other reusable containers shall enable easy multiple cleaning and disinfecting through washer.

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



If the empty containers are stored in the open air, they should be protected adequately against moisture, dust, exceptional weather conditions and pests. Protection against excessive heat and sunlight should also be necessary in the case of plastic containers.

Cleaning schedules for storage areas should be in place.

Regular hygiene audits of the warehousing should take place to verify good storage practices.

2.9.3. CONTAINER MANUFACTURING (ON-SITE INJECTION AND/OR BLOWING)



The container manufacturing operations shall adhere to the guidelines set in sections 2.3 (Layout of premises and workplace) and 2.4 (Utilities).

The container manufacturing areas (including notably the injection or resin reception area, the blowing or the extrusion-blowing equipment for the PET containers, all the conveyors for preforms or empty bottles) are critical.

AAir supply shall be filtered (gravimetric filter). The area shall be kept clean and in order (e.g. no plastic debris or debris of any kind).

The compressed air as well as the air in overpressure used for container blowing shall be dried, free of oil and micro-filtered (0.2µm or less) in order to avoid chemical or microbiological contamination of the empty containers. There shall be a procedure and an established schedule for maintenance of the air compressor system and filters.

PET pre-forms shall be protected and stored in good conditions (clean containers or clean dedicated silos). If plastic bags are used, they shall be one-way and food grade bags only.

There shall be a documented procedure and an established schedule for maintenance of the injection and blow molding machines and associated equipment.



SHOULD

The container manufacturing areas should be in a separate room (except blower/filler combi) with a positive pressure filtered air, tight fitting and self-closing doors.

Windows should be permanently sealed.



Filtered air flow to clean preforms before blowing



Preform conveyor covered to protect from contamination

Preforms, before blowing, should be cleaned with filtered air flow to ensure that there is no dust nor plastic or wood debris coming from packaging.

Conveyors and hoppers should be covered to protect the containers from contamination (dust, drips, sneezes, ...). The covers should be adjustable or designed to adequately protect all sizes of containers against contamination from all sides.

2.9.4. CAPS AND CLOSURES HANDLING



SHALL

Caps and closures shall be protected prior to loading into the hopper.

Boxes containing the caps and closures shall not be directly stored on the ground.

Caps and closures shall be stored in their original sealed container until time of use.

Caps and closures shall not be loaded into the hopper until just prior to use.

Caps and closures bins, hoppers, bowls, chutes, and conveyor system shall be cleaned in order to avoid the risk of particles in the finished product.

Caps and closures hoppers and cap delivery systems shall be effectively covered.

**SHOULD**

Conveyor-type cap delivery systems are preferred to pneumatic systems as they produce less cap dust.



Cap delivery system hygienically covered



Conveyor-type delivery system

2.10 PACKAGED WATER OPERATIONS

Reg 852/2004, annex II refers to art. 3 of chap. IX and art. 3 and 4 of chap X.
Guidelines specific to the bottled water industry.

2.10.1. GENERAL REQUIREMENTS

**SHALL**

At all stages of production, processing and distribution, food shall be protected against any contamination likely to render the product unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

Anything which has a direct contact with the water may have an impact on the food safety and quality of the final product.

Cleaning, disinfection and rinsing shall not represent a source of contamination for the product.

2.10.2. LOADING AND WASHING OF ONE-WAY CONTAINERS

**SHALL**

The container loading area shall be positioned within the processing facility so as to minimize contamination prior to filling and sealing.

Containers shall be handled in a hygienic manner.

**SHOULD**

Conveyors from the point of loading to capping and hoppers should be covered to protect the containers from contamination.

Rinsing of non-returnable (one-way) containers prior to filling should be considered as a preventive measure and its effectiveness should be evaluated on a case by case basis.

Container conveyors should be effectively covered from exit of washing machine or final rinser to capper.

Visual or automatic inspection of containers prior to filling and/or of filled products can be an appropriate preventive measure with regards to contamination by foreign bodies.

2.10.3. SNIFFING OF RETURNABLE PLASTIC BOTTLES

**SHALL**

Discarded containers shall be separated from good containers by an appropriate device.

Rejected plastic bottles (contaminated or non-cleanable) shall be segregated and then managed in a way to avoid the risk of putting the bottle back on the line by mistake (no risk of mixing).

**SHOULD**

Sniffing of every single bottle should be considered as an effective preventive measure. If an electronic sniffer is used, it should be periodically calibrated and tested.

2.10.4. BOTTLED WASHING OF RETURNABLE CONTAINERS

**SHALL**

The bottle design shall enable easy multiple cleaning and disinfecting through washer. Effective bottle washers shall be in place.

Effective monitoring and control program shall be in place to ensure the performance criteria are met and that the process itself does not present a source of contamination (e.g. caustic carry-over).

Bottle washers/sanitizers shall be installed in a protected area. The washer shall be positioned to minimize any possible post sanitizing contamination of the containers before they enter the filling room (no risk of mixing clean and dirty containers).

Conveyor cover material and design shall facilitate cleaning.

Products used for this cleaning shall be approved.

There shall be documented procedures on the operation, maintenance and sanitation of the bottle washers (detergent concentration, rinse cycles, nozzle pressure, operating temperatures, etc...). Maintenance and verification data shall also be recorded.

Visual or automatic inspection of containers prior to filling products shall be implemented as an appropriate preventive measure with regards to contamination.

**SHOULD**

There should be an automatic bottle unloading system at the washer exit.

Cleaned bottles should not be manipulated by hand at the washer exit and should be handled in a hygienic manner.

Rinsing containers prior to filling should be considered as a preventive measure and its effectiveness should be evaluated on a case by case basis.

There should be an appropriate procedure for cleaning of bottles rejected due to contamination or such bottles should be destroyed.



Covered bottle conveyor

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 sanitized 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.

2.10.5. DESIGN AND CONSTRUCTION OF THE BOTTLED WATER FILLING ROOM AREA



SHALL

The filling room shall be of impervious construction.

Doors of the filling room shall be self-closing, and windows non-opening.



Conveyor opening adapted to the size of the container

Conveyor openings passing into and out of the filling room shall not exceed the size of the container currently in production which would pass through the opening.

When not in use, and where multiple container sizes are processed within the same room, the opening shall be covered, unless there is a positive pressure system in continuous operation.

Only necessary equipment shall be inside the filling room. Operations which could contaminate the product and compromise the sanitary conditions of the filling room are not permissible.

Only authorized, properly-attired personnel shall be permitted to enter the filling room to conduct required tests or tasks.

The filling room's design shall be such that all surfaces contained therein can be thoroughly cleaned and sanitized on a regular basis. A procedure shall describe cleaning operations to be performed. Records of these cleaning operations as well as of efficacy controls shall be maintained.

The drainage in the filling room shall be adequate to prevent the presence of any standing water "ponding". Plumbing shall be adequately installed and maintained. Product water shall be separated from operations water to preclude contamination of product (either separate piping systems or suitable backflow prevention devices such as vacuum breakers).

Drains shall be well maintained and clean. Siphons are in place to assure a separation from waste water.

Equipment surfaces shall be impervious, smooth and made of sanitary material.

All equipment fixtures, pipes, electric cables, conveyor engines, etc., shall be installed so that they are not above the conveyors transporting the sanitized non-capped bottles in the filling room.

The filling room area shall be free of wood pallets, cardboard boxes and similar items.

**SHOULD**

The filling equipment (rinser, filler, capper) should be protected by a small cabinet under air filtered positive pressure (HEPA filter) or in a room under sterile air filtration with positive pressure.

A double entrance door should be located at the entrance of the fill room. A hand wash basin with automatic mixer tap, adequate supplies of hot and cold water a suitable un-perfumed liquid soap dispenser system (antiseptic), a hand drying system or paper towels and foot-operated waste container with cover are required in this area so that employees will use these items before entering the fill room. Doors should be self-closing.

"Wash hands now" notices should be located at point of entry to the filling room.

The double entrance door should also contain a shoe sanitizing device (footbath) unless over-shoes are to be worn.



Wash basin before entering the filling room with a shoe sanitizing device



Double entrance door system

2.10.6. FILLING AND CAPPING OPERATIONS

**SHALL**

In the filling room/area, all the staff shall wear specific clothes.

When in use, the filling room HEPA filter shall be checked on a regular basis for positive pressure. A written procedure shall describe the method, frequency of controls and frequency of filter change.

2.10.7. PLASTIC CRATES WASHING

**SHALL**

The plastic crates design shall enable easy multiple cleaning through washer.

**SHOULD**

Plastic crate washers and associated cleanliness controls should be in place as cleaned crates portray a good hygienic image.

2.11 LABELLING AND PACKAGING

Reg 852/2004, annex II: refers to art. 3 of chap. X

Reg (EU) N° 1169/2011

2.11.1. GENERAL REQUIREMENTS



Indirect contamination of the product shall be avoided during the packaging operation.

By design, during their storage, transfer to the packaging areas and in the operations, packaging materials (non primary packaging, e.g. labels, crates, cartons, films, pallets) shall not be a source of indirect contamination for the product on site or during its life.

Choice of appropriate equipment, maintenance of equipment and control of the packaging operations shall ensure no damage of the product occurs or will occur during its life.

2.11.2. LABELLING



The label shall comply with the regulation and give clear instructions to consumers for storage, preparation and use of the product where necessary.

Procedures shall be in place to ensure the application of correct labels to products.



If engineering or personnel organisation constraints require the labelers to be in the filling room, they should be separated from the filler as far as possible and a hooded vent should be installed (does not apply in case cold glue is used) to adequately remove any fumes from the labeler, solvents and glue. In such case the air circulation should be designed in order to avoid cross contamination.

2.11.3. PRODUCT CODING



The coding shall be legible.

Laser coding system shall only be allowed inside the filling room if equipped with adequate hooded vent in order to remove odors.



When used, the ink-jet or laser bottle coding equipment should be installed outside of the filling room (solvent hazards). If engineering or personnel organisation constraints require the coding equipment into the filling room, the coding head should be installed in the filling room and the other parts outside.

2.11.4. GROUPING AND PALLETISATION



Indirect contamination of the product shall be avoided during the grouping and palletising operations.



If wooden pallet is used, smelly pallets should be sorted from good pallets by an appropriate device.

Wooden pallets should be maintained in good condition to avoid wood splinters, nails or screws damaging products.

2.12 WAREHOUSING AND TRANSPORT

Reg 852/2004, annex II: refers to art. 1,2,5,6 and 7 of chap. IV, art. 2 and 3 of chap. IX and art. 2 of chap. X

2.12.1. GENERAL REQUIREMENTS



SHALL



Pallets of crates stored off the floor

Facilities used to store ingredients; packaging and products shall provide protection from dust, condensation, drains, waste and other sources of contamination.

Storage areas shall be dry and well ventilated. Monitoring and control of temperature, humidity and other environmental conditions shall be applied where specified.

All materials and products shall be stored off the floor, and with sufficient space between the material and the walls to allow inspection, cleaning and pest control activities to be carried out.

Incoming materials and finish product shall be stored in separated areas.

Warehousing shall not impact the integrity of the final product.

The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.



Separate and ventilated storage area for chemicals

A separate, secure (locked or otherwise access controlled) and well-ventilated storage area shall be provided for chemicals (cleaning products, lubricants and other hazardous substances).

Waste materials and chemicals shall be stored separately (see section 2.5.)

Diesel powered forklift trucks shall not be used in food ingredient or product storage areas. Electric and/or gas powered trucks shall be used.

Adequate procedures are to be in place to control pests.



SHOULD

Electric forklift trucks should be used inside the plant while gas or electric forklift trucks should be used in other parts of the plant, such as warehousing and transportation areas.

No automobiles, diesel trucks or diesel forklifts should be permitted inside the plant or the warehouse.

Chemical containers should be placed in open containers with sufficient capacity to trap any leaks, spills or splashes from contaminating surrounding areas.

2.12.2. INCOMING MATERIALS STORAGE

**SHALL**

Incoming materials (carbon dioxide, preforms, containers, caps and closures, films, pallets, etc ...) shall be stored in clean, dry, well ventilated spaces protected from dust, condensation, fumes, odors or other sources of contamination, to prevent harmful deterioration and malicious act.

Specified stock rotation systems (FIFO/FEFO) shall be observed.

**SHOULD**

It is recommended that where products are stacked, consideration is given to measures necessary to protect the lower layers.

Cleaning schedules for storage areas should be in place.

Regular hygiene audits of the warehousing should take place to verify good storage practices.

It is advisable to provide suppliers of incoming materials with required practices which they will be required to comply with as part of their contract. Agreed specifications should include the conditions of materials on receipt.

Bottles, closures and other packaging materials should at all times be kept from direct contact with the floor.

Suitable protective packaging, provided and supplied by the manufacturer, should remain intact until point of use.

2.12.3. FINISHED PRODUCTS STORAGE

**SHALL**

Finished products (bottles in pallets) shall be stored in clean, dry, well ventilated spaces protected from dust, condensation, fumes, odors (e.g. strong flavored/spicy foods) or other sources of contamination.

Outside storage is acceptable, if under cover, shrink-wrapped (or similar) and for limited periods only (less than 24 hours).

Packaged waters are generally stored and transported at ambient temperature.

Specified stock rotation systems (FIFO/FEFO) shall be observed.

A separate area or other means of segregating materials identified as non-conforming shall be provided.

**SHOULD**

Care should be taken to prevent freezing of product which, due to expansion, is liable to cause breakage and/or explosion of bottles and/or increase the risk of 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 risk of condensation developing on bottles which can give rise to damaged/moldy labels and damp secondary packaging.

Finished products should not be stored outside.

2.12.4. SHIPPING AND TRANSPORT

**SHALL**

Bottled NMW and SW must be carried in containers intended to final consumer (Directive 2009/54).

Specific temperature monitoring controls during transportation are generally not required.

Vehicles, conveyances and containers used to transport packaging materials and food shall be kept clean, free from odours and maintained in good repair and condition to protect products from contamination, and, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

Ingredients, raw materials, packaging materials and finished products shall not be transported together with other materials that may result in direct or indirect contamination (e.g. pesticides, chemicals, odorous materials and foodstuffs).



Where the same vehicles, conveyances and containers shall be used for food and non food products, cleaning shall be carried out between loads to avoid the risk of contamination.

Receptacles in vehicles and/or containers shall not be used for transporting anything other than foodstuffs where this may result in contamination.

Bulk containers shall be dedicated to food use only. Where required by the organisation, bulk containers shall be dedicated to a specified material. The containers shall be sealed with an appropriate closure system directly after filling.



SHOULD

Vehicles or containers for conveying finished products should be subjected to a thorough inspection before loading and such inspections should be documented.

Transportation at excessive high temperatures may result in quality reduction (e.g. risk of compound migration from primary packaging materials).

It is advisable to provide suppliers of primary packaging with required practices which they will be required to comply with as part of their contract. Agreed specifications should include the conditions of materials on receipt. Packaged bottles should at all times be kept from direct contact with the floor. Suitable protective packaging, provided and supplied by the manufacturer, should remain intact until point of use.

Specific contractual arrangements should be in place for the receipt of bulk gas supplies.

2.13 CONTROL OF FOREIGN BODIES

Reg 852/2004, annex II: refers to art. 3 of chap. IX

2.13.1. GENERAL REQUIREMENTS



SHALL

At all stages of production, processing and distribution, products shall be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.

Examples of such measures include:

- a) adequate covers over equipment or containers for exposed materials or products;
- b) use of screens, magnets, sieves or filters;
- c) use of detection/ rejection devices such as camera, metal detectors or X-ray.
- d) regular use of air sampling equipment to determine presence of moulds, yeast and dust in filling rooms.



SHOULD

Glass and brittle material (such as hard plastic components in equipment) should be avoided where possible.



2.13.2. WASHING AND FILLING OF GLASS BOTTLES



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

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

Dedicated optical device shall be installed to monitor the neck finish of glass bottles as well as the presence of glass debris inside. Defect bottles shall be automatically discarded from the line (detection/rejection device)

Glass breakage records shall be maintained.



Automatic rejection of a pre-determined number of bottles



Glass bottle fillers should be programmed to automatically reject a pre-determined number of bottles following glass bottle explosion/implosion.

2.14 CLEANING AND SANITISING

Reg 852/2004, annex II: refers to art. 2 of chap. II

2.14.1 GENERAL REQUIREMENTS: PREVENTION, CONTROL AND DETECTION OF CONTAMINATION



Programmes shall be in place to prevent, control and detect contamination.

Measures to prevent microbiological, physical and chemical contamination shall be included:

a) Microbiological cross contamination.

Areas where potential for microbiological cross contamination exists (airborne or from traffic patterns), shall be identified and a segregation (zoning) plan implemented.

A hazard assessment shall be carried out to determine potential contamination sources susceptibility of the product, and control measures suitable for these areas, as follows:

- separation of raw from finished products;
- structural segregation: physical barriers/walls/separate buildings;
- access controls with work wear requirements;



- traffic patterns: people, materials, equipment and tools (including use of dedicated tools);
- air pressure differentials
- air filtration.

b) Physical and chemical contamination:

Based on hazard assessment, measures shall be put in place to prevent, control or detect potential physical and chemical contamination.

Where glass and brittle material are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.



SHOULD

Written Glass and Brittle Plastics Policy should be put in place.

Examples of control measures for glass breakage include:

- adequate covers over equipment or containers for exposed materials or products;
- use of screens, magnets, sieves or filters;
- use of detection/ rejection devices such as camera, foreign materials detectors or X-ray.

2.14.2 CLEANING AND SANITISING



SHALL

Adequate facilities shall be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities shall be constructed of corrosion-resistant and non-absorbent materials, be easy to clean and have an adequate supply of hot and cold water.

The regularity and method with which the filling line, tanks, piping and any other equipment is cleaned and disinfected shall be guided by microbiological monitoring and the outputs of the HACCP programme.

Cleaning and sanitizing programmes shall be established and validated to ensure that the food processing equipment and environment shall be maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

Cleaning programmes shall specify at a minimum:

- areas, items of equipment and utensils to be cleaned;
- responsibility for the tasks specified;
- cleaning method and frequency;
- chemical concentration, contact time/temperature
- verification and monitoring arrangements;
- post-clean/pre-start up inspections

Any new plant and equipment shall receive very thorough cleaning prior to use to remove any residual grease, lubricant or solvent use in its manufacture, including passivation of new stainless steel pipe-work.

2.14.2.a Cleaning agents and tools



SHALL

Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and sanitation.

Cleaning food grade agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.

Cleaning tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter. Cleaning tools and equipment for production equipment and areas shall be separate from those used in toilets and employee hygiene facilities.



SHOULD

Master Safety Data Sheets should be readily accessible to users of chemicals.

2.14.2.b. Cleaning in place (CIP) and cleaning out place (COP) systems



SHALL

CIP systems shall be isolated from active product lines.

Parameters for CIP/COP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).



CIP system for the cleaning and disinfecting of operational surfaces

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

All traces of these agents shall be removed prior to the line returning to service. Care shall be taken to ensure that the rinsing water is of a suitable hygienic standard.

Where a line is used for other drinks as well as water, a rigorous cleaning and disinfecting procedure prior to each water run shall be used.

There shall be a procedure in place to verify all the previous product residues have been adequately removed and the line adequately disinfected prior to a change of product.



SHOULD

Wherever possible, filling lines should be dedicated to water bottling only. If not possible, water bottling should precede other beverage bottling. Allow sufficient time for changeover tasks.

Even after such rigorous procedures it is advisable to ensure that designated, experienced personnel (sensory profilers with acute palates and noses) evaluate the water at start up to ensure that there is no carryover of taste or odour from the flavoured product.

2.14.3. MONITORING SANITATION EFFECTIVENESS



SHALL

Cleaning and sanitation programmes shall be monitored, at specified frequencies, to ensure their continuing suitability and effectiveness.

The updating of the programmes shall be considered into periodical HACCP review.

2.15 PEST CONTROL

Reg 852/2004, annex II: refers to art. 2 of chap. I and art. 4 of chap. IX

2.15.1. GENERAL REQUIREMENTS



SHALL

The layout, design, construction, siting and size of food premises shall permit good food hygiene practices including protection against contamination and, in particular, pest control.

Hygiene, cleaning, incoming materials inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.



SHOULD

Pest control products (pesticides, rodenticides, etc.) should not be stored on the premises.



2.15.2. PEST CONTROL PROGRAMMES

**SHALL**

Adequate procedures shall be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored.

The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.

Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and where necessary, training requirements.

Programmes shall include a list of chemicals (pesticides) which are approved for use in specified areas of the establishment.

**SHOULD**

An external specialist pest control service should be used. This will advise on and monitor any proofing requirements which may otherwise have been overlooked.

It is recommended that baits in solid block form should be used, contained in sealed boxes. Bait stations should be clearly identified and anchored in place. Open dishes of granular bait should not be used in production or warehousing areas.



Examples of insect stunning devices.

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.

2.15.3. PREVENTIVE ACCESS



Ventilation opening to minimize the entry of pests.

**SHALL**

The buildings shall be designed to minimize the ingress of pests. Outer doors shall be well fitted and shall prevent bird, rodent or insect entry. External doors shall not open directly into open bottle areas.

Buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.

External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

**SHOULD**

Outer doors should be kept closed whenever possible, only opening them for receipt of materials or for loading out finished products. Automatic doors are available and can assist in protection.

Windows or ventilation openings should be wire mesh screened and kept closed when not in use.

2.15.4. HARBOURAGE AND INFESTATIONS

**SHALL**

Storage facilities shall be designed to prevent the availability of food and water to pests.

Material found to be infested shall be handled in such a way as to prevent contamination of other materials, products, or the establishment.

Potential pest harbourage (e.g. burrows, undergrowth, stored items) shall be removed.

Where outside space is used for storage, stored items shall be protected from weather and pest damage.

2.15.5. MONITORING AND DETECTION

**SHALL**

Pest monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity.

A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

Detectors and traps shall be of robust, tamperresistant construction. They shall be appropriate for the target pest.

The detectors and traps shall be inspected at a frequency intended to identify new pest activity.

The results of inspections shall be analysed to identify trends.

2.15.6. ERADICATION

**SHALL**

Evidence of infestations shall be dealt with when reported.

Pesticides use and application shall be restricted to trained workers and shall be controlled to avoid product safety or quality hazards.

Records of pesticides use shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.

2.16 PERSONAL HYGIENE AND EMPLOYEE FACILITIES

Reg 852/2004, annex II: refers to art. 1 and 2 of chap. VIII and to art. 3 of chap. IX

2.16.1. GENERAL REQUIREMENTS

**SHALL**

At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.



Standards for personal hygiene and behaviours proportional to the hazard posed to the process area or product shall be determined and documented.

All personnel, visitors and contractors shall be required to comply with the documented requirements.

Every person working in a food handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.

2.16.2. EMPLOYEE HYGIENE FACILITIES AND TOILETS (see also section 2.3.)



SHALL

Hygiene facilities shall be made available to employees and staff to ensure that the degree of personal hygiene required by the organisation can be maintained.

The facilities shall be located close to the points where hygiene requirements apply, and shall be clearly designated and easily accessible.

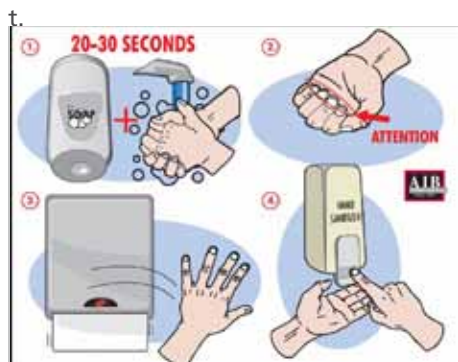
2.16.2.a. Toilets



SHALL

Establishments shall:

- a) provide an adequate number of toilets of appropriate hygienic design and according to number and sex of employees, each with hand washing, drying and, where required, sanitizing facilities;
- b) have toilets, shower rooms and other employee hygiene facilities that do not open directly onto production, packing or storage areas; toilets shall be well separated from production areas and other food handling areas by a suitable intervening space such as corridors or self-closing double doors.
- c) have natural or mechanical ventilation systems designed to discharge air from sanitary conveniences away from production areas and shall be separated from any ventilation systems within the filling plan



SHOULD

'Wash Hands Now' notices should be located in toilet areas and other employee hygiene facilities.

It is preferable to have taps that are not operated by hand.

Trash containers should be covered and foot-operated.

"Wash hand" notice.

2.16.2.b. Wash basins



SHALL

Establishments shall:

- a) provide adequate numbers, locations and means of hygienically washing and drying hands, and, where required, sanitizing (including wash basins, supply of hot and cold or temperature controlled drinking running water, soap, dryer, and sanitizer where required);
 - b) have sinks designated for hand washing, separate from sinks for food use and equipment cleaning stations;
- Hands shall be kept clean and shall be washed whenever being soiled and after use of toilet facilities, after eating, smoking and whenever entering open bottle areas.

**SHOULD**

Taps at hand wash stations should not be hand operated.

It is recommended to site wash hand basins at all entry points to open bottle areas, in laboratories, maintenance workshops, and canteen.

It is good practice to have signs which identify designated 'HAND WASH ONLY' basins.



Mixer taps are preferred.

Un-perfumed, bactericidal soap/detergent should be provided by dispensers. Nail brushes, maintained in hygienic condition, by regular boiling or frequent replacement, should also be available.

If warm air hand dryers are installed it is important that they are effective and efficient.

If towels are provided, it is important that they are single use. Roller towels should not be used.

Trash containers should be covered.

Single-use towel dispenser.

2.16.2.c. Changing facilities

**SHALL**

Establishments shall have adequate changing facilities for personnel.

Food handling personnel shall be able to move from changing facilities to production areas without going outside.

Sanitary conveniences shall have adequate natural or mechanical ventilation.

Natural or mechanical ventilation systems shall be designed to discharge air from sanitary conveniences away from production areas and shall be separated from any ventilation systems within the filling plant.

**SHOULD**

Lockers should be made available to each employee.

Lockers should be designed to have a slope on the top to prevent storage.

A space between the floor and the bottom of the locker should allow cleaning.

Segregation of clean from dirty clothes should be made available.

There should be no direct access to locker rooms from processing areas. Intervening space such as corridors should provide access. Locker areas need to be inspected for cleanliness.

Example of lockers in changing facilities.

2.16.3. STAFF CANTEENS AND DESIGNATED EATING AREAS

**SHALL**

There shall be no eating (including chewing gum), drinking or smoking outside of designated areas.

Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross contamination of production areas is minimized.

Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.

Storage conditions and storage, cooking and holding temperatures, and time limitations, shall be specified.

Employees' own food and beverages shall be stored and consumed in designated areas only.

**SHOULD**

A canteen or rest room should be provided for any meal breaks.

Non production related items and personnel objects should not be taken into production areas.

2.16.4. WORK WEAR AND PROTECTIVE CLOTHING

**SHALL**

Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition.

Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.

2.16.4.a. Work wear

**SHALL**

Work wear shall not have outside pockets above waste level or outside buttons. Zips or press stud fastenings are acceptable.

There shall be no pockets at all in protective clothing worn in high risk areas.

Work wear shall be laundered at intervals and to defined standards suitable for the intended use of the garments.

Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.

Hair, beards and moustaches shall be protected (i.e. completely enclosed) by restraints unless hazard analysis indicates otherwise.

Long hair shall be neatly contained with no grips outside the hair covering.

Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves shall be avoided where possible.

Shoes for use in processing areas shall be fully enclosed, and made from non-absorbent materials.

**SHOULD**

For the purpose of consistency and promotion of a good hygiene culture, it is recommended to use hair nets in all areas.

If working in open bottle areas it is advisable to protect beards with a net.

Fingernails should be kept clean and short. No nail varnish or false nails should be worn.

False eyelashes should not be used.

Invasive use of perfume or aftershave should be avoided.

No jewellery should be worn with the exception of single band wedding ring or other religious or ethnic jewellery specifically approved by the producer.

When used, gloves should be frequently replaced as needed. Recommend to use disposable gloves. A recommended alternative to gloves is to provide hand disinfection preparations, suitably used and changed as necessary.



2.16.4.b. Protective clothing**SHALL**

Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

**SHOULD**

Contract cleaning of protective clothing is recommended.

In open bottle areas, gloves and masks may further assist in maintaining integrity of the product. When used, gloves should be frequently replaced as needed. A recommended alternative to gloves is to provide hand disinfection preparations, suitably used and changed as necessary.

Protective clothing should be restricted for use on site only. Pockets should be restricted to below the waist and should only accommodate items required for work. Protective clothing should not have outside buttons.

2.16.5. HEALTH STATUS**SHALL**

Employees shall undergo a medical examination prior to employment in food contact operations (including site catering), unless documented hazard assessment indicates otherwise.

Additional medicals shall be carried out at intervals defined by the organisation, subject to legal restrictions in the country of operation.

2.16.6. ILLNESS AND INJURIES**SHALL**

No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhea shall be permitted to handle food or enter any food handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the packaged water producer.

Any sickness or injury shall be reported to supervisory staff and noted. Management is legally responsible to ensure protection of the food from risks through listed medical conditions. This may include exclusion of the member of staff from the premises whilst the condition lasts, or exclusion from working in open bottle areas. This applies also to contractors and visitors who shall be informed of such preventive measures upon arrival.

People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from entering food handling areas.

In food handling areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately.

**SHOULD**

Dressings should be brightly coloured and metal detectable where appropriate.

Sores, cuts or grazes should be covered with a coloured waterproof and metal detectable bandage. Any bandage should be accounted for at the end of each shift and replaced with a new one before each shift, and as required.

Visitors entering high risk areas should be required to complete a medical questionnaire before doing so.

2.16.7. PERSONNEL CLEANLINESS

**SHALL**

Personnel shall be required to wash and, where required, sanitise hands:

- a) before starting any food handling activities;
- b) immediately after using the toilet or blowing the nose;
- c) immediately after handling any potentially contaminated material;
- d) after smoking.

Personnel shall be required to refrain from sneezing or coughing over materials or products.

Spitting (expectorating) shall be prohibited.

Fingernails shall be kept clean and trimmed.

2.16.8. PERSONNEL BEHAVIOUR

**SHALL**

A documented policy shall describe the behaviours required of personnel in processing, packing and storage areas.

The policy shall at a minimum cover:

- a) permissibility of smoking, eating, chewing in designated areas only;
- b) control measures to minimize hazards presented by permitted jewellery; permitted jewellery includes specific types of jewellery which may be worn by the personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives.
- c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;
- d) prohibition of the use of nail polish, false nails and false eyelashes;
- e) prohibition of carrying of pens and pencils behind the ears;
- f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;
- g) prohibition of storage of product contact tools and equipment in personal lockers.
- h) prohibition of bringing personal items to production areas.

2.17 TRAINING

Reg 852/2004, annex II: refers to art.1, 2 and 3 of chap. XII

2.17.1. GENERAL REQUIREMENTS



SHALL

Packaged water producers shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

Packaged water producers shall ensure compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.

2.17.2. TRAINING IN FOOD HYGIENE MATTERS

All persons, including temporary staff, involved in water filling operations shall be supervised and instructed or trained in food safety and hygiene. Before any person is allowed to start work in the filling plant they shall receive written or verbal instruction in food hygiene practices essential to the safety of the product and in relation with the specific tasks.

Induction training shall include:

- a) General aspects of quality and food safety management,
- b) Personal hygiene,
- c) Good manufacturing and housekeeping practices,
- d) Specific roles and responsibilities in the HACCP program
- e) Health and first aid
- f) Food security & defense.

The training content and intensity shall be dependent upon the work activity and its potential impact on food safety. Special training arrangements shall be taken where difficulties with learning, literacy and language are identified. Re-training shall take place on a regular basis and whenever a need to do so is detected (e.g. changes, corrective action needs, new equipment, new regulations)

All staff shall be properly supervised to ensure they work hygienically.



SHOULD

A greater degree of supervision may be needed for new staff awaiting formal training and for less experienced staff, including seasonal workers.

2.17.3. TRAINING FOR THE APPLICATION OF THE HACCP PRINCIPLES



SHALL

Personnel responsible for establishing, maintaining and managing a HACCP system shall receive adequate training in the application of HACCP principles.

Emphasis shall be placed on maintaining product integrity and safety for the consumer.

The training shall provide instruction on any control or monitoring points as identified in the company's risk assessment.

2.18 PROCESS AND PRODUCT SPECIFICATIONS

(See example in annex N°1)

Reg 852/2004, annex II. Guidelines specific to the bottled water industry.

2.18.1. GENERAL REQUIREMENTS



SHALL

All different types of finished products shall be described in detail by written “process and product specifications”.



SHOULD

This should be part of the design & development process of the company. This process should clearly define the responsibilities and objectives regarding the realisation of these specifications.

A general rule is that a new product (e.g. introduction of a new type of packaging) should never be launched without specifications. For an existing product, the “process and product specifications” should be updated every time there is a change in the process of the product (e.g. addition of a filtration step, introduction of a new packaging format).

Process and product specifications should be drafted either by the R&D department or the technical services, with inputs from Industrial, Quality and other appropriate services when needed. Industrial department should in every case be responsible for verifying and validating these specifications prior to the launch of the production of a new or renovated product.

2.18.2. KEY ELEMENTS OF PROCESS AND PRODUCT SPECIFICATIONS



SHOULD

Key elements that should be part of “process and product specifications” are:

- a) Water resource characteristics: type of water, name of source, typical composition
- b) Process description (process steps with key operational parameters): water treatment, bottle washing process, filling conditions)
- c) Finished product characteristics that should be defined as often as possible with target, acceptable limits and rejection limits:
 - microbiological standards
 - physical-chemical standards (e.g. pH, conductivity or total dissolved solids (TDS), carbon dioxide (CO₂) level for sparkling waters, mineral composition, organic chemicals composition)
 - packaging parameters (e.g. torque standards, filling levels)
 - sensorial characteristics
- d) Packaging description (primary, secondary, tertiary packaging)
- e) Shelf life definition (e.g. Best Before Date definition)
- f) Batch definition and coding rules
- g) Specific handling, storage and transportation requirements
- h) Control plans (or at least reference to the applicable Control Plan)

2.18.3. COMPLIANCE TO SPECIFICATIONS



SHALL

A procedure shall define the rules and responsibilities for checking the compliance to the specifications.



2.19 PRODUCT MONITORING

Reg 852/2004, annex II. Guidelines specific to the bottled water industry.

2.19.1. CONTROL PLANS



SHALL

As mentioned in the previous section, product monitoring is one of the important steps for verifying that a product complies with the specifications.

Product monitoring will be operated through two types of monitoring plans: control plans and surveillance plans.

Depending on the laboratory facilities at the company's disposal as well as on regulatory requirements, these analyses can be either operated in-house or externally. Some controls could be done by operators (in-process controls). In such cases suitable training shall be developed.

Control plans shall cover not only finished products but also raw materials and packaging materials, process monitoring, and environmental monitoring (e.g. surface swabbing, air sampling.).

Control plans shall include, at a minimum,

- a) product and process specifications to be monitored,
- b) frequency of monitoring,
- c) target, minimum and maximum limits, (tolerances),
- d) person/s responsible for product monitoring,
- e) person/s responsible for reviewing monitoring results,
- f) corrective actions when specification limits are breached.

As regards non-conforming products, clear procedures, including responsibilities, for the control of non-conforming products shall be in place and understood by all authorised personnel. These procedures include disposition by rejection or acceptance with restrictions.

Corrections and corrective actions shall be commensurate with the seriousness of risk identified.

A suitably trained person shall be designated to evaluate and decide on the disposition of non-conforming product.

An example of control plan for the finished product is given in Annex I, of in-process control sheet for the primary packaging is given in Annex II and III, of in-process visual aids for bottle coding in Annex IV.



SHOULD

Visual aids for helping operators interpreting these in-process controls (notably for packaging defects) should be made available.

2.19.2. SURVEILLANCE PLANS



SHALL

The frequency of this extensive analysis will obviously be much lower than for routine checks. In general it varies from one to two times a year.

Given the large scope of this type of check-up, it has in general to be, at least partially, sub-contracted to one or several outside laboratories. If analyses are carried out in-house at the plant laboratory, good laboratory practices shall be enforced and approved methods used.



SHOULD

If analyses are sub-contracted to an outside laboratory, the laboratory/ies selected should be accredited, or at least officially recognised, and comply with the principles of ISO 17025 (i.e. qualified staff, proficiency tests, control of effluents and pathogens, etc.).



2.20 TRACEABILITY, COMPLAINT AND CRISIS MANAGEMENT, PRODUCT WITHDRAWAL AND RECALL PROCEDURES

Reg 852/2004, annex II

2.20.1. TRACEABILITY: UPSTREAM, INTERNAL, DOWNSTREAM TRACEABILITY, MAINTENANCE AND EVALUATION OF TRACEABILITY SYSTEM



SHALL

The organization shall design, implement and maintain a traceability system, taking account both regulatory constraints and consumers' needs.

Its objectives shall be to:

- a) improve food safety risk control
- b) allow reliable information to be found quickly in the event of a problem
- c) limit as much as possible the number of products to be put on hold, recalled and/or withdrawn, whilst maintaining maximum safety for consumers

An efficient traceability system shall cover the entire chain:

- a) Upstream traceability: traceability of incoming goods (water, raw materials and packs)
- b) Internal traceability: traceability within filling operations
- c) Downstream traceability: finished products from plant to consumer

The traceability system shall ensure a perfect link between these three domains in all ways.

The traceability system shall be based on:

- a) identification of all products potentially affected by a given problem at any time and anywhere (by downstream tracing)
- b) fast detection of the origin of the problem (by upstream tracing)
- c) communication of traceability data to public authorities and customers, in case of withdrawal or recall of products



SHOULD

The company traceability system, as a tool, should form an essential part of the Quality and Food Safety management systems (section 1).

The product traceability process should be based on:

- a) unique identification of each manufacturing batch and each logistic unit*
- b) record data to link manufacturing process to shipping batch and vice versa*

The traceability process should be tested at least at twelve monthly intervals.

2.20.1.a. Upstream traceability



SHALL

The procedures and tools implemented to guarantee the upstream tracing shall:

- a) define and implement the batch delivery management (e.g. batch number identification) with raw materials, processing aids and packaging suppliers
- b) ensure receipt of incoming products in conformity with law and with the company specifications
- c) allow to obtain additional information from suppliers of raw materials and packaging materials in contact with water, in the event of problem

**SHOULD**

For raw materials (including processing aids) and food contact materials (packaging), the following information should be required and recorded from the suppliers for each batch or lot received:

- a) product name, supplier name and receipt date*
- b) supplier batch number and/or manufacture date*
- c) "best before" date or "use by" date*
- d) specific storage conditions*
- e) quantity received*
- f) transporter name*
- g) conformity supplier batch report in accordance to specifications.*

A periodic audit of the supplier, including a tracking exercise, should be implemented in order to assess the real efficiency of suppliers' traceability systems.

2.20.1.b. Internal traceability

**SHALL**

The internal procedures and tools shall guarantee the links throughout the product manufacturing process, from receipt of materials to dispatch of finished products.

**SHOULD**

Internal traceability should allow the upwards or downwards relationship established between materials and finished product including all the stages of processing (incoming goods, production steps, maintenance and sanitation operations, or other specific events), notably by allocating a unique product batch number to every production lot in relationship to all materials and processes involved.

Regarding all products batches, retained samples should be kept to be used in case of investigation (for instance, a consumer complaint) until expiration date.

A good practice is to keep 2 bottles per shift and per type of product, representing at least a sampled volume of 0.5L until expiration date, plus three months.

A periodic audit of internal traceability system, including tracking exercise should be implemented in order to assess the real efficiency of the internal traceability procedure.

2.20.1.c. Downstream traceability

**SHALL**

Downstream traceability refers to the procedures and tools implemented to enable products to be traced following the physical transfer from producer to customer and then to consumer, including logistic service providers and distribution centres.

This traceability process shall be based on:

- a) unique identification code and labelling of all products.
- b) data capture, recording and link management along the supply chain in such a way that any relevant information can be retrieved whenever necessary in fast and accurate manner.
- c) ability to trace all finished products, from their initial delivery point to the final distribution point by a batch code on every consumption unit as well as on every sales unit (boxes, crates, cases, trays, etc.) and on every logistic unit (pallets).
- d) availability of a reliable system of identification and localisation to initiate recall operations when needed.
- e) communication of pre-determined traceability data along the supply chain to facilitate accurate and fast product withdrawal and recall (traceability data on delivery chain: bill of lading, despatches, list of shipping, etc.).

The system has to enable the tracking of products coming from packing or repacking activities.



Organisations shall define which product and process-related information shall be kept with regard to compliance with EU Directive 85/374 relating to defective product liability.



A periodic audit of the downstream traceability system, including a tracking exercise, should be implemented in order to assess the real efficiency of the downstream traceability procedure.

SHOULD

2.20.2. COMPLAINT MANAGEMENT



A complaint management system shall be installed in order to record and manage consumers' complaints.

SHALL

2.20.3. CRISIS MANAGEMENT



Each organisation shall implement an internal procedure for crisis management.

SHALL



Crisis management should include appropriate procedures, clear responsibilities and good training programmes. For this purpose, the organisation should:

SHOULD

- a) *provide a clear and precise definition of what is a crisis and the scope of its procedure.*
- b) *implement internal procedures, checklists and documentations to ensure the best practice to manage crises.*
- c) *build a formal crisis team where roles and responsibilities are clearly defined for each member*
- d) *establish and permanently update emergency contact lists, both internal and external (suppliers, customers, authorities, laboratories, PR agencies ...)*
- e) *implement a risk analysis, collecting the information needed to help to evaluate the possible legal and economic effects of the incident and to decide the action to be taken. The assessment should cover:*
 - *the type and degree of risk*
 - *the mitigating effects of different actions available*
 - *the methods of communication used*
 - *the potential consequences, taking into account the priority of consumer safety at all time*
- f) *establish clear rules and responsibilities regarding internal and external communication when a crisis occurs*
- g) *where appropriate, initiate a product recall or withdrawal plan*
- h) *systematically establish post-mortem analysis after every significant crisis in order to learn lessons about the causes and source of the problem so that plans of preventive and corrective actions can be prepared and implemented.*

The crisis team is responsible for managing and organising the following items:

- a) *Risk prevention:*
 - *detect as early as possible emerging topics (weak signals...) that potentially could be detrimental to the business (environmental, social, financial issues...)*
 - *anticipate food safety risks*
 - *monitor internal and external information (consumer and customer contacts, press and media review, supplier information,...)*

b) Risk management:

- make sure that risk evaluation is updated and capable of providing the required level of protection and information
- periodically update crisis management procedures, recall plan, contact lists and position statements

c) Training:

- crisis team members
- media training

d) System evaluation:

- periodic system review and audit
- mock exercises

2.20.4. PRODUCT WITHDRAWAL AND RECALL PROCEDURES

With regard to product related crises, a list of key contacts in the event of a recall shall be maintained.

Where products are withdrawn due to immediate health hazards, the safety of other products produced under the same conditions shall be segregated and evaluated. The need for public warnings shall be considered.

Recalled and withdrawn products shall be held under the company supervision until a decision is taken with regard to the final destination of the products (e.g. destruction).



The organisation should implement and maintain systems and procedures to withdraw or recall products when necessary (food safety risk, regulatory non compliance, etc) in order to minimise a consumer safety risk.

The cause, extent and result of a recall or withdrawal should be reported as input to the management review.

The organisation should verify the effectiveness of the recall and withdrawal programmes through the periodical use of internal auditing and challenge tests.

To facilitate the complete and timely withdrawal or recall of the implicated batch of product identified as unsafe, the system should have clearly established:

- a) people having the authority to initiate a withdrawal / recall programme and people in charge of executing it
- b) procedures and responsibility for handling withdrawn / recalled products as well as involved products still in stock
- c) procedures for the notification to relevant interested parties
- d) for recalls, procedures for activation of public warning to inform consumers
- e) record requirements

2.21 FOOD DEFENSE, BIOVIGILANCE AND BIOTERRORISM

Reg 852/2004, annex II

2.21.1 GENERAL REQUIREMENTS



SHALL

Each establishment shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

Potentially sensitive areas within the establishment shall be identified, mapped and subjected to access control.



SHOULD

Note: for further information and guidance on approaches to the protection of food businesses from all forms of malicious attack see PAS 96-Food Security: Guidance for the protection of the food supply chain against malicious ideologically motivated attack (published by the BSI – British Standards Institute).

2.21.2. RECOMMENDATION FOR RISK ASSESSMENT AND RISK MANAGEMENT



SHOULD

To ensure the risk of malicious or bioterrorist acts is managed effectively, companies should develop a HACCP-based approach as described in the text of the Codex Alimentarius, defining “critical points for the risk of malicious/bioterrorist acts”.

Protective measures should cover, but not be limited to:

- a) Management: e.g. contacts with relevant local services (police, fire service)
- b) Personnel (e.g. personnel identification system, restricted access to sensitive zones, training)
- c) Facilities (e.g. installations and buildings surveillance, admittance to plant)
- d) Water Resources (e.g. protection zones, catchments protection, storage tanks protection)

2.21.3. ASSESSMENT OF SYSTEM EFFICIENCY



SHOULD

Bioterrorist or malicious act risk management procedures should include a regular assessment giving rise to a critical analysis and an update of inspection methods and resources. The frequency with which the assessment is to be carried out under normal working conditions should be at least annually. However, any attempted malicious act, whether or not it has succeeded in adversely affecting the safety of products, should be analysed followed by system re-assessment.

1. GENERAL ASPECTS OF QUALITY & FOOD SAFETY MANAGEMENT	2. PREREQUISITE PROGRAMS - PRPs (GHPs-GMPs)	3. HACCP - HAZARD ANALYSIS AND CRITICAL CONTROL POINTS	4. REFERENCES
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HACCP- Hazard Analysis and Critical Control Points

3.1. INTRODUCTION

The intent of this section is to illustrate the HACCP methodology in the packaged water industry through a limited number of examples. As a result, it should not be considered as an exhaustive HACCP study for all possible cases.

As stated in article 5.1 of chapter 2 of regulation 852/2008, packaged water producers shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles adopted by the Codex Alimentarius Commission.

The HACCP system, which is science-based and systematic, identifies specific health related hazards and measures for their control to ensure the safety of packaged water. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing.

Any HACCP system must be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach.

The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems. It is also embedded in ISO 22000.

All records and documents relating to the HACCP system need to be kept in a format that is readily accessible by the competent authorities upon request.

A regular review and update of the HACCP system shall be carried out to ensure that it is kept relevant and up-to-date.

Production, process and product documents and records shall be kept for the length of time required by legislation if any and at least for the entire life of the finished product.



The Codex Alimentarius methodology includes 12 steps and 7 principles which are linked to the Article 5 of Reg 852/2004 as follows:

HACCP STEPS	PRINCIPLES	ARTICLE 5 OF REG 852/2004
1. Assemble HACCP team		
2. Describe product		
3. Identify intended use		
4. Construct flow diagram		
5. On-site confirmation of flow diagram		
6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards	PRINCIPLE 1 Conduct a hazard analysis	Article 5.2.a
7. Determine Critical Control Points	PRINCIPLE 2 Determine the Critical Control Points (CCPs).	Article 5.2.b
8. Establish critical limits for each CCP	PRINCIPLE 3 Establish critical limit(s).	Article 5.2.c
9. Establish a monitoring system for each CCP	PRINCIPLE 4 Establish a system to monitor control of the CCP.	Article 5.2.d
10. Establish corrective actions	PRINCIPLE 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.	Article 5.2.e
11. Establish verification procedures	PRINCIPLE 6 Establish procedures for verification to confirm that the HACCP system is working effectively.	Article 5.2.f
12. Establish Documentation and Record Keeping	PRINCIPLE 7 Establish documentation concerning all procedures and records appropriate to these principles and their application	Article 5.2.g

3.2. PRELIMINARY STEPS

After obtaining the management commitment, the organisation shall implement the following preliminary five steps:

3.2.1. ASSEMBLE HACCP TEAM

The filling operation shall ensure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. This should be accomplished by assembling a HACCP trained multidisciplinary team.

Where such expertise is not available on site, expert advice should be obtained from other sources (e.g. HACCP literature and HACCP guidance including existing national sector-specific HACCP guides).

The full scope of the organisation's activities, from receipt of raw materials to product consumption, shall be included in the HACCP plan and all the general classes of hazards have to be addressed :microbiological, chemical and physical health-related hazards.

3.2.2. DESCRIBE PRODUCT

A full description of the product shall be drawn up, including relevant safety information such as:

- Raw materials: water, CO₂ and added minerals ⁽³⁾
- Authorised water treatments
- Product contact materials
- Durability, storage conditions and methods of distribution

(3) As may be added to drinking water only for remineralisation purposes

3.2.3. IDENTIFY INTENDED USE

The intended use shall be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population (e.g. infants, special diets) should be considered.

An example of a product description and intended use sheet is described below:

The table below and its examples of associated questions should be considered when developing the product description:

TOPICS TO BE CONSIDERED	EXAMPLES OF QUESTIONS NEEDING TO BE ANSWERED
Product name	Common Name? NMW? SW? Processed / Prepared Water?
Sales description	Mountain SW? Well Water? Carbonated Water

Intended use	Drinking as such? Drinking after carbonation? Drinking after sweetening? Cooking?
End users	General population? Infants? Vulnerable groups? Specific groups?
Product specifications	Chemical and physico-chemical water parameters? Allowed applied water treatments? Carbone Dioxide level, type and origin? Added Minerals?
Packaging	Size and volume of packaging? Type of primary container (e.g. glass, plastic, metal, paper, bulk)? Type of closure (e.g. plastic, aluminium)? Type of secondary packaging (e.g. crates, boxes, packs)? Type of tertiary packaging (e.g. pallets, wrapping)?
Labelling	Type of labels (e.g. paper, Polypropylene) and glue specifications? Regulatory requirements?
Product shelf life	Shelf life Duration? Coding description? Type of coding (e.g. ink, laser)?
Storage and Distribution Conditions	Internal storage? External storage? Range of temperature storage? Bulk?

3.2.4. CONSTRUCT FLOW DIAGRAM

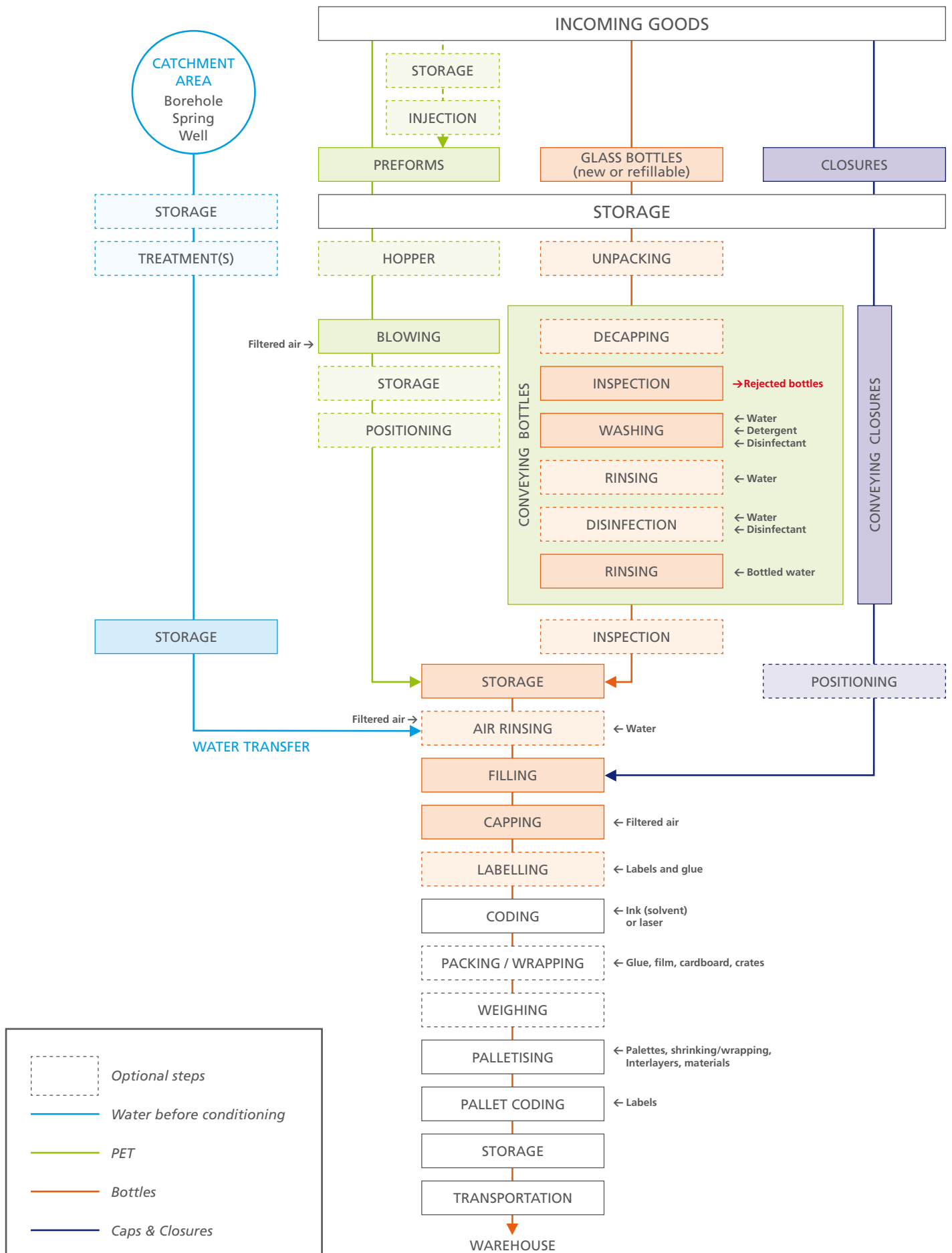
The flow diagram shall be constructed by the HACCP team and shall be specific to the filling operation.

The flow diagram shall cover all steps in the operation for a specific product (e.g. NMW, SW, and processed waters; still or sparkling) in a given packaging material.

The same flow diagram may be used for a number of products that are manufactured using similar processing steps (e.g. the same product with two different labels or grouping).

When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

3.2.5. ON-SITE CONFIRMATION OF FLOW DIAGRAM



Action shall be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

The flow diagram shall be kept up-to-date to reflect any change in the product and operations.

3.3. SEVEN PRINCIPLES

The final purpose of this chapter will be to fill the table below following the seven principles:

Step	Hazard	Risk level	CM	CCP Y/N	C Limits	Moni- toring	CA	Verifica- tion	Doc
P1				P2	P3	P4	P5	P6	P7

We need to define here what the abbreviations used in the table above mean (e.g, CM : Control Measure(s))

3.3.1. THE HACCP PRINCIPLES REFERRED TO IN 3.1. CONSIST OF THE FOLLOWING (cf chapter 1. 2):

3.3.1.a. Identifying any hazards that shall be prevented, eliminated or reduced to acceptable levels

The HACCP team (see step 1 above) shall list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. Each process step identified in the flow diagram (see steps 4 & 5 above) shall be assessed for the introduction or presence of a hazard.

The HACCP team shall next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe packaged water.

In conducting the hazard analysis, wherever possible the following shall be included:

- the likely occurrence of hazards and severity of their adverse health effects in view of risk evaluation
- the qualitative and/or quantitative evaluation of the presence of hazard survival or multiplication of micro-organisms of concern
- production or persistence in water of toxins, chemical or physical agents
- conditions leading to the above

Consideration shall be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

An example of risk evaluation tool is provided on the next page:



PROBABILITY of the HAZARD (P) which may occur		SEVERITY (S)	
1 improbable	e.g., every ten years	1 minor	e.g., no significant health impact
2 unlikely	e.g., yearly	2 medium	e.g., unease, nausea, mild diarrhoea
3 occasional	e.g., monthly	3 high (critical)	e.g., sickness or injury requiring medical intervention
4 likely	e.g., weekly	4 very high	e.g., serious health impact; could be fatal
5 frequent	e.g., daily		

		SEVERITY (S)			
		1 (minor)	2 (medium)	3 (high)	4 (very high)
PROBABILITY (P)	1 (improbable)	1	2	3	4
	2 (unlikely)	2	4	6	8
	3 (occasional)	3	6	9	12
	4 (likely)	4	8	12	16
	5 (frequent)	5	10	15	20

The HACCP team could decide that the hazards with a low risk number, e.g., lower than 2, are not significant and do not need *specific* control measures (CM).

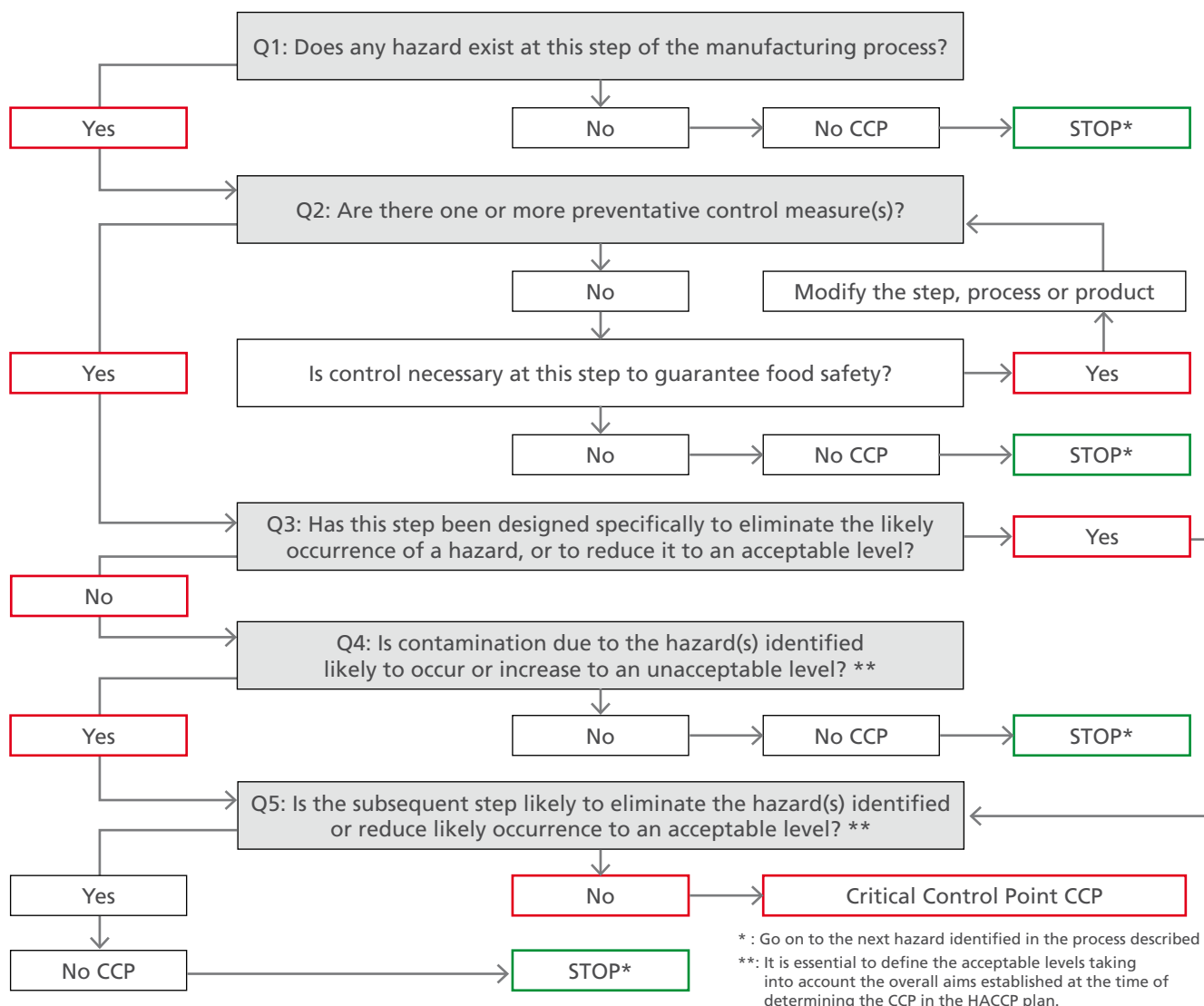
Step	Hazard	Risk level	CM
P1 (principle 1)			

3.3.1.b. Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels

The determination of a CCP in the HACCP system can be facilitated by the application of the following decision tree which indicates a logic reasoning approach:

DECISION TREE FOR THE DETERMINATION OF CRITICAL CONTROL POINTS (CCPs):

source= Codex Alimentarius.



Application of a decision tree should be flexible and should be used for guidance when determining CCPs. Other approaches may be used.

There may be more than one CCP at which control is applied to address the same hazard.

Step	Hazard	Risk level	CM	CCP Y/N
P1				P2

Example of CCP determination is provided in annexes.

3.3.1.c. Establishing critical limits at critical points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.

Critical limits shall be specified and validated for each Critical Control Point. Details of the establishment of critical limits shall be recorded.

These critical limits shall be measurable.



In some cases more than one critical limit will be elaborated at a particular step.

Step	Hazard	Risk level	CM	CCP Y/N	C Limits
P1				P2	P3

3.3.1.d. Establishing and implementing effective monitoring procedures at critical control points

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures shall be able to detect loss of control at the CCP.

Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.

Data derived from monitoring shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous then the amount or frequency of monitoring shall be sufficient to guarantee the CCP is in control.

Most monitoring procedures for CCPs will need to be done rapidly because they relate to online processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs shall be signed by the trained person(s) doing the monitoring and by a responsible reviewing official(s) of the organisation. Records are used to demonstrate that a CCP is under control.

Step	Hazard	Risk level	CM	CCP Y/N	C Limits	Monitoring
P1				P2	P3	P4

3.3.1.e. Establishing corrective actions when monitoring indicates that a critical control point is not under control

Specific corrective actions shall be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

A Corrective Action plan shall be designed to bring a non-conforming situation back into Control. The actions shall ensure that the CCP has been brought under control. Actions taken shall also include proper disposition of the affected product.

Corrective Action may also include review of control options, review of standards, and increased frequency of monitoring and retraining.

Deviation and product disposition procedures shall be documented in the HACCP record keeping.

Step	Hazard	Risk level	CM	CCP Y/N	C Limits	Monitoring	CA
P1				P2	P3	P4	P5

3.3.1.f. Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in sub-paragraphs (a) to (e) are working effectively

Verification is on top of monitoring.

Verification and auditing methods, procedures and tests, including sampling and analysis, shall be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

Examples of verification activities include:

- review of the HACCP plan and its records
- review of finished products' microbiological data
- review of deviations and product dispositions
- confirmation that CCPs are kept under control

Step	Hazard	Risk level	CM	CCP Y/N	C Limits	Moni- toring	CA	Verifica- tion
P1				P2	P3	P4	P5	P6

3.3.1.g. Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures shall be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

Documentation examples are, but not limited to:

- hazard analysis
- CCP determination
- critical limit determination

Record examples are, but not limited to:

- CCP monitoring activities
- deviations and associated corrective actions
- verification procedures performed
- modifications to the HACCP plan
- HACCP related staff training records

The record keeping system may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

Step	Hazard	Risk level	CM	CCP Y/N	C Limits	Moni- toring	CA	Verifica- tion	Doc
P1				P2	P3	P4	P5	P6	P7

3.4. ILLUSTRATION OF THE METHODOLOGY

The three following types of hazards at specific steps have been selected to illustrate the whole HACCP Methodology.

3.4.1. Microbiological hazard at the water storage step (grey shaded on the flowchart)

These examples are taking into account the following assumptions:

- the spring is relatively well protected (Non-Karstic Limestone)
- the air in contact with water and primary packaging materials is filtered
- the personnel are trained at an adequate level with respect to hygiene
- the residence time of water in storage tank is limited

STEP	HAZARDS	P*	S*	R*	CONTROL MEASURES (CM)
Water Storage	Contamination by coliforms due to: Human contamination during maintenance/ sampling	1	2	2	Hygiene Training Plan and Procedures
	Contamination by E. Coli O157 due to: Human contamination during maintenance/ sampling	1	3	3	Hygiene Training Plan and Procedures
	Contamination by yeasts due to: Air contamination	2	1	2	Maintenance of air filters
	Contamination by molds due to: Air contamination	2	1	2	Maintenance of air filters
	Contamination by algae due to : Air contamination	2	1	2	Maintenance of air filters
	Contamination by cyanobacteria due to: Air contamination	2	3	6	Maintenance of air filters
	Growth of: Coliforms E. Coli O157 Yeasts Molds Algae Cyanobacteria	1 1 1 1 1 1	2 3 1 1 1 3	2 3 1 1 1 3	Maximum residence time Hygienic design of the storage tank

*Notes:

- At this particular step, the study needs also to evaluate the chemical and physical hazards.
- P = Probability of the Hazard occurring
- S = Severity of the Hazard
- R = P multiplied by S



As a result of this hazard analysis, the HACCP Team may conclude that hazards with a R value equal or higher than 3 should be considered as significant hazards. In this case:

- Contamination by E. Coli O157 and Cyanobacteria, and
- Growth of E. Coli O157 and Cyanobacteria

are hazards that must be prevented, eliminated or reduced to acceptable levels

STEP	HAZARDS	RISK LEVEL (R)	CONTROL MEASURES (CM)	CCP Y/N
Water Storage	Contamination by E. Coli O157	3	Hygiene training plan and procedures for maintenance / sampling	Q1: Y Q2: N Q3: N -> Not a CCP
	Contamination by Cyanobacteria	6	Maintenance of filters	
	Growth of E. Coli O157	3	Maximum residence time and hygienic design of the storage tank	Q1: Y Q2: N Q3: N -> Not a CCP
	Growth of Cyanobacteria	3	Maximum residence time and hygienic design of the storage tank	

In this example, the study ends here as the water storage step has not been considered as a CCP for these four particular significant hazards.

Any significant change in the process or its environment should trigger a new evaluation that might yield to other conclusion(s).

3.4.2. CHEMICAL HAZARD AT THE WATER TREATMENT STEP FOR THE REMOVAL OF FLUORIDE (blue shaded on the flowchart)

STEP	HAZARDS	P	S	R	CONTROL MEASURES (CM)
Selective Adsorption of Fluoride on Activated Alumina	Release of aluminium from activated alumina at the first use and after each regeneration due to insufficient rinsing	1	3	3	Compliance to buying specifications of activated alumina Back wash at start up Correct application of the rinsing procedure after regeneration
	Non-adsorption of fluoride due to saturation of the activated alumina	2	3	6	Flow rate below the established maximum flow rate Regeneration at the pre-defined water filtration volume Replace adsorption media when appropriate
	Contamination by caustic soda and/or sulphuric acid due to insufficient rinsing after the regeneration process	1	2	2	Correct application of the rinsing procedure after regeneration

As a result of this hazard analysis, the HACCP Team may conclude that hazards with an R value equal or higher than 3 should be considered as significant hazards. In this case:

- Release of aluminium from activated alumina at the first use, and after each regeneration due to insufficient rinsing
 - Non-adsorption of fluoride due to saturation of the activated alumina
- are hazards that shall be prevented, eliminated or reduced to acceptable levels.

STEP	HAZARDS	R	CM	CCP Y/N
Selective Adsorption of Fluoride on Activated Alumina	Release of aluminium from activated alumina at the first use and after each regeneration due to insufficient rinsing	3	Compliance to buying specifications of activated alumina Back wash at start up Correct application of the rinsing procedure after regeneration	Q1: Y Q2: Y Q3: Y Q5: N -> CCP
	Non-adsorption of fluoride due to saturation of the activated alumina	6	Flow rate below the established maximum flow rate Regeneration at the pre-defined water filtration volume Replace adsorption media when appropriate	Q1: Y Q2: Y Q3: Y Q5: N -> CCP

In this example, the Selective Adsorption on Activated Alumina step has been identified as a CCP for the two following significant hazards:

- Release of aluminium from activated alumina at the first use and after each regeneration due to insufficient rinsing
- Non-Adsorption of fluoride due to saturation of the activated alumina

Any significant change in the process or in the water composition should trigger a new evaluation that might yield to other conclusion(s).

STEP	HAZARDS	R	CONTROL MEASURES	CCP Y/N	CRITICAL LIMITS
Selective Adsorption of Fluoride on Activated Alumina	Release of aluminium from activated alumina at the first use and after each regeneration due to insufficient rinsing	3	Compliance to buying specifications of activated alumina Back wash at start up Correct application of the rinsing procedure after regeneration	Y	Defined minimum flow rate Defined minimum rinsing time
	Non-adsorption of fluoride due to saturation of the activated alumina	6	Flow rate below the established maximum flow rate Regeneration at the pre-defined water filtration volume Replace adsorption media when appropriate	Y	Defined maximum flow rate according to the specific installation Defined maximum filtration volume according to water composition and media characteristics

As critical limits have been defined, there is now a need to establish and implement effective monitoring procedures:

CCP Y/N	CRITICAL LIMITS	MONITORING
Y	Defined minimum flow rate Defined minimum rinsing time	Water rinsing volume: flow rate monitoring and rinsing time monitoring
Y	Defined maximum flow rate according to the specific installation Defined maximum filtration volume according to water composition and media characteristics	Flow rate monitoring Water volume monitoring

There is now a need to establish corrective actions when monitoring indicates that the critical point is not under control:

MONITORING	CORRECTIVE ACTIONS
Water rinsing volume: flow rate monitoring and rinsing time monitoring	Continue rinsing step until minimum water rinsing volume value is reached Identify the reasons for not complying with the defined parameters: flow rates and rinsing times Implement corrective actions
Flow rate monitoring Water volume monitoring	Readjust flow rate and place on hold products produced since last measures within limits' control Stop production - place on hold products produced since volume went above limit – Regenerate and resume production Identify the reasons for not complying with the defined parameter: water volume. Implement corrective actions

It is now time to establish procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively:

CORRECTIVE ACTIONS	VERIFICATION
Continue rinsing step until minimum water rinsing volume value is reached	Dosage of aluminium in water at a pre-defined frequency to verify that the aluminium level is below 200 micro gramme / litre of water according to Regulation Internal audit of the process
Readjust flow rate and place on hold products produced since last measures within limits' control Stop production - place on hold products produced since volume went above limit – Regenerate and resume production	Dosage of fluoride in water at a pre-defined frequency to verify that the fluoride level is below 1.5 micro gramme / litre of water according to Regulation Internal audit of the process

The table ends by establishing documents and records that are needed to demonstrate the effective application of the measures described above:

VERIFICATION	DOCUMENTATION
Dosage of aluminium in water at a pre-defined frequency to verify that the aluminium level is below 200 micro gramme / litre of water according to Regulation Internal audit of the process	Buying specifications of activated alumina Regeneration operating procedures Filtration operating procedures Analytical methods Various monitoring and verification records, ...
Dosage of fluoride in water at a pre-defined frequency to verify that the fluoride level is below 1.5 micro gramme / litre of water according to Regulation Internal audit of the process	Buying specifications of activated alumina Regeneration operating procedures Filtration operating procedures Analytical methods Various monitoring and verification records, ...

3.4.3. PHYSICAL HAZARD (GLASS FRAGMENTS) AT THE BOTTLE WASHER/RINSE STEP

STEP	HAZARDS	P	S	R	CONTROL MEASURES
Bottle washer/ rinser step	Remaining presence of glass fragments after rinsing due to: - Disfunctioning of the rinser - The glass fragment remains inside (shape issue) - Glass fragments are created at the exit of the rinser	3	3	9	Maintenance of the rinser

As a result of this hazard analysis, the HACCP Team may conclude that hazards with a R value equal or higher than 3 should be considered as significant hazards. In this case (R=9):

- Remaining presence of glass fragments after rinsing due to:
 - Disfunctioning of the rinser
 - The glass fragment remains inside (shape issue)
 - Glass fragments are created at the exit of the rinser

Is a hazard that shall be prevented, eliminated or reduced to acceptable levels

RISK LEVEL (R)	CONTROL MEASURES	CCP Y/N
9	Maintenance of the rinser	Q1: N* Is control at this step necessary for safety? : Y * Maintenance of the rinser is not a measure that prevents, eliminates or reduces the identified hazard to an acceptable level in all described cases (e.g. shape issue)

The HACCP team might conclude that the identified significant hazard is not fully controlled at this step and that there is a need to modify the process. This conclusion would lead to the addition of an inspection step (e.g. automatic) at the exit of the washer / rinser.

To illustrate the process modification and its impact on food safety, let us consider the same hazard at this new process step:

STEP	HAZARDS	P	S	R	CONTROL MEASURES
Automatic inspection step at the exit of the washer / rinser	Remaining presence of glass fragments after rinsing due to disfunctioning of the inspection machine	1	3	3	Maintenance of the inspection machine Training of the operator in charge of the inspection machine

As a result of this hazard analysis, the HACCP Team may conclude that hazards with a R value equal or higher than 3 should be considered as significant hazards. In this case :

- Remaining presence of glass fragments after rinsing due to disfunctioning of the inspection machine is a hazard that shall be prevented, eliminated or reduced to acceptable levels



RISK LEVEL (R)	CONTROL MEASURES	CCP Y/N
3	Maintenance of the inspection machine Training of the operator in charge of the inspection machine	Q1: Y Q2: Y -> CCP

In this example, the automatic inspection step has been identified as a CCP for identified significant hazard.

CONTROL MEASURES	CCP Y/N	CRITICAL LIMITS
Maintenance of the inspection machine Training of the operator in charge of the inspection machine	Y	Absence of glass in any empty bottle passing the inspection step

As Critical Limits have been defined, there is now a need to establish and implement effective monitoring procedures.

CRITICAL LIMITS	MONITORING
Absence of glass in any empty bottle passing the inspection step	Periodic testing of the capability to detect and reject intentionally contaminated empty bottles (test samples)

There is now a need to establish corrective actions when monitoring indicates that the critical point is not under control:

MONITORING	CORRECTIVE ACTIONS
Periodic testing of the capability to detect and reject intentionally contaminated empty bottles (test samples)	Stop production - Place on hold finished products produced since last successful testing (eventually recall finished products that left the production site) – Re-inspect suspicious filled bottles if possible (if not, destroy the suspicious filled bottles) – Re-calibrate the inspection machine – Re-test suspicious empty bottles – Resume production

CORRECTIVE ACTIONS	VERIFICATION
Stop production - Place on hold finished products produced since last successful testing (eventually recall finished products that left the production site) – Re-inspect suspicious filled bottles if possible (if not, destroy the suspicious filled bottles) – Re-calibrate the inspection machine – Re-test suspicious empty bottles – Resume production	Internal audit of the process Glass complaints' review

It is now time to establish procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively.

The table ends by establishing documents and records that are needed to demonstrate the effective application of the measures described above:

VERIFICATION	DOCUMENTATION
Internal audit of the process Glass complaints' review	e.g. Manufacturer's operating manual, Maintenance procedures and records, various monitoring and verification records, Training records, calibration records...



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4.1. BOOKS

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- D. Tampo – Les eaux conditionnées – Tec & Doc Lavoisier – 1992 – ISBN 2-85206-801-X

4.2. GENERAL FOOD LEGISLATION AND CODEX RELATED DOCUMENTS

- 4.2.1. EC guidelines for the development of community guides to good practice for hygiene.
- 4.2.2. Regulation EC 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food in addition to Regulation EC 1935/2004 on materials and articles intended to come into contact with food
- 4.2.3. Regulation EC 1924/2006 of 20 December 2006 on nutrition and health claims made on food
- 4.2.4. Regulation EC 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to food
- 4.2.5. Regulation EC 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods
- 4.2.6. FAO/WHO 2005 Guidance to governments on the application of HACCP in small and/or less-developed food businesses – FAO Food and nutrition paper nr 86
- 4.2.7. Regulation EC 852/2004 of 29 April 2004 on the hygiene of foodstuffs
- 4.2.8. Regulation EC 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food
- 4.2.9. Regulation EC 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- 4.2.10. Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the member states relating to the labeling, presentation and advertising of foodstuffs
- 4.2.11. Purity criteria of carbon dioxide and mineral salts as defined in commission Directives 2000/63/EC and 96/77/EC
- 4.2.12. Codex and FAO/WHO basic texts on food hygiene including the recommended international code of practice – General principles of food hygiene (CAC/RCP 1-1969, Rev. 4, 2003) and the hazard analysis and critical control point (HACCP) system and guidelines for its application
- 4.2.13. First Report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (EU Directive 85/374)
- 4.2.14. ISO/TS 22002-1:2009 Prerequisite programmes on food safety



4.3. SPECIFIC LEGISLATION, GUIDELINES AND STANDARDS RELATED TO PACKAGED WATERS

- 4.3.1. Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (recast).
- 4.3.2. Commission Regulation (EU) N° 115/2010 of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters
- 4.3.3. Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of Natural Mineral Waters and the conditions for using ozone-enriched air for the treatment of Natural Mineral Waters and Spring Waters .
- 4.3.4. Guidelines on the conditions for using activated alumina for the removal of fluoride from Natural Mineral Waters and Spring Waters (guidelines of Dec 14, 2007)
- 4.3.5. Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
- 4.3.6. WHO Guidelines for Drinking-water Quality (incorporating first and second addenda to fourth edition)
- 4.3.7. Codex Standard for Natural Mineral Waters (STAN108 – 1981, Revisions 1997, 2008)
- 4.3.8. Codex General standard for bottled/package drinking waters (other than NMW) (CODEX STAN 227-2001)
- 4.3.9. Code of hygienic practice for collecting, processing and marketing of natural mineral waters (CAC/RCP 33-1985)“
- 4.3.10. Codex Code of hygienic practice for bottled/package drinking waters (other than NMW) (CAC/RCP 48-2001)
- 4.3.11. Regulation (EU) N° 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

4.4. OTHER USEFUL REFERENCE DOCUMENTS

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- 4.4.2. NFI (Nederlandse Frisdranken Industrie) 2006 Hygiëncode natuurlijk mineraal-en bronwater
- 4.4.3. MINERACQUA 2005 Manuale di corretta prassi igienica sulle acque minerali naturali confezionate
- 4.4.4. NSAI (National Standards Authority of Ireland) 2005 Irish standard specification for packaged water
- 4.4.5. IBWA (International Bottled Water Association) 2009 Bottled water code of practice.
- 4.4.6. GBWA - EBWA (German Bottled Watercooler Association – European Bottled Watercooler Association 2005 Code of good hygiene practice for water cooler companies
- 4.4.7. CFIS (Canadian Food Inspection Agency) 2003 Code of hygienic practice for commercial prepackaged and non-prepackaged water and appendices (www.inspection.gc.ca)
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- 4.4.9. IBWA (International Bottled Water Association) 2005 Plant Technical Reference Manual
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GENERAL GLOSSARY OF TERMS

Ambient: The temperature of the surrounding environment. Commonly used to mean room temperature

Aquifer: A geological unit that stores and transmits significant quantities of ground water under normal hydraulic conditions.

Batch (or production batch): Group of units produced under identical circumstances. Production units/batch sizes which are produced and packaged under identical conditions, the size of which is defined/determined by the manufacturer.

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

Bottled water: Any kind of packaged water including natural mineral water and spring water.

Carbonated water is water which contains dissolved carbon dioxide, added and/or naturally occurring.

Catchment: A catching or collecting of water, especially rainwater.

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

Cleaning: Removal of soil, food residues, dirt, grease or other objectionable matter.

Cleaning in Place (CIP): System that cleans solely by circulating and/or flowing chemical detergent solutions and water rinses by mechanical means onto and over surfaces to be cleaned

Cleaning out of place (COP): System where equipment is disassembled and cleaned in a tank or in an automatic washer by circulating a cleaning solution and maintaining a minimum temperature throughout the cleaning cycle

Compliance: Certification or confirmation that the manufacturer or supplier of a product, meets the requirements of accepted practices, legislation, prescribed rules and regulations, specified standards, or the terms of a contract.

Conformity: Fulfillment of a requirement

Contaminant: Any biological or chemical agent, foreign matter or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination: Introduction or occurrence of a contaminant in food or food environment.

Control measure: Action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level

Coved: Rounded finish to the junctions between walls and ceilings and walls and floors, or between two walls to make cleaning easier and more effective.

Critical Control Point (CCP): (Food safety) step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

Critical limit: Criterion which separates acceptability from unacceptability

Disinfection: Reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms

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

FIFO/FEFO: First in First Out / First Expired First Out



Flow diagram: Schematic and systematic presentation of the sequence and interactions of the steps.

Food Handler: Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

Food handling: Any operation pertaining to collecting, processing, filling, packaging of bottles, storing, transporting, distributing and marketing of packaged water.

Food hygiene: All measures necessary to ensure the safety of packaged water at all stages from its exploitation and processing until its final consumption.

Food safety: Concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food safety hazard: Biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect

Ground Water: Water contained in permeable rocks, it is a renewable resource, more stable than surface waters, it can be tapped by boreholes, wells, catchworks.

Ground water protection area: The surface area within which rainfall can either directly or indirectly enter the ground water system into which the well is tapped, and which can contribute to the yield of the well.

HEPA filter: High Efficiency Particulate Air filter

High Risk Area: An area where the potential for contamination of the product is elevated.

Hygiene: All measures necessary to guarantee the safety and soundness of water during preparation, processing, production, transporting, distribution and sale.

In-process control: In-process control is the control exercised by the worker himself regarding his own work, according to specified regulations (free translation from ISO 8402).

Lot: The amount of product of a specific container size, product style and code produced by a specific plant during a specified period of time not exceeding one day.

Material/product specification: Detailed documented description or enumeration of parameters, including

permissible variations and tolerances, which are required to achieve a defined level of acceptability or quality

Materials: General term used to indicate raw materials, packaging materials, ingredients, process aids, cleaning materials and lubricants

Micro-organisms: Microscopic organisms such as bacteria, yeasts, moulds.

Monitoring: Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended

Natural mineral water (NMW): Microbiologically wholesome water, originating in an underground water table or deposit, emerging from a spring tapped at one or more natural or bore exits, and bottled/packaged at source. It is clearly distinguished from ordinary drinking water by its nature (mineral content and trace element) and by its original state. It is bottled/packaged at source and is recognized as a Natural Mineral Water by the responsible authority.

Non-conformity: Non-fulfillment of a requirement

Open Bottle Area (OBA): Stages in the filling operation where uncapped bottles are transported, rinsed, filled and capped. It is advised to provide a controlled environment here.

Packaging material

- (a) Sales packaging or primary packaging, i. e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;
- (b) Grouped packaging or secondary packaging, i. e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics;
- (c) Transport packaging or tertiary packaging, i. e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers



Packaged water: Same as bottled water

Pest: Animal life unwelcome in food premises, especially insects, birds, rats and mice, capable of contaminating food directly or indirectly.

Prepared water: Waters whose composition has been changed by processes such as water treatments, removal/ addition of minerals, etc. They may originate from any type of water supply but may not include natural mineral waters or spring water.

Prerequisite program: Basic conditions and activities necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption

Preventive measures: Measure(s) to be taken to eradicate the risk of a hazard arising or reduce it to an acceptable level.

Primary Packaging: Packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase.

Process: Set of interrelated or interacting activities which transforms inputs into outputs

Procedure: Specified way to carry out an activity or a process

Product contact: All surfaces that are in contact with the product or the primary package during normal operation

Protection Area: An area defined around a water source to which restrictions and measures are applied to protect it from pollution, such as fuel storage, animal grazing and vehicle movement.

Quality: Degree to which a set of inherent characteristics fulfils requirements

REACH Regulation: REACH is a European Union regulation concerning the Registration, Evaluation, Authorisation and restriction of Chemicals. It came into force on 1st June 2007 and replaces a number of European Directives and Regulations with a single system.

Recharge: Precipitation (rain or snow) that infiltrates the ground surface and percolates down to the water table or aquifer to replenish ground water.

Recharge Zone: The area on the land surface where recharge occurs.

Requirement: Need or expectation that is stated, generally implied or obligatory

Sanitation: All actions dealing with cleaning or maintaining hygienic conditions in an establishment, ranging from cleaning and/or sanitizing of specific equipment to periodic cleaning activities throughout the establishment (including building, structural, and grounds cleaning activities)

Secondary Packaging: Packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sales; it can be removed from the product without affecting its characteristics (e.g. labels, glue, cartons, shrink wrap, pallets, etc...)

Shelf life: Prescribed period of time during which product can be stored, unopened, whilst retaining its safety and wholesomeness.

Source: Point of ground water abstraction which could originate from a spring, well or borehole.

Spring: Natural point of ground water outflow.

Spring water (SW): Water which is intended for human consumption in its natural state, originating in an underground water table or deposit, emerging from a spring tapped at one or more natural or bore exits, and bottled/packaged at source.

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

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

Traceability: Ability to trace the history, application or location of that which is under consideration

Treatments: (natural mineral and spring waters): Techniques allowed on the basis of Article 4 of Directive 2009/54/EC for the separation of some constituents present in natural mineral waters and spring waters in their natural state and carried out in compliance with EFSA's opinions

Water table: Free ground water surface of an unconfined aquifer.



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Council Directive (Directive 2009/54/EC) of 18 June 2009 on the exploitation and marketing of NMW

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European Commission,: consolidated lists of NMW : http://ec.europa.eu/food/food/labellingnutrition/water/index_en.htm

European Commission (2006): comparison between Codex limit values, NMW limit values and drinking water limit values

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ANNEXES

ANNEX 1

Name of the Bottled Water Company		FINISHED PRODUCT SPECIFICATIONS	Quality Assurance Department	
Type of Document	Specifications	NAME OF THE PRODUCT (CRYSTAL SPRINGS VITALITY)	Date	18 /05/2008
Refer.			Rev	1

R&D Recipe Code : GB-SNMW- PET-2007-2

Plant or SAP Recipe Code : PRE6011-PT

Revision record :

Revision #	Date	Description of Modification
0	09.05.2007	First release
1	18.05.2008	Modification of the formula (decrease of the CO2 level from 6g/l to 5g/l)
2		
3		

Distribution List :

CBU QA Director Industrial Director Plant QA Manager Purchasing Director Marketing Director R&D Director

	Written by	Validated by	Validated by	Validated by
	R&D Project Manager	R&D Director	QA Director	Industrial Director
Name :	J. Smith	B. Adams	C. Thompson	S. Pollak
Visa :				
Date :	18/05/2008	20/05/2008	21/05/2008	26/05/2008



Name of the Bottled Water Company		FINISHED PRODUCT SPECIFICATIONS		Quality Assurance Department	
Type of Document	Specifications	<i>NAME OF THE PRODUCT</i> (CRYSTAL SPRINGS VITALITY)		Date	18 /05/2008
Refer.				Rev	1

1- Product Definition

Innovation : No

Product Renovation : Yes

- **Brand : Crystal Springs**
- **Commercial Name : Vitality**
- **Legal definition : Sparkling Mineral Water**
- **Formats : 500ml, 1L**
- **Plant name : Liverpool**
- **Market Shelf life : 8 months**

2- Recipe

Finished Product Recipe

Specification #	Raw Material	Supplier	Ingredient Code	Density (20°C)** (g/cm ³)	Kg/1000 liters	Mixing Order
ING7020	Spring Water	Loeffler Spring		N/A	997.0	1
ING7004	CO2	Air Liquide	11301180DL	N/A	3.0	2
TOTAL					1000.0	

density = 1.0001 g / cm³



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Type of Document	Specifications		Date	18 /05/2008
Refer.			Rev	1

3- Technical Specifications

Specific precautions :

Maximum Storage time for Natural Mineral Water : 48 hours
Storage temperature of the Natural Mineral Water : Maximum 15°C

Finished Product characteristics :

Analytical characteristics :

Analysis	Unit	Method	Target	Minimum	Maximum
pH		SAB/CHEMB/ PC-001	5.80	5.70	5.90
CO ₂	g/l	SAB/CHEMB/ PC-005	5.0	4.8	5.2
Conductivity	µS/cm	SAB/CHEMB/ PC-003	1000	950	1050
Dissolved Oxygen	ppm	SAB/CHEMB/ PC-004	3	0	6
Color	N/A				
Taste / Smell	Normal sensorial characteristics of the water. No foreign odours like sulfur.				
	Sensory Profile of reference # : N/A				
<u>Other criteria :</u>					
Calcium	ppm	SAB/CHEMB/ PC-010	80	72	88
Magnesium	ppm		20	18	22
Iron	ppb		10	0	<100
Sodium	ppm		3	2	4
Potassium	ppm		5	4	6
Bicarbonates	ppm		1000	900	1100
Sulfates	ppm		30	27	33



Name of the Bottled Water Company		FINISHED PRODUCT SPECIFICATIONS		Quality Assurance Department	
Type of Document	Specifications	NAME OF THE PRODUCT (CRYSTAL SPRINGS VITALITY)		Date	18 /05/2008
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Microbiological characteristics :

Microorganisms	Units	Method	Target
Total Coliforms	cfu/250ml	IT-CC-003 Rev. 1	absence
Pseudomonas aeruginosa	Cfu/250ml	IT-CC-004	absence
Total flora at 37°C in the 12hours following bottling	Cfu/ml	IT-CC-001	<20
Total flora at 20°C in the 12hours following bottling	Cfu/ml	IT-CC-001	<100

Nutritional values :

Energy values / 200 ml	Kcal	KJ
	0	0

Calculated nutritional average values in g for 200 ml

Proteins	0 g
Carbohydrates	0 g
Including added sugar	
Lipids	0 g
Including saturated fat acids	
Sodium	< 25 mg
Calcium	16 mg
Magnesium	4 mg
Other minerals :	N/A
Vitamins	N/A

Authorized Claim : “SODIUM FREE”

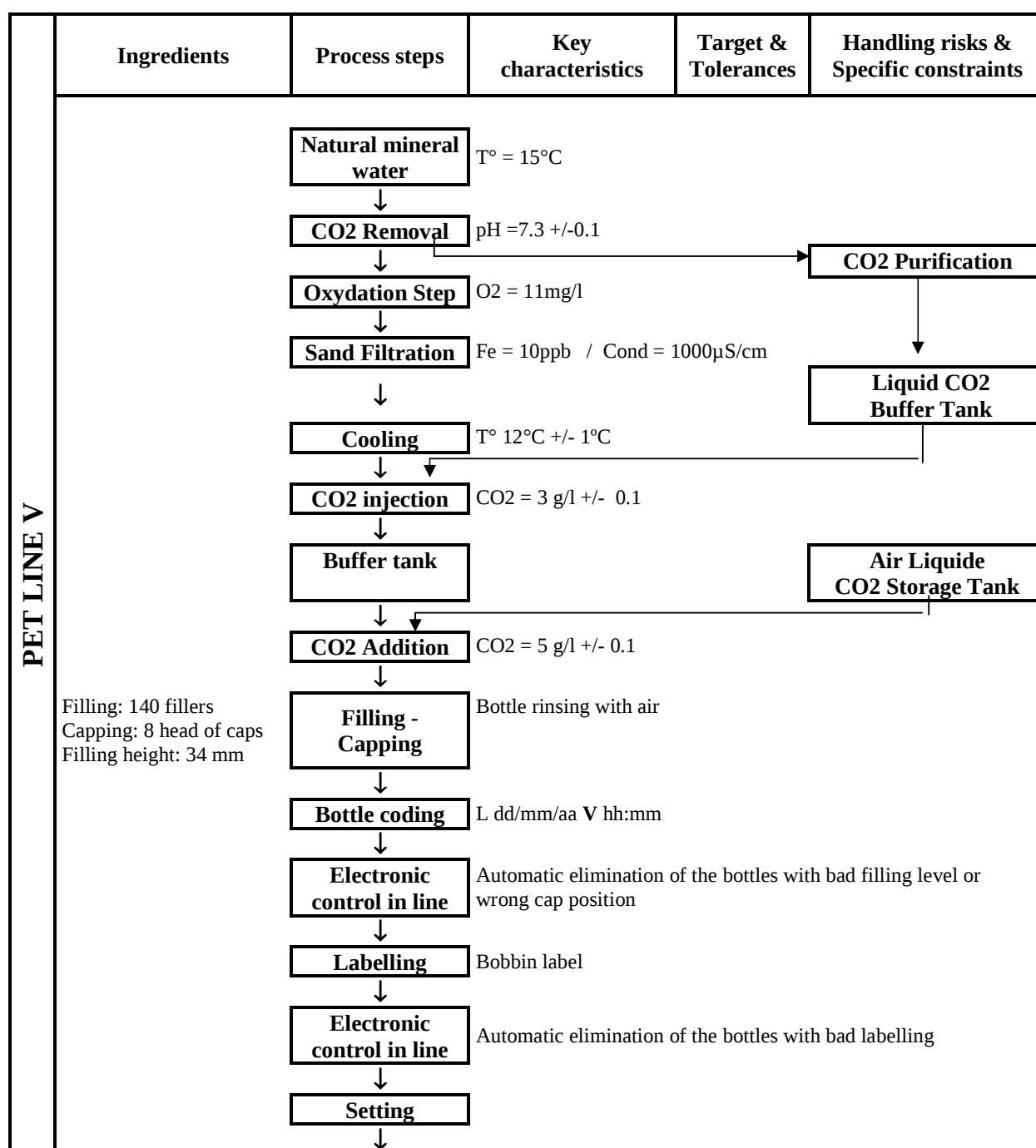
Analysis	Unit	Method	Target	Minimum	Maximum
Sodium	ppm	SAB/CHEMB/ PC-010	3	0	20



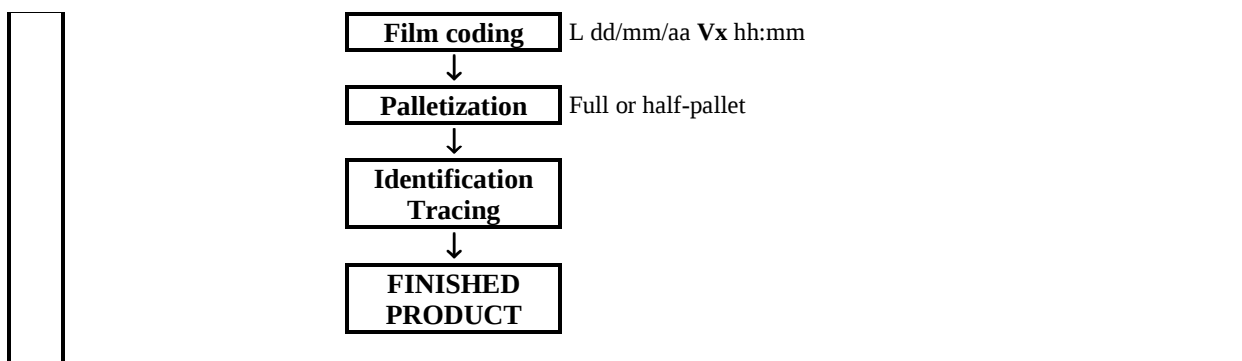
Name of the Bottled Water Company		FINISHED PRODUCT SPECIFICATIONS		Quality Assurance Department	
Type of Document	Specifications	NAME OF THE PRODUCT (CRYSTAL SPRINGS VITALITY)		Date	18 /05/2008
Refer.				Rev	1

4- Manufacturing process

Process Flow: detailed process diagram must be provided by the factory or Industrial Department.



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Type of Document	Specifications	NAME OF THE PRODUCT (CRYSTAL SPRINGS VITALITY)		Date	18 /05/2008
Refer.				Rev	1



5- Packaging specifications

This document must allow to have access to the specifications describing the elements of the primary, secondary and tertiary packaging, according to the documentary management system used in the Company.

Primary Packaging	Key characteristics		Specif #
Preform :	500 mL	25 g, 28 PCO 2F	ES-AMM-156
	1L	39 g, 28 PCO 2F	ES-AMM-157
Packaging :	500 mL	PET bottle, Sofía design	ES-AMM-011
	1L	PET bottle, Sofía design	ES-AMM-015
Cap :	28 PCO		ES-AMM-024
Others (lid, cup...) :	N/A		N/A

Secondary and Tertiary Packaging	Specif #	Secondary and Tertiary Packaging	Specif #
Label :	500 ml ES-AMM-203 1 L ES-AMM-036	Cardboard glue :	ES-AMM-099
Dividers :		Pallets label marking-out :	NA



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Floor sheet :	NA	Primary grouping :	500 ml six pack ES-AMM-204 1L cardboard tray 12 pieces ES-AMM-061
Stacking sheet :	NA	Secondary grouping :	
Cover :	ES-AMM-098	Palletization plan :	
Pallets :	CHEP	Others :	
Label glue :	ES-AMM-100		

6- HACCP & Control Plan

Plant Reference of the HACCP Study : HACCP Handbook

Routine Control Plan -> réf : PC-SNMW-001



ANNEX 2

annex 2 Example of In-Process Control Sheet

DATE: Month: _____ Day: _____ Year: _____	Operator's name: _____	Supervisor's name: _____
--	-------------------------------	---------------------------------

Shift: Day ()	Size: 1L ()	Evening ()	330ml () 1.5L ()	Brand name: _____	Product code: _____
Night ()	500ml ()				

Bottle code is correct: (Write the complete bottle code at the beginning of shift and each c/o (back of the sheet))		Pallet tag is correct: (glue a tag on the back of the sheet at the beginning of the shift and each c/o)
--	--	--

Hour												
Tick if production stop												TOTAL

Fill out the box with "0" if there is no bottle/pack/tray/pallet with the defect, "1" if there is one, 2 if there are 2, ...etc.(maximum "5")

Bottle code (5 bottles every hour) Missing code Illegible code Incorrect code	
---	--

Cap (5 bottle every hour) Improperly placed Dusty / stained cap More than 3 bridges broken	
--	--

Sleeve (5 bottles every hour) Missing sleeve Poorly placed	
---	--

Label (5 bottles every hour) Alignment Flag label Presence of glue	
--	--

Pack (5 packs every hour) Film corresponds to the product code Printing poorly located horizontally Printing poorly located vertically	
--	--

Handle (5 packs every hour) Poorly placed Not sturdy	
---	--

Tray (3 trays every hour) Tray does not correspond to the product code Insufficient amount of glue Tray flap not glued at right angle	
---	--

Case (3 cases every hour) Case does not correspond to the product code Missing / illegible / wrong code Absence / lack of glue	
--	--

Palletization (1 pallet every hour) Damaged wooden pallet Stained / wet / moldy wooden pallet Missing cases	
---	--

Pallet tag (1 pallet every hour) Incorrect date and hour Incorrect identification number	
---	--

Observations:	
----------------------	--

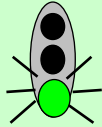
annex 2 If you have any issue, inform immediately the SUPERVISOR and write your observations

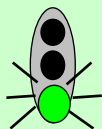


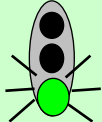
ANNEX 3

Page 1

Example of Packaging Defect Guide

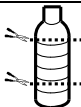
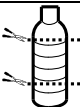
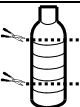
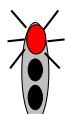
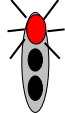
						
Category	Sub-category	Location of control	Definition	Everything is OK	Adjust	Stop line, inform supervisor, adjust
Bottle code	Missing code	Just after coder	When the videojet did not code the bottle		Not applicable	
Bottle code	Illegible code	Just after coder	As soon as part of the code is not legible			
Bottle code	Incorrect code	Just after coder	When there is more than a 3-minute difference between the "real time" and the time on the bottle When the plant, line or spring specified on the code are wrong	Plant Information: July 13, 2000-18:36pm plant (L) Line 3 (3) Big Spring (B) 	Plant Information: July 13, 2000- <u>18:33</u>  +/- 3 minutes	Plant Information: July 13, 2000- <u>15:30</u> OR <u>May 12, 1999</u> - 18:36 OR <u>Line 2</u> 

						
Category	Sub-category	Location of control	Definition	Everything is OK	Adjust	Stop line, inform supervisor, adjust
Bottle code	"Flying" / not centered code	Just after coder	When part of the code "flies away"			
Bottle code	Code baveux	Just after coder	When the code is blurry			Illegible
Cap	Missing cap	After filler room	When the cap is missing		Not applicable	
Cap	Improperly placed	After filler room	When the cap is improperly placed on the bottle		Not applicable	

						
Category	Sub-category	Location of control	Definition	Everything is OK	Adjust	Stop line, inform supervisor, adjust
Cap	Dusty / stained cap	After filler room	When the cap is dusty or there is evidence of stains		Not applicable	
Cap	More than 3 bridges broken	After filler room	When more than 3 bridges between the cap and the ring are broken		Not applicable	
Cap	Broken ring	After filler room	When the ring is broken		Not applicable	
Cap	Cap ring turned improperly placed	After filler room	When part of the cap ring is inside the bottle neck		Not applicable	
Cap	Damaged groove	After filler room	When some of the grooves are deformed		Not applicable	

ANNEX 4

Page 1

		Example of Bottle Weight Tolerances								
		330ml, 14g			330ml, 17g			500ml, 17g		
Bottle volume to the brim (g)		>350			>350			>520		
Bottle cut (cm)										
		4		14,8	4		14,8	4		20,4
		Top	Center	Bottom	Top	Center	Bottom	Top	Center	Bottom
	Verify 3 more samples per mold STOP blowing and inform technician if still in red zone	6.6		2.7				6.6		2.7
	Verify 3 more samples per mold Inform technician if still in yellow zone	6.5		2.6				6.5		2.6
		6.4		2.5				6.4		2.5
	OK	6.3		2.4				6.3		2.4
		6.2		2.2				6.2		2.2
		6.0		1.9				6.0		1.9
	Verify 3 more samples per mold Inform technician if still in yellow zone	5.9		1.8				5.9		1.8
		5.8		1.7				5.8		1.7
	Verify 3 more samples per mold STOP blowing and inform technician if still in red zone	5.7		1.6				5.7		1.6





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