Guidelines for Good Hygiene Practice

BOTTLED WATER COOLERS

Cleaning and Disinfection of Water Coolers, Reusable Bottles, Refilling and Distribution

Approved by WE National Associations

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INTRODUCTION

WE, “Watercoolers Europe” is a non-profit organisation that represents the interests of the water cooler industry in Europe (bottled water coolers and plumbed-in (point-of-use) water coolers) and ensures that national and international quality standards for the water cooler industry are implemented. Besides existing European legislation, industry members are requested to comply with relevant existing national legislations. It is important to note that that interpretation and implementation of Directives may lead to variations in National Regulations across Member States.

In accordance with the principles of Watercoolers Europe (WE), these guidelines are intended to ensure that the highest standards are reached in the fields of quality, safety, hygiene, and ethical behaviour in the water cooler industry. This aim can be achieved by ensuring that Bottlers, Distributors and Operators of Water Coolers are fully aware of their responsibilities to the environment and supply safe products and faultless services to their customers.

Within the meaning of Article 9 of European Regulation (EC) 852/2004, these guidelines for Good Hygienic Practice meet the objective of simplifying the application of the pertinent European legislation, particularly Regulation (EC) 852/2004 on the hygiene of foodstuffs.

These European “Guidelines for Good Hygiene Practice” were compiled with the aim of receiving official recognition from the European food authorities. The areas of water extraction and water treatment have not been covered in detail, since an earlier publication “Guide to Good Hygiene Practices for Packaged Water in Europe” (European Federation of Bottled Waters, dated 6 June 2012) provides sufficient information and that publication is already endorsed by the European Commission.

Watercoolers are free-standing devices which hold the product water in integrated, refillable containers to be dispensed for immediate consumption and which feature cooling systems or cooling and heating systems.

Watercoolers, which have a tradition dating back 100 years, allow people to meet their daily fluid requirements in a healthy, convenient, and environmentally friendly manner.

It is the constant aim of WE Technical Committees to improve the quality of our standards and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this, WE CoP would inform the Secretary of the Association.

This Code of Practice provides the basis of WE’s annual member plant and depot audits. WE requires an annual inspection of each member’s facility by an independent third-party food safety organisation, appointed by WE. The audit confirms members’ conformance with the technical and regulatory requirements.

This Code of GHP is divided into the following sections:

A) General hygiene measures in respect of the building, equipment, and personnel, as well as training
B) Description of a typical operational procedures in a bottled watercooler company
C) HACCP analysis (with a focus on water coolers)
D) Annexes with customer instructions, regulations, standards, and verification of sanitisation methodologies

DEFINITIONS AND ABBREVIATIONS

The terms listed are used in the Code of Practice and are given the meanings indicated here.

Bottled Water Cooler:	A watercooler used to chill and dispense bottled water for human consumption (some may have a water heating facility).
Carbon filter:	Carbon filter within a casing for improving the odour and taste of water.
CCP (Critical Control Point):	A 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.
CIP process:	Cleaning in place process. Cleaning enclosed equipment without dismantling the equipment.
Cleaning:	Removal of soil, dirt, organic/inorganic deposits, or other objectionable matter by means of water, mechanical action and/or chemical agents.
Commissioning:	Series of actions intended to put in operation the assembled system and to hand it over, as well as instruct the Keeper/Customer/Operator.
Consumer:	The person who drinks water from the water cooler.
Contamination:	Unwanted influence on the product water by physical, chemical, or biological contaminants.
CP (Control Point):	A key point in process controls.
Customer/Keeper:	Individual or enterprise operating and monitoring the water cooler.
Disinfection:	Reducing the number of cultivable microorganisms to a permissible level by using suitable disinfectants and/or suitable and special physical methods.
Distributor:	A natural person or company, who sells, installs and/or services water coolers in a commercial capacity.
EU:	European Union.
Extraction Site:	Point at which water is taken from the spring or bore hole.
Food Contact Materials ('FCM'):	All materials foreseeably used in contact with food, in case of drinking water all equipment behind the point of compliance.
Filters:	A water filter removes impurities from water by means of a fine physical barrier, a chemical process or a biological process.
Flow chart:	A detailed description of all the consecutive phases in the process, mainly consisting of a graphic diagram of each phase, supplemented with relevant information.

HACCP: (Hazard Analysis and Critical Control Points)	A system which identifies, evaluates, and controls hazards which are significant for food safety.
Hazard:	A biological, chemical, or physical agent in a food with the potential to cause an adverse health effect.
Hygiene:	All measures necessary to guarantee the safety and quality of water during preparation, processing, production, transporting, distribution, and sale.
Logbook:	Document supplied together with the device or released to the keeper on which there are recorded the main actions required to be performed on the device during its lifetime starting from its commissioning. NOTE: The logbook in its simplest form could be a sticker.
Maintenance:	Periodic action for keeping and ensuring the continuous performance of the device at the appropriate time, irrespective of the frequency of the required actions. NOTE: Maintenance can include cleaning the water cooler and replacing predefined worn or exhausted parts.
Mineral enrichment :	Various minerals that are added in a mixture to the water during the production process for enrichment.
Monitoring:	Planned series of observations which determine whether possible hazards are remaining under control.
Operation:	Series of automatic and non-automatic actions undertaken for the correct functioning of the water cooler.
Operator:	An individual or company who leases, installs and/or services water coolers in a commercial capacity.
Ozonisation:	1. Process of oxidising unstable water content, such as iron, manganese, sulphur compounds during water treatment. 2. The treatment of water with ozone gas during storage or bottling to kill any microorganisms which may be present (not permitted for mineral and spring water).
Process stage:	A particular functional phase in the process
Production batch:	Production unit sizes which are produced and packaged under identical conditions, the size of which is defined/determined by the manufacturer.
Repair:	Occasional action, performed by competent personnel only, intended to restore the performance of a defective water cooler.
Reverse osmosis:	A treatment process in which the water, at high pressure, is passed through a semi permeable membrane which will remove some microorganisms and dissolved matter from the water.
Risk analysis	Assessing potential hazards and their consequences.
Sanitisation:	Cleaning followed by disinfection.
Store:	A building (including temporary storage containers) used by the distributor or supplier to store and/or distribute drinking cups, water coolers, accessories, and replacement parts and for repair, maintenance, cleaning and/or disinfection of water coolers.

Supplier:	Enterprise that puts products and/or services on the market which may be the actual product manufacturer (e.g., private brand name). NOTE: For the scope of these European Guidelines, the supplier is assumed to be sufficiently expert to undertake the task of providing clear instructions for the equipment installation, operation, maintenance, and repair.

Types of water	
Natural mineral water:	Defined in the Directives 2009/54/EC and 2003/40/EC.
Spring water:	Defined in the Directive 2009/54/EC and (EU) 2020/2184.
Prepared water:	Product water which can be treated with other water-conditioning processes (such as reverse osmosis and remineralisation) and may contain one or more additives. Directive (EU) 2020/2184. Regulation (EC) Nº 178/2002.
Water from watercoolers:	This can be natural mineral water, spring water or prepared water which is intended for human consumption and provided to the consumer at room temperature, chilled or heated, according to EU Food Safety Regulation (EC) Nº 178/2002 and Food Hygiene Regulation (EC) Nº 852/2004, and such equipment is therefore subject to FCM legislation.
Process water:	Potable water used for various process phases in production, as defined in Directive (EU) 2020/2184.

A) GENERAL HYGIENE MEASURES

I. DESIGN OF THE PRODUCTION ENVIRONMENT AND WORK AREAS

1. General conditions

The working conditions in watercooler companies must be designed as follows:

a) The design and arrangement of work areas must allow reasonable maintenance, cleaning, and disinfection.
b) Equipment, which comes into direct contact with food, must be of suitable quality and be easy to clean.
c) Temperature, relative humidity, and atmosphere must be controlled, where necessary, in production areas.
d) Effective measures must be taken to prevent infestation by pests.

Therefore, attention must be paid at the design and construction stage to general hygiene aspects, a suitable location and the provision of adequate space and other arrangements to facilitate an effectively controlled production process.

2. Specific conditions

- Buildings and facilities must be in good condition.

- They must be easy to clean in a verifiable manner, provide sensibly organised workflows and production routes to avoid contamination and offer suitable climatological conditions for raw materials, the production process, and the final product.

- All openings, which provide access to the outside, such as doors, windows, ventilation openings and pipes, must be adequately protected and maintained to prevent the entry of pests.

- The inside of the building must be well maintained and kept neat and tidy. Production areas should not be refurbished during production. Where possible, it is advisable to plan annual plant shutdown for general routine repairs and refurbishment work. If essential equipment repairs are necessary during production, all the requisite precautions must be taken to prevent contamination of the product water and water coolers from dust and debris.

- Sanitary facilities (lavatories with water flush systems and washbasins) must be kept separate from the production rooms and fitted with self-closing doors. There should be an adequate number of washbasins within easy reach.

3. Water extraction, protection, and monitoring of the source

Equipment for the extraction of water must be constructed such that any possible contamination is prevented. Details of source construction must be on file. The spring or extraction site must be secure and protected against risks of contamination, minimum weekly inspections are recommended. There should be a sampling point at source, or if not possible, at the first point of entry to the production plant. In-house weekly testing for coliforms/E.coli is recommended (using presence/absence kits), or daily testing if the water is bottled untreated. Annually, an analysis of microbiological, chemical and pesticide content should be undertaken, including Cryptosporidium testing. The water-collection installations, the supply pipelines and the tanks must be made of a material suitable for water so that any chemical, chemical-physical and bacteriological changes to this water are avoided.

4. Production area

Careful attention must be paid to preserving the quality and safety of water for bottling and the general and specific requirements indicated in the next sections must be followed rigorously. Water can dissolve and absorb a whole host of substances. Therefore, the quality of the water can be jeopardised quickly by picking up tastes and/or odours. It is also impossible to rule out slight changes in composition, as well as contamination with pathogenic microorganisms. It is recommended to use a suitable quality class of stainless steel for all the pipelines, storage tanks and bottling facilities. The requirements for materials are deemed to have been met if the Food Contact Material Regulations (EC) N^{os} 2023/2006 and 1935/2004 are adhered to in the planning, construction, and operation of the installations and furthermore, in case of plastic materials in Regulation (EU) N^{o} 10/2011. Any materials which may come into contact with the potable water and may contain vinyl chloride monomer (such as some adhesives) will need to comply with Directive N^{o} 78/142/EEC. Similarly, for epoxy resins, compliance is required to Regulation N^{o} 1895/2005.

4.1. General requirements

The design and arrangement of the production facility must conform to the following criteria:

- Proper cleaning and disinfection must be facilitated.
- Product must be protected against contamination by foreign material.
- Formation of condensation and mould must be avoided.
- Contamination between/during production sequences must be avoided.
- There must be good atmospheric conditions for hygienic production in high-risk areas with a positive airflow above filling stations.
- There must be operational washbasins with hot and cold water, as well as soap dispensers,

disposable paper towels and hand disinfectants.
- There must be an effective ventilation system.
- There must be satisfactory lighting.
- There must be an adequate drainage system which is operational.

4.2. Specific requirements

- Floors must be made of chemical-resistant material and must be easy to clean.
- Walls must be impenetrable to water and have smooth, mould-resistant, washable surfaces.
- All doors in the high-risk area must be self-closing and should have a smooth, non- absorbent surface. The number of entrances must be kept to a practical minimum.
- All surfaces must be resistant to universal cleaning agents and mould.
- Windows must be properly provided with screens or not openable.
- Windows in the production area must be protected against breakage or shattering to prevent any product contamination in the event of glass breaking.
- Lights in the production area must be provided with a protective casing to prevent any product contamination in the event of a bulb/tube breaking.

Other installations such as stairs, steps, platforms etc. must be designed to hygienic standards.

Empty bottles must not be left in the open except for very short times prior to storage otherwise the bottles should be wrapped in black plastic for protection against the elements and sunlight.

- Buildings and production equipment must be in a good state of repair. All goods, tools, spare parts, packaging materials and other objects which are not used in production must be stored elsewhere. Water hoses must be equipped with a spray head, drained, and kept off the floor when they are not in use. Sufficient waste bins should be provided and must be regularly emptied. Industrial detergents and disinfectants should be handled carefully and used in accordance with the manufacturers' instructions.
- Care should be taken when using paints and varnishes. Only products which have been specifically developed for use in food-production operations and which have a neutral odour may be applied.

4.3. Air quality and ventilation

Appropriate natural or mechanical ventilation should be provided for the following reasons:

- To reduce airborne contamination from aerosols and condensation droplets in areas of water storage and production.
- To control the room temperature.
- To control odours, which could adversely affect the product water.
- To control humidity.
- Ventilation systems should be designed and constructed so that air does not flow from contaminated areas (e.g., lavatories, cafeterias) to areas which must be kept clean. Ventilation systems must be properly cleaned and maintained.

4.4. Storage areas

There must be adequate facilities available for the storage of product water and of other materials needed in the workflow and for the storage of chemicals (e.g., detergents, lubricants and fuels).

The design and arrangement of the storage areas must conform to the following criteria:

- To facilitate adequate maintenance and cleaning.
- To prevent the penetration of pests and possible sources of contamination.
- Effective protection for product water against contamination during storage.
- To minimise the deterioration in the product water due to temperature and light.
- The recommended storage temperature for bottled product water should be between 10°C and 20°C and may not be below 4°C.

- Bottled product water should be stored inside, away from direct sunlight and not stacked close to roof windows.
- Separate lockable storage facilities should be provided for detergents/disinfectants and food-grade lubricants.

5. Production equipment

- A high standard of maintenance should be guaranteed, and any damaged equipment must be reported and replaced. Compiling a preventative maintenance schedule is recommended as best practice. Temporary repairs, e.g., using wire or adhesive tape or cardboard may not be carried out. No small objects, such as nuts and bolts or washers are to be left lying around in the vicinity of open containers.
- Multi-purpose equipment and containers which come into contact with product water should be designed and constructed to be easily cleaned, disinfected, and maintained.
- Equipment that is only used for maintenance and cleaning of production equipment should be clearly marked.
- Equipment should be durable and movable or capable of being dismantled easily to facilitate maintenance, cleaning, disinfecting, and monitoring.
- Containers for water may not be misused for other purposes.
- It is essential that the conveyor belt is covered from the bottle washer to the station where containers are capped.
- Lubricants must be suitable for use in food-production operations (such as NSF H1 grade lubricants) and may not have any adverse effects on water or water containers.
- Containers for hazardous substances must be readily identifiable and held in a lockable area. The relevant statutory regulations on the storage of liquids which can potentially contaminate water must be observed.

6. Main operation system

- All pipelines must be made from a material which is suitable for water in compliance with Food Contact Material Regulations (EC) N^{os} 2023/2006 and 1935/2004, furthermore, and in the case of plastic material, Regulation (EU) N^{o} 10/2011. Stainless steel pipework must have smooth internal welds.
- It is imperative that all parts of the installation to be cleaned are installed in such a way that all inner surfaces can be reached by CIP.

7. Cleaning and disinfection

Each operating facility should prepare a “Cleaning and Hygiene Manual” which embodies the following requirements:

- Zoning in the bottling plant should define and mark various areas by colour codes. Tools and other working equipment used in these areas should be marked with the same colour codes.
- Each operating area must have a cleaning and disinfection programme with special attention paid to high-risk areas. The cleaning and disinfecting chemicals for use in each area should be listed, specifying type of chemical, concentration, and temperature of application and, in the case of disinfectants, the optimum contact time. The times for the requisite cleaning work must be specified in a work schedule.
- There are two possible ways of cleaning and disinfecting:
  a) Manual operation
  b) Automatic operation by means of the 'Cleaning in Place' process.
- There must be sufficient time available to perform the cleaning programme and, in the case of manual cleaning, there also must be adequate space available.
- There must be adequate cleaning utensils available (scouring sponges, scrubbing brushes, special sponges for cleaning the inside of operational equipment, foam lances, wet/dry vacuum cleaners). To avoid any detrimental influence, the utensils must also undergo thorough cleaning and

disinfection at regular intervals or be replaced by new equipment. Dedicated utensils must be used for cleaning and disinfecting dismantled components that come into contact with the product water.

- Water lines for product water: Removal of biofilm requires an oxidising biocide such as ozone or peracetic acid. CIP cleaning must be performed on a regular basis, the line from the holding tank to the filler is susceptible to microbiological contamination and should be flushed through with an appropriate disinfectant as often as possible without disrupting production. The disinfectant and the process water must be able to penetrate all areas of the product flow.
- It is recommended that product water be run through the machine briefly, e.g., for about 10- 15 minutes, prior to start up each day. After the machine has been changed for different bottle types and sizes, it is recommended to perform a CIP-cleaning procedure on the bottle washer. CIP-cleaning at a temperature of at least 80°C offers the added benefit of killing microorganisms without direct contact. Even though process water may be used to rinse after CIP-cleaning, the final rinse should always be with product water. The first container filled must be checked to ensure that it is free of detergent and disinfectant residue.
- Installations should be dedicated to bottling water only.
- Storage and mixing tanks must be equipped with internal spray heads for efficient cleaning.
- Pumps and control valves must have smooth internal surfaces without cracks or inaccessible corners.
- All traces of disinfectant must be removed before the installation (pipelines, pumps, and tanks) is put back in service. This may be checked by using the appropriate test strips or by titration. It must be flushed with process water.
- It is essential to keep documentary records, stating the name of the employee responsible for this work and describing the progress and the results of these procedures. Records need to be controlled and signed by senior staff.
- You may only use detergents and disinfectants which are approved for use in the foodstuffs sector.

8. Cryptosporidium control

Cryptosporidium is difficult to eliminate using disinfectants and the best way to remove this micro-organism is by selection of appropriate filters. Since the micro-organism is large (3-5 microns), filters should be installed prior to filling with a high-specification 1 micron filter. Filters of this size will not affect the natural bacterial population of NMW and spring water. UV is another alternative, but its use is not permitted for natural mineral waters and spring waters in Member States.

9. Pest prevention and control

Pests can mean rodents, insects, and birds. Attention should be paid to watchdogs and pets. Pests cause unhygienic conditions and, therefore, must be prevented from entering the building or otherwise trapped, if they do enter the building. A control programme with this aim must be established based on the following principles:

- To prevent pests from entering the building.
- To eliminate possible hiding places for pests; rodents are particularly attracted to the wooden pallets, cardboard, and paper labels in the storage area.
- To eradicate all pests in the building.

Pest control should also be extended to the well head or spring source building. A specialist, accredited company should be engaged to draw up and implement an effective control programme.

II. PERSONAL HYGIENE

- Production employees must undergo a medical examination at the start of their employment. It must be repeated later if there are grounds for this (such as diarrhoea-related illnesses, holidays in exotic countries, etc.). Any person working in an area where food is prepared is required by law to report any illness (Regulation (CE) N 852/2004). Employees suffering from a contagious illness or other illness/injury which could contaminate the product must be excluded from production

activities.

- Production employees will receive induction training when they start work to cover health, safety, and personal hygiene, as well as a more detailed Hygiene Awareness Course shortly thereafter; refresher courses to be taken at intervals.
- Production employees may not smoke anywhere within the building or eat/drink in areas where this is not permitted. This applies to production areas.
- Employees may not wear jewellery in the production area other than a plain marriage band.
- It is imperative that employees wash, and if necessary, disinfect, their hands thoroughly before they start work and every time they leave and resume work in the relevant production areas.
- Minor wounds, cuts, grazes, or sores must be covered by waterproof dressings which are conspicuously visible (blue band aid).
- Production employees must be always well-groomed. Whilst at work they must wear clean protective clothing with head covering and/or snoods to cover beards/moustaches. Use of equipment such as respirators must comply with Directive 89/686/EEC and bear the relevant CE marking where appropriate.
- It is important that all production employees observe good personal hygiene.
- Non-company personnel (visitors, tradesmen, auditors, etc.) must be informed about the prevailing hygiene regulations and wear reasonable protective clothing when they enter the production facilities. A brochure with the basic information, also as induction handout to all employees, is recommendable.

III. TRAINING

1. General provisions

Production employees must be trained in accordance with Food Hygiene Regulation (EC) No 852/2004. Information on the frequency and content of training courses is derived from WE guidelines and the instructions set out below:

- Production employees must be properly trained and well supervised. They must be fully aware of the relevant hygiene principles. After starting employment, particularly during the probationary/induction period, special attention and understanding must be given to hygiene and safety issues.

The WE Training & Education Committee offers Hygiene Awareness Courses to all WE personnel. Attendance is strongly recommended for all production and distribution personnel.

- Managerial personnel in watercooler companies must have a complete overview of food hygiene to assess potential risks and take the necessary measures. Management must demonstrate the importance of hygiene rules by setting a good example, motivating employees, involving them in improving production processes and, as far as possible, in drawing up working instructions.

The WE Training & Education Committee also offers "Plant Operators Training Courses" to all managerial and supervisory personnel of member companies. Attendance is strongly recommended to all managerial personnel; at least one member of management should have completed the course. Plant Operators training needs to be updated every three years.

The course can be given from an approved WE trainer.

- All employees must be aware of their role in protecting the products against contamination and damage. They are jointly responsible for the competent and hygienic handling of the products in the company. Employees must have the necessary knowledge to allow them to handle the products hygienically. People who handle chemicals must be trained in safe techniques. The employer should advise employees of their duties to report illness.
- There must be a personnel training plan for hygiene, and training courses must be documented for every single employee. An evaluation of personnel training must be carried out at least once a year.

If necessary, additional courses or training should be arranged to bring the necessary know-how and skills up to date.

B) General Process Description

The way in which processes are carried out varies from company to company. All the possible steps and treatments are listed here. In practice, the companies arrange individual techniques to suit their own requirements.

1. Extraction
Origin of the water
Protection of the water resources

2. Incoming goods
Watercoolers Product Water
Packaging (including new
and returned containers)
Chemicals

3. Water treatment (depending on the type of water)
Natural Mineral water Spring
water
Prepared water (for example, water which has been treated to change the mineral composition)

4. Containers
Disposable or reusable containers (polycarbonate/ PET/PET derivatives) and caps.

5. Cleaning and inspection of containers
Cap removal
Visual and odour test Pre-
rinsing
Washing containers
Disinfection
Rinsing

6. Filling and capping
Ozonisation (not permitted for natural mineral and spring waters)
Remineralisation (only for prepared waters)
Caps: Decontamination

7. End product storage
Intermediate storage Store

8. Cleaning and disinfection of installation
CIP Tanks/Pipelines

9. Distribution

10. Service and maintenance of watercoolers

1. EXTRACTION / POSSIBLE TYPES OF WATER FOR WATERCOOLERS

There are different types of water which can be used in the manufacturing process as water for watercoolers:

- Natural Mineral Water
- Spring Water
- Prepared Waters

Natural mineral waters and spring waters are regulated by Directive 2009/54/EC; Directive 2003/40/EC and for spring waters also by Directive (EU) 2020/2184, as amended.

Before a spring can be used for natural mineral water or spring water, the company must be in possession of an authorisation issued by the relevant national authorities. The lists of natural mineral waters officially recognised by the EU countries of the EU and of the EEA (Iceland and Norway) are published by the European Commission in the Official Journal of the European Union. These lists are regularly updated.

General objectives of extraction

Details of water extraction have been covered in the previous publication by the European Federation of Bottled Waters “Guide to Good Hygienic Practices for Packaged Water in Europe” and to avoid duplication, only minimal reference is made here.

Over and above the prevailing minimum legal requirements, watercooler companies should have water periodically analysed for microbiological constancy and chemical condition, by accredited laboratories. The type of analysis and sampling regime will be dictated by an effective HACCP plan being in place and implemented.

Radioactivity in water

- The Council of the European Union adopted a new Directive, 2013/51/Euratom, laying down requirements for the protection of the health of the public regarding radioactive substances in water intended for human consumption.
- The monitoring of tritium and “indicative dose” (a combination of gross alpha and beta radiation levels) is already required by the Drinking Water Directive for spring water and other bottled drinking waters but monitoring of radon is not. The requirements of the Euratom Directive supersede those laid down in the Drinking Water Directive and radon, tritium and indicative dose are subject to monitoring. For bottled water, compliance with parametric values must be checked at the point at which water is put into bottles.
- However, radon monitoring is only necessary where there is reason to believe that the levels will exceed the parametric values. Businesses producing spring or bottled drinking water will first consult existing information to assess the prevalence of radon in their area using national geological survey data. In some Member States it is obligatory to monitor radon e.g., Spain.

Natural mineral waters are exempt from the requirements of the Directive.

Hygienic extraction and collection of water

- It is worth noting that, for Natural Mineral Water and Spring Water, disinfection of the well borehole may be performed if the well becomes contaminated or the business can prove the presence of a biofilm. It should be stated that the business has a legal obligation to protect the well from sources of pollution under Annex II of Council Directive 2009/54/EC. As such, these disinfection events should be rare; a bottled water plant should not need to regularly decontaminate a well, as this would indicate that the business is not meeting its obligations to protect the source from pollution under Annex II of Directive 2009/54/EC.
- When the bottling plant disinfects a well, the water must return to its natural status and meet requirements under the respective Directives before it can be sold again.

Storage and transport of water intended for bottling.

- When transport and temporary storage of the water intended for bottling from the point of extraction to the processing plant is necessary, this must be conducted under hygienic conditions to prevent any contamination. Transporting the water in pipes from the source to the bottling location is preferable to transport by tanker as a means of avoiding risks of contamination. Pursuant to Directive 2009/54/EC, spring and natural mineral waters must be transported between the source and the bottling site along a pipeline system. Tanker or container transport is not permitted.

- If tankers, mobile water tanks and other containers can be used for transporting water intended for bottling, they must be kept in an appropriate state of cleanliness and repair. Tankers and containers may only be used for transporting liquid foodstuffs, and, where possible, only for water intended for bottling.

2. INCOMING GOODS

Apart from water intended for bottling, there is a series of other incoming goods: chemicals, packaging materials, process water and watercoolers. All incoming goods must comply with the applicable legal requirements and the specifications requested by the customer. They must be checked regularly (by means of a control system) on arrival. If the goods are not in order, they are to be returned to the supplier.

Chemicals

Various chemicals are used both in the treatment of water and for cleaning and disinfection. Chemicals must be approved and be suitable for the purpose, as well as satisfy internal requirements e.g., environmentally friendly, etc. Waste chemical effluent should be neutralised and discharged more than 500m away from the abstraction source.

The chemicals must be clearly labelled and periodically checked. The supplier must provide certificates of analysis upon delivery. If necessary, additional laboratory tests must be carried out to check and verify the specifications. Treatment of bottled water must comply with the relevant requirements as laid down in Directives 2009/54/EC (exploitation of spring and mineral water), 2003/40/EC (use of ozone) and Commission Regulation (EU) Nº 115/2010 for the use of activated alumina in the removal of fluoride from spring and mineral water. Addition of minerals to drinking water is regulated by Drinking Water Directive (EU) 2020/2184. Treatment of mineral and spring waters must not affect the microbiological and chemical characteristics.

Water containers

The product water is generally poured into refillable polycarbonate (PC) or single-use PET containers. Refillable containers based on PET derivatives have also entered the market. The containers are sealed with a plastic seal (sealing cap). Only disposable caps are used.

The containers and caps must be fit for the purpose, i.e., the migration assays, referred to in Regulation (EU) Nº 10/2011, must be carried out under appropriate conditions, in accordance with the type of food (water) and storage conditions, and they must comply with the migration limits stablished in that Regulation.

Watercoolers

The containers/bottles of water are placed on the water coolers; water is drawn off via the taps for drinking. The connection between the watercooler and the water container is generally secured by a

bayonet fitting. There are different types of watercoolers available on the market. They differ from one another in terms of their taps, the connection to the container and the reservoir. In addition to the cold-water tank, some of the watercoolers also possess a hot water tank.

Watercoolers are designed with an air filter which prevents impure outside air contaminating the cooler when water is drawn off.

The watercoolers must be safe, fit for their intended purpose and easy to clean; they must fulfil the requirements of:

- Food contact materials Regulations (EC) Nº 1935/2004, (EC) Nº 2023/2006 and (EU) Nº 10/2011.
- Electrical safety should follow EC Directive 2004/108/EC (electromagnetic compatibility, EMC).
- No hazardous materials must be used in materials of construction to comply with Directive (EC) 2002/95, Decision 2005/618/EC and Directive (EC) 2008/35 (RoHS Directive).
- The refrigeration system should use non-HFC based refrigerants and the unit should be provided with a CE certificate.

Users must ensure that certificates of conformity with the above requirements are present on site for inspection when required, for example during auditing for good hygiene practice. Food contact certificates are specifically required to be on site.

If disposable drinks cups from cup dispensers are supplied with the water coolers, they must be fit for the intended purpose and conform to Regulation (EU) 10/2011, Regulation (EC) Nº 1935/2004 and Regulation (EC) Nº 2023/2006 concerned with materials in contact with food. All cups supplied for hot liquids must be covered with a certificate of compliance that states the maximum safety temperature for each variant of cup. They should be supplied in packaging and stored in a dry place.

Incoming watercoolers are to be inspected visually, and each model must have the required certifications as indicated above.

3. WATER TREATMENT

This topic is described fully in the “Guide to Good Hygiene Practices for Packaged Water in Europe” published by European Federation of Bottled Waters and will not be considered in great detail here, to avoid duplication.

Use of Ozone during Filling

Ozone is sometimes used when filling prepared water. Ozone quickly oxidises existing organic and inorganic components and kills bacteria. Due to its instability, ozone decomposes back into oxygen over time. The concentration of ozone must be adjusted to the intended use to prevent the ozone values rising disproportionately in the water during filling. The formation of unwanted by-products (such as bromate) must be prevented. Regular monitoring of the ozone content and the possible secondary reaction products, particularly bromate, which can be carcinogenic at low levels, is necessary. Ozone may only be used in this manner in accordance with Directive (EU) 2020/2184 for waters other than natural mineral water and spring water. The use of ozone or other substances for water treatment is subject to national measures.

Process water

Process water is water which is used for cleaning and disinfection purposes and is not bottled as product water. Water of drinking quality must be used to clean containers and conveyor systems. There must be an adequate supply of this available with the requisite pressure and temperature.

Where possible or necessary, this water should be carried in a separate pipeline system. These pipelines should be colour-coded and indicate flow direction. Cross connections are discouraged unless a back-

flow preventer is in place and regularly checked for seepage.

4. PACKAGING / WATER CONTAINERS

In addition to the incoming goods inspection, attention should be paid to the storage conditions for containers.

Returned containers should not be stored outside for any length of time unless they are adequately protected against excessive heat and sunlight, moisture, dust, exceptional weather conditions and pests. All containers (new and returned containers) must be cleaned and disinfected to a reasonable standard before filling.

Caps must be stored in a dry place. They must be protected against heat, dust, pests, glass breakage and chemicals. Where possible, the caps should be hygienically treated with disinfecting agents/processes before being placed on the containers.

5. CLEANING, DISINFECTION, AND INSPECTION OF CONTAINERS

Inspection of refillable water containers

Refillable containers are first checked for any contamination before the caps are removed, and the containers are washed in a specially designated bottle washer.

The check for possible contamination is carried out by visual inspection and sniffing. Electronic sniffers will speed up production, although manual sniffing for smaller volumes is more usual. Containers which arrive without a cap should be examined carefully for possible contaminants. Contaminated or “green” bottles should be set aside for disposal. In case of manual sniffing, staff need to be trained on safe-sniffing techniques.

Cleaning

The bottle washer must supply clean containers to the bottling installation. The washing machine typically involves the following stages:

Pre-rinsing ➔ washing with detergent ➔ treating with disinfectant ➔ final rinsing.

- Pre-rinsing: During pre-rinsing the container is cleaned of any liquid residue and dirt.
- Washing with detergent: The bottles are washed with a detergent solution. They undergo intensive cleaning of the insides and outsides.
- Treatment with disinfectant: The bottles are then sprayed with appropriate. disinfectant solution. Appropriate use of disinfectants is described in Regulation (EU) Nº 528/2012.
- Final rinsing: The bottles are rinsed thoroughly during the final stage. This prevents residue from the detergent or disinfectant carrying over into the final product.
- Technical parameters must comply with the conditions established by the manufacturer of the containers, e.g., temperature, concentration and shall be monitored.
- The number of wash/fill cycles that a bottle can undertake before the bottle deteriorates to an unacceptable level will depend on many factors, including wash temperatures, causticity of the detergent, bottle specification and handling during transport, but at least 40 cycles should be possible as a minimum.

To verify the effectiveness of the cleaning process, the water containers must be regularly checked for microbiological and/or chemical contamination. Microbiological contamination points to inadequate cleaning, and chemical contamination to incorrect dosages and/or an inadequate final rinsing process.

6. FILLING AND CAPPING

Filling

Different companies use different filling machines. In the case of prepared water (“other” or table water, depending on National Regulations), sometimes minerals are added prior to the filling process. The filling machine must be kept hygienically clean by regular cleaning/disinfection procedures. The microbiological condition of the machine must be verified using appropriate investigation techniques and, if necessary, the cleaning and disinfection processes adjusted.

Capping/sealing

To prevent contamination after filling, the containers are capped immediately afterwards. The cap must be correctly positioned and the seal tight.

The capper must be cleaned, disinfected, and rinsed before use in accordance with the manufacturers’ instructions. Caps must be handled hygienically and preferably treated with a disinfectant spray before use.

Labelling

Each container must be labelled in accordance with the legal requirements specified in Directive 2009/54/EC. If ozone-enriched air treatment is used to separate unstable elements such as manganese, sulphur, arsenic or iron from natural mineral water, the obligatory labelling “Water subjected to an authorised ozone-enriched air oxidation technique” must be stated, in accordance with Directive 2003/40/EC. If fluoride is removed or reduced from natural mineral water, the obligatory labelling “Water subjected to an authorised adsorption technique” must be stated, In accordance with Regulation (EU) Nº 115/2010. In cases where remineralisation of water is included after treatment by reverse osmosis, the amount and type of minerals added must comply with the parametric values of (EU) 2020/2184 and subsequent labelling comply with the general principles and requirements of the food law Regulation (EC) Nº 178/2002. Any additions to mineral and spring water are not permitted.

Traceability

It is essential that product batches and the packaging materials used are traceable, in the event of a product recall. In general, caps are marked with a production date and quality assurance data is recorded and maintained for every batch. Batch numbers of components used during production, including caps and filters, must be recorded. A retain sample from each production should be stored in dark, cool conditions for a period relative to the shelf-life of the product. An annual traceability exercise should be conducted to, at least, the first level of distribution and any remedial action undertaken where appropriate.

7. END PRODUCT STORAGE

Products must be stored under the correct conditions. The storage area must be enclosed and have enough space for appropriate storage. There must be suitable pest control measures in place in the storage area.

To avoid mould forming on moist, cold packaging the storage area must be properly ventilated. Ideally the temperature should be kept at between 10°C and 20°C. The products also must be protected against frost.

Water that has been treated with ozone may not be dispatched for at least 24 hours, to allow the ozone to revert to oxygen.

The storage area must be set up in such a way that good hygiene practice can be followed. For example, this means that there must be sufficiently wide aisles and all goods should be stored on pallets. Sufficient space should be left between the walls and pallets for adequate floor cleaning. The store should be kept clean and tidy. Any damage or spillage must be cleared up as quickly as possible.

8. CLEANING AND DISINFECTION OF FILLING MACHINES

Cleaning and disinfection work should be performed regularly, conscientiously and in accordance with the manufacturers' instructions (where applicable, refer to EU Food Safety Regulation (EC) Nº 178/2002 and Food Hygiene Regulation (EC) Nº 852/2004). A Cleaning and Hygiene Manual shall be available for all areas of the plant.

Option A) Manual cleaning: During manual cleaning, filling equipment (dismantled if necessary), storage tanks and pipelines are rinsed with water, cleaned, and disinfected.

Option B) Automatic cleaning (CIP): During CIP cleaning, the storage tanks and pipelines are rinsed with water, cleaned with appropriate detergents, and disinfected with ozone or other suitable disinfectants, Regulation (EU) Nº 528/2012.

The following important parameters apply to both techniques and shall be documented in the Cleaning and Hygiene Manual:

a) Detergent used and corresponding concentration.
b) Temperature (80°C is recommended for cleaning).
c) Contact times.
d) Mechanical effects (e.g., turbulence in pipelines).

It is important during the final rinsing to check for residual traces of disinfectants. The effectiveness of the cleaning/disinfecting process must be assessed periodically by performing microbiological tests.

9. DISTRIBUTION

Transport

Watercoolers and water containers must be packed in such a way that they do not become damaged or contaminated during transport. Transport must take place with suitable, clean, enclosed vehicles to exclude any adverse effects.

Carriers must be able to provide information about the type of freight carried previously and this must not include materials which could cause taint in bottled water. The transport container shall be inspected for cleanliness before loading and locked immediately after loading.

Use by the customer

The customer must use the watercooler properly. To ensure that the watercooler is operated safely, not only is its siting important, but hygienic standards must be maintained in replacing water containers and keeping the taps clean. Instructions should be given after each new installation. A servicing contract involving cleaning and disinfection of the cooler, with change of air filter if appropriate, must be in place with a supplier accredited by a National Trade Association.

The dispensers for disposable cups should be designed and mounted in such a way as to be protected against contamination. Appropriate measures must be put in place to prevent used cups from being placed back into the dispenser.

Watercoolers may not be located in the following places:

- In areas where there is any risk of environmental contamination of the water.
- Outdoors or in direct sunlight.
- In a dusty, unventilated, or damp environment.
- On uneven or sloping surfaces or in the immediate vicinity of lavatories.
- In damp areas or in places where moisture may collect on the ground.
- In corridors, escape routes or on emergency exit staircases.

- Not immediately in front of a heater (it must be at least 20 cm away).
- In places where access for delivery and maintenance are difficult.
- In places without adequate cleaning facilities.
- In places where the system cannot be adequately supervised, to prevent tampering with the system or using it incorrectly.

The distributor/supplier/sales agent is responsible for training the customer in how to use the watercooler and in choosing where to site it. Customers should be advised of possible hygiene problems in operating watercoolers and how to avoid them.

The customer should also be given written documentation explaining how to choose an appropriate site for the watercooler and hygiene maintenance required in-between servicing visits.

An example of the instructions on how to use the watercooler for the customer is described in Annex 1.

10. SERVICE AND HYGIENIC MAINTENANCE OF WATERCOOLERS

To guarantee the quality of the drawn-off water, the watercooler must be cleaned and disinfected periodically. Various methods are used within the watercooler sector for doing this:

a) Complete cleaning and disinfection: Inspecting the outside of the device for signs of damage and contamination and rectifying any problems which are discovered. All the water-contact parts (water guard, reservoir, connecting pieces, taps) are then cleaned and disinfected completely.
b) Hygienic maintenance: Inspecting the outside of the device for signs of damage and contamination; cleaning the outside casing and drip tray; cleaning and disinfecting the water guard and taps.
c) Disinfecting using ozone.
d) Other disinfection techniques recommended by the manufacturer or distributor.
e) Note that all disinfectants used must comply with the requirements of the Biocidal Products Directive.

Whichever technique is used should comply with documented instructions.

Pursuant to the rules of the WE, manufacturers of watercoolers are required to provide distributors of watercoolers with a handbook recommending at least one appropriate technique for cleaning and disinfecting watercoolers.

The end customers normally have a choice between a service package and carrying out their own cleaning and disinfection, although they should be encouraged to sign up to a service package. If the customers perform the cleaning and disinfection themselves, they must undertake to do so in accordance with recommended instructions. Given the importance of a clean (microbiologically safe) watercooler, cleaning and disinfection by the supplier is advisable and recommended.

The frequency, nature and scope of cleaning and disinfection and/or hygienic maintenance are dependent upon the device and its accessories, siting of the cooler and the amount of use the cooler receives.

- Current standard models of watercooler require complete cleaning and disinfection periodically, at least every 13 weeks (± 20%), i.e., four times a year.

Longer intervals between cleaning and disinfection are only permissible if this is justified using additional accessories fitted to the cooler, such as auto-ozonation and UV irradiation. In this case the interval between cleaning and disinfection visits can be extended to every 26 weeks, although

hygienic maintenance visits are still required after 13 weeks and 39 weeks. The watercoolers must be tested according to Protocol 2 of the WE Standard Methodology, indicated in Annex 3, to be approved for these extended service intervals.

- The date and nature of the service visit should be noted on a sticker/data sheet affixed to the watercooler.
- Watercoolers with reusable reservoirs may have them cleaned and disinfected in the distributors' premises, along with taps and drip trays. The service engineer would remove these parts and replace them with cleaned and disinfected parts. In the case of watercoolers with a disposable reservoir, this can be exchanged for a new part, while the other parts of the cooler can be cleaned on-site.
- All chemicals which are used during the cleaning, descaling, and disinfecting of the watercooler must be suitable for use in the food environment and should satisfy the following criteria:
    a) They must be of suitable composition and concentration, with due regard for the materials of the watercooler. The manufacturers' recommendations for the chemicals must be taken into consideration.
    b) Storage before use without risk of contamination.
    c) They must be easy to rinse out without leaving any residue in the watercooler.
    d) They should be used only once and then discarded safely.

Service

The servicing of water coolers must be supervised, and inspections made at least annually to verify the work of the service engineer.

C) HACCP POLICY

1. Introduction

All products received, stored, and distributed are required to meet specifications agreed between the company and their customers and to comply with the Guidelines for Good Hygiene Practice. In addition, all products and related services must meet the legal requirements of members' National Regulations.

Distributor members of WE are dedicated to supplying safe, legal, and high-quality products and to meeting the requirements of their customers.

To this end, the distributor members of WE are committed to ensuring the safety of the products through implementation and diligent application of their food safety systems which are based on the HACCP principles.

2. Terms of Reference

All food safety hazards, microbiological, chemical, and physical, are included in the HACCP study. Contamination of the products with recognized allergens is also included.

The HACCP plan shall apply to all water dispensers supplied by the distributor members of WE and shall be based on the Codex Alimentarius Commission HACCP principles. Relevant legislation, codes of practice and guidelines have been referred to when appropriate. Legislation that has been considered includes the following:

1. Hygiene of Foodstuffs, Regulation (EC) No 852/2004
2. Materials in Contact with Food, Regulations (EU) No 10/2011, (EC) 2023/2006, 1935/2004, 1895/2005 and Directive No 78/142/EEC
3. General Principles and Requirements of Food Law and Procedures in Food Safety Regulation (EC) No 178/2002
4. Electromagnetic Compatibility (EMC) Directive 2004/108/EC
5. Use of Hazardous Materials and RoHS Directive 2002/95/EC, Decision 2005/618/EC, and Directive 2008/35/EC
6. Recycled Plastic Regulation (EU) 2022/1616

3. HACCP Team

Each distributor member of WE is required to review the generic HACCP plan and modify it to reflect operations at their premises. Where companies have more than one depot it may be necessary to modify the HACCP plan for each depot.

To achieve an appropriate standard of food (water) safety, each company should appoint a suitably qualified team to conduct the review and complete the modifications.

4. Product/Process Description

The products covered by this HACCP plan include all the water dispensers offered by the distributor members of WE for rental by customers, both commercial and domestic.

The process covered includes the purchase, preparation for use, rental, delivery, installation and maintenance of the water dispensers. It also includes the return to company premises and the preparation and re-issue of the dispensers to other customers.

The production of bottled water for use on dispensers is not covered by this HACCP plan.

A process description is included with the process flow diagram.

5. Intended Use

The products are intended for use by customers in their businesses and their homes. Certain vulnerable groups have been taken into consideration, including:

1. Hospital patients, and those in intensive care units.
2. Consumers with deficient immune response systems.
3. The very young.
4. School children.
5. The elderly.

6. Flow Diagram

A generic flow diagram has been produced.

7. Scope of the HACCP Study

The HACCP team must consider all types of food safety hazard, including microbiological, physical, chemical, and allergenic hazards.

Microbiological hazards were identified as contamination by, and/or survival of:

- *Salmonella* typhi, *paratyphi A* and *paratyphi B* (and, to a lesser extent, other bacteria of the Salmonella genus).
- *Shigella* species.
- *Vibrio cholerae.*
- *E coli* O157:H7 and other verocytotoxic E coli.
- *Pseudomonas aeruginosa* – mainly a spoilage bacterium but may occur as an opportunist pathogen.
- Protozoan parasites:
- *Cryptosporidium* spp, mainly *C. parvum* and *C. hominis.*
- *Giardia lamblia.*

Physical hazards were identified as contamination by:

- Glass, ceramics, and brittle plastics.
- Wood – from pallets and wooden containers.
- Packaging materials.
- Torn gloves and damaged clothing.
- Pests and their droppings.

- Personal items (e.g., jewellery).
- Fingernails, hair etc.

Chemical hazards were identified as contamination by:

- Cleaning chemicals and disinfectants.
- Aftershaves and perfumes.
- Rodenticides used for pest control.

Allergens:

No specific allergens were identified – as with all hazards, contamination risk is very low in water dispensers, but contamination may occur because of handling of bottles and dispenser taps by users.

8. Pre-requisite Programme

Pre-requisites to the HACCP plan have been identified:

- Good hygienic practice including cleaning and disinfection procedures and schedules.
- Glass and brittle plastic control in clean rooms.
- Use of potable water (for cleaning and disinfection of dispensers).
- Staff personal hygiene, including medical screening (fitness to work).
- Staff training.
- Supplier management and purchasing.
- Traceability.
- Maintenance of buildings and equipment.
- Complaints management.
- Vehicle Maintenance.

9. Validation

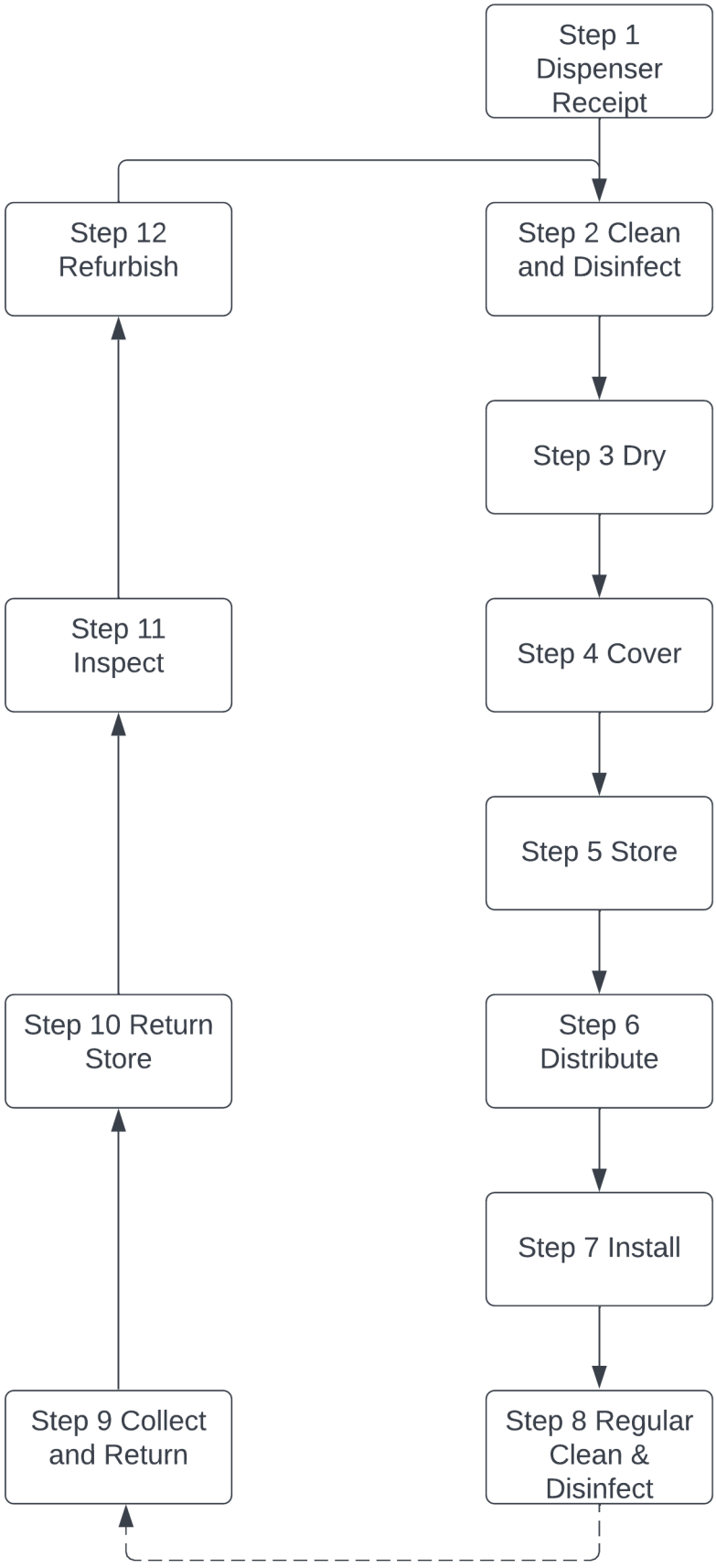
The food safety system is validated at each depot by quarterly audit of the food safety management system, by regular review of customer complaints and by independent annual audit against the WE audit guidelines.

10. Review of the Food Safety System

The food safety system will be reviewed on the following occasions:

- Annually.
- Following any change in procedures which may affect food safety.
- Following introduction of new operations, activities, legislation, or types of products.
- Following any food safety incident (as defined below).
- An increase in customer complaints.
- A need to recall products.
- Notification by an authorized regulatory person or body of a breach of food safety regulations.
- Following any change in the layout of clean rooms or the installation of new equipment.

11 HACCP Flow Diagram



Process Description

The process description is a generic explanation of the process shown in the Flow Diagram.

Each company should adjust the generic flow diagram and the process description to fit their own processes. It may be necessary to modify the flow diagram at depot level if there are differences between the depots that may affect the water safety and hygiene of the dispenser.

Step 1. Dispenser Receipt.

Dispensers are received from approved suppliers at the company's' premises. They are inspected at goods inwards to make sure that they are visibly sound, clean, and fit for purpose, as well as to ensure they are what was ordered. They may be held in storage in their original packaging or moved immediately to step 2.

Step 2. Clean and Disinfect.

Dispensers are unpacked and then moved into the clean room. They are cleaned and disinfected following the company's standard procedure and using approved chemicals which are rinsed out thoroughly after use.

In the case of dispensers with "disposable" water contact parts (trails and reservoirs), the process involves cleaning of the outside and non-disposable parts and installation of new disposable parts.

This process will be repeated on dispensers returned to the company's premises from customers' sites. In this case the cleaning and disinfection process will include descaling of the water contact surfaces. It may also involve replacement of some parts of the dispenser. Disposable parts will be removed, discarded to waste, and replaced with new parts.

It is also common practice to demount removable reservoirs and clean and disinfect them separately. When this is done, a kit is prepared and packed in a closed plastic bag for replacement on installation of the dispenser.

The date of cleaning and disinfection is marked on the cooler, usually by attachment of a label.

Step 3. Dry.

It is essential that the dispenser is thoroughly dried, externally and internally, before packing for storage. Failure to do so can result in corrosion and the growth of some micro-organisms on the wet surfaces.

Step 4. Cover.

Dispensers must be covered completely before storage to prevent the ingress of pests (insects and rodents) and contamination with dust.

Step 5. Store.

Cleaned and disinfected dispensers are stored in a separate, clearly identified area before distribution. They are inspected prior to distribution for the presence of contamination and/or moisture; if any is found, the cooler is returned to step 2 and the process is reviewed for weaknesses.

Step 6. Distribution.

Coolers selected for distribution may be marked (usually on the wrapping) with the destination for ease of operations. They are loaded onto delivery vans by the drivers and driven to the designated customers' premises as part of the routine delivery operation.

Care is taken during loading and delivery to avoid contamination of the dispensers with other goods carried in the vans.

Step 7. Install.

Bottled water dispensers are installed by delivery drivers with no special legal requirements for location or installation. They are installed away from sources of direct sunlight (windows) and heat (e.g., radiators). Users are briefed on the daily maintenance of the dispensers and the correct storage of bottled water. They are also shown how to change bottles on the dispensers, including the removal of protective labels from the bottle caps.

It is a requirement that customers are given appropriate information about the care and use of the dispensers, usually in the form of a dispenser care leaflet.

Step 8. Regular Clean & Disinfect.

Daily maintenance, including cleaning the outside of the dispenser and the taps, the emptying and cleaning of drip trays and the replacement of water bottles, is the responsibility of the customer. Cleaning and disinfection of the dispenser is done by the distributor to control the development of biofilm on water contact surfaces, thereby avoiding taste deterioration and potential pathogen contamination.

Bottled water dispensers must be cleaned and disinfected every 3 months. These time frames have been determined to maintain the wholesomeness of the water dispensed. This work is done at the customers' premises.

Water dispensers may remain in place for several years although some companies choose to limit the time, so that the dispenser may be returned to the depot for an overhaul and cleaning and disinfection in a more controlled environment.

Step 9. Collect and Return.

Dispensers are collected from customers' premises and returned to the company's depot on the following occasions:

1. When a cooler requires maintenance or repair that cannot be completed at the customers' premises.
2. At the end of a contract (including repossession of the dispenser on default of payment).
3. Periodically for regular overhaul and maintenance.
4. In some instances, for routine cleaning and disinfection.

Dispensers are covered to prevent ingress of dust and foreign bodies during transport.

Step 10. Return Store.

Returned dispensers are covered and stored in a separate, designated area away from clean dispensers, to avoid cross-contamination.

Step 11. Inspect.

Returned dispensers are inspected for damage and contamination before any work is done on them. This is carried out in a clean area but not necessarily in the clean room.

Step 12. Refurbish.

After inspection, dispensers may be refurbished to bring them back to a condition where they can be used by other customers. Refurbishment is usually done immediately before cleaning and disinfection but otherwise will be stored separately from both returned dispensers and cleaned and disinfected ones. The minimum amount of work done on all returned coolers is electrical testing, to ensure compliance with electrical safety regulations.

Following refurbishment, dispensers re-enter the usage cycle at step 2.

12 Hazard & Risk Analysis

Hazard Types	
M	Microbiological
P	Physical
C	Chemical
A	Allergenic

Risk						
Likelihood		Severity		Risk Factor (LxS)		
1	Low	1	Low	1x1	1	Low
2	Medium	2	Medium	1x2 or 2x1	2	Medium-Low
3	High	3	High	1x3 or 3x1	3	Medium
				2x2	4	Medium-High
				2x3 or 3x2	6	High
				3x3	9	Very high

Steps		Hazards				Risk			
No	Name	No	Type	Description	Control	L	S	R	CCP
1	Dispenser Receipt	1.1	M	Presence of pathogenic micro-organisms.	Purchase from approved supplier.	1	2	2 M-L	No
		1.2	P	None	Purchase from approved supplier.	0	0	0	No
		1.3	C	None	Purchase from approved supplier.	0	0	0	No
		1.4	A	None	Purchase from approved supplier.	0	0	0	No
2	Clean & Disinfect	2.1	M	Survival of pathogenic micro-organisms.	Use correct cleaning & disinfection procedure.	1	2	2 M-L	No
		2.2	P	Contamination with fragments of glass etc.	Work in controlled clean room.	1	1	1 - L	No
		2.3	C	Cleaning chemical residue left in reservoir.	Follow correct rinsing procedure.	1	1	1 - L	No
		2,4	A	Contamination of contact surfaces with food products.	Follow correct cleaning procedure.	1	3	3 - M	No
3	Dry	3.1	M	Growth of spoilage micro-organisms.	Complete drying.	1	1	1 - L	No
		3.2	P	Contamination with air-borne particles.	Drying in controlled clean room.	1	1	1 - L	No
		3.3	C	None	N/A	0	0	0	No
		3.4	A	Contamination of open surfaces with food products.	Drying in controlled clean room; avoidance of personal contact with dispenser parts.	1	3	3 - M	No
4	Cover	4.1	M	Growth of spoilage micro-organisms (moulds in particular).	Thorough drying before covering.	2	1	2 - ML	No
		4.2	P	None	N/A	0	0	0	No
		4.3	C	None	N/A	0	0	0	No
		4.4	A	None	N/A	0	0	0	No
5	Store	5.1	M	Growth of spoilage micro-organisms (moulds in particular).	Thorough drying before covering.	2	1	2 - ML	No
		5.2	P	None	N/A	0	0	0	No
		5.3	C	None	N/A	0	0	0	No
		5.4	A	None	N/A	0	0	0	No

6	Distribute	6.1	M	Growth of spoilage micro-organisms (moulds in particular).	Thorough drying before covering.	2	1	2 - ML	No
		6.2	P	Contamination from damaged packaging.	Secure loading of vehicle; careful handling during loading and unloading.	2	1	2 - ML	No
		6.3	C	None	N/A	0	0	0	No
		6.4	A	None	N/A	0	0	0	No
7	Install	7.1	M	Microbiological contamination of water contact parts due to handling during installation.	Good hygienic procedures; cleaning after installation.	1	2	2 - ML	No
		7.2	P	Contamination with damaged packaging during installation.	Careful removal of packaging before installation.	1	1	1 - L	No
		7.3	C	None	N/A	0	0	0	No
		7.4	P	Contamination with damaged protective gloves during installation.	Inspection of gloves for damage after installation.	1	1	1 – L	No
		7.5	A	Contamination of contact parts with food products during installation.	Good hygienic practice – no eating in vicinity of dispenser during installation.	1	3	3 - M	No
8	Regular Clean & Disinfect	8.1	M	Survival of pathogenic and spoilage micro-organisms due to inadequate removal of biofilm.	Good hygienic practice; diligent application of cleaning & disinfection procedure.	1	2	2 - ML	No
		8.2	M	Survival of pathogenic and spoilage micro-organisms due to incorrect use of disinfectant or sanitiser.	Good hygienic practice; diligent application of cleaning & disinfection procedure; correct contact time.	1	2	2 - ML	No
		8.3	P	Contamination with fragments of glass etc.	Complete a foreign body audit after cleaning & disinfection.	1	1	1 - L	No
		8.4	P	Contamination with damaged protective gloves during cleaning & disinfection.	Inspection of gloves for damage after cleaning & disinfection.	1	1	1 – L	No
		8.5	C	Chemical contamination due to inadequate rinsing after cleaning & disinfection.	Follow correct rinsing procedure.	1	1	1 - L	No
		8.6	A	Contamination of contact parts with food products during cleaning & disinfection.	Good hygienic practice – no eating in vicinity of dispenser during cleaning & disinfection.	1	3	3 - M	No

9	Collect & Return	9.1	M	Contamination with pathogenic and/or spoilage micro-organisms during transport.	Secure loading of vehicle and packing of dispenser before transit; cleaning & disinfection before further use.	2	1	2 - ML	No
		9.2	P	Contamination with foreign bodies from vehicle interior.	Secure loading of vehicle and packing of dispenser before transit; clean and tidy vehicle.	1	1	1 - L	No
		9.3	C	None	N/A	0	0	0	No
		9.4	A	None	N/A	0	0	0	No
10	Return Store	10.1	M	Contamination with pathogenic and/or spoilage micro-organisms during storage.	Keep covered during storage; cleaning & disinfection before further use.	2	1	2 - ML	No
		10.2	M	Contamination by pests during storage.	Keep covered during storage; cleaning & disinfection before further use.	2	1	2 - ML	No
		10.3	M	Contamination by algal spores in dust during storage.	Keep covered during storage; cleaning & disinfection before further use.	2	1	2 - ML	No
		10.3	P	Contamination by foreign bodies during storage.	Keep covered during storage; cleaning & disinfection before further use.	2	1	2 - ML	No
		10.4	C	None	N/A	0	0	0	No
		10.5	A	None	N/A	0	0	0	No
11	Inspect	11.1	M	Contamination with pathogenic and/or spoilage micro-organisms during inspection.	Good hygienic practice; cleaning & disinfection before further use.	1	1	0 - L	No
		11.2	P	Contamination by foreign bodies during inspection.	Good hygienic practice; cleaning & disinfection before further use.	1	1	0 - L	No
		11.3	C	None	N/A	0	0	0	No
		11.4	A	Contamination with allergens due to contact during inspection.	Good hygienic practice: no food allowed in vicinity of open dispensers; cleaning & disinfection before further use.	1	1	1 - L	No
12	Refurbish	12.1	M	Contamination with pathogenic and/or spoilage micro-organisms during refurbishment.	Cleaning & disinfection before further use.				
			P	Contamination by foreign bodies during refurbishment.	Cleaning & disinfection before further use.	1	1	0 - L	No
			C	None	N/A	0	0	0	No

			A	Contamination with allergens due to contact during refurbishment.	Good hygienic practice: no food allowed in vicinity of open dispensers; cleaning & disinfection before further use.	1	1	1 - L	No

13. HACCP Pre-requisite Programmes

Ser.	Prerequisite	Hazards	Control Measures	Limits	Monitoring Procedures	Corrective Action
1	Good hygienic practice	Physical (foreign bodies). Microbiological (contamination and cross-contamination). Chemical (contamination). Allergen (contamination).	Hygiene procedures Cleaning & disinfection Customer guidance Safe handling and storage of chemicals Staff training.	Full compliance.	Quarterly audit of control procedures.	Extra cleaning. Refresher training.
2	Glass and Brittle Plastic control	Physical (foreign bodies).	Physical and chemical contamination control procedure including breakage procedure. Protected lights and windows in clean rooms.	No product contamination by glass or brittle plastic.	Monthly glass and brittle plastic audit. Quarterly audit and review of glass and brittle plastic control records.	Clean up breakage. Discard potentially contaminated product to waste.
3	Staff personal hygiene, including medical screening (fitness to work)	Physical (foreign bodies). Microbiological (contamination and cross-contamination.) Chemical (contamination). Allergen (contamination).	Training of staff in all relevant procedures. Annual and return-to-work screening questionnaire for staff. Questionnaire on entry for visitors.	Full compliance.	Quarterly check of training and health screening records.	Train or re-train staff as appropriate.
4	Staff training	Physical (foreign bodies). Microbiological (contamination and cross-contamination). Chemical (contamination). Allergen (contamination).	Training of staff in all relevant procedures.	Full compliance.	Quarterly check of training records.	Train or re-train staff as appropriate.
5	Supplier management	Microbiological (contamination). Chemical contamination (use of unsuitable materials). Physical (foreign bodies).	Use of approved suppliers only.	Full compliance.	Quarterly check of supplier approvals and compliance documents.	Change to approved suppliers.

Ser.	Prerequisite	Hazards	Control Measures	Limits	Monitoring Procedures	Corrective Action
6	Traceability	Microbiological (growth of micro-organisms). Chemical (contamination of water).	Practice recalls at least annually.	Successful practice recall.	Annual practice recall.	Review traceability, amend and retest recall procedure.
7	Building and Equipment Maintenance	Microbiological (contamination). Physical (contamination). Chemical (contamination).	Check building is satisfactory before starting work. Check equipment is satisfactory.	Full compliance.	Quarterly check of maintenance records and certificates of compliance.	Repair and update maintenance records.
8	Complaints management	Food safety – potential need to recall product. Quality – potential quality issue with product.	Complaints management procedure, including full investigation, corrective, and preventive actions.	Food safety complaints below 1 in 100,000 items delivered. Quality complaints below 1 in 10,000 items delivered.	Bi-monthly review of complaints records.	Corrective actions depend on results of investigation. Trends and root cause analysis used to develop preventive actions.
9	Vehicle maintenance	Microbiological (contamination and cross-contamination or growth due to temperature abuse). Physical (foreign bodies). Chemical (contamination).	Vehicle hygiene procedures. Vehicle maintenance schedules.	No product contamination. Vehicles clean. Maintenance completed on time.	Vehicle operating records maintained by drivers. Maintenance records held by Transport Manager. Quarterly review of vehicle operation records.	Re-clean vehicle. Correct vehicle faults.
10	Pest control	Physical (foreign bodies). Microbiological (contamination and cross-contamination). Chemical (contamination).	Pest control contract. Staff training.	Pest infestation treated in a timely manner.	Ongoing monitoring. Monthly review of pest control records.	Call pest control contractor. Discard potentially contaminated product to waste.

D) ANNEXES

Annex 1: EXAMPLE: COOLER INSTRUCTIONS FOR THE CUSTOMER

1. Instructions on siting the watercooler

Select the site according to the exclusion criteria specified below:

- Not outdoors or in direct sunlight.
- Not in a dusty, unventilated, or damp environment.
- Not on uneven or sloping surfaces or in the immediate vicinity of lavatories.
- Not in damp areas or in places where moisture may collect on the ground.
- Not in corridors, escape routes or on emergency exit staircases.
- Not immediately in front of a heater (it must be at least 20 cm away).
- Not in places where access for delivery and maintenance are difficult.
- Not in places without adequate cleaning facilities.
- Not in places where the watercooler cannot be adequately supervised, to prevent people tampering with the watercooler or using it incorrectly.
- Position the watercooler centrally and accessibly.

2. Installing and starting to use the watercooler

- Installation (and initial service) should be done by a qualified service engineer from the distributor company. The “use by” date on the bottle must be observed and any bottles exceeding this date removed from the cooler.

3. Changing the water container

- Change the container as soon as it is empty; this ensures that the water reservoir does not run dry.
- Remove the empty container.
- Peel off the safety seal from the new container.
- Clear the bayonet area, making sure that it is clean.
- Place the container upside down on the watercooler, sitting fully on the bayonet, until it drops into place.
- Check that water comes out of the taps.
- Each time the container is changed, make sure the taps are clean and the drip tray emptied.

4. Maintaining and inspecting the watercooler

- Watercoolers require periodic cleaning and disinfecting in accordance with WE Codes of practice.
- Keep the outside of the watercooler clean.
- Empty and clean the drip tray regularly.
- Have the watercooler serviced every 13 weeks.

5. Duties of the customer

- The customer also has a duty to take good care of a watercooler. Concluding a service package alone does not exempt the customer from this duty. Only water from an authorised company should be dispensed from the watercooler.

Annex 2: REGULATIONS AND STANDARDS

- Exploitation and Marketing of Natural Mineral Waters and Spring Waters, Directive 2009/54/EC
- Drinking Water (EU) 2020/2184 (recast 2021)
- Hygiene of Foodstuffs, Regulation (EC) No 852/2004
- Materials in Contact with Food, Regulations (EU) No 10/2011, (EC) 2023/2006, (EC) No 1935/2004, Directive No 78/142/EEC and Regulation No 1895/2005
- Availability and Use of Biocidal Products Regulation (EU) No 528/2012
- Concentration Limits, Labelling Requirements and Conditions for Using Ozone, Directive 2003/40/EC
- Conditions for the Use of Activated Alumina for the Removal of Fluoride from Natural Mineral Waters and Spring Waters, Commission Regulation (EC) No 115/2010
- General Principles and Requirements of Food Law and Procedures in Food Safety Regulation (EC) No 178/2002
- Electromagnetic Compatibility (EMC) Directive 2004/108/EC
- Use of Hazardous Materials and RoHS Directive 2002/95/EC, Decision 2005/618/EC, and Directive 2008/35/EC
- Monitoring Radioactivity in Bottled Water, Directive 2013/51/EURATOM
- Recycled Plastic Regulation (EU) 2022/1616.

Annex 3 VERIFICATION OF METHODOLOGIES

Watercoolers Europe
Standards and Technical Committee

Standard Methodology for The Examination of Microbiological Efficiency Of Water Cooler Sanitisation Methods & The Frequency of Sanitisation

Module One THE BIOFILM TEST
Effectiveness of Sanitisation Methods in Removing Biofilm

Module Two THE BIOFILM BUILD-UP TEST
Reduction in Frequency of Full Sanitisations

Module ThreeTHE CHALLENGE TEST
Effectiveness of Sanitisation Methods in Removing Pathogens

1. Description & Purpose

Module One - The Biofilm Test

The Biofilm Test is intended to allow manufacturers of water coolers to provide their customers with a method of cooler sanitisation (cleaning and disinfection) - also known as Full Sanitisation - that has been proven to work to WE standards.
This test determines microbial growth within coolers which have been naturally soiled (as opposed to those deliberately contaminated as in Module Three), whilst coolers are in typical use for a period of three months. The procedure is to test swabs taken from the water contact surfaces on 50% of the test samples before sanitisation and on the remaining 50% after the sanitisation process is complete. The test is a guideline to aid the selection of appropriate sanitisation methods utilising similar procedures to ones used in food production lines.

Module Two - The Biofilm Build-Up Test

The Biofilm Build-up Test is intended to provide manufacturers of water coolers, or of sanitisation products to be used with water coolers, a standard test procedure by which to verify claims that such coolers/products would, if used as specified by the manufacturer, allow water coolers to require fewer Full Sanitisations than stated in the WE Code of Practice (recommended 4, but minimum 2 per year), but not any less than 2 per year.

This test addresses bio-film build-up (the primary source of microbiological growth) and is to be performed on coolers which have been naturally soiled whilst in typical use. It is a swab indicator test intended to

demonstrate the effectiveness of a material, method, or product claiming to offer extended protection from bio-film development thereby minimising the opportunity for microbial growth.

Note: Although a reduction in Full Sanitisations from 4 to 2 may be indicated by a successful test result, Hygienic Maintenance visits to coolers must still be undertaken at 3 monthly intervals, which mean that the cooler is still visited 4 times a year.

Module Three – The Challenge Test

The Challenge Test is intended to allow manufacturers of water coolers to provide their customers with a method of cooler sanitisation (cleaning and disinfection) that has been proven to work to WE standards, even when a cooler is heavily contaminated with pathogenic bacteria.

This test involves the deliberate contamination of water coolers with "*Pseudomonas aeruginosa"* and the undertaking of a Full Sanitisation. Once the sanitisation is completed, the *Pseudomonas aeruginosa* is allowed to re-grow for period of 14 days in order to test the ability of the organism to re-contaminate the cooler after sanitisation. Water drawn from the cooler is tested, rather than an internal water contact surface being swabbed. The sanitisation method utilised, and the disinfectant used to undertake this test protocol may be different (i.e., more intensive) than that utilised in Module One.

2. SCOPE

The standard test procedures are aimed at:

- proving that an efficient sanitisation of the cooler under test is achievable when the manufacturer's instructions and recommended sanitisation methods are followed.
- easing the identification of causes, remedies and responsibilities concerning microbiological contamination of water coolers in the field.

3. BENEFITS OF STANDARDISED TEST METHODOLOGIES

Module One

Enables manufacturers to assess by themselves the efficacy of different methods of sanitisation and choose those most appropriate for their products.

Modules One and Two

Enable the assessment of the cleanliness of cooler water contact surfaces during normal use. For the user, this facilitates a review of the frequency and intensity of cooler sanitisations. It also allows comparison between different manufacturers' claims based on a common test methodology.

Module Two

Enables comparative assessment of new sanitisation methods and antimicrobial materials claimed to reduce the frequency of Full Sanitisation.

Module Three

Demonstrates, on both quantitative and qualitative basis that a pathogen infected water cooler can be successfully sanitised.

4. WE REQUIREMENTS

Module One

Under the WE Code of Practice water cooler manufacturers must provide their customers with at least one "proven" sanitisation method, tested to the WE-standardised test parameters detailed in Module One (or Module Three, see below).

Module One or Module Three are mandatory for WE Supplier Members manufacturing water coolers and for all exhibitors, whether WE members or not, intending to show such products at WE trade shows.

Module Two

This is mandatory for any Supplier Member manufacturing water coolers, equipment, or products.

claiming to reduce the frequency of sanitisation to less than the WE Code of Practice requirement.
who intend to show such products at WE Trade Shows.

Module Three

This module may be submitted by manufacturers instead of Module One as the mandatory Module for WE Supplier members, or by those intending to show at WE Trade Shows. Other than that, the Challenge Test is an optional test, except in those countries where the National Association's Code of Practice may require it.

Notes: **All Modules**
Testing and Certification indicating that products have attained the WE standards must be undertaken by approved and accredited third-party test facilities.

Certification does not imply, or grant, WE approval or endorsement of the product tested. Strict guidelines relate to the use of such Certification in advertising and marketing material.

Water cooler and equipment manufacturers who consider that they are unable to execute any of the Test Modules on their equipment or with their products, should submit an alternative proposal (before commencing any testing) to the Protocol Results Evaluation Sub-Committee of the WE Standards & Technical Committee (called forthwith the WE Protocol Evaluation Sub-Committee), who will determine if the alternative protocol is acceptable.

5. WATER CONTACT SURFACES IN COOLERS

A wide range of water cooler water contact models are available and generally fall into four main types:

Disposable reservoirs
Sanitisation is undertaken by the replacement of all water contact surfaces by new ones. The replacement items normally comprise of a mix of hard and soft plastics.

Removable reservoirs
Dispensing taps, reservoir and cooler head system may be removed for sanitising off-site and replaced with pre-sanitised components. Alternatively, the relevant components may be sanitised in–situ. Water contact surfaces are generally made of hard plastic or stainless steel.

Fixed reservoirs
These coolers are sanitised without the reservoir being dismantled. Reservoirs are of stainless steel or plastic. The taps and head system are plastic and are removable. The coolers may be returned to a depot for full sanitisation or be sanitised in-situ.

Direct Chill
These coolers can either chill water in a coiled metal tube passing through an ice bank or use such tubing to surround the reservoir. The amount of water in the cooler at any time is therefore only a few hundred millilitres rather than several litres as with other coolers. Access to the coil interior for cleaning can be difficult as can microbiological examination of the surfaces.

6. Sanitisation

A Full Sanitisation is defined as **Cleaning followed by Disinfection.**

A wide variety of methods are in use, many of which are not approved or recommended by manufacturers. This may lead to inadequate standards of cooler hygiene.
Additionally, except for a few trials, only a few studies have been undertaken to investigate the hygienic quality of coolers as they approach sanitisation, or immediately after. Similarly, there is little public data on the build-up of biofilm and acquisition of contamination by water coolers in the field.

Sanitisation Methods

A) Cleaning

The objective is to physically remove as much scaling and biofilm as possible. This can be by:

- Use of a descaler
- Use of a detergent
- Physical cleaning using brushes and/or cloths

Descalers are especially effective and simultaneously achieve a reasonable kill of bacteria, whilst cleaning hard to access areas.

B) Disinfection

Materials may include the use of:

- Chlorine compounds
- Hydrogen Peroxide (H_2O_2)
- Peracetic acid (PAA) and other Peroxides
- Ozone (including permanently fitted ozonation devices)
- Steam (including internal steam generating devices)
- Hot water

C) One Step Sanitisation

- Replacement by pre-sanitised or disposable components.

Methods claiming reduction of frequency of sanitisations

Equipment/materials claimed to reduce the need for Full Sanitisations below those specified in the WE Code of Practice of 4 per year include:

- Antibacterial plastics
- In-cooler heating devices
- In-cooler ozonation devices

NOTE: Use of antibacterial materials for water contact surfaces or ozonation devices must comply with any existing National legislation.

Methodology

Modules One & Two

Testing the performance of sanitising materials and methods is complicated by the fact that artificial soiling of the cooler's water contact surfaces in the laboratory does not necessarily reflect the degree of biofilm that would build up during 3 months of usage between successive cooler sanitisations in the field.

To reflect field conditions more accurately for the test protocol application, it is necessary to reproduce field use by testing coolers in a controlled environment under conditions that most reflect real field use. For Module One, this means a minimum 'soiling' period of 3 months before sanitisation is undertaken. For Module Two, testing to assess water coolers, materials or technology intended to give extended periods between Full Sanitisations, is required to run for a longer period – e.g., if it is intended to claim that the period between sanitisations can be extended to 12 months the biofilm test must be run for 12 months.

Note: even should the 12-month test show acceptable biofilm build-up, WE continues to recommend no less than 2 Full Sanitisations a year i.e. 1 every 6 months.

Another option for preparing coolers prior to testing is to have them collected after three months use in the field and brought, still wet, to the test facility. There, they are paired-up with control coolers in similar condition and tested with swabs. The swabs are then delivered to a third-party test facility.

Note: A representative of the appointed third-party test facility must observe the sanitisation and swabbing procedures to ensure compliance with the prescribed manufacturers' methodology.

Because the swab removes the bacteriological population of the surface being sampled, the same surface cannot be swabbed twice. For example, samples of tap cleanliness cannot be taken before and after from the same cooler. It is required that a large number of coolers is tested and important that the control coolers are tested before sanitisation and the sanitised coolers after.

Coolers with inaccessible waterways and taps may require testing to be destructive. As such, sufficient coolers need to be included in the trial to allow for this.

Note: All replacement water contact components used for sanitisation shall be supplied in sealed packs and only handled with clean disposable gloves by the person qualified to execute the sanitisation.

A) <u>Bottled Water to be used</u>

To represent the most challenging conditions for sanitisation, it is required that only commercially available un-ozonated bottled water with a calcium content in excess of 90mg/l and a minimum TDS (total dissolved solids) in excess of 150 mg/l and a Langelier Index (L.I.) ≥ +0.5 at 20°C is used for the tests.

NOTE: Purified (RO) water should not be used as this generally does not produce sufficient bio-film growth. Ozonated purified water is similarly unacceptable.

B) Coolers to be tested

a) Ensure the correct number of coolers
* 10 total Module One Soiling Option 1
* 20 total Module One Soiling Option 2
* 10 for each extended testing period in Module Two, i.e. 10 coolers tested (as in Module One) at 3 months, again at 6 months, and so on, if desired, to 9 or 12 months.

b) Coolers are to be Cold only or Cook & Cold cooler models only, supplied by the manufacturer, half to be used as control, half to be sanitised.

c) Coolers of different body types but identical water contact surfaces are classed as of the same model for these purposes.

d) More coolers may be required if tests are destructive or if directed by the WE Protocol Evaluation Sub-Committee.

C) Testing Facility

To be acceptable to WE, laboratories to be used must be NAMAS or similarly accredited and able to demonstrate an ability to undertake the test work required in the following areas:

e) Technical ability and experience.
f) Adequate space to store and test the number of coolers and bottles of water needed for the trials.
g) A test facility in Europe. If the facility is outside Europe, the laboratory must be approved by the WE Protocol Evaluation Sub-committee before testing begins.
h) Accredited by a national or internationally recognised authority to test for HPC at 22ºC and 37ºC in water or surfaces (e.g. NATA (Australia), AA (Austria), BELTEST (Belgium), INMETRO (Brazil), HKAS (China), CAI (Czech Republic), DANAK (Denmark), EAK (Estonia), FINAS (Finland), COFRAC (France), DACH or DAP, or DATech (Germany), ESYD (Greece), INAB (Ireland), ISRAC (Israel), SINAL (Italy), LATAK (Latvia), LA (Lithuania), RVA (Netherlands), LANZ (New Zealand, NA (Norway), PCA (Poland), IPAC (Portugal), RENAR (Romania), SAC/spring (Singapore), SNAS (Slovakia), SA (Slovenia), SANAS (South Africa), ENAC (Spain), SWEDAC (Sweden), SAS (Switzerland), TURKAK (Turkey), UKAS (United Kingdom) and A2LA (USA)).
i) Accreditation must be according to UNE-EN ISO/IEC 17025

C) Soiling of Coolers

Option 1: At Third Party Testing Facility

For each Module One trial, 10 coolers need to be soiled by simulated field-usage for at least 3 months. For Module Two, longer usage periods are necessary, and as one cannot use the same surface/cooler for swab testing twice, more coolers will be required – 10 for each test period.

- During this time, 250 ml of water is drawn from each tap of each cooler twice a day (in the morning and in the afternoon). During weekends and public holidays, it is acceptable that this regular dispensing is interrupted.
- The required number of newly sanitised coolers should be set-up in the test facility.
- The test facility should be heated to an ambient temperature of 20˚C minimum if the trial is run in winter.
- Each cooler should be clearly coded.
- For assessing sanitisation methods 50% of the coolers (controls) will be tested immediately before sanitisation and the remainder (the sanitised coolers) afterwards. Label accordingly.
- After testing the first ten coolers at three months to reach Module One results, remove them (test & control units) from the test cooler area, so that only the originally set-up unused coolers are tested for subsequent Module Two test periods. After testing at each test period in Module Two, all the test and control coolers used are to be removed from the test area.
- Each cooler should be loaded with an 18.9 or 19.0 litre bottle of the chosen bottled water.
- Each day 4 litres of water should be run-off to represent typical field use. Empty bottles must be replaced immediately.
- Test period frequencies depend on the design of the product or equipment being assessed and are to be determined in consultation with the WE Protocol Evaluation Sub-Committee.

OR

Option 2: At Distributor Premises
For Module One, cooler manufacturers may wish to test coolers soiled during actual field use rather than soiling the coolers at a testing facility. Before selecting this option, the manufacturer must submit their procedural proposal to the WE Standards/Technical Protocol Results Evaluation Sub-committee so they can determine the manufacturers' capability to monitor and control the large number of coolers to be handled at such a distribution depot for the desired test period.

Option 2: Soiling at Distributor Premises
If approved, the coolers would then be collected, sanitised, and swabbed at a distribution depot, still under the supervision of an independent third party associated with an acceptable test facility. This supervisor is to ensure correct swabbing, compliance with Protocol procedures and adherence to the manufacturer's recommended sanitisation method.

Important Note: Coolers must be collected from the field with water inside – the internal components should remain wet during transport to the distributor's sanitisation area and for any time they may sit there before testing begins. They should be paired-up with control coolers in a similar condition and tested as in the test facility, using swabs which are immediately delivered to the third-party test facility by a representative of that third party test facility.

The approved independent third party will monitor the handling and preparation of the appropriate numbers of control and to-be-sanitised coolers. They will personally swab the coolers and deliver the samples to a lab facility. The independent third party shall do so in conformity with all the procedures and requirements set out in this Protocol.

D) Controls

j) For the assessment of cooler sanitisation methods and products, a control cooler in an un-sanitised condition must be tested with each sanitised cooler tested.
k) Where new technologies are being tested, both the treated coolers and untreated control coolers must be tested. Both these coolers must be of identical model and water contact surface construction.
l) If the device being tested is fitted to both coolers it must not be switched on in the control cooler.
m) If antibacterial materials are being tested, then the control coolers must be of the same model but omitting the antibacterial materials for the water contact surfaces.

Note: The assessment of antibacterial materials must only be done with the materials incorporated into coolers. Testing of the materials alone is not acceptable.

E) Storage of Water

n) Bottled water used throughout the test period should be from the same source and supplier with no variability other than bottling date or production batch codes. Identical batch codes should be used simultaneously on all coolers under test and control.
o) Water should be stored in a cool dark place (15˚C-25°C), away from polluting or contaminating substances.

F) Sanitisation Guidelines

p) Sanitisation must be undertaken in accordance with the methodology and materials supplied by the cooler or device manufacturer.
q) Staff undertaking sanitisation must be trained by a qualified representative of the cooler manufacturer or the manufacturer must provide trained staff to undertake the sanitisation at the appointed time.
r) The third-party testing facility representative must supervise the sanitisation operation.
s) All replacement water contact components used for sanitisation shall be supplied in sealed packs and only handled with clean disposable gloves by the person qualified to execute the sanitisation.

G) Testing Procedure

t) Drain the cooler fully before commencing to take swabs. This is especially important for testing the taps.
u) Do not let the water contact surfaces dry out.

v) Choice of swabs: dry swabs of a reputable make must be used.
w) Swab areas thoroughly whilst rotating the swab.
x) Return each swab to its container immediately after sampling.

H) Areas to be swabbed

Key areas for testing on all cooler types are the bayonet or pin entering the bottle and the dispensing faucets.

1. Fixed and removable reservoir coolers

In the interests of conformity, the following areas should be swabbed for each cooler:

- The sides of the interior of the water reservoir. Swab an area of 100sq cm. (approx. 10 cm. x 10 cm.)
- Remove and disassemble the tap before swabbing. Swab the entire accessible tap interior including the outlet nozzle, closing mechanism and the interior up-stream of that.

2. Disposable water contact surfaces/water trails

- Remove the disposable reservoir/flexible container from the cooler:
- Disconnect the pipes leading to the taps or cut-off with a sterile blade.
- Cut open the disposable reservoir/flexible container with a sterile blade.
- Swab an area of 100 sq. cm (approx. 10cm. x 10 cm.)
- A 5 cm length of piping leading to the taps should be swabbed. If the piping comprises two separate shorter lengths combine these to give 5 cm in total. Include the full length of the outlet pipe material.
- Lay the piping on a flat microbiologically clean surface.
- Cut longitudinally down one side of the pipe using a sterile blade taking care not to cut through the opposite lower side.
- Open the piping and swab the entire exposed surface taking especial care if the piping interior is corrugated.
- Note by diagram or in writing the area of piping swabbed.

I) Other cooler Types

Methodology for other cooler types i.e., direct chill coolers may require the sacrificing of the cooler components to gain access to the areas to be swabbed. The procedure adopted will need to be approved by WE Protocol Evaluation Sub-Committee before the trial commences.

J) Culturing of **Swabs**

Swabs must be kept between 2ºC to 8ºC prior to culturing.
The time lapse between sampling and culturing must be the same for pre and post sanitisation samples and should not exceed 2 hours.

Step 1 Dip the swab in 10 mls of sterile diluent (¼ strength Ringers Solution).

Step 2 Agitate the swab well in the diluent for 2 minutes in a vortex mixer to release trapped bacteria.

K) Microbiological Enumeration

Step 3 Remove the swab from the diluent.
Step 4 Culture the diluent using Yeast Extract Agar (Unipath).
Step 5 Prepare serial decimal dilutions of the sample in quarter strength Ringers solution.
Step 6 Aseptically pipette 1 ml of each dilution into two sets of sterile empty Petri dishes.
Step 7 Mix about 20 ml of molten R2A Agar[17] (held at 45-50°C) into each dish, distributing the sample evenly by moving the dish with a gentle side to side and rotary action for about 10 seconds.
Step 8 Allow the medium to solidify, leaving lid slightly raised to allow excessive moisture to dispel.
Step 9 Incubate the inverted plates at 22 ± 2ºC for 72hrs and 37± 1ºC for 24 hours.
Step 10 Count the colonies on those plates showing 30 - 300 colonies.

L) Colony Counts

Express counts (TVC) as cfu/sq. cm of surface area:
i.e., count/ml obtained x volume of diluent ÷ area swabbed.

TVC Colony Count Example

Reservoir sides/disposable containers	100 sq. cm
Tap interior	30 sq. cm (approx.)
Piping	18 sq. cm per 5 cm length

Tap count/ml	10
Volume diluent	10ml
Area swabbed	30 sq. cm

TVC **Count per sq. cm = 10 x 10 ÷ 30 = 3.33 cfu/sq. cm**

Ma) Testing order - Module One

i) Swab 50% (min. five (5)) of the coolers (the control set) prior to sanitisation as detailed above.
ii) Sanitise the other five (5) coolers (the test set).
iii) Swab the sanitised coolers as detailed above.

Mb) Testing Order - Module Two

i) Swab both the control and 'treated' cooler samples at the same required time periods. (E.g. weekly, monthly, 3 monthly, 6 monthly, yearly etc.).

N) Assessment of Results

a) Plate counts from reservoir sides and taps must be noted separately.
b) Compare counts before and after for treated/untreated coolers.
c) There will be a wide range of results, but a clear trend will emerge.
Note: un-sanitised cooler surfaces may exhibit counts more than 5 million per sq. cm but much lower counts may also be found.

Module One – Surface Plate Count Standards

>1000 cfu /sq. cm -unsatisfactory
>500<1000 cfu/sq. cm - satisfactory
>10<500 cfu/sq. cm good
<10 cfu/sq. cm excellent
Assessment is based on all test cooler results.

Module Two – Surface Plate Counts Standards

There should be demonstrated a minimum 90% reduction of TVC counts/sq. cm at 22˚C for the tested surfaces compared with the untreated control surfaces at the end of the 3-month test period or at each control period for the longer assessment periods.

O) Submission of Results

Results from all test coolers with full details of the methodology used should be submitted to the WE Secretariat accompanied by full details and relevant accreditation(s) of the laboratory used. This information will only be examined by members of the WE Protocol Evaluation Sub-Committee and will be kept strictly confidential.

Methodology

Module Three: The Challenge Test

The Challenge Test involves contamination of coolers with "*Pseudomonas aeruginosa*" before undertaking sanitisation using a method provided by the cooler manufacturer. *Pseudomonas aeruginosa* is allowed to re- grow for a period after sanitisation to test the ability of the organism to continue to contaminate the cooler after the sanitisation. The water dispensed by the cooler is tested, rather than a swab of an internal water contact surface.

Module Three has been created to assure national and other regulatory authorities of the preparedness of the water cooler industry for any potential contamination crisis. The sanitisation methods recommended and sanitisation solutions to the contamination of coolers may be different and more intensive than those recommended in Module One.
The prescribed testing method is aimed at proving that pathogenic contamination of the cooler can be completely and absolutely eliminated from the model of cooler under test having applied to it the sanitisation method specified by the manufacturer.

To allow adequate time for the pathogenic micro-organism to develop a biofilm in each cooler, a simulation

of normal usage is maintained over a 14-day period. During this time 250 ml of water is drawn from each tap of each cooler twice a day (in the morning and in the afternoon). During weekends and public holidays, it is acceptable that this regular dispensing is interrupted.

The Pathogen: Pseudomonas aeruginosa

The chosen pathogen is *Pseudomonas aeruginosa* for the following reasons:

- Cultivation in water is easy and fast.
- Biofilm is formed.
- It is difficult to eliminate; so, if the sanitisation method works to eliminate it, an equivalent result can be expected with other pathogens.
- Detection by a qualified laboratory is easy.
- It is a common cause of water cooler contamination that makes media headlines in many countries.

Acceptable Strains

At the present time only one strain can be used, as with other strains tested to date, adequate biofilm growth did not occur within 2 weeks. The acceptable strain is:

- Nutrient Agar from Laboratorio Dr Oliver Rodés (LDOR), S.A. of El Prat de Llobregat in Spain, wild strain Collection SS40. (See report 19.5.05)

Unacceptable Strains

The following strains are NOT acceptable:

- Lenticule discs from the Health Protection Agency in Newcastle, UK NCTC10662 - Inadequate biofilm development (See report 14.12.05)
- Bio reference pastilles from the Institute Pasteur de Lille in France ATCC 9027 (CIP82118) - Inadequate biofilm development (See report 30.6.06)
- DIN norm strain ATCC 27853 from DIN norm 19636 (ref: water softeners) **-** Inadequate biofilm development (See report 26.7.06)

A) Bottled Water to be used.

a) Best biofilm development results were obtained by LDOR with a natural mineral water with more than 90mg of Calcium per litre. This specification is strongly recommended.

b) In order to represent the most challenging conditions it is recommended that commercially available un-ozonated bottled water with a calcium content more than 90mg/l, a minimum TDS (total dissolved solids) and in excess of 150 mg/l and a Langelier Index (L.I.) ≥ +0.5 at 20°C is used for the tests.

c) Before undertaking any tests, an analysis of the water to be used should be submitted to the WE Results Evaluation Subcommittee for their approval.

Note: Purified (RO) water should not be used as this generally does not produce sufficient biofilm. Ozonated purified water is similarly unacceptable.

B) Coolers to be tested.

a) Three (3) of each model of Cold only or Cook & Cold coolers supplied by the manufacturer.
b) Coolers of different body types but identical water contact surfaces are classed as of the same model for these purposes.

C) Testing Facility

To be acceptable to the WE, laboratories to be used must be:

a) accredited to UNE-EN ISO/IEC 17025
b) able to demonstrate an ability to undertake the test work required in the following areas:
    i) Technical ability and experience.
    ii) Adequate space to store and test the numbers of coolers and bottles of water needed for the trials.

iii) A test facility in Europe. If the facility is outside Europe, the laboratory must be approved by the WE Protocol Results Evaluation Sub-committee before testing begins.

c) accredited to do testing of *Pseudomonas aeruginosa* in water by a National or international body (e.g. NATA (Australia), AA (Austria), BELTEST (Belgium), INMETRO (Brazil), HKAS (China), CAI (Czech Republic), DANAK (Denmark), EAK (Estonia), FINAS (Finland), COFRAC (France), DACH or DAP, or DATech (Germany), ESYD (Greece), INAB (Ireland), ISRAC (Israel), SINAL (Italy), LATAK (Latvia), LA (Lithuania), RVA (Netherlands), LANZ (New Zealand, NA (Norway), PCA (Poland), IPAC (Portugal), RENAR (Romania), SAC/spring (Singapore), SNAS (Slovakia), SA (Slovenia), SANAS (South Africa), ENAC (Spain), SWEDAC (Sweden), SAS (Switzerland), TURKAK (Turkey), UKAS (United Kingdom) and A2LA (USA)).

D) Storage of Water

a) Bottled water used throughout the test period should be from the same source and supplier with no variability other than bottling date or production batch codes.
b) Identical batch codes should be used simultaneously on all coolers under test and control.
c) The water should be stored in a cool (15˚C-25°C) dark place, away from polluting or contaminating substances.

E) Sanitisation

a) This must be undertaken in accordance with the methodology and materials supplied by the cooler or device manufacturer.
b) Staff undertaking sanitisation must either be trained by a qualified representative of the cooler manufacturer, or the manufacturer must provide trained staff to undertake the sanitisation at the appointed time.
c) The third-party testing facility representative must supervise the entire sanitisation operation.
d) All replacement water contact components used for sanitisation shall be supplied in sealed packs and only handled with clean disposable gloves by the person qualified to execute the sanitisation.

F) Summary of Requirements

a) 3 Water coolers of each model to be tested.

b) 6 Bottles of water (3 to be contaminated).

c) 3 Supplementary bottle caps for the contaminated bottles.

d) Alcohol 70% (70°).

G) Testing

The test procedure module has 5 steps, described in more detail below:

Step 1: Prepare 3 (three) 19 litre bottles of water contaminated with *Pseudomonas aeruginosa.*

Step 2: Place the contaminated bottles on 3 coolers and simulating 14 days of field use.

Step 3: Sanitise the 3 coolers with a method specified by manufacturer.

Step 4: Place a new bottle on each cooler with water free of *Pseudomonas aeruginosa.*

Step 5: Test for absence of *Pseudomonas aeruginosa* in 250 ml water samples drawn from cooler taps.

Step 1: Preparing the Bottles

1.a The 19 litre bottles should be contaminated with a concentration between 10^4 to 10^5 cfu per inoculate, to reach a homogenised concentration in the bottle of ≥100cfu /250mL of *Pseudomonas aeruginosa*.

1.b The concentration of contamination (≥100cfu /250mL) must be submitted by the laboratory in order to compare the evolution of the contamination.

1.c Once the *Pseudomonas aeruginosa* has been introduced into each bottle, the bottle should be re-capped and the water contents fully homogenised.

Step 2: Contaminating Coolers

2.a Place one of the 3 contaminated bottles on each of the 3 coolers to be tested. To ensure that the contaminated water is in contact with all internal components 250 ml. of contaminated water should be drawn off from each tap.

2.b The coolers are NOT to be plugged into the electrical supply because the bacteria best develop at room temperature (20 to 30°C). If the taps require that the electrical supply is switched on to allow them to open, do this for only the minimum time required to open and draw-off water and then unplug the water cooler from the electrical supply.

2.c After a 3-day period, a *Pseudomonas aeruginosa* count performed on water samples drawn off from the cold tap of each of the 3 coolers. If necessary, the water cooler can be plugged into the electrical supply long enough to allow for this.

2.d The level of contamination of each water sample after 3 days must be at a minimum 100 cfu / 250 ml. If that level has not been attained, the water cooler must be re-contaminated (start with a new inoculated bottle and return to Step 1).

2.e Simulation of normal use is maintained for the period of 14 days by drawing off 250 ml samples of water from each tap of each cooler twice a day (in the morning and in the afternoon). During weekends and public holidays regular dispensing may be interrupted.

2.f On Day 14, a *Pseudomonas aeruginosa* count should be undertaken on water drawn from each tap of each of the 3 coolers.

2.g The level of contamination measured from samples taken from each tap after the 14-day period **must be at least the inoculation level** (≥100 cfu / 250 ml). This ensures the *Pseudomonas aeruginosa* is still vigorous. If the count reaches this level, proceed to Step 3.

2.h If the level of contamination after 14 days on a sample taken from any cooler is lower than the inoculation level, a new inoculation will have to be undertaken with a new contaminated bottle (i.e. return to Step 1 and repeat procedures to here). 24 hours after such a new inoculation, a *Pseudomonas aeruginosa* count must be done on each tap of the cooler. The count must be at least ≥100 cfu / 250 ml before you can proceed to Step 3.

Step 3: Sanitising as Specified by Manufacturer

3.a Undertake the sanitisation method specified by the manufacturer of the cooler. This sanitisation method must be the one specified in the manufacturer's manual supplied with the cooler when distributed to users or the method officially notified by the manufacturer to its clients.

3.b The sanitisation method should specify which cooler models (made by the same manufacturer) have been tested with, and therefore use, that sanitisation method.

3.c Laboratory staff undertaking sanitisation must either be trained by a qualified representative of the cooler manufacturer or the manufacturer must provide trained staff to undertake the sanitisation at the appointed time. Should the manufacturer's staff undertake sanitisation then qualified laboratory staff must supervise the operation.

3.d In case of any difference in the methodology of sanitisation between the written manufacturer's manual and the procedure applied, the manufacturer's manual must be modified accordingly, and a new manual distributed to all clients of the manufacturer.

Step 4: New Bottles Free of Pseudomonas aeruginosa

4.a Before the new bottles are placed on the test coolers, each bottle should be sampled and checked for the absence of *Pseudomonas aeruginosa* in 250 ml samples of the water. The test result must be less than quantification limit/250ml.

4.b The tested bottles with the absence of *Pseudomonas aeruginosa* must be immediately re-caped with the caps having previously been sterilised with alcohol 70º for a period of 10 minutes.

Step 5: Testing for Absence of *Pseudomonas aeruginosa* in 250 ml Samples

5.a Samples of water are drawn from each tap.

5.b Immediately after loading, the new bottles should be tested to be free of *Pseudomonas aeruginosa,* water samples of 250 ml should be drawn from each tap of the cooler and the absence of *Pseudomonas aeruginosa (t'$_0$)* verified. The test result must be less than quantification limit/250ml.

5.c Testing of samples drawn from the coolers should continue for a period of 14 days, in the same manner as in Step 2. Water samples must remain free of *Pseudomonas aeruginosa.*

H) Results Expected Module 3 - the challenge test

A pass is registered only when 12 results from each cooler under test are less than quantification limit/250ml on each tap at *t'$_0$* and *t'$_{14}$.*

WHERE *t'* means *Time &* *t'$_0$* and *t'$_{14}$* mean *Day One* and *Day Fourteen*

t'$_0$ and t'$_{14}$ ≥ quantification limit/250ml -FAIL

t'$_0$ *and t'$_{14}$* < quantification limit/250ml - PASS

Notes

Note 1: The test result will be valid for each model of cooler with identical water contact surfaces as the ones tested. "Identical models" is defined here as, "two different looking coolers whose surface materials and design of all parts in contact with water are the same".

Note 2: The test result will be valid only for the sanitising method tested for any Module of the protocol. Each new sanitising method would then have to be fully tested to be certified in the Module.

Note 3: The result of the level of contamination (≥100cfu /250ml) must be given by the laboratory in exact counts to compare the evolution of contamination. (≥100cfu /250m is not acceptable because it could be 10000000 or 101).

Note 4: Manufacturers, at their own discretion, may extend the test period in Step 5 from 14 to 21 days if they wish to demonstrate extended performance of their cooler and/or sanitisation method.

I) Submission of Results

Results from all test coolers with full details of the methodology used should be submitted to the WE Secretariat accompanied by full details and relevant accreditation(s) of the laboratory used. This information will only be examined by members of the WE Protocol Results Evaluation Sub-committee and will be kept strictly confidential.

Annex 3 document approved by the WE Board Meeting Sept. 22nd, 2006, Final Edition 1:1 May 2007

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