CAYMAN ISLANDS

DEPARTMENT OF

ENVIRONMENTAL HEALTH (DEH)

Guidelines for

The Production and Supply of Bottled Water in the Cayman Islands

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DEPARTMENT OF ENVIRONMENTAL HEALTH

Guidelines for the Production and Supply of Bottled Water in the Cayman Islands

These guidelines give advice to bottled water plant operators on how to comply with the requirements of the Department of Environmental Health for the safe processing, packaging, storage and supply of bottled water in the Cayman Islands. If you require further assistance with these Guidelines please call the Department of Environmental Health on 949 6696.

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International Bottled Water Association – http://www.bottledwater.org

PART 1 - INTRODUCTION

1.1 These Guidelines apply to all bottled water proprietary brands manufactured in the Cayman Islands.

1.2 Definitions of terms can be found in Appendix 4.

PART 2 – IDENTIFICATION OF STEPS CRITICAL TO WATER SAFETY

2.1 The Department of Environmental Health requires that:

Bottled water plant operators shall put in place, implement and maintain a permanent procedure or procedures based on HACCP (Hazard Analysis and Critical Control Point) principles.

2.2 The HACCP principles referred to above consist of the following:

(a) The identification of any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) The identification of the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) The establishment of critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(d) The establishment and implementation of effective monitoring procedures at critical control points;

(e) The identification of corrective actions to be taken when monitoring indicates that a critical control point is not under control;

(f) The identification of procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and

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

2.3 When any modification is made in the product, process, or any step, bottled water operators shall review the procedure and make the necessary changes to it.

For a detailed explanation of HACCP and further information refer to Appendix 1.

PART 3 – PRODUCT QUALITY AND SECURITY

3.1 WATER SOURCE

3.1.1 Water intended for bottling must be from a source approved by and meet the standard of quality as required by the DEH.

3.1.2 If treatment is necessary to reduce, remove or prevent growth of microbial contaminants, and to reduce or remove chemical, physical and/or radiological substances from water during processing, the finished bottled water product shall be safe and suitable for human consumption.

3.1.3 When necessary, treatment of waters intended for bottling, to reduce, remove or prevent growth of microbial contaminants, may include the application of chemical processes (such as chlorination, ozonation, carbonation) and physical agents or processes (such as high heat, ultraviolet radiation, filtration). These treatments can be used singly or in combination as multiple barriers.

3.1.4 When necessary, treatments to remove or reduce chemical substances may include:

- Chemical and particulate (mechanical) filtration such as achieved with surface filters (e.g. pleated membrane filters)
- Depth filters (e.g. sand or compressed fiber cartridge filters),
- Activated carbon filtration,
- Demineralization (deionization, water softening, reverse osmosis, nano-filtration),
- Aeration.

These treatments for chemicals may not adequately reduce or remove microorganisms and, likewise, treatments for microorganisms may not adequately reduce or remove chemicals and particulate matters.

3.1.5 All treatments of water intended for bottling should be carried out under controlled conditions to avoid any type of contamination, including the formation of by-products and the presence of residues of water treatment chemicals in amounts that raise health concerns.

3.1.6 Monitoring requirements for source water:

i. Daily in-house total coliform monitoring on source water. Daily in-house microbiological sampling and analysis shall be performed by qualified plant personnel.

ii. Total coliform analysis of source water at least once per week by an approved laboratory.

iii. Annual analysis for the residual disinfectant used (chlorine, chloramine, or chlorine dioxide).

iv. For chemical, physical, and radiological contaminants, analyze at least annually, in accordance with International Bottled Water Association (IBWA) Model Code Monitoring Requirements, 2005 Monitoring Matrix – see Appendix 2. In lieu of source monitoring required by this guideline, a plant operator using a public water system as its source may obtain or have available for inspection a certificate from said system demonstrating that the public water system conducts the monitoring required. All required chemical analysis shall be performed by an approved laboratory.

v. Records of sampling and analysis shall be maintained on file at the plant for not less than five years and shall be available for official review upon request by the DEH.

3.2 FINISHED PRODUCT QUALITY

3.2.1 All bottled water products shall meet the chemical, physical, and microbiological standard of quality prescribed by parameters attached as Appendix 2 (IBWA Model Code Monitoring Requirements, 2005 Monitoring Matrix).

3.2.2 All bottled water products shall be free of coliform bacteria, including E. coli. If any laboratory results indicate the presence of coliform organisms, the bottler shall immediately implement and comply with the Procedure for Response to Coliform and Escherichia Coli Testing Results described in Appendix 3 of these Guidelines.

3.2.3 Bottled water production, including transporting, processing, packaging, and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination of the finished product.

3.2.4 Monitoring requirements:

i. Daily in-house total coliform monitoring on finished product of each product type. Such analyses shall be performed daily by qualified plant personnel and at least weekly by an approved laboratory.

ii. Quarterly rinse/swab tests on containers (incoming as well as those immediately from the washer) and closures, performed by qualified plant personnel or by an approved laboratory.

iii. For chemical, physical, and radiological contaminants a representative sample from a batch or segment of continuous production run for each type of bottled drinking water produced by the plant must be analyzed at least annually in accordance with Appendix 2 – IBWA Model Code Monitoring Requirements, 2005 Monitoring Matrix. This analysis must be performed by an approved laboratory.

iv. Testing data records should be made available to the DEH inspection team on request. Methods and Standard Operating Procedures (SOP's) for in-plant microbiological testing must be approved by the DEH.

3.3 PRODUCT SECURITY

3.3.1 Bottled water plant operators shall adopt written policies and procedures designed to protect the integrity and security of their operations and products. The company's HACCP plans, as specified in Part 2 of these Guidelines (Identification of Steps Critical to Water Safety) shall address water safety and quality issues that affect the security of bottled water products. In addition, the bottled water plant operator must document other security measures, including but not limited to those addressing security of buildings, employees, materials, transportation, and products.

3.3.2 In support of the HACCP program, a sanitization standard operating procedure (SSOP) and other appropriate standard operating procedures (SOPs) shall be developed and maintained. Appropriate documents and records will be made available to DEH inspection staff on request.

3.3.3 Water intended for bottling shall not be stored, transported, processed, or bottled through equipment or lines used for milk, other dairy products, non-beverage foods, or any non-food product.

3.4 PRODUCT RECALL

3.4.1 Beyond processing and packaging, the companies' shall have a recall plan that shall address tracing and retrieval of product.

3.4.2 Each bottled water plant operator shall develop and maintain procedures for the notification of the DEH and consumers in the event of a product recall. The procedures shall be implemented as necessary with respect to any product for which the operator or DEH knows, or has reason to believe that circumstances exist that may adversely affect its safety for the consumer.

3.4.3 A bottled water operator who knows or has reason to believe that circumstances exist which may adversely affect the safety of bottled water, including but not limited to source contamination, spills, accidents, natural disasters, or breakdowns in treatment, shall notify DEH promptly. If DEH determines, based upon representative samples, risk analysis, information provided by the bottled water operator, and other information available, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, DEH may order the bottled water operator to initiate an approved level of product recall or, if appropriate, issue a form of notification to customers.

3.4.4 The bottled water operator shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem and where appropriate, may include radio and television media or to the newspaper, or alternatively directly notify affected users. Product recall plans shall be approved by the DEH.

3.4.5 In order to facilitate product identification or recall, each bottled water product shall contain a code that is designed to remain affixed to the container during use and which contains either the date of manufacture, or a lot or batch number.

3.4.6 Where the standard of quality has been exceeded but circumstances, including risk analysis and representative samples, indicate that the violation has been promptly corrected and that already-distributed product will not cause illness and presents no significant health risk, a recall and media notification of consumers is unnecessary. In such circumstances where a recall or media notification is unnecessary but where there may be significant consumer complaints of product taste or odor, the DEH may require the bottled water operator to communicate the extent of the problem and the implementation of corrective measures to affected customers.

3.4.7 It is strongly recommended that bottled water labels include the telephone number of the bottler, distributor, or brand owner. Bottlers may also include other forms of contact information, including but not limited to, the bottler's or brand owner's E-mail address or website.

3.5 QUALIFICATIONS AND LICENSING

3.5.1 A bottled water plant shall be operated under the supervision of a competent person qualified by experience, education, and training to operate and maintain the plant's facilities. Said person must hold a certificate from International Bottled Water Association (IBWA) or an applicable regulatory agency demonstrating that he or she has successfully passed the IBWA certified plant operator examination or an equivalent examination acceptable to IBWA, that covers periodic instruction and testing in plant, source, HACCP, and product sanitation, operation and maintenance of water treatment technology, and the maintenance and monitoring of source and product water quality in accordance with these applicable bottled water standards.

3.5.2 Suitably qualified officers from the Department of Environmental Health may inspect the premises at all reasonable times to ensure compliance with these Guidelines. They may take samples, documentation and any other evidence necessary to determine compliance.

PART 4 – GENERAL REQUIREMENTS FOR BOTTLED WATER PLANTS

4.1 GENERAL REQUIREMENTS

4.1.1 When a bottled water plant is to be constructed or extensively remodeled, or when an existing structure is converted for use as a bottled drinking water plant, properly prepared plans and specifications for such construction, remodeling or alteration shall be submitted to the Department of Environmental Health for approval before such work is begun. These plans shall include the layout, arrangement and construction materials of work areas, and the location, size and type of, and technical specifications for fixed equipment and facilities, plumbing, and water heating systems.

4.2 LOCATION

4.2.1 Bottled water plants shall be located in areas free from objectionable odours, smoke, flies, ash and dust or other contamination.

4.2.2 Adequate dust-resistant access ways for all vehicular traffic, connecting loading and unloading areas of the plant to the public streets, shall be available.

4.2.3 Employee parking areas and access roads adjacent to the food processing plant shall be hard surfaced with a binder of tar, cement, asphalt, or other approved material.

4.3 GENERAL PLANT LAYOUT

4.3.1 Product preparation and processing departments or areas shall be of sufficient size to permit the installation of all necessary equipment with ample space for plant operations and with unobstructed ways for conveyances of materials and processed products.

4.3.2 The plant shall be so arranged that there is a proper flow of product, without undue congestion or back-tracking, from receipt of the water for potable water production, through storage, production until the finished product is shipped from the plant.

4.3.3 Doors connecting various rooms or openings to the outside shall be tight-fitted, solid, and kept in a closed position by self-closing devices.

4.3.4 Packaging and labelling material shall be stored in a separately enclosed space convenient to the processing area. Packaging and labelling material shall not be stored in the product-processing area. Only those small quantities of such supplies as are necessary for maintaining continuity of operations will be permitted in the processing areas.

4.3.5 A separate, well ventilated room or area and proper facilities for cleaning equipment shall be provided in a location convenient to the processing area.

4.3.6 Loading/unloading areas shall be of adequate size, constructed of impervious materials and so drained as to minimize the entrance into the plant of dust, dirt and other contaminants from the receiving and shipping operations.

4.3.7 No food room, including bottled water production room and any bottled water storage facilities, shall be used as a sleeping place, and no sleeping place shall be used as a food room.

4.3.8 No food room, including bottled water production room and any bottled water storage facilities, which communicates directly with a sleeping place, shall be used for the handling of open food.

4.4 PLANT CONSTRUCTION

4.4.1 Floors shall be constructed of durable material, which is easily cleanable, and where necessary disinfect. They must be skid resistant. This will require the use of impervious, non-absorbent, washable and non-toxic materials.

4.4.2 Floors shall be sloped to a drain outlet.

4.4.3 Interior walls shall be capable of being easily cleaned. They shall have a smooth and washable surface applied to a suitable base.

4.4.4 Ceilings shall be of adequate height and constructed of smooth, washable material.

4.4.5 In processing areas, walls shall be light in colour so that any soiling is easily visible for cleaning.

4.4.6 Window ledges shall be sloped at least 45º to the interior to promote sanitation.

4.4.7 Plants shall be so constructed as to be rodent resistant.

4.4.8 All exterior window and door openings shall be equipped with effective insect and rodent screens. Where doors in outside walls of food handling areas are used for loading or unloading, "fly chaser" fans and ducts or other effective means shall be provided at such doors to prevent the entrance of insects.

4.4.9 Dressed lumber shall be used for exposed interior woodwork.

4.4.10 All exposed interior wood surfaces shall be finished with non-toxic finishes and shall be capable of being easily cleaned.

4.4.11 Hollow walls and partitions shall not be provided.

4.4.12 Waste product water must be capable of running to a suitable drainage system.

4.4.13 Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

4.5 LIGHTING AND VENTILATION

4.5.1 Suitable and sufficient means of lighting shall be provided in every food room, including processing rooms, bottling rooms, and in container washing and sanitizing areas.

4.5.2 Except in the case of a humidity-controlled or temperature-controlled chamber, suitable and sufficient means of ventilation shall be provided and maintained in every food room.

4.5.3 There shall be sufficient ventilation in each room and compartment thereof to prevent excessive condensation of moisture, control visible mould, control objectionable odours, and to ensure sanitary and suitable processing and operating conditions.

4.5.4 The ventilation system, which shall always flow from a clean to a dirty area, must prevent excessive heat, condensation, dust, steam, and remove odours and contaminated air. The discharge from the exhaust system, if used, shall be located well away from fresh air inlets into the plant.

4.5.5 Air sources for ventilation shall be designed and maintained to prevent the entrance of dust, dirt, insects, and other contaminating materials.

4.5.6 Where necessary, a satisfactory fan ducted to the atmosphere in a manner, which does not cause a nuisance to the neighbouring properties, shall be provided.

4.5.7 Light fittings shall be fitted with unbreakable (non-glass) diffusers or covers to prevent risk of contamination.

4.6 THE PROCESSING AND BOTTLING OF DRINKING WATER

4.6.1 The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors.

4.6.2 The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room or controlled environment.

4.6.3 All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package or transport product water.

4.6.4 All product water-contact surfaces shall be constructed such that cleaning and sanitizing can be adequately accomplished.

4.6.5 Storage tanks shall be of the type that can be closed and shall be adequately vented.

4.6.6 Sanitizing operations, including those performed by chemical means or by any other means such as circulation of steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area.

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

4.7 WATER SUPPLY – GENERAL REQUIREMENTS

4.7.1 The plant shall have an adequate supply of potable water.

4.7.2 Where a public system is available, connection must be made thereto; otherwise, the water shall be obtained from a supply meeting the requirements of the DEH.

4.7.3 If a non-potable water supply is necessary it shall not be used in a manner, which will bring it into contact with the product or product zone of equipment.

4.7.4 Hot and cold water in sufficient supply shall be provided for all plant clean-up needs. Hoses used for clean up shall be stored on racks or reels when not in use.

4.7.5 All plumbing shall be in compliance with the current edition of the Cayman Islands Plumbing Code.

4.8 HOT WATER SUPPLY

4.8.1 The hot water supply shall be sufficient to satisfy the continuous and peak hot water demands of the establishment.

4.8.2 For water bottling operations, in the absence of specific hot water usage figures for equipment, Table 4.8.2 shall be used to provide an approximation of the peak hot water consumption.

Table 4.8.2 – Hot Water Demand

Equipment	Hot Water Demand
Utensils sink - 18" x 18"	14 gal/compartment
Utensils sink - 24" x 24"	25 gal/compartment
Janitorial sink	15 gal/sink
Hand wash sink	5 gal/sink
Pre-rinse sink	45 gal/sink
Showers	20 gal/shower
Garbage can wash	15 gal/facility
Customized sinks	Cu ft x 7.5 gal/compartment

4.8.3 A water heater shall be provided which is capable of generating an adequate supply of hot water, at a temperature of at least 120° Fahrenheit, to all sinks, janitorial facilities, and other equipment and fixtures that use hot water, at all times.

4.8.4 All hot water generating equipment shall conform to internationally recognized standards. The manufacturer's specification sheets shall be consulted for hot water supply requirements.

4.8.5 Water heaters and their installation must be in compliance with all local building code requirements.

4.8.6 In order to determine the required capacity and recuperative rate of the hot water generating equipment it will be necessary to calculate both the demand in gallons per hour (GPH) and temperature rise required (assume an incoming water temperature of 70°F to the food establishment unless specific data are available) for each piece of equipment.

4.8.7 Where feasible, water heaters shall be located in an area of the food facility separated from all food and utensil handling areas.

For further information on the sizing requirements for storage water heaters, instantaneous heaters and recirculation pumps please contact the Engineering and Development Control Section of the Department of Environmental Health (Tel: 949 6696).

4.9 WASHING FACILITIES

4.9.1 There shall be provided and maintained suitable and sufficient sinks or other facilities (not being wash hand basins) for washing equipment used in the production of bottled water.

4.9.2 For every such sink or other facility there shall be provided and maintained an adequate supply either of hot and cold (or appropriately mixed) water.

4.9.3 All sinks and other facilities available for the said purposes shall be kept clean and in efficient working order.

4.10 HAND WASHING FACILITIES

4.10.1 A separate hand-washing sink; hand drying device, or disposable towels; supply of hand cleaning agent; and waste receptacle shall be provided for each bottled water production area.

4.10.2 Hand-washing sinks shall be easily accessible. A hand wash sink shall be located within 25 feet of bottling and filling equipment.

4.10.3 Hand-washing sinks may not be used for purposes other than hand washing.

4.10.4 Each hand-washing sink shall be provided with hot and cold water tempered by means of a mixing valve or a combination faucet to provide water at a temperature of at 120°F.

4.10.5 Any self-closing, slow-closing or metering faucet shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

4.10.6 Splash from a hand wash sink must not contaminate product-water, equipment or utensils. Splashguard protection is required if adequate spacing is insufficient to adjoining equipment, product-water contact surfaces, and/or utensil washing area surfaces used for the production of bottled water.

4.11 SANITARY FACILITIES

4.11.1 No fresh air intake of any ventilation pipe included in the soil drainage system of food premises shall be situated in a food room.

4.11.2 Every inlet into such system situated in any such room shall be trapped.

4.11.3 No cistern for the supply of water in a food room shall supply a sanitary facility otherwise than through an efficient flushing cistern or some other flushing apparatus equally efficient and suitable for the prevention of contamination of water supplies.

4.11.4 All food premises shall be provided with minimum sanitary facilities in accordance with Table 4.1. These facilities shall be located in a position conveniently accessible to patron and food handlers.

Table 4.1 - Minimum Number of Sanitary Fixtures

Water Closets		Urinals		Lavatories	
Persons	**Fixtures**	**Persons**	**Fixtures**	**Persons**	**Fixtures**
1 – 50	1	1 – 50	1	1 – 150	1
51 – 100	2	51 – 200	2	151 - 200	2

4.11.5 Every sanitary facility designed and situated on any food premises shall be kept clean in efficient order.

4.11.6 Every sanitary facility shall be so placed that no offensive odour there from can penetrate into any food room. This includes bottled water production room and any bottled water storage facilities.

4.11.7 Any room or other place, which contains a sanitary facility shall be suitably and sufficiently lighted and ventilated.

4.11.8 No room or other place, which contains a sanitary facility, shall be used for the production or storage of bottled water.

4.11.9 No room, which contains a sanitary facility, shall communicate directly with a room used for the production or storage of bottled water.

4.11.10 No room, which contains a sanitary facility, shall be used for the cleaning of equipment in any bottled water plant.

4.11.11 There shall be affixed and maintained in a prominent and suitable position near every sanitary facility used by staff within the bottled water plant a clearly legible notice requesting users to wash their hands after using a facility.

4.11.12 A supply of water sufficient in quantity to adequately supply the sanitary facilities shall be provided and maintained in all bottled water plant.

4.11.13 Any supply of water provided for the said purposes shall be clean and wholesome.

4.11.14 All hand-washing sinks within sanitary conveniences shall have an adequate supply of hot and cold running water.

4.11.15 A separate hand-washing sink; hand drying device, or disposable towels; supply of anti-bacterial hand cleaning agent shall be provided for sanitary convenience.

4.11.16 Each set of sanitary facilities shall be fitted with at least one approved container for the storage of solid waste.

4.12 FIRST AID EQUIPMENT AND LOCKER FACILITIES

4.12.1 Suitable and sufficient bandages, dressings and antiseptic for first-aid treatment shall be provided and maintained in all food premises, in a readily accessible position, for the use of persons engaged in the handling of food on those premises.

4.12.2 Suitable and sufficient cupboard or locker accommodation shall be provided and maintained for the clothing and footwear not worn during working hours of all persons engaged in the handling of water, both source-water and product-water.

4.13 CONTROL OF PESTS

4.13.1 Birds, rodents, insects, frogs and lizards and other animals shall be excluded from the plant. Effective measures for the control of pests shall be maintained at all times.

4.13.2 To exclude rodents, space around doors and windows shall not exceed 1/8 inch. Wooden sills and doors at ground level must be sheeted in 26-gauge or heavier sheet metal.

4.13.3 All openings, vents, or holes entering into the storage area larger than 1/4 inch shall be closed or covered (including gratings around all piping, wire conduits, beams, and fire walls) with either 26-gauge or heavier sheet metal, 1/4 inch mesh hardware cloth or neat cement as required to make rat-proof.

4.13.4 When a woven wire enclosure is required within a storage area for security purposes, tubular steel will not be utilized for support posts.

4.13.5 Insecticides and rodenticides, if used, shall be only those for which the Environmental Protection Agency or United States Department of Agriculture Publication has issued regulations prescribing safe use condition.

4.13.6 Pesticides used within any portion of the plant and storage buildings must be labeled for use in a food establishment and applied in strict accordance with label instructions. They shall be employed by approved methods and handled in a safe manner.

4.13.7 All insecticides and rodenticides shall be stored in a separate room away from food storage and processing areas.

4.14 WASTE HANDLING AND ACCUMULATIONS

4.14.1 Waste and other refuse must not be allowed to accumulate in any bottled water production area or storage area, except so far as is unavoidable in the proper functioning of the business.

4.14.2 Waste and other refuse must be deposited in closable containers. These containers must be of an appropriate construction, kept in a sound condition, and be easy to clean and disinfect.

4.15 PERSONAL HYGIENE

14.5.1 Every person working in a bottled water operating plant shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where appropriate, protective clothing.

14.5.2 There must be no smoking, eating or drinking in the production areas.

14.5.3 No person, known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through product-water shall be permitted to work in any bottled water production area or any other area where there is any likelihood of directly or indirectly contaminating product-water with pathogenic microorganisms.

4.16 STAFF TRAINING

4.16.1 All operatives involved in the production and handling of bottled water shall be trained and/or supervised and instructed in food hygiene matters commensurate with their work activities.

APPENDIX 1

Explanatory notes for Hazard Analysis Critical Control Point (HACCP) systems

What is HACCP?

HACCP stands for 'Hazard Analysis Critical Control Point'. It is an internationally recognized and recommended system of food safety management that identifies where hazards might occur in the production of bottled water and puts into place control measures to prevent those hazards from occurring. By strictly monitoring and controlling each step of the process, there is less chance for hazards to occur.

HACCP is particularly appropriate to the bottled water industry and is most effectively applied through a multi-disciplinary team.

It is being adopted by an increasing number of countries to ensure that the food and drinks industry take proper precaution in their production of products for the consumer. The National Academy of Sciences, National Advisory Committee for Microbiological Criteria for Foods, and the Codex Alimentarius have endorsed HACCP as the best process control system available today.

Why is HACCP Important?

HACCP is important because it prioritizes and controls potential hazards in food production. By controlling major food risks, such as microbiological, chemical and physical contaminants, the industry can better assure consumers that its products are as safe as good science and technology allows. By reducing food/water borne hazards, public health protection is strengthened.

What are the Advantages of HACCP?

HACCP offers a number of advantages. Most importantly, HACCP:

- focuses on identifying and preventing hazards from contaminating food;
- is based on up-to-date technological information;
- permits more efficient and effective government oversight, primarily because the recordkeeping allows investigators to see how well a firm is complying with food safety laws over a period rather than how well it is doing on any given day;
- places responsibility for ensuring food safety appropriately on the food manufacturer or distributor;
- helps food companies compete more effectively in the world market;
- reduces barriers to international trade.

How to do a HACCP Study?

The next stage is to carry out the actual HACCP study, which involves working through a logical sequence of tasks and as described below:

1. Assemble a HACCP Team

   The successful application of HACCP requires the full commitment and involvement of management and the workforce. By involving a team of people, a greater diversity of skills and knowledge appropriate to the product will be available. Where the necessary expertise is not available on site, expert advice should be obtained from other sources.

2. Define the Terms of Reference

   Identify the process to be looked at e.g. the production and supply of bottled water to consumers within the Cayman Islands, and the limits of the study e.g. will all hazards microbiological, chemical and physical be

looked at as a whole, or will each type of hazard be considered individually? Each process stage is studied individually e.g. distillation, ozonation, filling, capping.

3. Describe the Product and Identify the Intended Use

A full description of the product should be drawn up including information on composition and the method of distribution. Identify the consumer target group for the product.

4. Construct a Flow Diagram

Draw a flow diagram of all aspects of the food operation, from raw materials, through processing to packing, storage and distribution. An example is given in Appendix 1a. Details of each step of the operation must be addressed. It is vitally important that this diagrammatic plan provides an accurate representation of the process, as it forms the basis for the HACCP study.

5. List All Hazards Associated With Each Step And Consider Any Preventative Measures To Control The Hazard (Principle 1).

Make a list of all the microbiological, chemical and physical hazards that may reasonably be expected to occur at each step. Describe the preventative measures that can be used to control these hazards. More than one preventative measure may be required to control a specific hazard.

Examples of Hazards

a) Microbiological Hazards
- Pathogenic Bacteria - presence, contamination, survival, growth
- Parasites and Protozoa
- Viruses
- Moulds

b) Chemical hazards
- Raw materials e.g. - pesticides, microbial toxins, natural toxins, allergens
- Packaging e.g. - plasticizers, ink/adhesive
- During process e.g. - cleaning agents, lubricants, hydrocarbon, pest control, allergens, fumes/dust, microbial toxins

c) Physical Hazards
- People e.g. - buttons, teeth, hair, jewellery, paper clips, matchsticks,
- Natural e.g. - material bone, nut shells, seeds, fruit stones
- Environment e.g. - glass, wood, metals, chips from tiles, gaskets
- Equipment – nuts, bolts, screw, rusting metal flakes, plastic
- Pests e.g. crawling insects, frogs, lizards, mice

6. Identify the Critical Control Points (Principle 2)

The identification of a Critical Control Point (CCP) in the HACCP system is facilitated by the application of a Decision Tree (see Appendix 1b). Application of the Decision Tree determines if the step is a "critical" control point for the identified hazard.

If a hazard has been identified at a step where control is necessary for safety and no preventative measure exists at that step, or any other steps, then the product or process must be modified at that step, or an earlier or later stage, to include a preventative measure.

7. Establish Critical Limits for each CCP (Principle 3)

Critical limits should be specified for each preventative measure. Criteria often used include measurements of time, temperature, concentration of disinfectant agent, pH, absence of metal, microbiological limits, sensory parameters e.g. visual appearance and texture etc.

8. Establish a Monitoring System for each CCP (Principle 4)

Monitoring is a planned sequence of observations or measurements of a CCP target level and tolerance. Monitoring must be able to provide confidence in the established controls, be able to detect any loss of control and enable timely corrective action. Typical monitoring methods include visual evaluations, physical measurements e.g. temperature, chemical analysis, and microbiological assessment.

Records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official of the company.

If monitoring is not continuous, then the amount of frequency of monitoring must be sufficient to guarantee the CCP is under control.

9. Establish Corrective Action (Principle 5)

Specific corrective actions must be developed for each CCP in order to deal with any deviations. The action must ensure the CCP is brought under control and include details of what to do with affected product.

10. Validate the HACCP System (Principle 6)

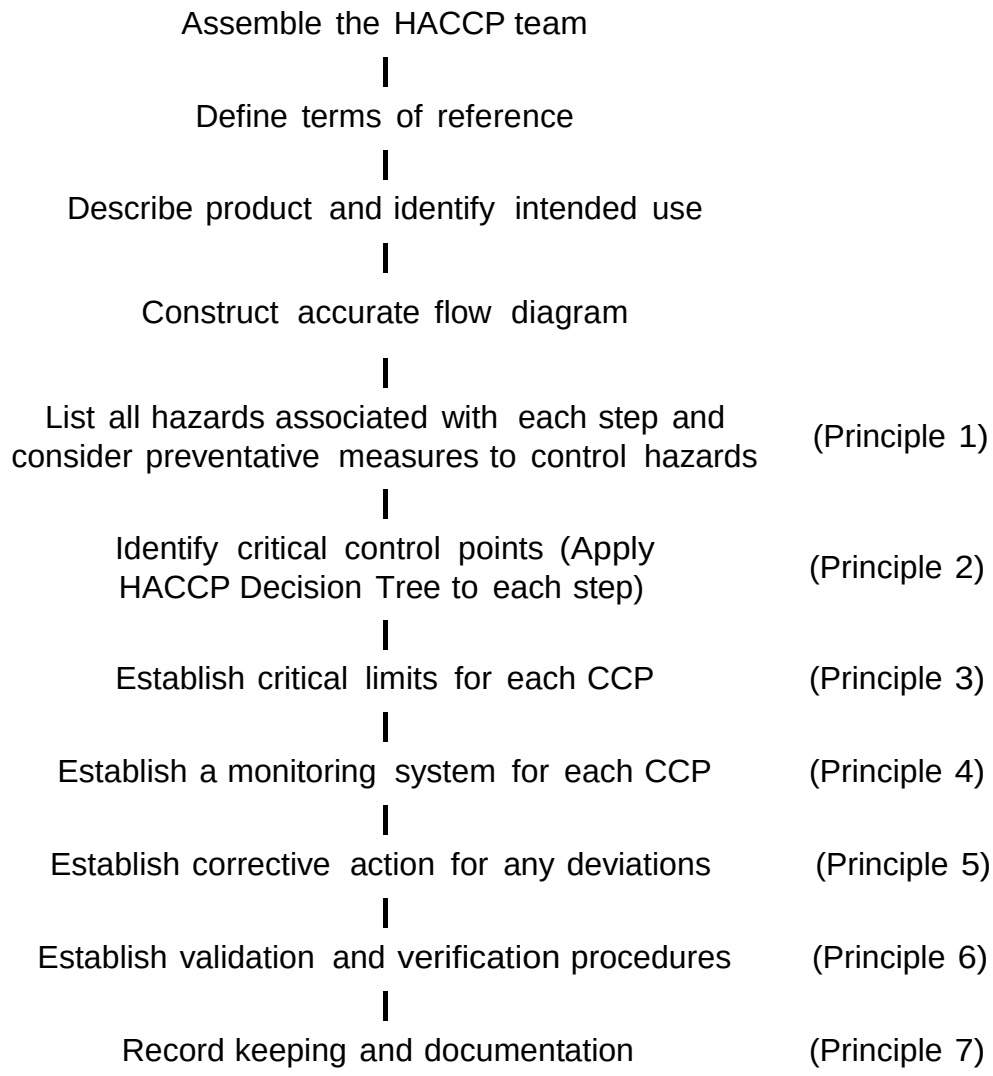
Monitoring and auditing should be carried out to determine if the system is working correctly. Examples include a review of the HACCP system and its records, review of deviations, checks to ensure CCPs are under control, validation of established critical limits etc.

Validation helps to maintain confidence in the system, identifies areas for improvement and provides documentary evidence of due diligence in managing food safety.

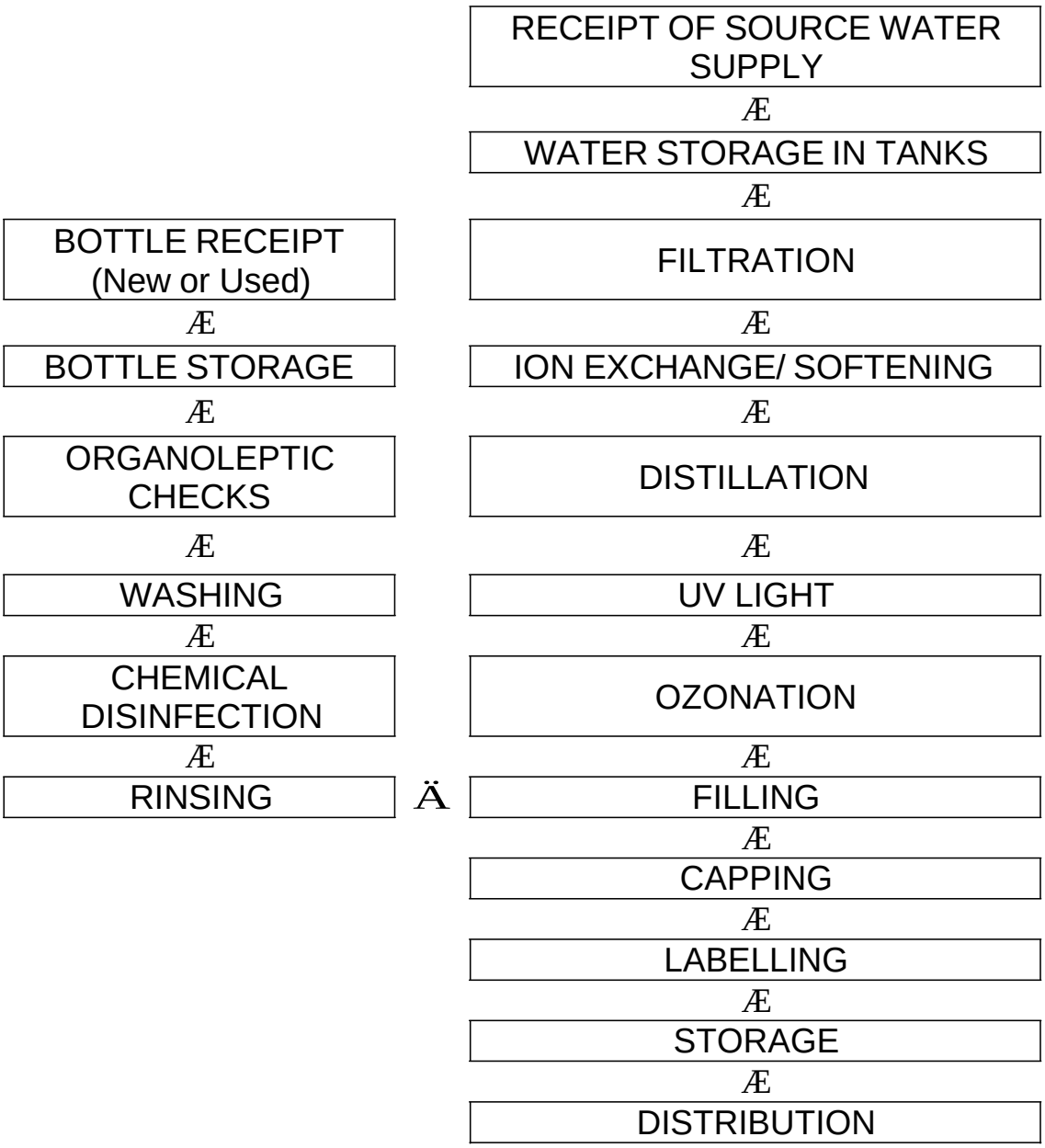
11. Establish Record Keeping and Documentation (Principle 7)

In order to be efficient and effective, the keeping of records is essential. Such records help to illustrate compliance with these Guidelines and are important in establishing a due diligence defence. An example of a HACCP chart is given in Appendix 1c. Each process step as documented in the flow diagram must be detailed in the HACCP chart and the controls, monitoring, corrective actions etc determined accordingly. This will ensure that the hazards at each process step are duly considered and controlled. These records must be reviewed periodically e.g. annually or when there is a significant change in operation.

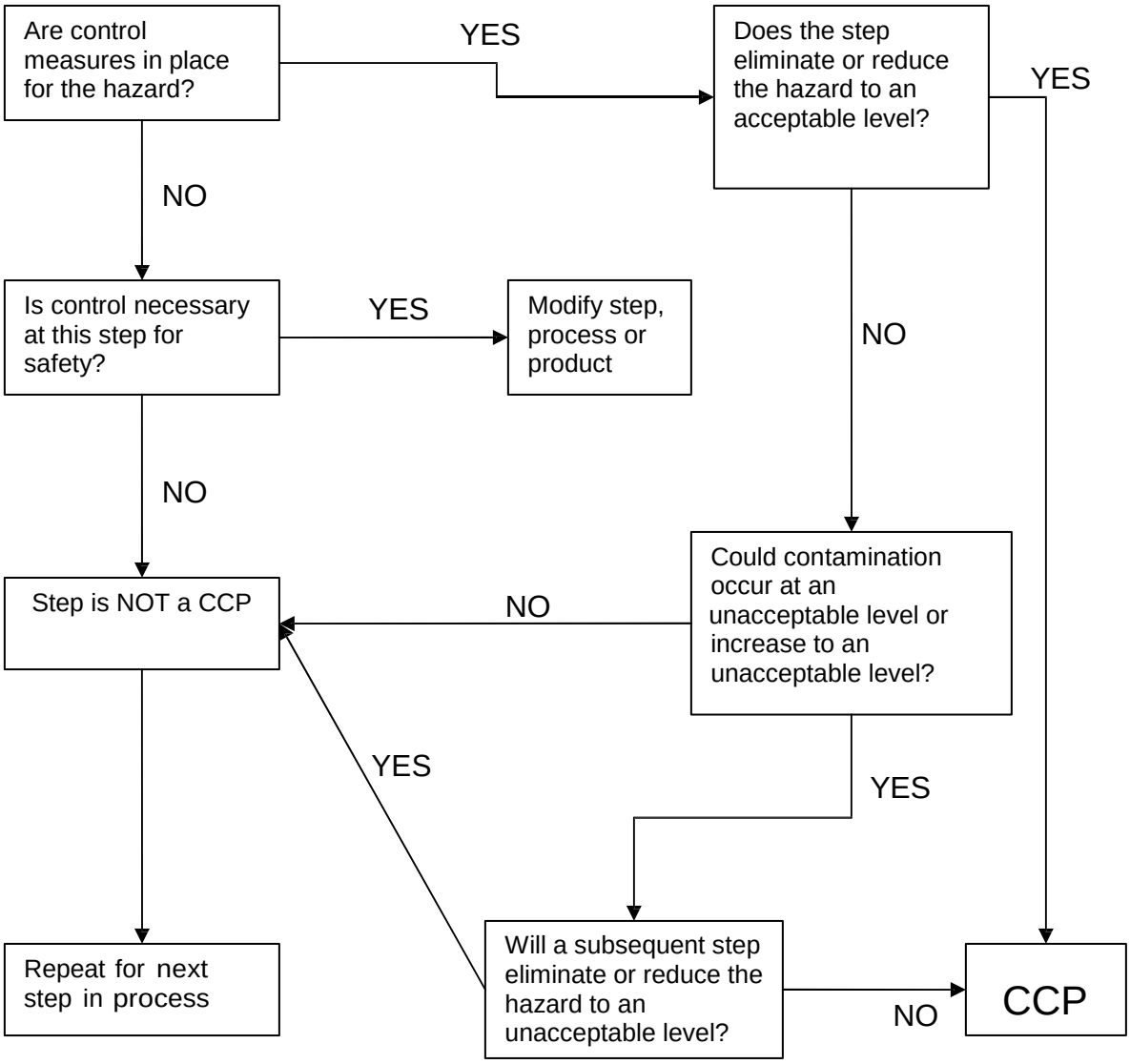
Therefore, the HACCP process can be summarized as follows:



APPENDIX 1a - EXAMPLE PRODUCT FLOW DIAGRAM FOR NON-CARBONATED BOTTLED WATER PRODUCTION



APPENDIX 1b – HACCP Decision Tree: Identification of Critical Control Points (CCP's)



Appendix 1c - SAMPLE HACCP CHART FOR BOTTLED WATER

PROCESS STEP	HAZARD	CONTROL	MONITORING & FREQUENCY	CRITICAL LIMIT	PERSON RESPONSIBLE & CORRECTIVE ACTION	RECORDS USED
You must provide information on each hazard, controls, monitoring, critical limit, corrective action etc at every process step e.g. water source, storage, softening, distillation, UV/ ozonation, filling, capping, labelling, bottle rinsing etc. Below are two examples.						
Example HACCP for step regarding FILLING OPERATION only						
FILLING	Microbiological contamination	Cleaning In Place (CIP) at specified frequency Quality of rinsing water Quality of filling water Flushing at start-ups	Micro sampling at daily weekly intervals CIP as per Cleaning schedules Quarterly swabs	In accordance with DEH Micro. Guidelines/ IBWA	Supervisor – stop production – inform manager & investigate cause	Cleaning Schedules/ Production Records/ Sampling Records
	Chemical Contamination	Thorough rinsing following CIP program Stainless steel or other non-tainting construction of equipment	Chemical/ organoleptic checks	Flushing times in accordance with Standard Operating Procedure	Supervisor/ Manager	Cleaning Schedules
	Physical/ Foreign Body Contamination	Protection of empty rinsed bottles Visual checks of equipment prior to start-up	Prior to start-up and after every break in production	Visually clean	Supervisor – clean up prior to production start	Production Records/ Maintenance records
Example HACCP for step regarding CAPPING OPERATION only						
CAPPING	Microbiological contamination	Ensure caps are kept wrapped and sealed. Remove from capping machine at end of every batch.	Visual checks before production starts and prior to restart of operation	Visually clean	Supervisor – stop production – inform manager & investigate cause	Daily Production record
	Chemical Contamination	All chemicals are stored in sealed containers in the locked chemical store located away from the cap storage area or processing area	Visual/smell tests before production starts and prior to restart of operation	Chemicals absent form storage and processing area	Supervisor – stop production – inform manager & investigate cause	Daily Production record
	Physical / Foreign Body contamination	Ensure caps are kept wrapped and sealed. Visual checks No pests allowed in production or storage area – see pest control policy	Visual checks before production starts and prior to restart of operation	Visually clean	Supervisor – stop production – inform manager & investigate cause	Daily Production record

APPENDIX 2
International Bottled Water Association (IBWA) Model Code Monitoring Requirements, 2005 Monitoring Matrix

Appendix 2
2005 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Inorganic Chemicals (IOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Antimony (1)	(Product and Source)	0.006	0.006	0.006
Arsenic		0.01	0.05	0.05
Barium	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	1	2	2
Beryllium (1)		0.004	0.004	0.004
Bromate (2)		0.010	0.010	0.010
Cadmium		0.005	0.005	0.005
Chlorine (2)		0.1	4.0	4.0
Chloramine (2)		4.0	4.0	4.0
Chlorine dioxide (2)		0.8	0.8	0.8
Chlorite (2)		1.0	1.0	1.0
Chromium		0.05	0.1	0.1
Cyanide (1)		0.1	0.1	0.2
Fluoride		(3)	(3)	4
Lead		0.005	0.005	0.015 AL
Mercury		0.001	0.002	0.002
Nickel (1)		0.1	0.1	
Nitrate-N		10	10	10
Nitrite-N		1	1	1
Total Nitrate + Nitrite		10	10	10
Selenium		0.01	0.05	0.05
Thallium (1)		0.002	0.002	0.002
Secondary Inorganic Parameters	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**SMCL (4)**
Aluminum	(Product and Source)	0.2	0.2	0.2
Chloride (5)		250	250	250
Copper		1	1	1
Iron (5)		0.3	0.3	0.3
Manganese (5)		0.05	0.05	0.05
Silver		0.025	0.1	0.1
Sulfate (5)		250	250	250
Total Dissolved Solids (TDS) (5)		500	500	500
Zinc (5)		5	5	5
Volatile Organic Chemicals (VOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
1,1,1-Trichloroethane	(Product and Source)	0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.002	0.007	0.007
1,2,4-Trichlorobenzene		0.009	0.07	0.07
1,2-Dichloroethane		0.002	0.005	0.005
1,2-Dichloropropane		0.005	0.005	0.005
Benzene		0.001	0.005	0.005
Carbon tetrachloride		0.005	0.005	0.005
cis-1,2-Dichloroethylene		0.07	0.07	0.07
trans-1,2-Dichloroethylene		0.1	0.1	0.1
Ethylbenzene		0.7	0.7	0.7
Methylene chloride (Dichloromethane)		0.003	0.005	0.005
Monochlorobenzene		0.05	0.1	0.1
o-Dichlorobenzene		0.6	0.6	0.6
p-Dichlorobenzene		0.075	0.075	0.075
Haloacetic Acids (HAA5) (2)		0.06	0.06	0.06
Styrene		0.1	0.1	0.1

(1) Included in FDA's 9 contaminant regulations.
(2) Included in FDA's D/DBP rule. See D/DBP monitoring requirements section on page 21 in Appendix A for details.
(3) SOQ dependent upon temperature and other factors. See fluoride section on page 22 of Appendix A for details.
(4) SMCL = Secondary maximum contaminant level. SMCLs are guidelines established by the USEPA for use in evaluating aesthetic, non-health-related properties in water. SMCLs are not enforceable for public water systems.
(5) Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix 2
2005 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Volatile Organic Chemicals (VOCs) (Continued)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Tetrachloroethylene	(Product and Source)	0.001	0.005	0.005
Toluene		1	1	1
Trichloroethylene	For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.001	0.005	0.005
Vinyl chloride		0.002	0.002	0.002
Xylenes (total)		1	10	10
Bromodichloromethane		(6)	(6)	(6)
Chlorodibromomethane		(6)	(6)	(6)
Chloroform		(6)	(6)	(6)
Bromoform		(6)	(6)	(6)
Total Trihalomethanes (2)		0.01	0.08	0.08
Semivolatile Organic Chemicals (SVOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Benzo(a)pyrene	(Product and Source)	0.0002	0.0002	0.0002
Di(2-ethyhexyl)adipate		0.4	0.4	0.4
Di(2-ethyhexyl)phthalate		0.006	NA	0.006
Hexachlorobenzene		0.001	0.001	0.001
Hexachlorocyclopentadiene		0.05	0.05	0.05
Total Recoverable Phenolics		0.001	0.001	NA
Synthetic Organic Chemicals (SOCs)	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
2,4,5-TP (Silvex)	(Product and Source) (unless otherwise noted)	0.01	0.05	0.05
2,4-D (Dichlorophenoxy acetic acid)		0.07	0.07	0.07
Alachlor		0.002	0.002	0.002
Aldicarb		0.003	NA	0.003
Aldicarb sulfone		0.003	NA	0.003
Aldicarb sulfoxide		0.004	NA	0.004
Atrazine		0.003	0.003	0.003
Carbofuran		0.04	0.04	0.04
Chlordane		0.002	0.002	0.002
Dalapon		0.2	0.2	0.2
Dibromochloropropane (DBCP)		0.0002	0.0002	0.0002
Dinoseb		0.007	0.007	0.007
Dioxin (2,3,7,8-Tetrachlorodibenzo-p-dioxin) (1)(7)	Product: Every 3 years Source: Annually	$3x10^{-8}$	$3x10^{-8}$	$3x10^{-8}$
Diquat (1)(7)		0.02	0.02	0.02
Endothall (1)(7)		0.1	0.1	0.1
Endrin	ANNUALLY (Product and Source)	0.002	0.002	0.002
Ethylene dibromide		0.00005	0.00005	0.00005
Glyphosate (1)(7)	Product: Every 3 years Source: Annually	0.7	0.7	0.7
Heptachlor	ANNUALLY (Product and Source)	0.0004	0.0004	0.0004
Heptachlor epoxide		0.0002	0.0002	0.0002
Lindane		0.0002	0.0002	0.0002
Methoxychlor		0.04	0.04	0.04
Oxamyl (vydate)		0.2	0.2	0.2
Pentachlorophenol		0.001	0.001	0.001
Picloram		0.5	0.5	0.5
Polychlorinated biphenyls (PCBs)		0.0005	0.0005	0.0005
Simazine		0.004	0.004	0.004
Toxaphene		0.003	0.003	0.003

(1) Included in FDA's 9 contaminant regulations.
(2) Included in FDA's D/DBP Rule. See D/DBP monitoring requirements section in Appendix A for details.
(6) No SOQs or MCLs established for individual trihalomethane contaminants. The sum of the 4 THMs is regulated as total trihalomethanes (TTHMs).
(7) FDA requires that the four synthetic organic chemicals (SOC) listed must be tested quarterly for four consecutive quarters for each type of finished bottled water (e.g., spring, purified, etc.). If none of the SOCs are detected, then once every three years for each type of finished product. If SOCs are detected, maintain monitoring for four consecutive quarters in each three-year period. New products and new companies must do an initial round of quarterly monitoring in the first year of operation.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix 2
2005 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP *Individual Group Analytes*	MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Additional Regulated Contaminants	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Methyl tertiary butyl ether (MTBE)	(Product and Source)	0.07	NA	NA
Naphthalene		0.3	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants		**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Total coliform / *E. coli*	SOURCE: at least once each week (21 CFR §129.35(a)(3)) PRODUCT: at least once each week (21 CFR §129.35(g)(1))	No *Eschericia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling. NOTE: Confirmation AND validation of all positive total colifrm results in finished product required. See Appendix C of the Model Code.	**MPN:** <2.2 organisms per 100 ml. **MF:** <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Radiological Contaminants	SEE BELOW	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
Gross Alpha Particle Radioactivity	SOURCE: Every 4 years PRODUCT: Annually	15 pCi/L	15 pCi/L	15 pCi/L
Gross Beta Particle and Photon Radioactivity (8)		50 pCi/L	50 pCi/L	50 pCi/L
Radium 226/228 (combined)	SOURCE: Every 4 years PRODUCT: Annually	5 pCi/L	5 pCi/L	5 pCi/L
Uranium	SOURCE: Every 4 years PRODUCT: Annually	0.030	0.030	0.030
Water Properties	ANNUALLY	**IBWA SOQ**	**FDA SOQ**	**GUIDELINE**
Color	(Product and Source)	5 Units	15 Units	5 Units
Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
'pH (9)		5-7/6.5-8.5	NA	6.5-8.5
Odor		3 T.O.N.	3 T.O.N.	3 T.O.N.

(8) If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present. Compliance (with § 141.16) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/1 and if the average annual concentrations of tritium and strontium–90 are less than those listed in table A, *Provided,* That if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year. Consult with your testing laboratory for more information.

(9) The Model Code guideline for pH in purified water is 5.0-7.0 (see Appendix B for definition and requirements for purified water). The guideline for source water and other product waters is 6.5-8.5. NOTE: This guideline is not enforceable.

All SOQs, MCLs, SMCLs, and guidelines in mg/L(ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix 2
2005 MONITORING MATRIX
IBWA Model Code Monitoring Requirements

FDA D/DBP Rule Monitoring Requirements

Public Water System (PWS) Source Water

If current PWS D/DBP data is available, no source water analysis is required.

If current PWS D/DBP data is NOT available, ANNUAL testing for the following is required:

- Disinfectants: Chlorine, Chloramine, Chlorine dioxide
- Disinfection Byproducts: Bromate, Chlorite, Haloacetic acids (HAA5), and Total Trihalomethanes (TTHMs)

Natural Water Sources

If no disinfection is applied at the source, including use in bulk water hauling, no source water analysis is required.

If disinfection is applied at the source, including use in bulk water hauling, ANNUAL testing for the following is required:

- The residual disinfectant used (chlorine, chloramine, or chlorine dioxide)
- Ozone: Bromate, Haloacetic acids (HAA5), Total Trihalomethanes (TTHMs)
- Chlorine-based disinfectants (chlorine, chloramine, or chlorine dioxide): Haloacetic acids (HAA5) and Total Trihalomethanes (TTHMs)

ALL FINISHED PRODUCTS

ANNUAL testing is required for ALL of the following in each finished product type:

- Chlorine
- Chloramine
- Chlorine dioxide
- Bromate
- Chlorite
- Haloacetic acids (HAA5)
- Total Trihalomethanes (TTHMs)

APPENDIX 3

PROCEDURE FOR RESPONSE TO COLIFORM AND ESCHERICHIA COLI TESTING RESULTS
(From IBWA Model Code)

Appendix 3

Escherichia coli (*E. coli*) and Total Coliform Standard and Policy

IBWA STANDARD OF PRODUCT QUALITY

- No *Escherichia coli* detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by retesting.

NOTE: Confirmation AND validation of all positive total coliform results in finished product required.

PROCEDURE FOR RESPONSE TO COLIFORM AND *ESCHERICHIA COLI* TESTING RESULTS

A representative unit of production for each package size shall be tested for total coliform (which includes *E. coli* in this group) during each daily production. If positive for total coliform, an *E. coli* determination is performed from that test. When a unit of production results in a positive result for coliform organisms by a total coliform method in *Standard Methods for the Examination of Water and Wastewater*, 20th Edition, the following policy and procedure should be employed:

1. Immediately analyze 10 additional samples from the same production lot for total coliform. Also examine the original sample for presence of *Escherichia coli* (*E. coli*) by a method in Standard Methods, 20th Edition.
2. Review sampling and analytical procedures to determine if the original sample contamination may have occurred due to sampling or laboratory error. If the review of sampling and analytical procedures demonstrates a source of contamination, such as contaminated media or analyst error, INVALIDATE results and proceed with total coliform analysis of five additional samples from the same lot using uncontaminated media and proper technique.
3. Company plant personnel should use the following guidelines for decisions on the disposition of the lot:

    a. If the re-sampling does not show *E. coli* or total coliform, consider the first sample an invalid result.

    b. If the original sample AND any of the additional four samples collected are positive for total coliforms or *E. coli*, consider the results valid and conduct follow up actions pursuant to the company's recall plan.

APPENDIX 4 - DEFINITIONS

"Approved Laboratory" means a competent commercial laboratory acceptable to the DEH.

"Approved Source" when used in reference to a bottled water plant's product water or water used in the plant's operations, means the source of the water and the water there from.

"Bottled Water" means water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as "water", "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water." The processing and bottling of bottled water shall comply with this guideline.

"Bottled Water Plant" means any place or establishment in which bottled water is either processed, prepared and/or packaged for sale.

"Critical Control Point" means a step or stage in a process where a hazard could occur and where control measures will either eliminate the hazard or reduce its occurrence to an acceptable level.

"Demineralized Water" means bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water.

"Deionized Water" means water that has been produced by a process of deionization and that meets the definition of "purified water".

"Distilled Water" means water which has been produced by a process of distillation and meets the definition of "purified water".

"Drinking Water" means water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.

"Food" includes bottled water.

"Food room" includes any bottled water production room and any bottled water storage facilities.

"Ground Water" means water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water as defined herein.

"HACCP" means Hazard Analysis and Critical Control Point. It is a food safety management system which identifies steps which are critical to consumer safety, imposes controls and highlights corrective action where necessary.

"Hazard" means anything that could pose a threat to consumer safety. These occur in three main categories: microbiological, physical and chemical.

"**IBWA**" means the International Bottled Water Association.

"Natural Water" means bottled spring water, mineral water, artesian water, artesian well water, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).

"Plant Operator" means any person who owns or operates a bottled water plant, and who meets the requirements of these guidelines.

"Purified Water" means bottled water produced by distillation, deionization, reverse osmosis, or other suitable process to render the Purified Water sterile and thereafter protect it from microbial contamination.

"Reverse Osmosis Water" means water that is produced by a process of reverse osmosis and that meets the definition of "purified water".

"Standard of Quality" means the DEH Standards of Quality for bottled water as set forth in these guidelines.

"Water Dealer" means any person who imports bottled water or causes bulk water to be transported for bottling for human consumption or other consumer uses.

"Well Water" means water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.