CERTIFICATION SCHEME FOR BOTTLED DRINKING WATER

1 Scope

This conformity evaluation document specifies the specific requirements for the evaluation of conformity of bottled drinking water to its corresponding product standard (CES 99).

This document gives technical rules for factory production control by the manufacturer, which includes testing, process control, management system and surveillances.

2 Normative references

This document is incorporated by dated or undated references, provision from other publications. These normative references are cited at the appropriate places in the text and the publications are listed here after. For dated references, subsequent amendments to or revisions of any of these publications apply to this document only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

PCP, product certification procedure

CAB's product certification procedure

CES 99, Bottled drinking water - Specification

ISO 9001:2008, Quality management system

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

Directive for the ES Mark Licensing

3 Terms, definitions and abbreviations

For the purposes of this document the terms and definitions given in the CES 99 bottled drinking water Requirement and the following shall apply.

3.1 Definition

3.1.1 Declaration of conformity

Document issued by the manufacturer under the rules of this document for the evaluation of conformity indicating that adequate confidence is provided that the bottled drinking water is in conformity with CES 99.

3.1.2 Declared bottled drinking water

Bottled drinking water which is declared by relevant legal body for its conformity with relevant bottled water quality standards.

4 Requirements for the factory, employees and the extraction area

Requirements for the factory, employees and the extraction area which produces bottled drinking water shall comply with annex B of CES 99.

4.1 Requirements for the product

Permissible treatment, composition and product quality factors of bottled drinking water shall comply with the requirements specified in clause 5 of CES 99.

4.2 Requirements for the factory production control by the manufacturer

4.2.1 Definitions and concept

Factory production control means the permanent internal control of bottled drinking water production exercised by the manufacturer and consists of internal quality control, sampling plan and testing at the point of raw water extraction, intermediates and finished product.

4.3 Management system

4.3.1 Quality Manual

The manufacturer's documentation system and documents of procedures with respect to factory quality production control shall be described in detail in the quality product manual. The quality production manual shall adequately describe, among other that:

a) The quality aims;

b) Organization structure;

c) Responsibilities and powers of the management with regard to product quality;

d) The means to monitor the achievement of the required product quality;

e) The effective operation of the factory production control;

f) The manufacturing and quality control techniques, processes and systematic actions that will be used and

g) The examinations and tests that will be carried out before, during and after manufacture and the frequency in which the company will carry out.

NOTE: Manufacturers having a factory production control system which compiles ISO 9001:2008 and fulfill the requirements in clause 6 of this document, the system shall document in their operation manual.

The operational manual shall address:

a) Procedures operated to ensure that the manufactured bottled drinking water conforms to CES 99

b) It may be referred to associate documents which provide further details sampling and internal quality control.

4.3.2 Quality policy statement

The quality manual shall include a statement developed by management defining its quality policy, objectives and commitments to the attainment of product quality, handling of non-conforming product, record and document control system.

4.3.3 Management representative

The manufacturer shall appoint a management representative, who irrespective of other responsibilities, shall have defined authority and responsibly for ensuring that the requirements of this document for the evaluation of conformity are implemented and maintained.

4.3.4 Management review

The manufacturer shall review the factory production control at appropriate intervals as specified in the Quality Manual at least every six months in order to ensure its continuing suitability and effectiveness to meet the requirements of this document for the evaluation of conformity.

4.3.5 Training

The' quality manual shall describe the measures to be taken to ensure that all the personnel involved in operations that can affect internal quality control and product quality have appropriate relevant educational level and field, experience and trainings. Moreover, relevant records with respect to the competency of the experts shall be retained.

4.4 System of documentation

4.4.1 Document control

The management representative shall be responsible for the control of all documents and data related to factory production control and to this document for the evaluation of conformity. In addition she/he shall ensure all appropriate documents are available at essential locations. All outdated documents shall be withdrawn and that changes or modifications to any document shall be made effectively and timely. A master list which comprises the current version of all necessary documents hall be prepared in order to prevent misuse of the documents.

4.4.2 Quality records

The manufacturer shall retain test results, appropriate records and quality records for the period required to comply with its operational manual.

4.4.3 Documents of quality control

The manufacturer shall establish documented procedures and appropriate test methods to ensure that the produced bottled water meet the requirements of product specification (CES 99) and establish suitable critical control points to ensure effective and sustainable process control measure.

4.5 Internal quality control

4.5.1 Process control

The Quality Manual documentation shall describe:

a) Parameters for production process;

b) Validated procedures for testing other than test methods specified in CES 99 (if any);

c) Verification methods;

d) Inspection procedures;

e) Corrective action procedures;

f) The methods used by the manufacturer to ensure that the bottled drinking water produced conforms CES 99

g) Needs procedure to ensure that non-conforming product is adequately managed,

h) Dispatch with the associate records.

4.6 Measuring and testing

4.6.1 Measuring and testing equipment

The equipment used for measuring and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the operation manual. These procedures may include comparison of test results with other laboratories. (External quality assurance)

4.6.2 Inspection and test status

Procedures for the inspection and test status at the level of manufacture shall be detailed in the quality manual. These shall include procedures for the control of non conforming intermediate materials.

4.6.3 Handling, storage, packaging and delivery (beer)

Handling, storage, packaging and delivery of bottled drinking water shall be in accordance with CES 99.

4.7 Sampling and testing

The manufacturer shall design and operate testing system for each certified bottled water. This system shall be used to demonstrate conformity to the requirements in the relevant product specification standard. The properties to be tested, the testing methods, the minimum frequency of testing during routine and initial period testing , The conformity criteria shall be in accordance with the basic requirements given in the relevant product certification standard. For bottled drinking water not being dispatched continuously, the frequency of testing and the point of sampling shall be as specified in the quality manual. All test result data shall be documented properly.

4.8 Evaluation of test results

The manufacturer shall check that all individual test results meet the requirements of CES 99.

4.9 preventive and Corrective actions

4.9.1 Preventive action

Preventive actions are measures that are taken to remove the causes of potential nonconformities or potential situations that are undesirable.
The preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist. It tries to prevent occurrence by eliminating causes.

4.9.2 Corrective action

The Quality Manual shall describe procedures for the handling of non-conforming products. The action shall be recorded. In the event of a test result not conforming to the requirements of clause 5 of CES 99, the manufacturer shall:-

a) Immediately determine the affected product quality;

b) Take appropriate action to prevent the dispatch of this quality and inform the affected customer if such bottled drinking water has been released;

c) Determine the cause (s) of such non-conformity;

d) Take corrective action

e) Under take a management review of all factory production control procedures.

f) Verify if the preventive and corrective action are effective. And all such actions and findings shall be recorded.

4.10 Initial audits of the factory and the factory's production process control (beer)

4.10.1 Application criteria for acceptance

The application is made as specified in general requirement and the relevant CAB's application form

4.10.2 Application reviewing time frame

Application review time shall be as defined in CAB's criteria document /product certification procedure/.

4.10.3 Initial audit

Initial audit shall be carried out as specified in CAB's criteria document /product certification procedure/. In the case of a new factory (a newly constructed facility or a facility previously not audited) CAB's audit team shall make a relevant audit of the factory and the factory production control in accordance with its product certification procedure.

CAB's audit team shall, among others:

a) Verify that the Quality Manual complies with the requirements of clause 4.4 of this document.

b) Verify that the equipment used to produce and test the bottled drinking water meets the criteria in operation manual. In the case of a new type of bottled drinking water in an existing factory CAB's audit team shall decide whether a particular audit is necessary.

4.10.4 Initial testing

4.10.4.1 Sampling

a) Sampling shall be carried out in accordance with the method specified in annex A of CES 99. The manufacturer shall permit the drawl and collection of samples from their facility for independent evaluation of the product quality by the CAB. No fee shall be levied for the same.

b) Three sets of sample per product per type shall be subjected to testing: the first set will be tested in the factory (or in the outsourcing facility) witnessed by a duly authorized CAB's representative; the second set will be tested in CAB's testing laboratory. The third set will be sealed and signed by both parties and kept by the CAB's manufacturer as reference for complaint handling purpose.

c) Test sample(s) taken for independent test (CAB's laboratory) shall be packed /sealed and signed in the presence of both parties and shall be submitted to the CAB's Testing Laboratory by the CAB's representative.

d) The auditor/audit team checks the availability of testing facilities required in CES 99 / and or established outsourcing systems in the manufacturing Quality Control for adequacy.

e) The auditor/audit team verifies competence of testing personnel and the testing facility by witnessing testing of the sample in the laboratory of manufacturer.

4.10.4.2 Testing by CAB

a) The tests shall be carried out in accordance with the test method specified in CES 99

b) The results of both in plant and in CAB's Testing Laboratory shall comply with the requirements of CES 99

c) If the result of the test conducted by the CAB's Testing Laboratory shows non conformance with respect to the specified requirements, the provision for rejection specified in CES 99 shall apply. Retest shall be carried out on the reference sample kept by the CAB on new samples collected by CAB's representative, on which full testing shall be carried out, if necessary.

d) If the retests comply, the initial product certification audit is considered conforming to product specification if not; the manufacturer will be advised to take corrective action.

e) CAB shall maintain records of all certification activities: application registration, documents provided by applicant, on site evaluation report, including factory test results and test reports of sample.

Note: When, CAB chooses to use test data produced by others (including supplier laboratory under certain conditions), CAB shall ensure that the requirements for the suitability and competence of the party conducting the testing as specified in ISO/IEC 17025.

4.11 Reports

Following each evaluation of audit test results, a confidential report shall be prepared and send a copy to the manufacture without delay.

4.12 Declaration of conformity

The declaration of conformity of bottled drinking water can be made by the client following the certification of the factory production control by CAB shall be in accordance with the directive for the ES Mark licensing and CES 99.

4.13 Conformity mark

The declaration of conformity entitles the manufacturer to use the conformity mark on packaging and documentation used for the declared bottled water (where it is required)

4.14 Action to be taken by the manufacturer in the event of non-conformity

The control of non- conforming product and the corrective action to be taken by the client are dealt with clause 4.9.2 of this document. These are the full responsibility of the client who shall document the procedures in the operational manual.

In the event that the results of the client's testing indicate that the requirements given in clause 5 of CES 99 are not met, the client shall double the frequency of testing (see Table 1 and 2 of in this document) which shall be specified in its Quality Manual (including inspection, sampling , test verification plan) until the problem is resolved.

The client shall declare and report to CAB if it is established that the product no longer complies with the requirements for the declaration of conformity statements that the product conforms to the requirements of CES 99 and the evaluation of conformity described in this document.

4.15 Surveillances

CAB shall conduct factory and market Surveillance audit in accordance with its surveillance audit procedure every quarter and renew the certificate every year.

4.16 Re-certification audits

CAB shall conduct re-*certification audit* every 3 years. A re-certification audit takes place prior to end of a certification period. The audit shall be planned in due time, in order to avoid expiration of the certificate.

Note:

• A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording "certified since" cannot be included on the certificate.

• If a re-certification is conducted after the expiry of a certificate, Initial Audit shall be carried out.

4.17 Sample size and sampling methodology

During the initial and surveillance audit CAB's representative(s) shall take sample as specified in annex A of CES 99.

4.18 Classification of non-conformities and recommendations

4.18.1 Major non-conformities

A Major non-conformity exists when the auditor observes a regulatory violation or mandatory requirements of CES 99 failure which requires that the manufacturer:

a) Immediately interrupts production.

b) Holds products in quarantine.

c) Discontinues distribution to customers.

d) Recalls the product.

4.18.2 Minor non-conformities

A minor non-conformity exists when requirements of these evaluation criteria document requirements have been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.

4.18.3 Opportunity for improvements (recommendations)

In addition to non-conformities, opportunities for improvements may be made by an auditor according to his observations, with a view to help the continuous improvement of the manufacturer's Quality Management System.

The basic requirement to identify and to record improvement opportunities is that the requirements of CES 99 and this conformity evaluation document have been fulfilled but there are still areas for potential improvement of system effectiveness and efficiency.

Opportunity for Improvement will be checked during the following regular audit. If an opportunity for improvement is not resolved and closed by then, the certificate will become non-conformity.

4.18.4 Consequences of non-conformities

on-conformity	Initial audit	Surveillance or Re-certification audit
Major	Certification cannot be granted until the non-conformities have been	1. Certification continues. 2. The client shall take the actions specified in clause 12.1 as appropriate. 3. The action plan shall be presented to the CAB, at the latest 14 calendar days after the audit date. Evidence that non-conformities have been closed will

	closed.	be checked 60 days after the presentation of the action plan at the latest.CAB shall check the factory within 3 days after the report has been received. If non-conformity is not resolved and closed by then, certificate will be withdrawn.
Minor	Certification cannot be granted until the non-conformities have been closed.	1. Certification continues. 2. An agreement on the action plan shall be reached between the CAB's and the manufacturer. The deadline for this agreement is 60 calendar days after the CAB has received the action plan from the manufacturer. 3. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.

The auditor shall confirm that he/she has reviewed, accepted and verified the effectiveness of corrective actions.

4.19 Certification decision and certificate

4.19.1 The information provided by the auditor/audit team to the CAB, for the product certification decision, shall include, as a minimum:

a) The audit report,

b) Comments on the non-conformities and, where applicable, the corrective actions taken by the client,

c) Recommendation from the auditor on whether or not to grant the certification, together with any conditions or observations.

If there are sufficient evidence to demonstrate compliance with the conformity evaluation criteria of document and other related requirements (such as signing of product certification agreement and service fee settlement), a certificate shall be granted. The decision to issue a certificate remains the CAB's responsibility.

4.19.2 A certificate is valid for a period of 3 years.

4.20 Sample testing frequency

The manufacturer shall determine frequency of sampling and sampling points, and conduct testing as specified in Table 4.20.1 and4.20. 2.

Manufacturers who use UV as a treatment method are supposed to be tasted every an hour.

Table 4.20.1: input material and process Testing and Inspection Plan

Ser. No		Parameters	Acceptance Criteria	Method of test	Frequency of test	No. of Samples
1	**Physical**	Test	As per CES 99	As per CES 99	Every 24 hours*	As per CE 99
		Odour	"	"	Every 2 hours	"
		Turbidity	"	"	"	"
		Colour	"	"	"	"
2	**Chemical**	pH	Every 1 hour	,,	,,	,,
		TDS	,,	,,	,,	,,
		Hardness	,,	,,	,,	,,
		Ozone test	,,	,,	,,	,,
		Characteristics that affect palatability of bottled drinking water other than pH, TDS, hardness and ozone test	,,	,,	Every 3* *months	,,
		Toxic and or disease causing substances	,,	,,	Once a year**	"
3	**Bacteri ological**	Coliform	,,	,,	Two times a week	"
		E.Coli	,,	,,	,,	"
		Total viable organisms	,,	,,	,,	"
		Faecal Streptococci	,,	,,	,,	"
4	**Radioac tivity**	Gross alpha	"	"	Once a year	"
		Gross beta	"	"	"	"

4.20.2: Input finished product Testing and Inspection Plan

Ser. No		Parameters	Acceptance Criteria	Method of test	Frequency of test	No. of Samples
1	**Physical**	Test	As per CES 99	As per CES 99	Every 24 hours*	As per CES 99
		Odour	"	"	Every hour	"
		Turbidity	"	"	"	"
		Colour	"	"	"	"
2	**Chemical**	pH	Every hour	,,	,,	,,
		TDS	,,	,,	,,	,,
		Hardness	,,	,,	,,	,,
		Ozone test	,,	,,	,,	,,
		Characteristics that affect palatability of bottled drinking water other than pH, TDS, hardness and ozone test	,,	,,	Every 3** months	,,
		Toxic and or disease causing substances	,,	,,	Once a year**	"
3	**Bacteriological**	Coliform	,,	,,	Every day	"
		E.Coli	,,	,,	,,	"
		Total viable organisms	,,	,,	,,	"
		Faecal Streptococci	,,	,,	,,	"
4	**Radioactivity**	Gross alpha	"	"	Once a year**	"
		Gross beta	"	"	"	"

**:If there is an indication and increasing trend of characteristics that affect palatability, toxic and or disease causing substances frequency of testing and inspection plan given in table 1 shall be three times.