

# UL 2584

## Specification for Bottled Water Program



Specification for Bottled Water Program, UL 2584

Second Edition, Dated September 15, 2011

### ***Summary of Topics***

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**SEPTEMBER 15, 2011**

Prior to this second edition the requirements for products covered by this Specification were included in the first issue of the Outline of Investigation for Bottled Water Program.

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**UL 2584**

**Specification for Bottled Water Program**

**Second Edition**

**September 15, 2011**

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## BOTTLED WATER PROGRAM

### INTRODUCTION

#### 1 Scope

1.1 These requirements cover bottled water produced and packaged for distribution and consumption within the United States (U.S.A.).

1.2 These requirements also cover bottled water produced and packaged for consumption on vessels that carry 13 or more passengers with a foreign or domestic itinerary.

1.3 This program is available for the following bottled water types:

- a) Sparkling water;
- b) Municipal water packaged for sale in bottles;
- c) Natural water including:
  - 1) Artesian water;
  - 2) Mineral water;
  - 3) Spring water;
  - 4) Well water.
- d) Purified water including:
  - 1) Deionized water;
  - 2) Demineralized water;
  - 3) Distilled water;
  - 4) Reverse osmosis water.

1.4 This program does not cover the following product types:

- a) Sterile water;
- b) Flavored water;
- c) Vitamin-fortified water; and
- d) Water containing color additives.

1.5 This program covers bottled water intended for sale and distribution within the U.S.A. This program also covers water that is packaged and consumed on vessels that carry 13 or more passengers.

## 2 Undated References

2.1 Any undated reference to a code or standard appearing in the requirements of this specification shall be interpreted as referring to the latest edition of that code or standard.

## 3 Units of Measurement

3.1 Values stated without parentheses are the requirement. Values in parentheses are explanatory or approximate information.

## 4 Normative References

4.1 This specification incorporates requirements for bottled water from the following (regulations):

IBWA Bottled Water Code of Practice (Model Code)

IBWA Audit Handbook

Codex Alimentarius

21 CFR Section 101.9 (Nutrition Labeling of Food)

21 CFR Part 110 (General GMPs)

21 CFR Part 120 (HACCP Systems)

21 CFR Part 129 (Bottled Water GMPs)

21 CFR Section 165.110 (Standards of Identity and Quality)

The Standard for Safety for Shatter Containment of Lamps for Use in Regulated Food Establishments, UL 2007A

US FDA Hazard Analysis and Critical Control Point Principles and Application Guidelines

US FDA Food Code

Department of Health and Human Services Centers for Disease Control and Prevention  
National Center for Environmental Health Vessel Sanitation Program

## 5 Glossary

5.1 For the purposes of this specification, the following definitions apply.

5.2 **APPROVED LABORATORY** – A competent commercial laboratory (e.g., Environmental Protection Agency (EPA), state-certified laboratory, ISO 17025 compliant laboratory, or laboratory acceptable to the government agencies having jurisdiction).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.3 **APPROVED SOURCE** – Shall be produced water as defined in this document, or one of the following:

- For production on land, an approved source is the source of the water and the water therefrom, whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found to be safe and sanitary quality with or without treatment, according to applicable laws and regulations of state and local government agencies having jurisdiction. Approval is obtained and maintained through the compliance with the requirements of HACCP and analytical monitoring. The presence in the plant of current certificates or notifications of approval from the government agency having jurisdiction constitutes approval of the source and the water supply.
- For production aboard a vessel, the source may also be source water bunkered from shore supplies, provided that the water is from a potable source that meets World Health Organization standards for potable water. Where available, the vessel shall have a copy of the most recent microbiological report from each port before bunkering potable water to verify that the water meets potable standards. The date of said analysis must be 30 days or less from the date of potable water bunkering, and the report must include analysis for *E. coli*, at a minimum.

Water samples collected and analyzed for the presence of *E. coli* may be substituted for port water system supplied reports. Samples shall be analyzed utilizing a method accepted in *Standard Methods for the Examination of Water and Wastewater*. If a vessel bunkers potable water from the same port more than once per month, only one test per month is required.<sup>a b</sup>

<sup>a</sup>IBWA Code of Practice

<sup>b</sup>Vessel Sanitation Program

5.4 **ARTESIAN WELL WATER** – Means bottled water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer. [21 CFR Section 165.110(a)(2)(i)]<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.5 **BOTTLED WATER** – 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. Fluoride may be optionally added within the limitations established in 21 CFR Section 165.10(b)(4)(ii). The common or usual name of the resultant product must reflect these additions. 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 applicable regulations in 21 CFR Part 129.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.6 BOTTLED WATER PLANT – Any place or establishment in which bottled water is prepared for sale.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.7 BUNKERED WATER – Water that is stored on the vessel from shore supplies. These shore supplies shall be from a potable source which meets World Health Organization standards for potable water.<sup>b</sup>

<sup>b</sup>Vessel Sanitation Program

5.8 CLEANING – The action of washing to remove unwanted dirt and debris from the material surface by physical and/or chemical means.

5.9 CRITICAL CONTROL POINT (CCP) – 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.

5.10 CRITICAL LIMIT – Criterion that separates acceptability from unacceptability. A critical limit is a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a critical control point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.11 DEIONIZED WATER – Water that has been produced by a process of deionization and that meets the definition of "purified water" in the 23rd revision of the United States Pharmacopoeia, January 1, 1995, and specified by FDA in 21 CFR Section 165.110(a)(2)(iv).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.12 DEMINERALIZED WATER – Bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the 23rd revision of the United States Pharmacopoeia, January 1, 1995.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.13 DISTILLED WATER – Water which has been produced by a process of distillation and meets the definition of "purified water" in the 23rd revision of the United States Pharmacopoeia, January 1, 1995 and specified by FDA in 21 CFR Section 165.110(a)(2)(iv). Distilled water may also be referred to as "evaporated water" for production aboard a vessel.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.14 DRINKING WATER – 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. Fluoride may be optionally added within the limitations established in 21 CFR

Section 165.110(b)(4)(ii). The common or usual name of the resultant product must reflect these additions. Drinking 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 drinking water shall comply with applicable regulations in 21 CFR Part 129.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

**5.15 FINISHED PRODUCT (LAND BASED PRODUCTION)** – Water that is in sealed, ready to ship containers. Bottled water shall mean any product, including natural spring or well water taken from municipal or private utility systems or other water, distilled water, deionized water or any of the foregoing to which chemicals approved by the bottler for human consumption may be added, which are put into sealed bottles, packages or other containers, to be sold for domestic consumption or culinary use, involving a likelihood of such water being ingested by human beings. Water that has undergone a complete water quality analyses, including inorganic, organic, microbiological, and radiological analyses for each source and each finished product.<sup>c</sup>

<sup>c</sup>IBWA Audit Handbook

**5.16 FINISHED PRODUCT (VESSEL BASED PRODUCTION)** – Water that is in sealed containers and ready for distribution throughout the vessel. Bottled water shall mean any product made from a source that is approved by the Vessel Sanitation Program, to which chemicals approved by the Code of Federal Regulations for human consumption may be added, which is placed in bottles, packaged and distributed throughout the vessel for human consumption or culinary use. The finished product has undergone a complete water quality analysis, including organic, inorganic, microbiological, and radiological parameters.

**5.17 GOOD MANUFACTURING PRACTICE (GMP)** – Combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources.

**5.18 GROUND WATER** – 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 at 40 CFR Section 141.2.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

**5.19 HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINT)** – A systematic preventive approach to food safety and pharmaceutical safety that addresses physical, chemical, and biological hazards as a means of prevention rather than finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key actions, known as Critical Control Points (CCP's) can be taken to reduce or eliminate the risk of the hazards being realized. The system is used at all stages of food production and preparation processes including packaging, distribution, etc.

**5.20 HAZARD** – Biological, chemical, or physical agent in food, or condition of food with the potential to cause an adverse health effect.

**5.21 HAZARD ANALYSIS** – Process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are impactful to food safety, and therefore should be addressed in the HACCP plan.

5.22 MAXIMUM CONTAMINANT LEVEL (MCL) – The highest concentration of a contaminant that is allowed in drinking water. MCLs are set as close to the MCLG (see 5.23) as feasible using the best available treatment technology and taking cost into consideration.

5.23 MAXIMUM CONTAMINANT LEVEL GOAL (MCLG) – Under the Safe Drinking Water Act, a non-enforceable concentration of a drinking water contaminant, set at the level at which no known or anticipated adverse effects on human health occur and which allows an adequate safety margin. The MCLG is usually the starting point for determining the regulated Maximum Contaminant Level, or MCL (see 5.22).

5.24 MINERAL WATER – Water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.25 NATURAL WATER – Bottled spring water, mineral water, artesian water, artesian well water, or well water which is derived from an underground formation, is not derived from a municipal system or public water system, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.26 PRODUCED WATER – For production aboard a vessel, the source may also be seawater obtained outside of a defined harbor area, provided that the water is subjected to the proper filtration technology.

5.27 PURIFIED WATER – Bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the 23rd revision of the United States Pharmacopoeia, January 1, 1995, and specified by FDA in 21 CFR 165.110(a)(2)(iv).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.28 PUBLIC WATER SYSTEM (PWS) – A Public Water System is a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year. Such term includes: any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system; and any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. Such term does not include any "special irrigation district." A public water system is either a "community water system" or a "noncommunity water system," defined in 40 CFR 141.2.

5.29 REVERSE OSMOSIS WATER – Water that is produced by a process of reverse osmosis and that meets the definition of "purified water" in the 23rd revision of the United States Pharmacopoeia, January 1, 1995, and specified by FDA in 21 CFR Section 165.110(a)(2)(iv).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.30 SANITIZATION – The treatment of clean surfaces and equipment by a process that destroys pathogenic bacteria and substantially reduces the population of all other microorganisms.

5.31 SOURCE WATER – Water in its natural state, before any treatment to make it suitable for drinking. Source product water supply is defined as all sources that are used to make the final bottled water product. See 5.3 for approved sources. A typical plant might bottle a product that is comprised of one spring, or three wells, or a blend of city and on-site waters.<sup>c</sup>

<sup>c</sup>IBWA Audit Handbook

5.32 SPARKLING BOTTLED WATER – Bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it has at the emergence from the source.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.33 SPARKLING WATER – Sparkling water is a common or usual name for unsweetened and unflavored water containing compressed carbon dioxide. "Sparkling water" is in the same category as "carbonated water," "seltzer water," "soda water," and "tonic water," regulated by the FDA as "soft drinks."

5.34 SPRING WATER – Water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must comply with the FDA standard of identity at 21 CFR 165.110(a)(2)(vi). Spring water shall be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified and such identification shall be maintained in the company's records. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the borehole and the natural spring, and shall have all the physical properties before treatment, and be of the same composition and quality as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method which an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.35 STANDARD OF IDENTITY – The FDA Standard of Identity for bottled water as set forth in 21 CFR Section 165.110(a).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.36 STANDARD OF QUALITY – The FDA Standards of Quality for bottled water as set forth in 21 CFR Section 165.110(b).<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

5.37 WELL WATER – Water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.<sup>a</sup>

<sup>a</sup>IBWA Code of Practice

## AUDIT CRITERIA

### 6 Audit Schedule

6.1 An annual audit is to be completed for the bottling facility each year.<sup>c</sup>

<sup>c</sup>IBWA Audit Handbook

### 7 Audit Assessment Summary

7.1 An evaluation is based on "conformance" or "non-conformance" with a bottled water plant's HACCP plan, regulatory requirements, and GMPs. The audit report does not assign a numerical score upon completion of the audit.

7.2 There are two categories of non-conformances, "major" and "minor". Major non-conformances are those giving evidence of systemic failure, which requires reassessment (partial or full) prior to the auditor's recommendation to issue, or maintain acceptance of the UL Mark. Generally, major non-conformances are directly related to compliance with the HACCP plan or to food safety; there is a critical failure to comply with food safety or legal issue; or a situation is identified which would on the basis of available objective evidence, raise significant doubt as to the conformity of the product.

7.3 Major non-conformances must be corrected as soon as possible and follow a corrective action procedure. A corrective action plan is to be conducted, which shall include:

- A root cause analysis;
- Corrective action plan;
- Preventive action;
- Target date of completion;
- Person(s) responsible for implementation;
- Documentation of implementation.

7.4 Major non-conformances must be resolved prior to the issuance of the UL Notice to Apply the UL Mark.

7.5 Minor non-conformances are those not requiring reassessment (partial or full) that generally could be resolved through correspondence with further verification during subsequent reassessments. Generally, minor non-conformances deal with other GMP and administrative items, **where the conformity of the product is not in doubt**, and for which corrective action is necessary.

7.6 The auditor will release a report to the organization. The report includes all major and minor non-conformances. The company has up to thirty business days to address the major non-conformities using a corrective action plan, and submit the results of the corrective action to comply with the terms of the audit program.

## **8 Notice of Authorization to Apply the UL Mark**

8.1 If the initial audit results in no major non-conformances and no more than ten (10) minor non-conformances, the bottled water plant will receive a Notice of Authorization to Apply the UL Mark. The notification acknowledges that the plant is in compliance with the applicable requirements.

8.2 If the initial audit results in one or more major non-conformances and/or more than ten (10) minor non-conformances, the bottled water plant is considered as not passing the audit. These bottled water plants will be requested to provide a plan for reestablishing compliance with the applicable requirements. UL reserves the right to conduct a follow up audit to verify that necessary corrective actions have been efficiently implemented.

## **BOTTLED WATER AUDIT REPORT**

### **BOTTLED WATER PLANT MANAGEMENT**

## **9 Bottled Water Plant Management**

### **9.1 Employee Training**

9.1.1 Employees shall be provided training in HACCP, GMP, employee hygiene, and food security, prior to working in the bottled water production area of the plant.

9.1.2 Employee training records shall be maintained for a minimum of five years.

### **9.2 Internal Audits**

9.2.1 Internal audits shall be conducted at least annually and involve each section of this document.

9.2.2 The records of these internal audits and corrective actions for deficiencies noted during the audit shall be maintained for a minimum of five years.

### **9.3 Customer Complaints**

9.3.1 A system shall be in place that captures, records, and manages customer complaints. Records shall be maintained for a minimum of five years.

9.3.2 The investigation and resolution of complaints shall be documented and stored for future analysis.

9.3.3 Complaint data shall be analyzed and used to implement ongoing improvements to product quality, safety, and legality to avoid recurrence. This analysis shall be made available to relevant staff.