

Model Code



Model Bottled Water Regulation

Revised October, 2002

International Bottled Water Association
1700 Diagonal Road, Suite 650
Alexandria, VA 22314
(703) 683-5213
<http://www.bottledwater.org>

INTERNATIONAL BOTTLED WATER ASSOCIATION

Model Bottled Water Regulation

Table of Contents

<u>SECTION</u>	<u>PAGE</u>
Rule 1: Definitions	3
Rule 2: Product Quality and Security	5
Rule 3: Good Manufacturing Practices and Operational Requirements	6
Rule 4: Source Water Monitoring	11
Rule 5: Finished Product Monitoring	13
Rule 6: Labeling Requirements	13
Appendix A: Monitoring Matrix - IBWA Model Code Monitoring Requirements	16
Appendix B: Purified Water – Official Monograph (USP XXIII)	21
Appendix C: IBWA Total Coliform Standard of Quality and Laboratory Results Response Procedure	22

This Model Code for Bottled Water has been prepared by the International Bottled Water Association, its membership, Board of Directors, Government Relations Committee, and Technical Committee. It is designed to be used as model "regulation" or "legislation" in states or municipalities. For questions about the Model Code contact: International Bottled Water Association, 1700 Diagonal Road, Suite 650, Alexandria, VA 22314. (703) 683-5213.

INTERNATIONAL BOTTLED WATER ASSOCIATION

Model Bottled Water Regulation

RULE 1: DEFINITIONS

As used in these rules:

- (a) **"Approved Laboratory"** means a laboratory approved by the applicable state agency or certified by the U.S. Environmental Protection Agency (EPA), or certified by the primary enforcement authority in any state which has been granted primacy by EPA, or certified (accredited) by a third-party organization acceptable to a primacy state.
- * (b) **"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 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 of a safe and sanitary quality with or without treatment. Approval shall be obtained and maintained in accordance with rule 3(c) and rule 4(a) through (e). The bottler shall maintain in the plant a current certification or notification of approval from the applicable state agency which shall constitute approval of the source and which shall be available for inspection by the applicable state agency, and a copy of which shall be made available to consumers upon request.
- * (c) **"Artesian 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.
- * (d) **"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. Fluoride may be optionally added within the limitations established in 21 CFR Section 165.110(b)(4)(ii). Firms may manufacture nonstandardized bottled water products with ingredients such as minerals for flavor. 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.
- (e) **"Bottled Water Plant"** means any place or establishment in which bottled water is prepared for sale.
- * (f) **"Sparkling Bottled Water"** means bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously

noncarbonated bottled water products and label such water appropriately (e.g., sparkling spring water).

- * (g) **"Demineralized Water"** means bottled water which is produced by distillation, deionization, reverse, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia, 23rd revision, January 1, 1995, attached as Appendix B.
- * (h) **"Deionized Water"** means water that has been produced by a process of deionization and that meets the definition of "purified water" in the United States Pharmacopoeia, 23d Revision, January 1, 1995, attached as Appendix B and specified by FDA in 21 CFR Section 165.110(a)(2)(iv).
- * (i) **"Distilled Water"** means water which has been produced by a process of distillation and meets the definition of "purified water" in the United States Pharmacopoeia, 23d Revision, January 1, 1995, attached as Appendix B and specified by FDA in 21 CFR Section 165.110(a)(2)(iv).
- * (j) **"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. Fluoride may be optionally added within the limitations established in 21 CFR Section 165.110(b)(4)(ii). Firms may manufacture nonstandardized drinking water products with ingredients such as minerals for flavor. 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 a "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.
- * (k) **"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.
- * (l) **"Mineral Water"** means 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.
- (m) **"Natural Water"** means bottled spring, mineral, artesian, 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).
- (n) **"Plant Operator"** means any person who owns or operates a bottled water plant, and who meets the requirements of Rule 3(o) herein.
- * (o) **"Purified Water"** means bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the most

recent edition of the United States Pharmacopoeia, 23d Revision, January 1, 1995, attached as Appendix B, specified by FDA in 21 CFR 165.110(a)(2)(iv).

- * (p) **"Reverse Osmosis Water"** means water that is produced by a process of reverse osmosis and that meets the definition of "purified water" in the United States Pharmacopoeia, 23d Revision, January 1, 1995, attached as Appendix B and specified by FDA in 21 CFR § 165.110(a)(2)(iv).
- * (q) **"Spring Water"** means 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 in 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 bore hole 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, that an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole.
- * (r) **"Standard of Identity"** means the FDA Standard of Identity for bottled water as set forth in 21 CFR Section 165.110(a).
- * (s) **"Standard of Quality"** means the FDA Standards of Quality for bottled water as set forth in 21 CFR Section 165.110(b).
- * (t) **"Sterile Water"** means water that meets the requirements under "Sterility Tests" <71> in the United States Pharmacopoeia, 23d Revision, January 1, 1995, attached as Appendix B and specified by FDA in 21 CFR Section 165.110(a)(2)(iv).
- (u) **"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.
- * (v) **"Well Water"** means water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.

RULE 2: PRODUCT QUALITY AND SECURITY

- * (a) All bottled water shall be from an approved source and shall meet the standard of quality prescribed by the FDA in 21 CFR Section 165.110(b).
- (b) All bottled water products shall meet the chemical, physical, and microbiological standard of quality prescribed by this Model Code attached as Appendix A.

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 confirmation and response procedure described in Appendix C of this Model Code.

- (c) IBWA bottler members believe that consumers have a right to know what is in the bottled water they drink. To demonstrate a sense of openness and cooperation by IBWA members, bottler members shall, upon request, provide to consumers meaningful information about their bottled water brands. The bottler shall provide to consumers information that demonstrates compliance with applicable federal and state Standards of Quality. Bottlers must provide analytical testing data results generated for the most recent IBWA Model Code compliance audit. No new or additional testing is required under this informational requirement. Bottlers shall have this information in written form at the time of the company's annual plant audit. IBWA members are free to determine how information is provided to consumers (e.g., via mail, web site, phone, etc.) but shall provide the information in written form upon request.

This IBWA Model Code requirement applies to IBWA members' proprietary brands. While not required, IBWA recommends that private label brands produced by IBWA members provide this same water quality information upon request.

- (d) IBWA bottler members shall adopt written policies and procedures designed to protect the integrity and security of their operations and products. The companies' HACCP plans, required under Rule 3 of this Model Code, address vendor programs and materials management issues that affect the security of bottled water products. In addition, the bottler member must document other security measures, including but not limited to those addressing security of buildings, employees, materials, transportation, and products. Beyond processing and packaging, the companies' recall plans, as required under Rule 3, shall address tracing and retrieval of product.

RULE 3: GOOD MANUFACTURING PRACTICES AND OPERATIONAL REQUIREMENTS
--

- (a) When a bottled water plant is utilizing a treatment technology in order to reduce the level of any constituent in its source water below the FDA Standard of Quality, or to prevent a contaminant from entering the product water in amounts that exceed the FDA Standard of Quality, said treatment shall be operated in accordance with the Good Manufacturing Practices of 21 CFR Section 129.80 and shall be properly maintained with supporting records (which shall be kept at the plant for five years) in accordance with the requirements and schedule of the Operation and Maintenance Plan. All bottled water shall be packaged and stored in accordance with the FDA Good Manufacturing Practice Regulations (GMPs) 21 CFR Parts 110 and 129, and any other GMP regulations prescribed by applicable state laws.
- (b) Each IBWA member bottled water plant shall develop and maintain a Hazard Analysis and Critical Control Point (HACCP) program. As a part of the program, the plant shall develop and write a HACCP Plan that addresses product safety with respect to the seven principles of HACCP, as defined by the Codex Alimentarius Commission and the U.S. Food and Drug

Administration. The plan shall address, but is not limited to, the following:

- (1) Results of a hazard analysis of the plant's processes.
- (2) Location and substantiation for each critical control point (CCP) in the plant's process, including but not limited to internal manufacturing and processing and supplies and equipment provided by external vendors.
- (3) The critical limits established at each CCP.
- (4) Detail of the monitoring program established at each CCP.
- (5) Description of corrective action to be taken by the plant at each CCP should a critical limit be exceeded.
- (6) Description of the plant's HACCP verification system.
- (7) Description of the plant's HACCP recordkeeping system. Plants shall maintain HACCP records for a period of five years.

In support of the plan's 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 IBWA and government agency inspection staff upon request.

- (c) Microbiological Control Standards. 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. These conditions and controls shall include the following:
 - (1) Bottled water shall be subject to effective germicidal treatment by ozonation or carbonation at a minimum of three volumes of carbon dioxide or other equivalent disinfection approved by the applicable state agency except that the requirement for filtration and germicidal treatment shall not apply to a bottled water product for which an exemption has been granted by the applicable state agency pursuant to the criteria outlined in subpart (d) of this section.
- (d) This exemption applies only to the requirement for filtration and germicidal treatment. All bottled water shall comply with all other provisions of this Model Code/section.

A bottled water product may be granted an exemption from filtration and germicidal treatment by the applicable state agency. An exemption shall be based on the bottler's demonstration to the applicable state agency's satisfaction that, based on review of long-term baseline microbiological monitoring data of the source and product, and consideration of the nature and extent of source monitoring, source protection and bottling sanitation procedures instituted by the bottler, filtration, and germicidal treatment are not necessary to assure that the product will consistently comply with the microbiological standards herein. An exemption may be granted and maintained only upon a demonstration that:

- (1) The bottled water product and source are in compliance with the Codex Alimentarius standard (CAC/RS 108) for natural mineral water, as amended, and the requirements of Rule 2 herein.

- (2) The bottled water product and source are in compliance with the Code of Hygienic Practice for the collecting, processing, and marketing of natural mineral water of the Codex Alimentarius, Alinorm 83/13A, as amended.
- (3) The bottler has submitted a basic hydrogeological survey of the source and an annual sanitary survey, both prepared by a professionally qualified hydrogeologist demonstrating the integrity of the source, which sanitary survey shall include:
 - (i) Watershed surveillance consisting of an inspection of portions of the drainage area necessary to identify and evaluate actual and probable sources of contamination.
 - (ii) Evaluation of source construction and protection, and where appropriate, intake structures, and transmission facilities.
 - (iii) Evaluation of finished water storage facilities.
 - (iv) Continued compliance of the bottled water product and source with the Codex Alimentarius standards is demonstrated (1) by a weekly microbiological testing as described in the Code of Hygienic Practices for the collecting, processing, and marketing of natural mineral water of the Codex Alimentarius, Alinorm 85/13A; and (2) by an annual inspection by an independent organization acceptable to the applicable state agency demonstrating compliance with the Code of Hygienic Practices for the collecting, processing, and marketing of natural mineral water of the Codex Alimentarius, Alinorm 85/13A; and with 21 CFR Sections 110 and 129.
 - (v) The bottled water product is bottled in an enclosed filling room/chamber that is under positive pressure of filtered air; and using facilities and Good Manufacturing Practices that comply with the requirements of 21 CFR Sections 110 and 129.
 - (vi) That the exemption to the requirement for filtration and germicidal treatment for the bottled water product is renewed every year by the submission of an annual report establishing compliance with (1) the microbiological standards described in 21 CFR Section 165.110(b) and (2) the above-mentioned requirements pertaining to said water and source. Bottled water that is not in compliance with any of the above requirements shall be subject to the requirement for filtration and germicidal treatment.
- (e) Dedicated Equipment. Bottled water shall not be transported or stored in bulk tanks, or processed or bottled through equipment or lines used for any non-food product.
- (f) This section applies to the handling of bulk water.
 - (1) Bulk water shall refer to water intended for potable uses which is transported via tanker truck or equivalent means from one area to another for the purpose of treatment, packaging and human consumption.
 - (2) Bulk water sources shall be approved by the state agency having local jurisdiction and maintained for sanitary quality at all times. Bulk water shall be loaded,

transported and unloaded in a sanitary manner to ensure the overall safety and quality of the finished drinking water product.

- (3) Bulk water tankers, storage tanks, hoses, pumps and connections used for loading, transporting and unloading of bulk water shall be constructed of materials that are FDA food-grade, smooth, non-absorbent and easily cleaned such as stainless steel (300 series).
 - (4) Tankers, hoses, pumps, and other appurtenances shall be cleaned, sanitized and inspected on a routine basis.
 - (5) Tankers that have been previously used to haul non-food commodities such as toxic materials, petroleum products, or other harmful substances shall not be used to haul drinking water for human consumption.
 - (6) Tankers used for the transporting of potable water shall be properly secured with manhole cover gaskets and safety seals.
 - (7) Connections (hoses) and pumps used for the loading and unloading of bulk water shall be properly maintained and stored to prevent contamination. When not in use, pumps, hoses, connections and fittings shall be properly capped, securely stored and protected from possible contamination.
 - (8) If required by the state agency having local jurisdiction, the bulk shipment of water prior to transporting shall be treated with an effective disinfectant (e.g., chlorine, ozone). Unless waived by the state, the concentration of this disinfectant shall be consistent with the requirements of the local state agency.
 - (9) Representative samples shall be taken from shipments of bulk water for the analyses of coliform bacteria and Heterotrophic Plate Count (HPC). The minimum frequency of sampling shall be one sample from each tanker on a weekly basis.
 - (10) Records shall be maintained for a minimum of two years that include but are not limited to:
 - (i) Name of the transporter and/or driver.
 - (ii) Tanker number.
 - (iii) Date of shipment.
 - (iv) Vendor and location of the source water.
 - (v) Name of the receiver and the location to which the water was shipped.
 - (vi) Date of delivery.
 - (vii) Date of tanker cleaning and sanitization (includes name of operator).
 - (viii) The concentration of the disinfectant residual (if required by the local state agency having jurisdiction) at the time of loading and unloading.
 - (ix) Results of coliform bacteria and HPC testing performed on representative samples taken from shipments of bulk water for each tanker to be performed at least once per week.
- (g) Multi-Food Equipment: Water intended for bottling shall not be stored, transported, processed, or bottled through equipment or lines used for milk, other dairy products, and non-beverage foods. Non-dedicated beverage equipment and lines used for other beverages shall be sanitized using a hot clean-in-place (CIP) process, or equivalent. The process must be addressed in the plant's sanitization standard operating procedure (SSOP) manual and HACCP plan, and shall include provisions for monitoring, critical limits, appropriate corrective action, and records.

- (h) Bottled water which originates from a source which is not protected from surface contamination shall be subjected to ozonation, filtration rated at one micron, or another effective process which removes or inactivates the cysts of the parasites *Giardia* and *Cryptosporidium*.
- * (i) Daily in-house total coliform monitoring on finished product of each product type and quarterly rinse/swab tests which may be performed in-house or by an approved laboratory on containers (incoming as well as those immediately from the washer) and closures as stipulated in 21 CFR Section 129.80 (f).
- (j) Each bottled water plant operator shall develop and maintain procedures for the notification of the applicable state agency, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or applicable state agency knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. 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.
- (k) A bottled water supplier who knows that the Standard of Quality has been exceeded 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 the applicable state agency promptly.
- (l) If the applicable state agency determines, based upon representative samples, risk analysis, information provided by the bottled water supplier, and other information available to the applicable state agency, 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, the applicable state agency may order the water supplier to initiate a level of product recall approved by the applicable state agency or, if appropriate, issue a form of notification to customers. The bottled water supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem. The water bottler shall where appropriate provide the notice to radio and television media or to the newspaper serving the affected public, or shall in the alternative directly notify affected users where doing so in a manner approved by the applicable state agency can effectively avoid or minimize the risk to health. Product recalls shall conform to the procedures and policies of 21 CFR Section 7.
- (m) Where the Standard of Quality has been exceeded but circumstances, including risk analysis and representative samples, indicate that the violation of the Standard of Quality 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 applicable state agency may order the bottler to communicate the exceedance of the Standard of Quality and the implementation of corrective measures by direct mailings to affected customers.
- * (n) For compliance purposes, the following provisions are applicable to the collection of spring water:

- (1) Manufacturers must maintain documentation confirming the location of the spring. FDA does not require that the identity or spring location appear on the label;
 - (2) There must be evidence that the water is flowing naturally to the surface through a natural orifice;
 - (3) If a bore hole is used to collect spring water, firms must demonstrate and be able to verify to regulatory officials that there is a measurable hydraulic connection between the bore hole and the natural spring and; the water must continue to flow naturally to the surface of the earth through the spring's natural orifice.
- (o) Where an applicable program is established, no person shall operate a bottled water plant or bottle water for the purpose of sale or distribution without first obtaining a permit demonstrating that the source, bottling facility, treatment and bottling practices, and product water meet the requirements of this law and regulations adopted thereunder. The applicable regulatory agency may establish a reasonable fee for a permit application, for which the fee shall be based on the cost of processing the application, and which shall be the same for in-state and out-of-state bottlers. An annual renewal fee shall be established.
- (1) For bottled water imported from outside the United States, the required showing shall include a certification signed by the applicable regulatory agency with jurisdiction over bottled water in the country of origin that (a) describes the requirements of said country for the source, bottling facility, treatment, bottling practices, and product water; (b) states the date of the last officially authorized inspection by the applicable regulatory agency or acceptable third-party inspection organization and review of said source, facility, treatment, bottling practices, and product water in light of such requirements; and (c) certifies that said source, facility, treatment, bottling practices, and product water meet the standards of the country of origin except those that are in conflict with U.S. State and Federal laws and regulations.
 - (2) As a condition of IBWA membership, the bottler shall receive a plant audit demonstrating compliance with the Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practices (GMPs), and Operational Requirements of this Model Code. Said audit shall be conducted by a third party audit organization acceptable to the IBWA. Said audit may also be conducted by the county, state, or country regulatory agency having appropriate jurisdiction in which the bottling facility is located, by the federal FDA, or by a third party audit organization acceptable to the applicable regulatory agency. The results of such audits will be reviewed to determine the plant's qualifications for IBWA's Excellence in Manufacturing and Certificate of Compliance award programs. Major nonconformances reported in the audit findings will disqualify the plant from receiving such awards.
- (p) 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 IBWA or an applicable regulatory agency demonstrating that he or she has successfully passed the IBWA certified plant operator examination or an equivalent examination developed and administered by the applicable regulatory agency or by a third party organization that is acceptable to the applicable regulatory agency and IBWA, that covers periodic instruction and testing in plant, source 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.

RULE 4: SOURCE WATER MONITORING

- (a)(1) If any source does not comply with the Standard of Quality required by the state or federal agency for the production of bottled water, the bottler must show by analysis, that this treatment reduces the contaminant(s) below the Standard of Quality in the finished product. See Rule 3(a). Approval of the source water product derived from a source other than a public water supply must be based upon a field inspection of the source and a review of information prepared by a professionally qualified hydrogeologist that shall demonstrate the integrity of the source and safety of the catchment operations, and that shall include:
- (i) An evaluation of the chemical, physical, microbiological, and radiological characteristics of the source.
 - (ii) A report on the regional geology surrounding the site and the specific site geology. A description of the vertical and horizontal extent of the source aquifer using existing data. The information will be used to define the recharge area of the aquifer, or in the case of regional aquifers, the zone of influence of the subject source.
 - (iii) A report detailing the development of the source; the method of construction including spring design, well installation, surface catchment, and intake structures; and transmission facilities as appropriate.
 - (iv) A watershed survey of the recharge area or zone of influence of subject source that identifies and evaluates actual and potential sources of contamination, and which shall be updated every three years, including any reported discharge that may affect the source.
 - (v) Based on the findings in item (iv), a plan for special monitoring of any significant contaminant source and for taking restrictive preventive or corrective measures as appropriate to protect the source water.
- (a)(2) The plant operator shall be responsible for sampling and analysis of all approved sources for the contaminants specified in Rule 2. Such monitoring shall be at least annually, except that analysis for microbiological contaminants shall be weekly if the source is other than a public water system.
- (b)(1) In lieu of source monitoring required by this Rule, a plant operator using a public water system as its source may obtain and display a certificate from said system demonstrating that the public water system conducts the monitoring required by the Rule.
- (b)(2) In lieu of source monitoring required by this Rule, a plant operator not using a public water system as a source may reduce the testing frequency of that source, as well as the number of chemical contaminants tested, if it can be documented that such reduction is consistent with a State-issued monitoring waiver.

- (c) Where a bottled water plant operator, water dealer, or regulatory agency knows or has reason to believe that a contaminant not otherwise monitored is present in the source water because of a spill, release of a hazardous substance, or otherwise, and its presence would create a potential health hazard to consumers, the plant operator or water dealer upon receipt of such information shall monitor the source water for said contaminant.
- (d) Detection of contaminant(s) in source monitoring required pursuant to Rule 4 shall be followed immediately by a program of periodic monitoring to confirm the presence in the source water of said contaminant(s). If such listed regulated contaminant(s) is confirmed to be present in the source water at a concentration that exceeds a published U.S. FDA, or applicable state agency requirement for drinking water, the plant operator or water dealer shall employ appropriate treatment techniques to remove or to reduce said contaminant in the product water below said concentration, and shall employ a program of periodic monitoring for said contaminant in the source water until such time as said contaminant is not detectable in the source water.
 - (1) (e) Total coliform analysis of source water shall be performed at least once per week by an approved laboratory. Daily in-house microbiological sampling and analysis shall be performed by qualified plant personnel. All required chemical analysis shall be performed by an approved laboratory. Records of the 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 of the applicable state agency.

RULE 5: FINISHED PRODUCT MONITORING
--

- (a) To assure that bottled water complies with Rule 2, the following product monitoring, using representative samples derived from the bottled product, shall be performed:
 - * (1) For microbiological contaminants (i.e., total coliform) analyze daily a representative sample from a batch or segment of a continuous production for each type of bottled water produced by the plant. Such analyses shall be performed daily by qualified plant personnel and weekly by an approved laboratory.
 - * (2) For chemical, physical, and radiological contaminants, analyze annually a representative sample from a batch or segment of continuous production run for each type of bottled drinking water produced by the plant.
- b) For all required microbiological analysis on product water, the sampling shall be performed by qualified plant personnel and the analysis shall be performed by an approved laboratory at least once per week. All daily in-house microbiological sampling and analysis shall be performed by qualified plant personnel. All required product water chemical analysis shall be performed by an approved laboratory.
- (e) Records of required sampling and analysis shall be maintained at the plant not less than five years and shall be available for official review upon request of the applicable state agency.

***RULE 6: LABELING REQUIREMENTS**

- (a) Bottled water product terms shall comply with all applicable provisions under 21 CFR Section 165.110(a) and other FDA requirements under 21 USC Section 343, including, but not limited to 21 CFR Section 165.110(a)(3) which reads:
- (i) If the TDS content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement "low mineral content" or the statement "high mineral content," respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.
 - (ii) When bottled water comes from a community water system, as defined in 40 CFR 141.2, except when it has been treated to meet the definitions in paragraphs (a)(2)(iv) and (a)(2)(vii) of this section and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.
 - (iii) When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants that the bottled water is for use in feeding infants, and the product is not commercially sterile under §113.3(e)(3)(i) of this chapter, the product's label shall bear conspicuously and on the principal display panel the statement "Not sterile. Use as directed by physician or by labeling directions for use of infant formula."
- (b) The following labeling criteria will trigger the need for a Nutrition Facts panel and compliance with related FDA nutrition labeling requirements:
- (1) All nutrition labeling shall comply with the applicable provisions under 21 CFR Section 101.9.
 - (2) Presence of significant amounts of any of the nutrients identified in 21 CFR Section 101.9(c).
 - (3) Nutritional statements on the label or any statements used in advertising which convey nutritional information about the product, i.e., sodium free claims. Any such claims as to the "nutrient content" of a food must also comply with FDA requirements contained in 21 CFR Section 101.13.
- (c) When the microbiological, physical, chemical or radiological quality of bottled water is below that prescribed in 21 CFR Section 165.110(b), the label of the product shall bear a statement of substandard quality as follows:

- (1) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of 21 CFR Section 165.110(b)(2).
 - (2) "Excessively Turbid," "Abnormal Color," and/or "Abnormal Odor," as appropriate, if the bottled water fails to meet the requirements of 21 CFR Section 165.110(b)(3).
 - (3) "Contains Excessive _____" with the blank filled in with the name of the chemical for which an alternative level established under the Standard of Quality as described in 21 CFR Section 165.110(b)(4) is exceeded.
 - (4) "Excessively Radioactive" if the bottled water fails to meet the requirements of 21 CFR §165.110(b)(5).
- (f) In addition to the label information required under 21 CFR Sections 101.5 and 165.110 and 21 USC Section 343, IBWA member proprietary brands must also include on the label a telephone number of the bottler, distributor, or brand owner as a means of contact for consumers who wish to obtain additional product information. It is strongly recommended that private label brands produced by IBWA members included the telephone number of the bottler, distributor, or brand owner.

In addition to the telephone number, bottlers or brand owners 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.

The mandatory telephone requirement is effective January 1, 2002. Labels made before January 1, 2002, for IBWA member proprietary brands may be sold through without telephone numbers. However, members are encouraged to comply with this requirement as soon as possible.

Appendix A

2002 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP	MONITORING FREQUENCY	SOCs, MCLs, SMCLs, and Guidelines		
<i>Individual Group Analytes</i>				
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 <i>FDA D/DBP Rule Monitoring Requirements</i> on page 19.	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 <i>FDA D/DBP Rule Monitoring Requirements</i> on page 19.	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 19 in Appendix A for details.
- (3) SOQ dependent upon temperature and other factors. See fluoride section on page 20 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.
- (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.

Appendix A

2002 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP		MONITORING FREQUENCY	SOCs, MCLs, SMCLs, and Guidelines		
Individual Group Analytes					
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 19.	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
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-ethylhexyl)adipate		0.4	0.4	0.4
	Di(2-ethylhexyl)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)	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)		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		0.002	0.002	0.002
	Ethylene dibromide		0.00005	0.00005	0.00005
	Glyphosate (1)(7)		0.7	0.7	0.7
	Heptachlor		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 four synthetic organic chemicals (SOC) listed must be done quarterly for four consecutive quarters, then annually for new products and new companies.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted.

Appendix A

2002 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP		MONITORING FREQUENCY	SOCs, MCLs, SMCLs, and Guidelines		
Individual Group Analytes					
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 / <i>E. coli</i>	NOTE: Confirmation AND validation of all positive total coliform results required. SEE APPENDIX C OF THE MODEL CODE	No <i>Escherichia coli</i> detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling.	MPN: <9.2 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	SOURCE: Every 4 years	15 pCi/L	15 pCi/L	15 pCi/L
	Gross Beta	PRODUCT: Annually	50 pCi/L	50 pCi/L	50 pCi/L
	Radium 226/228 (combined)	When gross alpha exceeds 5 pCi/L.	5 Pci/L	5 pCi/L	5 pCi/L
	Strontium 90	When gross beta exceeds 8 pCi/L	8 pCi/L	8 pCi/L	8 pCi/L
	Tritium and other man-made nuclides	When gross beta exceeds 8 pCi/L	NA	NA	NA
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 (8)		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) 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.

Appendix A

2002 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 FINAL PRODUCTS

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

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

Appendix A

2002 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

FDA Requirements for Fluoride in Bottled Water

Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

Appendix B

Purified Water - Official Monograph USP XXIII

H₂O 18.02

Purified Water is water obtained by distillation, ion-exchange treatment, reverse osmosis, or other suitable process. It is prepared from water complying with the regulations of the federal Environmental Protection Agency with respect to drinking water. It contains no added substance.

Note--Purified Water is intended for use as an ingredient in the preparation of compendial dosage forms. Where used for sterile dosage forms, other than for parenteral administration, process the article to meet the requirements under Sterility Tests <71>, or first render the Purified Water sterile and thereafter protect it from microbial contamination. Do not use Purified Water in preparations intended for parenteral administration. For such purposes use Water for Injection, Bacteriostatic Water for Injection, or Sterile Water for Injection.

Packaging and storage--Where packaged, preserve in tight containers.

Labeling--Where packaged, label it to indicate the method of preparation.

pH-- <791>: between 5.0 and 7.0, determined potentiometrically in a solution prepared by the addition of 0.30 mL of saturated potassium chloride solution to 100 mL of test specimen.

Chloride--To 100 mL add 5 drops of nitric acid and 1 mL of silver nitrate TS: no opalescence is produced.

Sulfate--To 100 mL add 1 mL of barium chloride TS: no turbidity is produced.

Ammonia--To 100 mL add 2 mL of alkaline mercuric-potassium iodide TS: any yellow color produced immediately is not darker than that of a control containing 30 µg of added NH³ in *High-purity Water* (see under *Reagents in Containers* <661>) [0.3 ppm].

Calcium--To 100 mL add 2 mL of ammonium oxalate TS: no turbidity is produced.

Carbon dioxide--To 25 mL add 25 mL of calcium hydroxide TS: the mixture remains clear.

Heavy metals--Adjust 40 mL of Purified Water with 1 N acetic acid to a pH of 3.0 to 4.0 (using short-range pH indicator paper), add 10 mL of freshly prepared hydrogen sulfide TS, and allow the liquid to stand for 10 minutes: the color of the liquid, when viewed downward over a white surface, is not darker than the color of a mixture of 50 mL of the same Purified Water with the same amount of 1 N acetic acid as was added to the test specimen, matched color-comparison tubes being used for the comparison.

Oxidizable substances--To 100 mL add 10 mL of 2 N sulfuric acid, and heat to boiling. Add 0.1 mL of 0.1 N potassium permanganate, and boil for 10 minutes; the pink color does not completely disappear.

Total solids--Evaporate 100 mL on a steam bath to dryness, and dry the residue at 105° for 1 hour: not more than 1 mg of residue remains (0.001%).

Bacteriological purity--It complies with the federal Environmental Protection Agency regulations for drinking water with respect to bacteriological purity (40 CFR 141.14; 141.21).

Appendix C

***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.

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.

**IBWA'S MODEL CODE OF REGULATIONS HAS BEEN USED AS A
BASIS FOR NEW BOTTLED WATER REGULATIONS IN THE
FOLLOWING STATES:**

Arizona
California
Connecticut
Florida
Hawaii
Louisiana
Maryland
Massachusetts
New Hampshire
New Jersey
New York
Ohio
Oklahoma
Pennsylvania
Texas
Wyoming

(#) Some changes have been made in the Model Code in each state to fit certain standards, procedures, etc. specific to the state.