Code of Practice

Bottled Water Code of Practice

Revised March, 2012

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INTERNATIONAL BOTTLED WATER ASSOCIATION
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This Code of Practice for Bottled Water has been prepared by the International Bottled Water Association, its membership, Board of Directors, Government Relations Committee, and Technical Committee. For questions about the Code of Practice, contact: International Bottled Water Association, 1700 Diagonal Road, Suite 650, Alexandria, VA 22314. (703) 683-5213.

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Foreword

The IBWA Model Bottled Water Regulation, known as the "Model Code," was first published in 1982. At that time, the U.S. Food and Drug Administration's regulations for bottled water were limited in scope. IBWA developed a set of standards that could be used as minimum standards to which association members would subscribe and to encourage state agencies to adopt it as a model for their own bottled water regulations.

IBWA has continued to advance the Model Code in the 1980s, 1990s, and up to the present day. In November 13, 1995, FDA published a standard of identity and quality for bottled water at 21 C.F.R. §165.110. The Model Code was revised to adopt the provisions that FDA had promulgated, but it was still considered a document that could be used to raise the standards for bottled water and distinguish IBWA bottlers from others in the industry. This was done partly by adopting industry and regulatory requirements that were sometimes more stringent than FDA, primarily in the area of good manufacturing practices (GMPs). In 2000, IBWA adopted the Hazard Analysis of Critical Control Points (HACCP) system into the Model Code. This was a significant advance for the industry since HACCP was not mandated for bottled water at either the federal or state levels of government. The association felt it was important to adopt HACCP.

The IBWA Model Code has adopted many of the state requirements for bottled water. However, there are some instances where an individual state requirement may not be included in the Model Code, such as source and finished product monitoring requirements for certain substances, and bulk water hauling regulations. If a bottler sells in a particular state, they must ensure they comply with the state bottled water regulations. IBWA bottler members are encouraged to use the contact list of state regulatory agencies, included in this Model Code at Appendix D, for ready access to state bottled water regulations.

In recent years, with improved FDA and state regulations in place, IBWA's focus began to shift from providing a regulatory model to the following set of principles:

The IBWA Code of Practice is a set of self-regulating industry standards.

The Code of Practice establishes a comprehensive set of standards for bottler members to ensure product safety and quality.

The Code of Practice provides specific guidance to current IBWA members.

The Code of Practice is a reference document that provides, in one place, information members need regarding government and industry standards.

The Code of Practice provides valuable guidance to "startup" companies, who are prospective members of IBWA.

For companies who seek to enter the bottled water industry, the Code of Practice is a valuable resource to educate them on our industry's technical and regulatory requirements and provides a framework within which they can establish their facilities.

The Code of Practice enhances the FDA Good Manufacturing Practices (GMPs), and provides the basis for HACCP in the bottled water industry.

IBWA has long sought enhancements to FDA's GMP regulations. This was partly accomplished with the publication of FDA's final rule for bottled water GMPs at 21 CFR Part 129. However, the Code of Practice has enhanced the FDA GMPs and has incorporated HACCP as an integral part of IBWA's approach to food safety.

The Code of Practice is a valuable communication tool and a benefit of IBWA membership.

The Code of Practice is a valuable tool to provide to representatives of the media and consumers to help them better understand IBWA's efforts to provide consumers with a safe, quality food product. Members can be confident in knowing that their conformance to the Code ensures that they are above federal regulatory requirements for safety and quality.

The Code of Practice provides the basis for IBWA's annual plant inspection program.

A key provision of the Code of Practice, and a principal benefit of membership, is IBWA's requirement for an annual inspection of each member bottlers' facility by an independent third-party food safety organization, currently NSF International for domestic companies. The program confirms the member's conformance with the technical and regulatory requirements of the Code of Practice, and rewards them for achieving superior performance at the plant; a valuable tool for the company's promotional activities.

Whether you are a current member of IBWA, are new to the bottled water industry, or if you are simply interested in learning more about the industry, we hope you find this *Bottled Water Code of Practice* to be an asset.

General Requirements

The IBWA Bottled Water Code of Practice ("Code of Practice") provides comprehensive guidance for bottled water technical and federal regulations. Bottlers are also required to comply with all applicable state or local agency regulatory requirements for bottled water in the states in which products are distributed and/or sold. Bottler members are encouraged to use the state regulatory agency contact list in Appendix D of this Code of Practice as a resource for state regulators and access to current state-based regulatory requirements.

RULE 1: DEFINITIONS

As used in these rules:

(a) **"Approved Laboratory"** means a competent commercial laboratory (e.g., Environmental Protection Agency (EPA), state-certified, or laboratories acceptable to the government agencies having jurisdiction).

*(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 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 of a safe and sanitary quality with or without treatment, according to applicable laws and regulations of state and local government agencies having jurisdiction. Approval shall be obtained and maintained in accordance with rule 3(c) and rule 4(a) through (e). The presence in the plant of current certificates or notifications of approval from the government agency(ies) having jurisdiction constitutes approval of the source and the water supply.

*(c) **"Artesian Water"** or “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 §165.110(a)(2)(i).

*(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). 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.

*(g) **"Demineralized Water"** means bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the 23rd revision of the United States Pharmacopoeia, 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 23rd revision of the United States Pharmacopoeia, 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 23rd revision of the United States Pharmacopoeia, 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). 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 as defined at 40 CFR §141.2.

*(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 water, mineral water, artesian water, artesian well water, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).[1]

(n) **"Plant Operator"** means any person who owns or operates a bottled water plant, and who meets the requirements of Rule 3(p) 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 23rd revision of the United States Pharmacopoeia, January 1, 1995, attached as Appendix B, specified by FDA in 21 CFR 165.110(a)(2)(iv).

[1] In a letter to FDA, dated March 23, 2000, IBWA confirmed FDA's acknowledgement that selective removal of undesirable elements is a form of limited treatment. *IBWA PERFORMANCE STANDARD*: A process to remove any undesirable element (e.g., bromide, arsenic) from bottled water must be selective and not alter the water significantly. As long as such processing is selective and complies with FDA's stated policies on use of the term 'natural,' such processing shall not preclude labeling the product as 'natural.' Minimal treatment of spring, mineral, artesian, or well water to selectively remove or reduce the concentration of naturally occurring undesirable elements shall not preclude labeling the product 'spring water', 'mineral water', 'artesian water' or 'well water', as appropriate, as long as all other requirements of the applicable standard of identity are met. If the process alters the water significantly, that fact must be reflected in the Statement of Identity and the product cannot be labeled "natural."

*(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 23rd revision of the United States Pharmacopoeia, 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 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.[2] 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"** or "Sterilized Water" means water that meets the requirements under "Sterility Tests" <71> in the 23rd revision of the United States Pharmacopoeia, January 1, 1995, attached as Appendix B and specified by FDA at 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.

[2] The following is from the preamble of the November 13, 1995 final rule for the bottled water standards of identity and quality regarding spring location and development: "Comments requested that FDA address the issues of ownership and control in the regulations. Comments questioned whether proper inspections could be mandated in a case where a spring is located on one owner's property, and the bore hole is on another's property. One comment stated that the ownership and control of the bore hole should be the same as that of the spring for quality control purposes. One comment stated that, if a company owns, or owns the rights to, a legitimate spring, it should not matter how it collects the water as long as it does so in a sanitary way.

The issues raised by these comments are outside the scope of this rulemaking and really beyond the coverage of the act. Issues of ownership and control turn on property laws, water rights, and access to the spring's natural orifice. However, FDA cautions that a manufacturer must be able to test the water that flows naturally to the surface of the earth to ensure that the water that it is collecting from the bore hole is the same water as that from the spring that flows to the surface, and that there is a hydraulic connection between the bore hole and the natural spring. If the manufacturer cannot establish that the water that it is calling ''spring water'' is the same as that from the identified spring, it runs a significant risk that its product is misbranded, and, thus, that it will be the subject of a regulatory action."

RULE 2: PRODUCT QUALITY AND SECURITY

*(a) Product water shall be from an approved source and shall meet the standard of quality prescribed by the FDA at 21 CFR Section 165.110(b).

(b) All bottled water products shall meet the chemical, physical, and microbiological standard of quality prescribed by this Code of Practice 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 Code of Practice.

(c) 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 Code of Practice, shall 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, distributor member, and supplier member shall comply with FDA's rules for compliance with the Public Health Security and Bioterrorism Act of 2002 (PL 107-188), including all applicable sections and provisions for administrative detention of food products, registration of food facilities, prior notice of imported food shipment, and establishment and maintenance of records. Each member facility to which these rules apply shall prepare a security plan[3].

(c) 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.

[3] A framework for such a security plan can be found in an FDA document entitled "Guidance for Industry: Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance." A copy of the document is available at http://www.fda.gov/oc/bioterrorism/bioact.html.

(d) 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.

(e) Water intended for bottling must be from a source approved by the applicable regulatory agency. If treatment is necessary to reduce, remove or prevent growth of microbial contaminants, chemical, physical and/or radiological substances (including multiple barrier treatments such as filtration, disinfection, reverse osmosis, etc.) of that water during processing, the finished bottled water product shall be safe and suitable for consumption. These treatments can be used singularly or in combination as multiple barriers. A hazard analysis (such as HACCP) should be undertaken to provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, hazards (microbiological, chemical and radiological) for the production of safe bottled water.[4]

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

When necessary, treatments to remove or reduce chemical substances may include chemical and particulate (mechanical) filtration such as achieved with surface filters (e.g., pleated membrane filters) or depth filters (e.g., sand or compressed fiber (cartridge) filters), activated carbon filtration, demineralization (deionization, water softening, reverse osmosis, nano-filtration), and aeration. These treatments for chemicals may not adequately reduce or remove microorganisms and, likewise, treatments for microorganisms may not adequately reduce or remove chemicals and particulate matters.

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

(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,

[4] As stated in the Codex Alimentarius *Code Of Hygienic Practice For Bottled/Packaged Drinking Waters (Other Than Natural Mineral Waters)*, *CAC/RCP 48-2001*: "Generally, the higher the quality of the water intended for bottling [i.e., source water], the less treatment is required to produce safe bottled drinking water products.

Surface waters should be tested for safety frequently and treated as necessary.

Waters originating from protected underground supplies are less likely to require treatment than waters originating from surface supplies or unprotected underground supplies."

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) 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.

(9) 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, non-beverage foods, or any non-food product. 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 by qualified plant personnel 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) As a condition of IBWA membership, bottlers shall receive an annual plant inspection demonstrating compliance with this code of practice. Said inspection shall be conducted by an independent third-party inspection organization acceptable to the IBWA for inspections.

(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 acceptable to IBWA, that covers periodic instruction and testing in plant, source, HACCP, and product sanitation, operation and maintenance of water treatment technology, and the maintenance and monitoring of source and product water quality in accordance with these applicable bottled water standards.

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 treatment processes utilized reduce 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 (e.g., 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 at least weekly by an approved laboratory.

*(2) For chemical, physical, and radiological contaminants, analyze at least annually, in accordance with Appendix A of this Code of Practice, 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.

(c) Records of required sampling and analysis shall be maintained at the plant not less than four 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).

(d) 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.

Appendix A
2011 MONITORING MATRIX
IBWA Code of Practice Monitoring Requirements

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

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

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

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

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

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

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

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

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

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

Appendix A
2011 MONITORING MATRIX
IBWA Code of Practice Monitoring Requirements

FDA D/DBP Rule Monitoring Requirements

Public Water System (PWS) Source Water

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

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

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

Natural Water Sources

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

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

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

ALL FINISHED PRODUCTS

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

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

Appendix A
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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 lev-els shall be based on the annual aver-age of maximum daily air tempera-tures 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

Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

Appendix B

Purified Water - Official Monograph USP XXIII

H_2O 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 NH^3 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.

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

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

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

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

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

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

Appendix D

List of State Regulatory Contacts (revised 06/01/04)

ALABAMA (051704)
Environmental & Health Facility Standards Administration
Division of Food, Milk & Lodging
201 Monroe Street, Suite 1250
Montgomery, AL 36104
CONTACT: Mr. Ronald Dawsey, Director
Voice: (334) 206-5375
Fax: (334) 206-5788
Email: rdawsey@adph.state.al.us

ALASKA (042604)
Dept. of Environmental Conservation
Division of Environmental Health
Food Safety & Sanitation Program
555 Cordova
Anchorage, AK 99501
CONTACT: Ms. Nancy Napolilli
Voice: (907) 269-4552
Fax: (907) 269-7510
Email: nancy_napolilli@dec.state.ak.us

ARIZONA (042604)
Arizona Dept. of Health Services
Food Safety & Environmental Services
150 N. 18th Avenue, Suite 430
Phoenix, AZ 85007-6412
CONTACT: Mr. Ron Holley R.S. Registered Sanitarian
Voice: (602) 364-3135
Fax: (602) 364-3146
E-mail: rholley@hs.state.az.us

ARKANSAS (042604)
Arkansas Dept. of Health
Food Protection Services
4815 West Markham Street
Little Rock, AR 72205-3867
CONTACT: Mr. Randy Carter, Environmental Health Program Specialist
Voice: (501) 661-2171
Fax: (501) 661-2572
Email: jrcarter@healthyarkansas.com

CALIFORNIA (042604)
California Dept. of Health Services
Food and Drug Branch (MS-7602)
P.O. Box 997413
1500 Capitol Avenue
Sacramento, CA 96899-7413
CONTACT: Dr. Chang-Rae Lee, Research Scientist IV
Voice: (916) 650-6601
Fax: (916) 440-5369
e-mail: CLee1@dhs.ca.gov

COLORADO (050404)
Dept. of Public Health & Environment
Consumer Protection Division
4300 Cherry Creek Drive South
MailCode: CPD-GS-B2
Denver, CO 80246-1530
CONTACT: Ms Susan Parachini, Wholesale Food Manufacturing & Storage Program Mgr.
Voice: (303) 692-3646
Fax: (303) 753-6809
Email: susan.parachini@state.co.us

CONNECTICUT (050404)
Dept. of Consumer Protection - Food Division
165 Capitol Avenue, Room 165
Hartford, CT 06106
CONTACT: Timothy Spillane, Supvr.
Voice: (860) 713-6160
Fax: (860) 713-6167
Email: timothy.spillane@po.state.ct.us

DELAWARE (042704)
Delaware Division of Public Health
PO Box 637
Dover, DE 19903-0637
CONTACT: Robert Hoffner, Manager, Food Protection Program
Voice: (302 744-4546
Fax: (302) 739-3839
Email: Robert.Hoffner@state.de.us

DISTRICT OF COLUMBIA (051904)
Dept. of Consumer & Regulatory Affairs
941 North Capitol Street NE, Suite 9500
Washington, DC 20002
CONTACT: Mr. David A. Clark, Director
Voice: (202) 442-8947
Fax: (202) 442-9445

FLORIDA (051804)
Dept. of Agriculture & Consumer Services
Division of Food Safety
3125 Conner Blvd., Room 297
Tallahassee, FL 32399-1650
CONTACT: Ms Rita J. Johnson, R.S.,
Biological Scientist IV
Voice: (850) 488-3951
Fax: (850) 488-7806
Email: johnsor@doacs.state.fl.us

GEORGIA (052004)
Dept. of Agriculture
Consumer Protection Division
Capitol Square Room 309
Atlanta, GA 30334
CONTACT: Mr. Mark Norton, Agricultural
Manager
Voice: (404) 656-3621
Fax: (404) 463-6428
Email: mnorton@agr.state.ga.us

HAWAII (051804)
State Department of Health
Food & Drug Branch
591 Ala Moana Boulevard
Honolulu, HI 96813
CONTACT: Ms Margaret Yung, Acting
Program Manager, Consumer Safety
Voice: (808) 586-4725
Fax: (808) 586-4729
Email: myung@ehsdmail.health.state.hi.us

IDAHO (042704)
State Dept. of Health & Welfare
450 West State-4th Floor
Boise, ID 83720-0036
CONTACT: Mr. Patrick L. Guzzle, MPH
Food Protection Program Mgr.
Voice: (208) 334-5936
Fax: (208) 332-7307
Email: guzzlep@idhw.state.id.us

ILLINOIS (051804)
State Dept. of Public Health
Division of Food, Drugs, and Dairies
525 W. Jefferson Street
Springfield, IL 62761
CONTACT: Elizabeth Watkins
Voice: (217) 785-2439
Fax: (217) 782-0943
Email: ewatkins@idph.state.il.us

INDIANA (051704)
State Department of Health
Food Protection
2 North Meridian Street
Indianapolis, IN 46204
CONTACT: Ms. Vonda Allen, Wholesale
Food Program Coordinator
Voice: (317) 233-7360
Fax: (317) 233-7334
Email: vallen@isdh.state.in.us

IOWA (042604)
State Department of Inspections & Appeals
Food & Consumer Safety Bureau
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