AUDIT

International Bottled Water Association

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AUDIT HANDBOOK

A Guide for IBWA Annual Third Party Plant Audits
and Plant Self Audits

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Revision 9.2

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Acknowledgements

IBWA acknowledges and appreciates the contributions to this handbook by members of the IBWA Audit Program Evaluation Team and Technical Committee.

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(1) Contact IBWA for copies of the latest revisions of the FDA regulations IBWA guidance documents, and Bottled Water Code of Practice.

Introduction

All food manufacturing facilities in the United States are subject to inspections, some by the U.S. Food and Drug Administration (FDA), others by the U.S. Department of Agriculture, or their respective surrogate state agencies. These inspections focus on the Hazard Analysis and Preventive Controls/Good Manufacturing Practices (GMPs) outlined in the Code of Federal Regulations (CFR) at 21 C.F.R. Part 117. Bottled water, regulated by FDA as a packaged food product, is also subject to processing and bottling standards in 21 C.F.R., Parts 129 and 165. Under the General Provisions section in Part 129, the Code stipulates that "the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water must conform with or be operated or administered in conformance with GMPs to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions."

The IBWA Audit Program

The International Bottled Water Association (IBWA) requires, as a condition of membership, that bottlers submit to an annual audit of their facilities. From 1984 to 2018, the annual audit focused on requirements of 21 CFR Parts 110, 129, and 165 as well as the IBWA Bottled Water Code of Practice ("Code of Practice"). Beginning in 2019, Part 110 was replaced in the audit program with Part 117. The audit also covers IBWA requirements for a food defense plan and membership requirements at each member facility. The audits are conducted by third party certification bodies (CBs) contracted by IBWA. The primary purpose for the annual audits has been to assist members in verifying compliance with FDA regulations and IBWA's Bottled Water Code of Practice. Beginning in 2002, the Hazard Analysis and Critical Control Point (HACCP) approach to food safety was adopted by IBWA, and annual audits through 2018 included a review of each member company's HACCP program as well as GMP compliance. IBWA's voluntary implementation of HACCP in the bottled water industry was based partially on HACCP regulatory requirements set by the Codex Alimentarius Commission and the U.S. Department of Agriculture and the FDA. By September 2018, all food facilities, including bottled water facilities, were required to comply with FDA's regulations under the Food Safety Modernization Act (FSMA). The IBWA Audit Program will continue its long-established goal of assisting members with compliance.

The Audit Handbook

This Handbook was prepared for you, the IBWA member, to assist you in preparing for your plant's annual audit. IBWA also provides the handbook to its audit contractors to assist them in interpreting FDA and IBWA requirements and their application to bottled water facilities. The handbook also serves to provide you with the means to conduct self-audits, an important part of any plant's food safety and security program. Self-auditing helps prepare you and your facility for audits by IBWA's contractor as well as government representatives.

When IBWA's auditor notes nonconformances during your audit, you should implement any necessary corrective action to return your plant into conformance/compliance with your food safety and defense plans and any applicable regulatory requirements.

Preparing for an Audit

As was mentioned earlier, the best method to prepare for an IBWA audit is to conduct a series of self-audits of your facility(ies). Meet with your quality assurance and production staff and with your food safety team on a regular basis. It is important, whenever feasible, to prepare more than one individual in the company for the audit. If, when the auditor arrives, no one is available to work with the auditor, and the auditor is turned away at the door, it may be a costly decision as your company will be charged for any rescheduled audits. It is critically important to train two or more company employees in handling the audit, including the food safety and food defense plans and location of all supporting records that will be requested during the audit.

All materials necessary to conduct your own self audit are included in this handbook, including an audit checklist, item-by-item discussion, and applicable regulations.

Audit Program Administration

The audit is designed to be carried out in a constructive, consultative manner. This is not a regulatory audit; the auditor is not authorized to shut down your operations. However, if a serious food safety or operational matter is brought to your attention during or after the audit, you should take immediate steps to correct the nonconformance(s).

The audit form includes a total of 144 items. Of those 144 items, 85 are GMP requirements as cited by FDA and IBWA; 28 are directly linked to your food safety plan as cited by FDA; 26 address your food defense plan; and 5 are requirements for membership in IBWA.

The auditor will generally start with a review of your plant's food safety and food defense plans. He/she will usually tour the plant to verify the process flow diagram, then return to an office area to continue review of the food safety and food defense plans and associated records. Upon completion of the plan and record review, the auditor will proceed into the plant to verify information presented in the food safety and food defense plans and to conduct the GMP portion of the audit. When completed, the auditor will return to the office for report generation and debriefing with the plant representatives.

The auditor should encourage you to ask questions during the audit. Do not be afraid to ask questions; remember, this is a constructive, consultative event! You should take your own notes during the audit, including the auditor's suggestions and recommendations as well as issues that you may wish to discuss during the debriefing. If you have any questions that cannot be answered by the auditor, you should contact IBWA's Vice President of Science, Education and Technical Relations at (703) 647-4614 for assistance. Issues that require further consideration may be referred to the IBWA Audit Program Evaluation Team.

After the audit is completed, the auditor will conduct a debriefing session. At that time, a list of nonconformances is provided to the plant's representatives. The auditor should provide forms (CAR-1, explained below) with a brief explanation of each nonconformance and space for the company's root cause analysis and corrective action. The company has up to

ten (10) business days to complete the form and submit it to the audit contractor to comply with the terms of the audit contract.

There are two types of nonconformances employed in the IBWA audit program:

- *Food Safety, Food Defense, and IBWA Membership Major Nonconformances (FSMj, FDMj, and MMj, respectively)*
  Major nonconformances (Mj) are generally equivalent to a "critical deficiency." IBWA and its third-party audit contractors have determined that these items are directly related to compliance with your food safety plan or to food safety. Items cited as "Mj" must be corrected as soon as possible. The plant is required to perform a root cause analysis of the problem and record the results of that analysis on the Corrective and Preventive Action Report form (CAR-1) provided by the auditor. When the root cause is determined, the plant is required to BRIEFLY, but as specifically as possible, explain on the form what corrective action has been, or will be, implemented. Return a copy of the CAR-1 form to the audit company within 10 business days after the date of the plant audit.
- *Food Safety and Food Defense Minor Nonconformances (FSMn and FDMn, respectively)*
  Minor nonconformances (Mn) are generally other GMP and administrative items for which corrective action is necessary. Items cited as "Mn" must be reported to IBWA on a second Corrective and Preventive Action Report (CAR-2) form. Unlike the CAR-1 form, the CAR-2 form requires the plant to provide only information for corrective action taken by the plant. No root cause analysis is required. ***Please note that IBWA no longer requires that a CAR-2 form be submitted for minor nonconformances; however, the audit company may require that the form be submitted for other certification purposes.*** If required due to another third-party certification, return a copy of the CAR-2 form to the audit company within 10 business days after the date of the plant audit.

While the audits are intended to focus on more of a "black and white" approach to "conformance" or "nonconformance" with a plant's food safety and food defense plans and GMPs, every effort will be made to accommodate concerns over variability in interpretation of the requirements. However, that accommodation will be focused more on the IBWA Audit Program Evaluation Team (APET), whose function is to rule on areas of dispute. APET generally will concentrate on issues that affect the industry as opposed to rulings on individual plant matters. For example, APET is more likely to become involved in rulings on where weekly source samples may be collected rather than the condition of a source water tanker at a specific facility.

With automation of the audit report process, including use of web access by the plant to their own audit reports for entry of root cause analysis and corrective action information, a more efficient process for responding to nonconformances will be available. The process

also expedites implementation of corrective action by the plant due to a shortened response period (10 business days).

Customarily, IBWA audit reports are not assigned a numerical score. Rather, they are evaluated based on “conformance” or “nonconformance” with the plant’s food safety and food defense plans and regulatory GMPs. However, IBWA maintains an awards program that continues to recognize plants that demonstrate “Excellence in Manufacturing” and acknowledges those who are following their food safety and food defense plans. To qualify for certificates for the above recognition, the following guidelines have been established:

Excellence in Manufacturing

If a plant’s audit findings contain no major nonconformances and seven (7) or fewer minor nonconformances, the plant will be awarded a certificate for “Excellence in Manufacturing.” A list of all plants awarded the certificate will be published in IBWA’s *Bottled Water Reporter*.

Certificate of Compliance

If a plant’s audit findings exhibit no major nonconformances and from seven (8) to seventeen (17) minor nonconformances, the plant will be awarded a “Certificate of Compliance.” The certificate acknowledges that the plant is following its food safety and food defense plans and GMPs. A list of all plants awarded the certificate will be published in the *Bottled Water Reporter*.

Plants that are cited by the auditor for 1 or more major nonconformances and/or more than 18 minor nonconformances are considered as not passing the annual audit. These plants may be requested by IBWA to provide a plan for returning to compliance with their food safety/defense plans and all applicable GMP requirements. IBWA reserves the right to conduct a follow up audit, at its own cost, to verify that necessary corrective actions have been implemented. IBWA may also request further corrective action if a plant fails its IBWA annual audit for two (2) or more consecutive years.

Questions regarding the IBWA audit program should be directed to the IBWA technical department. They may be contacted at (703) 683-5213.

Evaluation Criteria for Third Party Audit Services

The Plant Audit Program administered by the International Bottled Water Association (IBWA) is part of the proactive self-regulation platform used by IBWA to assure bottler member compliance with Title 21 of the Code of Federal Regulations (CFR) Parts 117, 129 and 165. These regulations collectively cover the quality standards, preventive controls, and good manufacturing practices (GMPs) for bottled water as promulgated by the U.S. Food and Drug Administration (FDA).

The plant audit is conducted by third-party audit certification bodies (CBs) under contract with the IBWA. These evaluation criteria have been prepared in order that those parties desiring to perform such audit services under the IBWA Plant Audit Program, may submit a bid to IBWA for providing such contractual services when IBWA seeks such services from time to time. The qualifications outlined below are the minimum requirements acceptable to the IBWA Board of Directors.

Third Party Requirements

1. The organization delivering the audit service must be registered as a legal entity doing business in a legal jurisdiction in one or more of the following regions: North America, Europe, Asia, Latin America or Australasia.
2. The organization shall have fiscal integrity to ensure that the loss of a specific client or program will not significantly impact its future viability.
3. The organization shall be recognized as an outside, independent third party.
4. The organization must have adequate time and manpower to conduct the work required by IBWA. It must be “user friendly” (i.e., easy to access personnel assigned and responsive to inquiries).
5. The organization shall have qualified, competent staff (with training in the chemical, biological, occupational/public health, or food sciences) to perform audits and make informed decisions and have a documented system to properly manage any and all subcontractors.
6. The organization shall be knowledgeable of the public health impacts of bottling plant design, construction, water treatment, bottling and packaging equipment and the IBWA Bottled Water Code of Practice.
7. The organization shall be knowledgeable of the public health impacts of good manufacturing practices including, but not limited to, hygiene, sanitary operations, pest control, and sanitization procedures relative to food and beverages.
8. The organization shall have a demonstrated understanding and working knowledge related to all applicable sections of the U.S. FDA standards for bottled water, Hazard Analysis Critical Control Point (HACCP) System, preventive controls, Codex Alimentarius, and the IBWA Bottled Water Code of Practice.

9. The organization shall provide evidence that its service structure, administration, and operation are accredited to uniform national and international criteria by recognized program accreditors such as the American National Standards Institute (ANSI- US); Raad voor Accreditatie (RvA- Europe, Asia); and Standards Council of Canada (SCC).
10. The organization shall demonstrate public health expertise and have effective liaisons with regulatory agencies and organizations such as the U.S. FDA, Health Canada, USDA, CDC, World Health Organization, Pan-American Health Organization, and Food and Agricultural Organization of the United Nations.
11. The organization must use comprehensive audit forms and other tools that assist in achieving the high standards, goals and objectives of the IBWA Audit Program.
12. The organization shall provide a complete history of any adverse actions taken against it by any governmental body or standards setting organization.
13. The organization shall properly train staff and update its training program annually with input from IBWA.

Section 1 General Good Manufacturing Practices (GMPs)

DISEASE CONTROL

Verification of internal health policy.

Does the FSP address adverse employee health conditions?

Item G1	Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors	§117.10(a)

The auditor will ascertain if management is aware it is their responsibility to exclude from work areas, where product contamination is possible, any employee with a communicable disease. The auditor will also determine whether employees working around product contact surfaces have obvious colds, infected cuts, sores, etc.

CLEANLINESS

Item G2	Outer Garments: The methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.	§117.10(b)(1)

Item G3	Unsecured Jewelry and Other Objects: The methods for maintaining cleanliness include removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by	§117.10(b)(4)

	these objects of the food, food-contact surfaces, or food-packaging materials.	

Item G4	Gloves: The methods for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	§117.10(b)(5)

Item G5	Clothing and Other Personal Belongings: The methods for maintaining cleanliness include storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	§117.10(b)(7)

Item G6	Eating Food, Chewing Gum, Drinking Beverages, and Using Tobacco: The methods for maintaining cleanliness include confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.	§117.10(b)(8)

Item G7	Any Other Necessary Precautions: The methods for maintaining cleanliness include taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.	§117.10(b)(9)

G2 – G7

Are there written policies for G2-G7 in the facility's food safety plan?

Smoking, eating and drinking anywhere except in designated areas is unacceptable. Water coolers for employee use are prohibited from areas where there are exposed products or product contact surfaces or where equipment or utensils are washed (bottle washers, cooler refurbishing, etc.). Use sound judgement. Vending machines located immediately outside lunch/break rooms because of space limitations are acceptable as long as the vended products are consumed only in the lunch/break rooms. Hair and beard restraints must be worn in all areas where there is a potential for hair to contaminate the product or container. If employees are observed not washing their hands regularly, it would be cited as a nonconformance.

Street clothes are acceptable inside the bottling room as long as they are clean and provide sanitary coverage. Uniforms are not required. Employer-provided garments that are required for any employee performing work in a specific area, and which are in addition to the usual outer garments, can be stored adjacent to the specific area.

Example: Lab coats employees must put on when entering the bottling room can be hung on wall hooks outside the bottling room.

PLANT GROUNDS, CONSTRUCTION, AND DESIGN

Item G8	Management Responsibility for Maintaining Grounds: The grounds of a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include: • Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests. • Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. • Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests. • Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. • If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in the rule, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.	§117.20(a) (b) (1)-(4)

This item applies to the exterior premises. Nonconformances would include improper, unsanitary storage of equipment, areas of debris or litter accumulation, etc. This also applies to weeds, grass, landscaping, etc. This item applies to grounds under the control of the bottler.

Examples:

- Old unused equipment was stored along the perimeter of the yard.

- Excessive growth of weeds in gutter area behind plant.

Note: If outside storage of product is not done in a sanitary fashion then it would be cited as a minor nonconformance

Outside storage of discarded multiservice containers, if it is done in a sanitary manner and there is no vermin harborage, is not a nonconformance.

During course of audit, the condition of exterior yard areas under the control of the bottler and their effect upon the sanitary operations are apparent.

Example: Unpaved lot area adjacent to open loading dock doors contributes to excessive dust build-up on plant equipment and stored product.

Note: If grounds are dirt or gravel, is there some sort of dust control program in place?

The surrounding environs under the control of the bottler shall be well-drained and not present breeding/harborage areas for pests.

Example: Standing water at the side and rear of the building provides active breeding sites for insects and pests.

Note: If puddles are present because of rain during the audit (or within the last 24 hrs.), a nonconformance will not be cited unless it is apparent that the puddles will become stagnant.

Item G9	Suitability of Plant Construction and Design: The plant buildings and structure must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).	§117.20(b)

Is this addressed in the facility's food safety plan?

Item G10	Placement of Equipment and Storage of Materials: The plant must provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.	(b)(1)

Is this addressed in the facility's food safety plan?

This item deals strictly with interior areas of the plant, as opposed to Item G17, which is outside. All interior areas should be accessible. There should be a suitable distance between shelving and walls and between underside of shelves and the floor. All areas (processing, warehouse, etc.) always must be accessible for cleaning and for pest inspections. Are employees able to perform their duties unimpeded and not create potential to contaminate product? "Clean" and product-related items such as containers, closures,

and coolers should not be immediately adjacent to "dirty" non-product related items such as truck parts, waste drums, and plant maintenance supplies.

Example: Storage of materials 6" off the floor or 18" away from a wall is a recommendation. Intent is that area be accessible.

- Nonproduct related items can be stored directly on the floor if done in a sanitary manner.
- Turnaround times are a factor in ascertaining compliance. For example, if refurbished coolers are stored directly on the floor, but are turned around in one or two days, it would not be a deficiency.
- Pallets are not acceptable for “long term” storage unless they are regularly removed for cleaning. This will be obvious because dirt, dust and debris will accumulate. Long term or permanent storage should be on a shelf or platform that allows easy access to the floors and walls for cleaning (6" off the floor or more).

Item G11	Reduce Potential for Contamination and Allergen Cross-Contact Through Adequate Food Safety Controls and Operating Practices or Effective Design: Adequate precautions must be taken to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.	(b)(2)

Is this addressed in the facility’s food safety plan?

Item G12	Food in Outdoor Bulk Vessels (including storage tanks and silos): Adequate precautions must be taken to protect food in installed outdoor bulk vessels by any effective means, including using protective coverings, controlling areas over and around the vessels to eliminate harborages for pests, checking on a regular basis for pests and pest infestation, and skimming fermentation vessels, as necessary.	(b)(3)

Is this addressed in the facility’s food safety plan?

Item G13	Lighting: Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.	(b)(5)

Fifty (50) foot-candles is required wherever there is an exposed product or product contact surfaces to be able to determine the presence of physical contamination. These areas would include bottling, cooler refurbishing, processing equipment and areas where these items are repaired, handwashing, rest rooms and the kitchen or break room. Twenty (20) foot-candles should be provided in other areas. If product related items are stored in a trailer which lacks lighting, it would be cited here. If citing a deficiency, the actual foot candles measured must be in the audit report.

Note: Most of the hand-held light meters cannot be calibrated and are not particularly accurate instruments. 20% leeway is recommended before citing a deficiency.

Measure light at work surfaces. In the warehouse or in open areas, face the light source and measure at waist height (approximately 3' off the floor.) Always allow for temporary obstructions such as piles of boxes or bottles.

All light fixtures in the bottling room must be properly protected. Covers are not needed in processing, storage areas, etc. if you determine that breakage cannot contaminate the product. End pieces must be present as part of the safety aspect. Lights over cooler maintenance areas shall be covered if there is a potential for breakage to contaminate the cooler.

Item G14	Ventilation: Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.	(b)(6)

Any area exposed to fumes, moisture accumulation and condensate should exhibit adequate ventilation. Such areas include the bottling room, washer area, processing area, etc. The inadequate cleanliness of the ventilation equipment would be cited as a minor nonconformance.

Note: Because ozone is an intentional ingredient in bottled water, any ozone odor that is noticed is the result of the bottled water itself and is not considered a condition of inadequate ventilation that may contaminate the bottled water (see 21 CFR Part 117.20(b)(6)). Bottlers are advised that there are OSHA requirements relative to worker exposure that they need to take into consideration.

Item G15	Adequate ventilation provided to minimize odors, noxious fumes, or vapors and condensate in processing, bottling, container washing and sanitizing rooms; ventilation equipment clean.	§129.20(c)

This item focuses on ventilation in the clean room.

Any area exposed to fumes, moisture accumulation and condensate should exhibit adequate ventilation. Such areas include the bottling room, washer area, processing area, etc. The inadequate cleanliness of ventilation equipment would be cited as a minor nonconformance.

Note: Because ozone is an intentional ingredient in bottled water, any ozone odor that is noticed is the result of the bottled water itself and is not considered a condition of inadequate ventilation that may contaminate the bottled water (see 21 CFR Part 117.20(b)(6)). Bottlers are advised that there are OSHA requirements relative to worker exposure that they need to take into consideration.

Item G16	Screening: The plant must provide, where necessary, adequate screening or other protection against pests.	§117.20(b)(7)

All exterior openings should be provided with screening. Exterior doors should be self-closing. Holes should be sealed, closed, or screened if applicable. Vent openings to exterior shall be screened if not self-closing. Dock doors not effecting a tight seal when closed would be cited here, as well as holes or other penetrations in dock doors. Dock doors should always be kept closed unless in use. If dock doors are open during the audit it should not be cited by the auditor as a nonconformance, but noted, unless a pest problem directly attributable to the open dock doors is observed. Insect electrocution devices are acceptable in the plant if they meet the FDA recommendations for mounting distances from exposed product or product contact surfaces: six (6) feet away for wall-mounted traps and 10 feet away for ceiling hung traps.

Note: A skirt or other means of sealing is required around semi-trailers when unloading at open dock doors to protect interior of plant from dust and flies, particularly if single service bottles are unloaded directly to line during production.

Item G17	Bottle washing/sanitizing in an enclosed room; positioned to minimize post-sanitization contamination.	§129.20(d)

NOTE: Auditor discretion applies. Current FDA regulation does not permit units outside clean rooms, but any available manufacturer validation of units may be helpful in determining compliance via intent.

Operations that could contaminate the product and compromise the sanitary condition of the bottling room are not permissible. However, bottling items of similar nature as well as laboratory set-ups are acceptable if they are maintained in a sanitary condition and are in a well-defined area. Storage of any item inside the room would not be acceptable (e.g. ozone generators, ink, old equipment, etc.). The bottling room's design shall be such that all surfaces and all equipment contained therein can be thoroughly cleaned and sanitized daily. Units that have a totally self-contained design, wherein filling and capping occurs in an enclosed chamber, meet the bottling room requirement provided there is an air handling system equivalent to a whole room system, e.g., it can provide a clean, positively pressurized atmosphere inside the filling and capping portions of the unit. However, placement is a potential problem. The unit does not need to be installed in a separate room, but the unit should not be exposed to excessive dust and fumes.

The bottling room shall be of tight design and construction. Doors shall be self-closing, and windows non opening. Ventilation portals shall not open to the outside of the building unless provided with appropriate protection such as screening combined with louvers that close when the ventilation is off. Plastic strip curtains are not acceptable for use on bottling room entrance ways. While strip curtains may meet the self-closing requirement for doors, they do not provide a tight fit, especially at the floor level. The use of strip curtains on conveyor openings is acceptable provided the following provisions are met:

a. There is a positive air flow at the conveyor opening.

b. The conveyor cover is designed to preclude repeated contact of the curtain with the lip of sanitized bottles.

c. The curtains are cleaned and sanitized daily.

The use of air curtains on conveyor openings is discouraged. If used, the blower shall be mounted inside the bottling room so that cleaner air will be moved through the unit's filter and around the bottles. A small V-shaped piece of stainless steel shall be mounted over the spot where the bottle lip passes. Air curtain housings, blower, or fan blades shall be kept free of dust. Air curtains are not acceptable in lieu of a self-closing door on entranceways to bottling rooms, because they do not provide the integrity against large pests.

The use of screens in a bottling room (doors or windows) is not acceptable because they do not preclude the entrance of airborne dust and dirt and are not easily cleaned.

Conveyor openings passing into and out of the bottling room should not exceed the size of the container which would pass through the opening. When not in use, and where multiple container sizes are processed within the same room, the opening should be covered, unless

there is a positive pressure system in continuous operation. Although not required, if a positive pressure system is used it should provide an adequate supply of filtered air. A post-filter UV light system is recommended.

Labelers, mineral injection systems etc. do not belong in fill room. Ozone contact tanks are considered part of the filling system and are allowed. The actual ozone generator must be outside the fill room. If ink jet coding is done before bottle filling, the coder must be located outside the clean room.

The presence of employees in the bottling room should be discouraged except as needed for adequate inspection of processing and operation equipment. Only authorized, properly attired personnel (see Item G2) should be permitted to enter the bottling room to conduct required tests or work. Determine if the fill room is used as a walkway, i.e., is the treatment equipment in a room off the fill room accessible only through the fill room? Is the fill room the closest walkway between points in the plant? Any unnecessary foot traffic, etc. affects the integrity of the "closed" fill room and is a deficiency.

Bottle washers/sanitizers shall be installed in a protected area. The area does not necessarily need to be an enclosed room specifically built to house the bottle washer, but the washer shall be positioned to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room. It is acceptable to permit the bottle washer to exit directly in the bottling room only if the bottling room's Heating, Ventilation and Air Conditioning (HVAC) system is designed to accommodate the increased heat and moisture dissipation/exhaust needs. The load end of a bottle washer need not be in an enclosed room. The area shall be protected and the washer penetration through the building wall or bottling room wall shall be closed to be dust and pest tight.

Item G18	Processing, washing, other rooms not directly connected to room(s) used for domestic household purposes.	§129.20(e)

Activities which are not pertinent to a bottled water facility should not be present within the confines of the plant. For example, hotel laundry located next to product-supply processing area.

SANITARY OPERATIONS

Item G19	General Maintenance: Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.	§117.35(a)

Is this addressed in the facility’s food safety plan?

Item G20	Cleaning Compounds and Sanitizing Agents: Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: • Those required to maintain clean and sanitary conditions; • Those necessary for use in laboratory testing procedures; • Those necessary for plant and equipment maintenance and operation; and • Those necessary for use in the plant's operations.	(b)(1)

A nonconformance is cited if cleaning is conducted during active product processing, thereby creating the possibility of contaminating the product, product containers, or product contact surfaces. Also, if cleaning solutions are not clean, or sanitizing solution is dirty, a nonconformance should be cited.

Item G21	Identification and Storage of Toxic Materials: Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.	(b)(2)

This item deals with toxic materials in the plant, not in the yard. If present, are they labeled and stored in a separate designated area? Product containers used for toxic storage must be conspicuously and permanently labeled. This includes cleaning, sanitizing materials, pesticides, lubricants, etc. Cleaning and sanitizing supplies should not be stored commingled with pesticides or other products with chemical contamination potential such as paint thinners, degreasers, etc.

Item G22	Pest Control: Pests must not be allowed in any area of a food plant. Guard, guide, or pest detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.	(c)

Every facility must have a rodent and insect control program which is under the supervision of a licensed pest control operator - either an outside firm or a licensed PCO on staff. All inspections, activity and pesticide applications must be documented.

The auditor will observe for droppings and presence of pests to determine effectiveness of the program. Overloaded glue traps, signs of roaches or mice etc. is a variation and should be cited as a nonconformance

If the bottler has cans of insecticides for coolers etc., the auditor will examine them to determine if they are acceptable for use in food areas.

Item G23	Sanitation of Food-Contact Surfaces: All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.	(d)

Is this addressed in the facility's food safety plan or SSOP?

Item G24	Sanitation of Non-Food-Contact Surfaces: Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.	(e)

Any nonconformance dealing with non-product contact cleanliness should be assessed. It is not a nonconformance if dust accumulation appears to be light enough to have been accumulated during the day's operation.

Item G25	Storage and Handling of Cleaned Portable Equipment and Utensils: Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.	(f)

Is this addressed in the facility's food safety plan?

SANITARY FACILITIES AND CONTROL

Item G26	Water Supply: The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.	§117.37(a)

Is this addressed in the facility's food safety plan?

Plumbing: Plumbing must be of adequate size and design and adequately installed and maintained to:

Item G27	Carry adequate quantities of water to required locations throughout the plant.	§117.37(b)(1)

Is this addressed in the facility's food safety plan?

Item G28	Properly convey sewage and liquid disposable waste from the plant.	(b)(2)

Is this addressed in the facility's food safety plan?

Item G29	Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition	(b)(3)

Is this addressed in the facility's food safety plan?

Item G30	Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.	(b)(4)

The floors in the bottling room, around the bottle washer, the storage tank area, etc. should not show significant ponding or be continuously flooded. There should be enough drains to ensure that water does not accumulate.

Item G31	Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing	(b)(5)

Is this addressed in the facility's food safety plan?

Item G32	Toilet facilities: Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.	(d)

Toilet facilities shall not open directly into areas where there is exposed product, clean containers, or exposed product contact surfaces unless they exhibit double door construction. Ventilation by itself is not acceptable; a vestibule must be provided. Also, self-closing doors, and a screened window or exhaust system are required.

Note: If there is an adequate fill room and the bathroom is down a hallway, and around a corner or more than 100 feet from the nearest place where there may be an exposed bottle (For example - Truckers rest room in the corner of a large warehouse), a nonconformance for "double door construction" will not be cited. The section of the FDA Code this rule is taken from is for general food plants, where "processing" has a different meaning than water processing, which occurs in an enclosed system.

Bathrooms should be readily accessible. The plumbing fixtures should be operational, soap and paper towels or electric hand dryers provided, and the toilet facility clean and well-lighted (50 foot-candles). Handwashing reminder signs are to be posted. In very rare circumstances, “Porta Johns” may be acceptable.

Note: Bathrooms in the office area that are not connected to the plant and are used by office personnel only, do not need to meet these guidelines.

Item G33	Hand-washing facilities: Each plant must provide hand-washing facilities designed to ensure that an employee’s hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.	(e)

The absence of specific hand sinks within the processing area would not be a deficiency. Properly maintained hand dip stations are acceptable substitutes for hand sinks. However, it is recommended that convenient, accessible hand sinks be present in all processing areas. Typically, there should be a sink, with hot and cold water or tempered water, towels and soap, in very close proximity to the bottling room(s). To supplement these hand sinks, sanitary dip stations should be present where needed.

Note:

- It is acceptable to use cooler refurbishing room sinks for handwashing, but not simultaneously with cooler refurbishing operations.
- Sanitary or sterile gloves may be used if they are changed regularly between non-sanitary and sanitary jobs, but their use does not eliminate the need for a hand wash sink or sanitary dip station.
- Alcohol gels are acceptable as a hand sanitizing agent but are not effective if there is any dirt buildup on hands. Observe employee habits in this regard.

Hand dipping stations must be maintained free of gross accumulation of dirt, grease, and other matter. They should be used only to clean and sanitize hands that are free of gross quantities of such matter. Hand sinks should be used first to remove most material from hands.

Item G34	Rubbish and offal disposal: Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.	(f)

This does not include locker or lunchroom's rubbish disposal. Dry paper or plastic waste related to product packaging does not have to be in covered containers. Dumpsters, garbage cans, etc. containing putrescible waste located inside and/or outside must have covers which are kept closed.

Item G35	Operations water meets applicable regulatory standards and requirements.	§129.35(a)(2)

Operations supply is any water which is being used to operate the plant; i.e., water for the washer, toilet facilities, maintenance and janitorial activities, etc. If it is a municipal supply, then a water bill is adequate documentation. If it is a nonmunicipal supply, then appropriate regulatory documentation and a site visit are pertinent.

Item G36	Source water approved by agency having jurisdiction or by certified or licensed professional geologist or hydrogeologist.	§129.35(a)

IBWA accepts the following as evidence of source approval:

- Permit or license from state or local government.
- Letter from state or local agency attesting to the source's suitability as a source for bottled water.
- Current (<2 years) inspection report from state or local agency indicating no problems with source.
- Sanitary survey and approval by a certified hydrogeologist.

Item G37	Air under pressure directed at product water or contact surfaces free of oil, dust, rust, excessive moisture; does not affect bacteriological quality.	§129.35(b)

Any air under pressure which is directed at product contact surfaces shall be properly treated. This would include air used to affix closures, blow out single-service containers, and cool off bottle washer operators. Common deficiencies are fans directed at mouths of clean, sanitary containers as they exit washer, blades of fan exhibiting accumulations of dust, or air under pressure directed at closures not adequately treated to remove oil, dust, etc. Records indicating cleaning, inspection, and maintenance of these items must be maintained.

Note: Air Compressors have been identified in some cases as providing bacterial and fungus/mold contamination. Check filters on compressors, records must be maintained of compressor filter changes etc.

Item G38	Locker and lunchrooms separate from plant operations and storage areas; doors are self-closing; rooms are clean and sanitary; refuse container(s) provided; packaging, wrapping materials and processing supplies absent.	§129.35(c)

Locker and lunchrooms must be totally separate from the plant operations. This includes areas for the storage of employee personal items such as coats, hats, etc. Employee lockers must be separate from processing, warehousing, bottling, etc. Employer provided protective clothing may be stored adjacent to the activity area.

Note: If lunchroom does not open directly into production/warehousing areas, a self-closing mechanism is not required.

Item G39	Product water contact surfaces (utensils, pipes, equipment) clean and adequately sanitized daily; records maintained.	§129.37(a)

This item relates to how all product contact surfaces are cleaned and sanitized daily. How is the cleaning of fillers, cappers, etc. done? The sanitizing? Are tanker hoses sanitized before each use? Are tankers? How is this done at the source site? Records are required if tankers are owned by the bottler, otherwise the plant must document that proper cleaning and sanitizing are being done. Acceptable methods of cleaning and sanitizing are detailed in the IBWA technical manual. At a minimum must comply with FDA 129.80 (d) (1), -(2), -(3), -(4), or -(5). Ask questions. How often are the fill heads sanitized? What is used for a sanitizing agent? What is the cleaning/sanitizing procedure?

If a company is not keeping records of sanitizing operations, and there is no other indication or evidence that sanitizing is not being performed, it is a records issue.

Item G40	Product water contact surfaces are maintained free of scale, oxidation, and other residues. Presence of any unsanitary conditions corrected immediately.	§129.37(a)

Product contact surfaces must not exhibit rust, oil, dust accumulation, etc. Determine if they are being properly maintained, and if oxidation is a problem, how the plant is handling it.

Item G41	Cleaned multi-service containers, utensils, disassembled piping, and equipment transported and stored in a sanitary manner.	(b)

Tanker hoses must be stored off the floor and capped when not in use. The same is true for transfer pipes/hoses, spare gaskets, etc. It also includes the U-shaped pipes, and connectors used at manifolds and tanks.

Item G42	Containers, closures, or seals purchased and stored in original containers in clean, dry place; examined before use; handled, dispensed in a sanitary manner. Washed, rinsed, and sanitized as needed.	(c)

Deficiencies in the handling and storage of the single-service containers are cited as a minor nonconformance. Common items cited include packages of containers stored directly on the floor, containers on floor prior to debagging, inadequate coverage where containers are debagged, lack of conveyor covers on single service lines, single service containers stored directly on the floor of a semi-trailer in an unsanitary manner, etc. Packages of caps and/or containers can be stored on mezzanine floors provided the following conditions are met:

a. The only traffic on the mezzanine is to retrieve the packages or to service processing/treatment equipment also on the mezzanine.
b. Storage is orderly, and the packaging is not damaged from handling or because of malfunction of equipment on the mezzanine.
c. The traffic paths and mezzanine floor are kept clean.

Bottlers are not required to wash, rinse, and sanitize single-service items. Rinsing of containers and closures is not required. If done, the processing should be in a sanitary manner; product water is frequently used. Closures may be left in the "Syntron" or hoppers during normal down-time periods throughout the day if they are adequately protected from contamination. Because the closures must be protected against splash and spillage during required cleaning of the bottling room and equipment, they shall be removed from the

hopper and "Syntron" bowl to clean and sanitize the hopper and bowl daily (but not for "breaks"). Hand capping should be avoided. Florida, Missouri, New York and South Carolina prohibit hand capping and, if observed at plants in these states, cite the nonconformance under item G45.

Note: Exposed caps in a “Syntron” bowl or chute without a cover would be cited here.

Storage of single service items directly on the floor of a semi-trailer is allowed, provided that the floor is in good repair and clean. The trailer of course, must be tight - no holes or gaps that may allow pests to enter.

Item G43	Filling, capping, closing, sealing, and packaging done in a sanitary manner.	(d)

Is this addressed in the facility’s food safety plan?

EQUIPMENT AND PROCEDURES

Item G44	Equipment suitable for intended use, designated, and of materials to be cleanable and properly maintained.	§129.40(a)(1)

Nonconformances that pertain specifically to the equipment as an entity unto itself are covered here: lack of cover over "Syntron," lack of back panel on 1-gallon closure reservoir, lubricant dripping from valves, etc. Nonconformances pertinent to placement of equipment would be cited under this item.

Examples:

- Presence of wood in bottling room filling/capping equipment.
- Rust, flaking paint, general disrepair of equipment.

Item G45	Storage tanks can be closed to exclude all foreign matter; filtered vents provided; filters readily cleanable or replacement elements.	(b)

Determine if vents are provided and if so, whether they are filtered. Is the overflow acting as a vent? Tanker manhole or air vents are required to have filters to preclude the entrance of insects and airborne contaminants as the tank is emptied. The vent filter housing and replacement filters are available commercially from dairy supply outlets. Caution: Filters, if mounted in such a manner that they may become wet, may freeze and block in the winter causing the tank to collapse. For this reason, bottlers in colder climates may elect to have a clean dry filter available for unloading. The decision to mount on the tanker or to remove and store in a sanitary manner each time should be made on a case-by-case basis by the

bottler. Records detailing tank and filter cleaning, inspection, and maintenance are to be kept.

Note: For tankers, the plastic venturi or "screw" type filter which collects dust by centrifugal force is acceptable, provided the filter is kept clean. There are many other acceptable fiber filters etc. Remember, the filter need only be on the tanker during the unloading process, if the tanker lid is sealed during transportation, etc.

Item G46	Product water separate from operations water to preclude contamination of product; either separate piping systems or suitable backflow prevention.	IBWA CoP

If the piping for the non-product related supply is not totally separate from the piping for the product supply, proper cross-connection controls are required. If it is not provided, then it would be cited as a major nonconformance. If it appears there is not a separation between product and operations water, but the plant personnel believe there is, it may be cited as a note, and the local plumbing agency or equivalent will be required to inspect the system.

Note: There will be instances where you cannot tell if a system is separate or protected, and in these cases a "note" should be written indicating this and recommending that a licensed plumber be contacted. In old buildings or in industrial park situations, it is sometimes impossible to follow the lines. In some small plants it may be possible to determine if all the end use points are protected against back siphonage, with air gaps, anti-siphon ball cocks in toilets, anti-siphon devices on hose bibs etc. This would be acceptable as a separation.

PROCESSES AND CONTROLS

Adequate Sanitation Principles

Item G47	All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.	§117.80(a)(1)

Is this addressed in the facility's food safety plan?

Item G48	Quality Control Operations: Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.	(a)(2)

Is this addressed in the facility's food safety plan?

Item G49	Supervising Overall Sanitation: Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.	(a)(3)

Is this addressed in the facility's food safety plan?

Item G50	Production Procedures: Adequate precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.	(a)(4)

Is this addressed in the facility's food safety plan?

Item G51	Chemical, Microbial, or Extraneous-Material Testing Procedures: Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.	(a)(5)

Is this addressed in the facility's food safety plan?

Item G52	Contaminated Food: All food that has become contaminated to the extent that it is adulterated be rejected, or if appropriate, treated or processed to eliminate the contamination.	(a)(6)

Is this addressed in the facility's food safety plan?

Item G53	Inspection, Segregation and Handling of Raw Materials and Other Ingredients: Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.	§117.80(b)(1)

Is this addressed in the facility's food safety plan?

Item G54	Levels of Microorganisms in Raw Materials and Other Ingredients: Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.	(b)(2)

Is this addressed in the facility's food safety plan?

Item G55	Holding Raw Materials, Other Ingredients, and Rework in Bulk: Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.	(b)(5)

A raw materials program should, at a minimum, designate an individual or group to be responsible for inspection of raw materials received to assure their condition and suitability for use in producing their products. In the case of assigning responsibility for raw materials receipt at the plant, the bottler should be able to produce records that document the

condition and suitability at time of receipt, and should be signed by the responsible individual, such as an employee in the receiving department.

Item G56	Liquid and dry raw materials and other ingredients: Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.	(b)(7)

Is this addressed in the facility's food safety plan?

Item G57	Treatment equipment processes and substances used preclude contamination or adulteration of product. Bottled water products shall not be transported, stored or processed through non-food equipment. If equipment is used for other foods, a documented cleaning/sanitizing procedure shall be made available.	§129.80(a) CoP 3(d) CoP 3(f)

Evaluate if the equipment's design and/or operation can adulterate the product. The product water cannot be transported, stored or processed through non-food equipment.

Example: A filler is used Monday for shampoo, Tuesday for anti-freeze and the rest of the week for pure spring water.

If a filler is used for other food products such as juice or milk, a comprehensive and detailed procedure for cleaning and sanitization must be available. When this procedure is performed between uses, it must be documented.

Item G58	Multi-service shipping cases maintained to assure they will not contaminate primary container or product.	§129.80(b)(2)

Reusable plastic crates should be routinely cleaned using either "wet" or "dry" cleaning. Wooden crates are acceptable as long as they are maintained in good repair. Sanitization of either type is not required.

Item G59	Records maintained of kind of product, volume produced, date produced, lot code used, and distribution to wholesale and retail outlets.	§129.80(e)

The production and distribution records and the coding must be sufficient to insure thorough recall. A written recall plan must be available. If it is not, a nonconformance will be cited. The IBWA Plant Technical Reference Manual contains a sample format. A list of names is not sufficient.

These are the basics for a recall plan.[1] The recall plan is covered in detail in the IBWA Plant Technical Reference Manual if bottlers have questions.

1. The recall plan must be written down.

2. It must include the name of the person who is in charge

3. It must include the classes of recalls with definitions.

4. It must define strategies for each class of recall:

- Depth of recall for each category (wholesale, retail, consumer etc.)
- Public warning requirements.
- Level of effectiveness checks for each class. How is the bottler going to go back and determine response from wholesalers and retailers? Were records maintained by all parties involved in the recall?

The IBWA has determined that it is not necessary to track product for home delivery, because most 5-gallon product turns frequently and a date code, under most circumstances, could be tracked to routes within a day or two. It is not a nonconformance if the bottler does not keep distribution records for home delivery. It should, however, be considered a recommendation.

MANUFACTURING OPERATIONS

Item G60	Condition of equipment, utensils, and finished food containers: Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.	§117.80(c)(1)

Is this addressed in the facility's food safety plan?

1 This references the facility's general food recall plan, not the recall plan required under the FSMA Preventive Controls Rule.

Item G61	Conditions and controls for food manufacturing, processing, packing, and holding: All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.	(c)(2)

Is this addressed in the facility's food safety plan?

Item G62	Measures to destroy or prevent the growth of undesirable microorganisms: Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.	(c)(3) (c)(4)

Is this addressed in the facility's food safety plan?

Item G63	Work-in-Process and Rework: Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.	(c)(5)

Is this addressed in the facility's food safety plan?

Item G64	Equipment, containers, and utensils: Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.	(c)(7)

Is this addressed in the facility's food safety plan?

Item G65	Metal and other extraneous material: Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.	(c)(8)

Is this addressed in the facility's food safety plan?

Item G66	Disposal of adulterated food, raw materials, and other ingredients: Food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food; or if the adulterated food is capable of being reconditioned, it must be: 1. Reconditioned (if appropriate) using a method that has been proven to be effective; or 2. Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.	(c)(9)

Is this addressed in the facility's food safety plan?

Item G67	Filling, Assembling, Packaging and Other Operations: Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.	(c)(13)

Is this addressed in the facility's food safety plan?

WAREHOUSING AND DISTRIBUTION / DEFECT ACTION LEVELS

Item G68	Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.	§117.93

Is this addressed in the facility's food safety plan?

Item G69	The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.	§117.110

Is this addressed in the facility's food safety plan?

SECTION 2 Bottled Water-Specific GMPs (21 CFR 129 and IBWA Code of Practice)

Item BG1	Product water from approved source; complies with applicable laws and regulations; documented; complies with GMPs and SOQs; source integrity verified; source free of surface water influence.	§129.35(a)(1)

Source product water supply is defined as all sources that are used to make the final bottled water product. A typical plant might bottle a product that is comprised of one spring, or three wells, or a blend of city and on-site waters. The source for the final product should be ascertained at the start of the audit. Whenever possible, every source should be inspected.

The audit may include a visit to your spring or well sites. The audit should determine if the source supply is constructed, operated, maintained, and located in a sanitary manner. Regardless of whether a site visit is feasible, the plant must have on file documentation indicating that the source is located and constructed in accordance with applicable regulatory requirements. In many instances only a recent regulatory inspection report will be available, and most likely it will only obliquely reference the source.

Several instances have been found wherein the government agency having jurisdiction for approval of bottled water sources has given legal approval to source sites that use plumbing components not considered suitable for potable water use. Because FDA regulations vest approvals with the government agency having jurisdiction, and because the auditor has no authority to the contrary, he/she can point out concerns to the bottler/source water owner about the use of non-potable water materials. But the auditor cannot mandate changes, unless regulated contaminants are detected in the bottled water products at levels exceeding FDA or IBWA standards of quality (SOQs).

If the source is not located operated and/or maintained in a sanitary manner, then a control should be cited. For example, "dead mice observed around the perimeter and inside of the spring source" or "source located in a flood plain." At times, the source may exhibit some item of serious public health concern. When this is encountered, cite it as a control and the situation should be discussed immediately with the regional manager and the program manager.

If there is no source approval documentation from a local authority it should be written under Item BG15. See Item BG15 for list of documents which can suffice as “approval.”

None of the above applies if the source is a municipal supply, and a current water bill can be produced documenting same.

Item BG2	Source waters are analyzed as required by FDA in 21 CFR 129 and Appendix A of the IBWA Bottled Water Code of	(a)(3)

	Practice, including annually for chemical/physical parameters; every four years for radiological parameters. Non-PWS source waters analyzed weekly for microbiological contaminants.	

This item pertains only to source supplies (regardless of product or operations end use) and not finished product. At a minimum each individual source must have on file at least a yearly analysis for chemical and physical parameters listed in Appendix A the IBWA Code of Practice. Radiological results are needed every four years. Coliform is required on each source weekly.

If the plant can document that its sources are drawing from the same aquifer and therefore each well head, spring, etc. is not being individually sampled, or is utilizing a blend and generating a composite sample, a nonconformance will not be cited.

It is a major nonconformance if parameters are missing. However, a control would not be cited if a parameter exceeded an MCL, because source water is considered a "raw material" subject to treatment. This applies to coliform counts as well. A major nonconformance will not be cited if results are on file for the preceding calendar year but not yet available for the current calendar year. In this case, submit the previous year's data to IBWA's with a copy of the audit report. If there are no results for both the current year and the preceding year, then it shall be cited as a major nonconformance. For example, an analysis dated 12/18 is for 2018; another must be done in 2019.

If it is municipal source, a major nonconformance will not be cited for not having the required analysis; all that is required is a water bill. It is highly recommended, however, that it be obtained from the public water system.

Item BG3	Product water contact surfaces comply with FDA, Codex, or other applicable standards; are of nonabsorbent, nontoxic materials; can be adequately cleaned and sanitized.	§129.40(a)(2)

This item relates to how all product contact surfaces are cleaned and sanitized daily. How is the cleaning of fillers, cappers, etc. done? How is sanitizing done? Are tanker hoses sanitized before each use? Are tankers sanitized? At what frequency? How is this done at the source site? Records are required if tankers are owned by the bottler, otherwise the plant must document that proper cleaning and sanitizing are being done. Acceptable methods of cleaning and sanitizing are detailed in the IBWA technical manual. At a minimum, sanitization procedures must comply with 21 CFR §129.80 (d) (1), -(2), -(3), -(4), or -(5). The auditor may ask questions, such as “How often are the fill heads sanitized? What is used for a sanitizing agent? What is the cleaning/sanitizing procedure?”

Wherever possible, certifications from suppliers are to be on file for plastics and other synthetic materials that the ingredients are nontoxic and in compliance with the FDA standards for all product contact surfaces such as piping, valves, gaskets, fittings, etc. Item G9 covers containers/closures. In some cases, where equipment is very old and/or the manufacturer is out of business, material certifications may not be available.

If a file has been established with some information, then the intent of this requirement has been met. However, the audit report should note what certifications were missing from the file and need to be obtained. The auditor may recommend that the certifications on replacement parts and frequently purchased equipment and supplies be renewed every two years if it is not provided per shipment. Remember, if the product has the certification directly on it then this would be acceptable (e.g., NSF Listed piping).

This item would also cover the integrity of the material. Severely cracked gaskets, spacers exhibiting deep, uncleanable crevasses would be cited here because they cannot be easily cleaned and sanitized. Copper piping not under constant pressure would be a deficiency cited under this item.

Note - inclusion of a supplier in the IBWA Directory does not constitute material acceptance.

If a company is not keeping records of sanitizing operations, and there is no other indication or evidence that sanitizing is not being performed, it is a records issue under Item BG8, not a major nonconformance under Item BG3.

Item BG4	Treatment process achieves intended purpose; inspection records maintained and reviewed.	§129.80(a)

The auditor will determine what if any treatment the product or product supply receives. The maintenance, inspections, and servicing of these treatment systems and the effectiveness of the treatment must be monitored and logged.

A. Records of all filter changes and/or backwashing, inspections and sanitizing.
B. Daily monitoring of pressure gauges on R.O. and filters.
C. Ozone levels monitored, routine maintenance to ozonator logged.
D. Logs of UV light inspections.
E. Logs of backwashing softeners, D.I. or TDS testing, etc. indicating that the system is functioning properly (many softeners and D.I. systems backwash automatically).

Item BG5	Product water samples taken after processing prior to bottling to verify effectiveness of treatment process; approved analysis methods.	§129.80(a)

This item applies to in-house quality control monitoring and testing, and all samples are to be taken prior to bottling. Quality control monitoring does not require the same precision and accuracy as compliance testing; however, the method must be reliable. The IBWA Plant Technical Reference Manual details several kits which can be used for monitoring purposes. If the plant is not conducting the test as required by the manufacturer, a minor nonconformance would be cited here. For example, ozone meter is not clean, reagents have expired, etc. If a different monitoring method is used, the auditor may request that IBWA decide as to acceptability.

IBWA sets forth recommendations for satisfying the monitoring standards. For example, it recommends that if products are ozonated, the ozone residual be monitored no less than 3 times (start-up and twice per shift). Other recommendations include pH, taste, fluoridation, chloride, conductivity. The frequency depends upon the individual plant's operations and the survey form provides guidelines. If QC monitoring is not being done at all, cite a minor nonconformance. If QC monitoring is done at frequencies other than specified by IBWA, ascertain the effectiveness, and, if inadequate, cite a minor nonconformance.

Records must be available indicating that the plant is monitoring the effectiveness of its processing, as well as the performance and condition of the equipment. Results must be recorded as quantitative values and not "checks" unless the record sheet shows an acceptance range. If in-line equipment is used to monitor performance, the auditor will determine how that equipment's effectiveness is monitored.

Note: IBWA recommends that the daily chemistry tests (pH, TDS, taste, ozone, etc., be performed on finished product from the package. These tests are performed to verify product consistency. For example, the pH on a product normally is 7. One day it tests at 5.5. Obviously, something is wrong. There may be chemicals leaching into product, residual sanitizer in the bottle etc. It is not a violation to take the product testing samples at the filler, but the bottler should be advised that for these tests the finished, packaged product is preferred.

Item BG6	Unsanitary or defective containers reprocessed or discarded; multi-service containers cleaned, sanitized prior to filling and capping; records maintained.	§129.80(b)

All multi-service containers (e.g., 3, 5, & 6 gal) must be cleaned and sanitized. Washes with non-caustic detergents must be followed by a sanitizing step. Are the containers inspected prior to filling and capping? Unsanitary or defective containers should be rendered unusable prior to discarding, although this by itself should not result in the plant receiving a control point.

Note: It is acceptable to wash, rinse, sanitize, then rinse again with municipal water, or with an ozonated product water rinse.

- Failure to inspect the container just prior to filling or loading bottle washer would be cited as a minor nonconformance here.

- Ozonated product or ozonated clean city water is acceptable as a sanitizer in a final rinse.

Item BG7	Mechanical washers inspected and records maintained for maintenance and performance.	§129.80(b)(1)

This item relates to records of washer inspection and maintenance. Such things as screen cleaning, checking detergent and sanitizer concentrations, and other maintenance are the type of records evaluated. Deficiencies regarding exterior surfaces of the washer should be cited under Item G24. The plant must have information on proper operation of the washer, detergent concentration, rinse cycles, operating temperatures, etc.

Item BG8	Sanitizing operations comply with applicable regulations and manufacturer's directions; records maintained.	§129.80(c)

Records noting cleaning and sanitizing operations are covered under this item. It is permissible to use a check-off system if and only if a written, standard operating procedure is available detailing exactly what is done, how, by whom, agents used, contact times, etc. for each activity. Otherwise, the records must contain the required details.

All regular and routine cleaning activities in the plant, including housekeeping, must have procedures and records of the cleaning activities must be maintained. Besides the fill room and equipment this would include warehouse floors, overhead fixtures such as lights and fans, the washrooms, lunchroom, etc. If an outside firm is used to clean lunchrooms, restrooms etc., no procedures for those activities are required. Invoices are sufficient records of cleaning being performed.

Item BG9	Containers and closures nontoxic; comply with applicable regulations. Each product is identified by production code. Code identifies batch or segment of continuous run and day produced.	§129.80(c)/(f)

This item addresses container and closure materials. Again, a file is sufficient to satisfy the requirement as long as there are some material certifications in it. If any certifications are missing, cite as a note and list what needs to be obtained. If these certifications are not in the file at the time of the next audit, cite as a major nonconformance.

It is acceptable to notch the label, ink jet code, or use some other key for the coding, as long as the method used is legible and can be explained by the bottler. If there is no date code

on a product, a nonconformance will be cited. If date code is illegible and the problem is widely prevalent, a nonconformance will be cited.

Note: Applying the date code by hand with a "price marker" type gun is acceptable, so long as it is not applied to removable caps, which is a nonconformance. Application to safety type caps, which are not normally removed, is allowed.

Item BG10	Filling, capping, and sealing monitored; filled containers inspected; records maintained.	§129.80(f)

Is the bottling monitored? The container fill levels should be verified by an appropriate method, such as volumetrically or gravimetrically and if it is not being done, cite as a minor nonconformance. If the containers are not satisfactorily capped or sealed, they must be discarded/reprocessed.

The handling and processing of reusable containers and the protection of single-service containers are covered under this item. Common items cited are lack of conveyor covers, or conveyor covers of inadequate design to afford proper protection. Conveyor covers must be in place from the point of the container accessing the line to the capper. If the operation is manual, the same logic applies, and some type of protection must be present. Some high-speed bottle washers require the unload end operator to swiftly transfer several bottles to conveyor and the physical actions necessary to do this precludes covering a short section at the start of the conveyor. This is not a nonconformance unless the uncovered bottle or bottles are unprotected for more than ten (10) seconds. If the uncovered bottles are unprotected because of filler or other equipment malfunctions, observe whether the unprotected bottles are rewashed. If they are not, cite a nonconformance

Once on the line, placement of the filler next to a highly trafficked area without adequate protection of containers would be cited here. It is necessary to cover the conveyor between filler and capper to avoid contamination, unless due to either the filler design or the capper design is not feasible, or the run is very short - less than one foot.

The entire system must be such that the product's integrity is maintained throughout. Observe the conduct of employees when processing. Note: Florida, Missouri, New York and South Carolina prohibit hand-capping which should be cited here if observed at plants in these states.

Note: If outside storage of product is practiced, regardless of turnaround time, it is not a violation.

A self-contained design wherein the bottle is filled and capped in a totally enclosed chamber meets the bottling room requirement, provided there is an air handling system equivalent to a whole room system, e.g., it can provide a clean, positively pressurized atmosphere inside the filling and capping portions of the unit. However, placement is a potential nonconformance. A separate room for these units is not required.

For other designs of self-contained units, if the placement of the unit is satisfactory but the design is such that the filling, capping, closing, and sealing section does not provide protection equivalent to a bottling room, a minor nonconformance is cited. If the design is satisfactory but the placement is deficient. If placement and design are both problems, cite nonconformances under both items.

Item BG11	Containers and closures tested for microbiological contaminants at least quarterly; records maintained.	§129.80(f)

It is an FDA requirement that "All containers and closures shall be sampled and inspected to ascertain that they are free from contamination." IBWA interprets that to mean each container type and each closure type, i.e., each resin type. The sizes of the containers are not considered when sampling containers and closures. FDA requires that at least four containers and at least four closures be tested quarterly using either rinse or swabbing methods. IBWA recommends that containers be rinsed, and closures be swabbed. The containers and closures must be tested separately and recorded as such.

Bacterial testing for containers and closures includes BOTH Coliform and Heterotrophic Plate Count (HPC) testing. If both tests are not performed it is a major nonconformance. If there is presence of Coliform in either containers or closures, it is a major nonconformance. With the HPC test, if more than one of the four containers in a quarterly test shows more than one count per ml of volume it is a major nonconformance. The same rule would apply to closures. This test can be performed in-house by qualified plant personnel or by an outside lab.

Item BG12	Samples taken at least once per week for each product type; analyzed at an approved laboratory for microbiological contaminants; records maintained.	§129.80(g)(1) CoP 5(b)

At least once per week, each product type must be monitored for coliform by an approved or certified lab. If the in-house laboratory is state-certified, samples do not have to be sent out once per week.

The following methods are acceptable for weekly total coliform analysis:

1. The Multiple Tube Fermentation/Most Probable Number (MPN) technique
2. The Membrane Filter technique
3. The Presence/Absence technique
4. The Chromogenic Substrate technique (Colisure and Colilert)

Item BG13	Bottled water products tested daily for total coliform by an in-house laboratory or an approved laboratory.	CoP 3(h)

Product must be monitored daily for coliform on an in-house basis or at an approved laboratory. In-house total plate count monitoring is recommended, but not a major nonconformance if not performed, and should be listed as a "note" on the report.

The following methods are acceptable for "in house" total coliform analysis:

1. Multiple Tube Fermentation/Most Probable Number (MPN)
2. Membrane Filter
3. Presence/Absence
4. Chromogenic Substrate (Colisure and Colilert)

Item BG14	Samples analyzed at least once per year for each product type for chemical and physical parameters by an approved laboratory.	§129.80(g)(2)

At a minimum, an annual analysis must be on file for each product type for the chemical, physical and radiological parameters detailed in the FDA standards. IBWA periodically requires its members to have additional testing performed which varies from year to year. The current parameters are included as Appendix A of the IBWA Code of Practice. If no analyses are available for the current calendar year, nor for the preceding calendar year, then it will be cited as a major nonconformance. If results are on file for the preceding year, but not yet available for this year, submit to the auditor a copy of the preceding year's data for the report to be forwarded to IBWA.

If a parameter exceeds the IBWA SOQ, then it is cited as a major nonconformance. If some of the required parameters are missing, it is also cited as a major nonconformance.

Item BG15	All records of certifications and approvals of source and operations water on file.	§129.80(h)

If the plant is unable to produce acceptable documentation that verifies source compliance (both product and operations) with appropriate regulatory requirements, then it will be cited as a minor nonconformance. This item encompasses the paper aspect of the source(s). For example, "State approval indicates outstanding conditions which must be resolved, yet no subsequent documentation on file indicating that the items have been corrected satisfactorily." Municipal supplies meet this requirement.

Note: If the approvals are not current (i.e., they have expired), cite the major nonconformance under item BG1.

Because permitting and approval varies from one jurisdiction to another, IBWA and the auditors will accept the following items as “approvals” of the source:

- Permit or license from state or local government.
- Letter from state or local agency attesting to the source’s suitability as a source for bottled water.
- Current (<2 years) inspection report from state or local agency indicating no problems with source.
- Sanitary survey and approval by a certified hydrogeologist.

Item BG16	All records retained for a minimum of two years.	CoP 3,4,5

IBWA members are required by the Code of Practice to maintain key records for a period of two (2) years.

SECTION 3 PC Rule Hazard Analysis, Preventive Controls, and Food Safety Plan

FR	The facility is registered with FDA under the facility registration rule.	

Facility registered with FDA? YES or NO.

FSP	The facility has a written food safety plan (FSP). The FSP addresses the following:	§117.126(a)

Facility has a food safety plan? YES or NO.

Item PC1	A written hazard analysis (HA);	§117.126(b)(1)

Present in FSP?

Item PC2	Written risk-based preventive controls (RPC);	(b)(2)

Present in FSP?

Item PC3	Written procedures for monitoring the implementation of the preventive controls;	(b)(3)

Present in FSP?

Item PC4	The written corrective action procedures;	(b)(4)

Present in FSP?

Item PC5	Written verification procedures;	(b)(5)

Present in FSP?

Item PC6	A written supply-chain program as required by subpart G of the Preventive Controls Rule;	§117 Subpart G

Present in FSP?

Item PC7	A written recall plan.[2]	§117.126(b)(6)

Present in FSP?

HAZARD ANALYSIS

Item PC8	Biological Hazards Identified:	§117.130(b)(1)

Present in FSP?

Item PC9	Chemical (including Radiological) Hazards Identified	§117.130(b)(2); (b)(4)

Present in FSP?

Item PC10	Physical Hazards Identified	§117.130(b)(3)

Present in FSP?

2 This references the recall of product that has been adulterated by a hazard identified in the facility's food safety plan, as per the FSMA Preventive Controls Rule.

Item PC11	Hazard Analysis Revisions: Hazard analysis is evaluated when changes to the facility or food safety plan occur, or at a minimum, every 3 years.	§117.130

Addressed in FSP?

Preventive Controls: The written FSP addresses the following preventive controls:

Item PC12	Process controls (e.g., operational controls for filters, UV units, ozone, RO). Note that as appropriate to the nature of the control and its role in the facility's food safety system, process controls must include parameters and the min/max value to which the parameter must be controlled.	§117.135(d)(1)

Addressed in FSP?

Item PC13	Food allergen controls (e.g., protecting food from allergen cross contact during storage, handling and use; ensuring proper labeling).	(d)(2)

Addressed in FSP?

Item PC14	Sanitation controls (e.g., cleanliness of food contact surfaces; prevention of cross contamination)	(d)(3)

Addressed in FSP?

Item PC15	Any other controls employed by the facility. (including supply chain, recall plan, other controls)	(d)(5)

Addressed in FSP?

Monitoring Requirements

Item PC16	The bottling facility must establish and implement written procedures for monitoring preventive controls, including frequency. Monitoring must be performed at adequate frequency to ensure that the preventive controls are being performed consistently. Monitoring activities must be documented, but exception records are permitted. Monitoring records are also subject to verification, including records reviews.	§117.140

Addressed in FSP?

Corrective Actions

Item PC17	The bottling facility must establish and implement written corrective action procedures to be used if the preventive controls are not properly implemented. Corrective actions are, as FDA states, as appropriate to the nature of the hazard and the nature of the preventive control. Corrective action procedures must address product testing and environmental monitoring results.	§117.145

Addressed in FSP?

VERIFICATION

Verification activities must include “as appropriate to the preventive control and its role in the facility’s food safety system:”

Item PC18	The food safety plan has been validated; signatures document validation with date.	§117.150(a)

YES or NO.

Item PC19	Verification that monitoring is being conducted.	(b)

YES or NO.

Item PC20	Where applicable, verification that appropriate decisions about corrective actions are being made.	(c)

YES or NO?

Item PC21	Where applicable, verification of implementation and effectiveness of corrective actions and corrections.	(d)

YES or NO?

Item PC22	Reanalysis of portions of the food safety plan, or the entire food safety plan are being completed at least once every three years.	(f)

Complete or not complete? Is the reanalysis documented?

Item PC23	All verification activities are documented and records maintained for 2 years.	(g)

Verified with records?

Preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazard via:

Item PC24	Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)	

Addressed in FSP? Verified with records?

Item PC25	Product testing (daily/weekly/quarterly/annually)	

Addressed in FSP? Verified with records?

Item PC26	Environmental monitoring (containers and closures)	

Addressed in FSP? Verified with records?

Records reviews:

Item PC27	Records of monitoring and corrective actions must be reviewed within 7 working days after the records are created, or within a reasonable timeframe provided that the preventive controls qualified individual prepares (or oversees preparation of) a written justification for a timeframe that exceeds 7 working days;	§117.175

Addressed in FSP? Verified with records?

Item PC28	Records of calibration, testing (e.g., product testing; environmental monitoring), supplier verification activities, and other verification activities must be reviewed within a reasonable time after the records are created.	§117.10(b)(9)

Addressed in FSP? Verified with records?

SECTION 4 IBWA Food Defense Plan

Item FD1	Does the company and facility have a documented food defense plan? Is there a designated person to oversee it?	

Addressed in FDP?

Item FD2	Is access to the facility limited? Is entry controlled?	

Addressed in FDP?

Item FD3	Are immediate supervisors aware of which employees should be on the premises and the area they are assigned to?	

Addressed in FDP?

Item FD4	Are all employees screened prior to hiring (e.g. reference checks, criminal background check, etc.), including temporary employees?	

Addressed in FDP?

Item FD5	Has food defense training been provided to all employees?	

Addressed in FDP? Are training records maintained?

Item FD6	Is the security team for each facility identified and the member list current? Do they meet at least quarterly?	

YES or NO / YES or NO.

Item FD7	Are employees aware of whom in management they should contact about potential security problems/issues?	

Addressed in FDP?

Item FD8	Does the company keep a current roster of employees, full time and temporary?	

Addressed in FDP?

Item FD9	Is there an employee identification system in place? Are uniforms, name tags or identification badges collected from employees prior to the termination of employment?	

Addressed in FDP?

Item FD10	Is there a system of traceability of computer transactions, and is computer access restricted?	

Addressed in FDP?

Item FD11	Does the facility have a documented policy to prevent storage or holding of finished product in unsecured areas?	

Addressed in FDP?

Item FD12	Are routine security checks of the premises performed to identify signs of tampering, criminal or terrorist act?	

Addressed in FDP?

Item FD13	Is the security of doors, windows and other points of entry monitored?	

Addressed in FDP?

Item FD14	Are keys to the facility monitored or tracked?	

Addressed in FDP?

Item FD15	Does the facility have an emergency lighting system?	

Addressed in FDP?

Item FD16	Is the delivery and off-loading of incoming materials supervised?	

Addressed in FDP?

Item FD17	Does the facility have a program in place to inspect product returned to the facility for tampering?	

Addressed in FDP?

Item FD18	Are floor plans, product flow charts and/or segregation charts are in a secure location?	

Addressed in FDP?

Item FD19	Is there a documented contractor and visitor policy?	

Addressed in FDP?

Item FD20	Are visitors required to show ID? Is the purpose of the visit verified before entry into the factory? Is there evidence the policy is being followed?	

Addressed in FDP?

Item FD21	Are visitors prohibited from sensitive areas in the plant (production, treatment etc.), unless accompanied by an authorized employee?	

Addressed in FDP?

Item FD22	Is there a policy in place stating where personal items are allowed and not allowed in the facility?	

Addressed in FDP?

Section 5 IBWA Membership Requirements

The following items are evaluated by IBWA staff, and do not determine the plant's pass or fail status regarding Sections 1 through 4 of the audit check sheet.

Item M1	Plant is operated under the supervision of a competent person qualified by experience, education, and training to operate and maintain the plant's facilities. Said person holds a certificate from IBWA or an applicable state agency.	CoP 3(p)

Each IBWA member plant is required to have personnel who have adequate experience, education, and training to operate and maintain the plant's facilities. At least one of these individuals is required to be an IBWA Certified Plant Operator, meaning that he/she has completed the IBWA training program and has passed the IBWA CPO final examination. In lieu of IBWA certification, IBWA will accept certain state certification programs (e.g., Texas and Kentucky). If you have a question regarding acceptability of state certification programs or other CPO issues, contact IBWA.

Item M2	IBWA member proprietary brands 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.	CoP 6(d)

IBWA members are now required to include on their proprietary, or "house," labels a telephone number that consumers may call to obtain additional product information. In limited areas of the U.S., bottlers may be required by local regulation to include a toll-free telephone number. A toll-free number is not required by IBWA. Although strongly recommended by IBWA that they also include a telephone number, labels for non-proprietary (co-packed) products are not required. Copies of all product labels are provided to the auditor, who forwards them to IBWA staff for review.

Item M3	Written document containing analytical test results and any other pertinent water quality information for bottler's proprietary brands available for inspection during audit. Document is made available by company to consumers upon request.	CoP 2(c)

Beginning in 2002, IBWA members were required to provide a written document to consumers upon request with information on proprietary product quality. The document may be based on the IBWA product quality template, a copy of the product laboratory analysis report, or another layout selected by the member that contains the required information. A copy of the document must be presented to the auditor upon request.

Item M4	Annual audit completed each year.	IBWA Bylaws

Annual audit of bottling facility(ies) completed, as required by IBWA's bylaws. Refusal of plant access to auditor(s) will be assessed as a failure of the annual audit. Rescheduled audits will be performed by the audit contractor at the expense of the bottler.

Item M5	Written policies and procedures designed to protect the integrity and security of their operations and products (bottled water facility security plan). Facility registered with the U.S. Food and Drug Administration.	CoP 2(d)

IBWA bottler members are required to develop and maintain a facility security plan that employs the guidance provided in FDA's "Guidance for Industry - Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance," published in 2003 and available from IBWA. IBWA bottler members, like all food producers, processors, and warehouses, were required to register their facilities with FDA by December 12, 2003. NOTE: Verify that the bottler has registered with FDA and note such on the audit form.

Miscellaneous Items/Issues

	Sanitization SOP	MC 3(b)

A sanitization standard operating procedure (SSOP) manual is an essential part of the company's overall food safety and sanitation programs. The auditor will verify the existence and availability of such a plan in the plant. If the HACCP plan references the SSOP, at least a few of the cross-references will be verified.

	Recall program	21 CFR 7

A recall plan is a regulatory requirement and must be available in the event of the necessity of a product recall. The auditor will verify the plan's availability. It must include provisions for product tracking and disposition.

Gray Areas Clarifications

	Should additional points be deducted for repeat deficiencies in successive years?

Logical arguments can be made for deducting additional points. However, as the inspection is intended to be consultative and not punitive, additional points shall not be deducted. It is understood that IBWA will follow-up with those members who have control points (critical deficiencies, aka “criticals”) or repeat non-compliance items as noted on the "Discussion with Management" page of the inspection report.

	Are tanker manhole vent filters required? If so, why? Are they commercially available?

Tanker manhole or air vents are required to have filters to preclude the entrance of insects and airborne filth as the tank is emptied. The vent filter housing and replacement filters are available commercially from dairy outlets. **Caution:** Filters, if mounted in such a manner that they may become wet, may freeze and block in the winter causing the tank to collapse. For this reason, bottlers in colder climates may elect to have a clean, dry filter available for unloading. The decision to mount on the tanker or to remove and store in a sanitary manner each time, should be made on a case-by-case basis by the bottler.

	Should outside storage of product be permitted?

Yes. However, FDA has indicated that outside storage may not comply with Title 21 of the U.S. Code of Federal Regulations, Part 117.93, Warehousing and Distribution, which states "Storage and transportation of finished food shall be under conditions that will protect food against microbial contamination as well as against the deterioration of the food and container." Compliance with this provision will be handled on a case-by-case basis.

	Should a letter from state regulatory agencies accepting less than the “highest standard” be accepted?

No. IBWA requires that its members meet the 'highest standard.' IBWA membership requires that all bottlers will consistently adhere to the most stringent manufacturing and quality standards or regulations to ensure that their products protect the public health and safety. If the state regulation exceeds FDA requirements, then the state requirements prevail and if the Code of Practice exceeds both FDA and the state, the IBWA requirements shall prevail. The acceptance of "lesser standards," even if the regulatory agency having jurisdiction accepts, is not permitted.

	Why is it not possible to receive a sanitary compliance rating (SCR) when the bottler has critical control point deficiencies?

The IBWA inspection program is intended to be consultative and instructive. Not providing an inspection score if there are control point (critical) deficiencies is intended to focus attention on the need for prompt, if not immediate, correction of the deficiencies. A SCR has little meaning if there are "criticals" present.

	Which methods shall be used when performing required analyses?

All required analysis, whether performed in-house or by an outside laboratory, shall be performed according to the methods referenced in the most recent edition of Standard Methods for the Examination of Water and Wastewater or analytical method referenced by the US EPA for use in drinking water.

	Must a bottler have analytical results on file for a city water supply, and if so, what analyses should be on file (EPA Primary, EPA Secondary, FDA Quality Standards, etc.)? What analyses are required for a private source?

If a bottler uses a city water supply, a water bill is sufficient evidence. If a non-community supply is used, the bottler must, at a minimum, have on file a weekly microbiological analysis and an annual analysis for the EPA Primary parameters. This applies to operations or product water source supplies. Private water sources such as springs and wells must be analyzed in accordance with Appendix A of the IBWA Code of Practice.

	Should weekly individual source (wells, springs) coliform samples be taken directly from the source only or is it acceptable to take a source coliform sample from the delivery tanker if the source is not under the control of the bottler, or at a distance from the plant that makes it difficult to retrieve samples directly from the source itself?

The source should be considered as the earliest point in the process where the bottler has control over the process. In the case of delivery tankers in the situations cited above, or a public water system source, that point will most likely be where the water enters the plant.

Therefore, samples collected from delivery tankers, under the conditions stated, are acceptable as "source" samples. It is the group's **strong recommendation**, however, that the bottler obtain, and file weekly reports of samples collected by the source owner or tanker operator, and that these records be made available for review during an on-site inspection. Furthermore, it is recommended that samples be collected at the *well or spring source* when contamination is found in weekly delivery tanker samples to help determine the cause of the contamination.

	What materials are acceptable for product water contact, and how can I document their acceptability?

The U.S. Code of Federal Regulations (Title 21, Part 177) contains a comprehensive list of substances i.e. polymers, as basic food components of single and repeated use food contact surfaces. Any materials included in this list are acceptable for the appropriate application. Bottlers should request that the suppliers of these various components (caps, bottles, etc.) provide the required documentation.

	Does FDA approve materials?

No. FDA approves direct and indirect food additives but does not approve the materials they are incorporated into. Material suppliers can certify that the ingredients they use in the manufacture of specific materials do meet FDA requirements.

	Do internal corporate or company quality control procedures and microbiological sampling techniques have to meet *Standard Methods*?

Standard Methods procedure may not exist for many internal (in-house) methods used for noncompliance quality control monitoring. At a minimum, procedures used to monitor effectiveness of treatment processes and/or in-process quality control must be reliable, adequately documented, and shall meet the corporate requirements e.g. monitoring frequency, prescribed by each individual firm. All microbiological sampling techniques used for compliance purposes must be conducted in accordance with Standard Methods.

	Is inspection of returnable bottles required?

Yes. Each plant will determine the scope of the inspection process/procedure for incoming, returnable bottles, based on the plant's operations and documented HACCP plan.

	Must containers and closures be sampled and microbiologically tested each quarter?

Yes. IBWA members are required to perform these bacteriological analyses on a quarterly basis. For containers (bottles), at least four (4) of each type, style and size must be selected just prior to filling and sealing and tested for total coliform and heterotrophic plate count (HPC) bacteria using a rinse test. Four (4) closures (caps) of each type, style and size must be selected just prior to capping and tested for total coliform and HPC using a swab test. When selecting the four (4) samples of a specific cap design; cap color is not a factor. No more than one of the four (4) bottle samples can exceed one (1) CFU/ml capacity of the container type, style or size. No more than one of the four (4) cap samples can exceed one (1) CFU/sq. cm. of product contact surface area of the cap type, style or size. All bottles and caps tested each quarter must be free of coliform organisms.

	Must weekly coliform testing on finished product be done at an approved laboratory? Must daily product samples also be done at an approved laboratory?

The FDA states in 21 CFR §129.80(g)(1) that weekly product samples must be analyzed for microbiological contaminants at an approved laboratory. If a bottled water plant's testing laboratory is approved, e.g., certified by a state drinking water laboratory certification program, the weekly microbiological testing may be done at the plant. Daily samples may be done either in-house at the plant by qualified plant personnel using approved analytical methods or by an outside approved laboratory.

	Should IBWA members use an approved laboratory to perform finished product testing for total coliform?

Total coliform tests must be performed daily and those daily tests may be performed in-house as long as the analyses are performed according to a method referenced in the most recent edition of Standard Methods for the Examination of Water and Wastewater. In addition, at least once per week, bottled water products shall be tested by an approved laboratory for total coliform.

	Why are copies of chemical, microbiological, and radiological analytical test results copied to send to IBWA as part of the inspection report?

The plant's product testing reports are reviewed during the on-site audit by IBWA's audit contractor(s). Copies of the reports are NOT required to be sent to IBWA.

	When fluoridated water products are produced, and the product consists of fluoride added to purified, spring, or another finished water product, is it necessary to analyze the fluoridated water for ALL FDA-required and Appendix

	A contaminants, or may the bottler simply analyze samples of fluoridated water for fluoride and microbiological contaminants?

The U.S. Food and Drug Administration responded directly to an IBWA inquiry ruling that fluoridated water is considered by FDA to be a separate and distinct product. Therefore, the product must be tested annually for all FDA-required and IBWA Appendix A contaminants.

	Should air curtains be accepted on conveyor openings? Should air curtains be accepted on entranceways to bottling rooms? Are screens on the doors and windows acceptable?

The use of air curtains on conveyor openings is discouraged. If used, the blower shall be mounted inside the bottling room so that cleaner air will be moved through the unit's filter and around the bottles. A small V-shaped piece of stainless steel shall be mounted over the spot where the bottle lip passes. Air curtain housings, blower, or fan blades shall be kept free of dust. The positive pressure required in bottling rooms is difficult to maintain with air curtains. Air curtains are not acceptable on entranceways to bottling rooms because they do not provide the integrity of a self-closing door.

The use of screens (doors or windows) is not acceptable because they do not preclude the entrance of airborne dust and dirt.

	Should other food processing or packaging operations be permitted in the bottling room? Should cardboard shipping boxes be made up in the bottling room?

21 CFR Parts 117 and 129 clearly state, "The bottling room should be separate from other plant operations." Shipping boxes should not be made up in the bottling room since carton dust could contaminate the water and compromise the sanitation of the filling room. Bottling products of a similar nature are permissible. Laboratory equipment and related reagents are permissible if a defined area (work bench) is provided and used. Other operations such as construction of shipping boxes, tow motor traffic, or that which could contaminate the water and compromise the sanitation of the filling room are not permissible.

	Are multi-purpose, "monoblock" fillers approved for use in the clean room?

"Monoblock" fillers are often comprised of a rinser, filler, capper, and labeler, all enclosed in one unit. If separate, one or more of the components would not normally be permitted in the bottling room; however, the IBWA Gray Areas Task Force ruled that new technologies, such as "monoblock" fillers, may be permitted, provided their sanitary use and operation can be validated, and the plant's sanitization SOP and/or HACCP plan address monitoring that assures that their use does not contaminate product water.

	Are micron filter housings and/or granular activated carbon (GAC) filters permitted in the bottling room?

As was stated above for “monoblock” fillers, Micron filter housings and/or GAC filters are permitted in the bottling room provided their sanitary use and operation can be validated, and the plant’s sanitization SOP and/or food safety plan address monitoring that assures that their use does not contaminate product water.

	At what locations within the plant does the 50-foot candle recommendation apply?

The 50-foot candles are recommended wherever there is an exposed product or product contact surface, to be able to determine the presence of physical contamination. These areas would include packaging/bottling, cooler refurbishing, equipment cleaning/repair, and handwashing. As a rule, 20-foot candles should be provided in other areas.

	Can the requirements for lighting in process and other areas of the plant be “de-emphasized” or relaxed?

In lieu of “de-emphasizing” or relaxing current lighting requirements, the IBWA Gray Areas Task Force received a recommendation from IBWA’s audit contractor that an acceptable alternative in areas of the plant that do not meet the requirement for 20-foot candles is use of temporary lighting fixtures. For example, these devices can be used when cleaning in warehouses, then removed when cleaning is completed.

	Is always it necessary for building exterior doors and windows to be closed?

As a rule, doors should be closed.

Whether it is necessary to keep doors closed always is a matter of judgement taking into consideration the following factors:

a. General level of accumulated dust and dirt on horizontal surfaces in the plant.
b. Evidence of vermin.
c. Condition of plant grounds and parking lot.
d. Traffic in and out, and level of activity in the area.
e. Nature of operation taking place in the area of the door .
f. Interior layout/design of plant.

	Should bottle washers be installed in an enclosed room? Should washers of either type (“carousel” or “straight through”) exit into bottling room? Must the load end (dirty bottles) be in an enclosed room?

Bottle washers shall be installed in an enclosed (protected) area. The area does not necessarily need to be an enclosed room specifically built to house the bottle washer, but the washer shall be positioned to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room. It is not an accepted practice to permit the bottle washer to exit directly into the bottling room unless the bottling room HVAC system is designed to accommodate the increased heat and moisture dissipation/exhaust needs. The load end of a bottle washer need not be in an enclosed room. The area shall be protected and the washer penetration through the building wall or bottling room wall shall be tightly closed off to be free of dust and vermin.

	Are plastic strip curtains acceptable for use on bottling room entrance ways or conveyor openings?

Plastic strip curtains are **not** acceptable for use on bottling room entrance ways. While they may meet the self-closing requirement for doors, they do not provide a tight fit, especially at the floor level. The use of strip curtains on conveyor openings is acceptable provided the following provisions are met:

a. There is positive air flow at the conveyor opening.

b. The conveyor cover is designed to preclude repeated contact of the curtain with the lip or sanitized bottles.

c. The curtains are cleaned and sanitized daily.

	Are ozone contact tanks and generators permitted in the bottling room?

Generally, it is acceptable for the ozone contact tank to be in the bottling room, but it is not customary to place ozone generators in the room. However, the bottler may install separation or containment devices such as shrouds around the generator to control the release of ozone into the bottling room. It is the bottler's responsibility to ensure the safety of ozone generators in the bottling room.

	Are natural gas or propane-powered forklifts permitted to be used in areas where finished, sealed product is present, such as in case packing, palletizing, and warehouse storage areas of the plant?

Gas-powered forklifts are permitted in areas where there is no risk of airborne contamination of the final product, provided the product is in sealed containers.

	Are 5-gallon coolers with cup dispensers for employees acceptable in production areas?

To clarify this issue fully, it is necessary to define certain portions of the plant in order to clearly differentiate acceptable and unacceptable locations for water coolers. Production areas and warehouse areas will be addressed here.

The current definition of “production area” is valid and consumption of any food or beverage items in this area will continue to be discouraged, with the following exception. Concern regarding compliance with occupational health and safety rulings for employee water availability has led to discussion and determination of a recommended policy. Water will continue to be prohibited in production areas except in cases where a local, state, or federal occupational health agency has issued a written directive requiring the plant to provide water to employees in areas of the plant specified by the agency. The bottler must then provide IBWA’s plant inspectors with a copy of the directive during the annual inspection. In such cases, only stationary water units, such as 5-gallon coolers, will be acceptable. Consumption of water from single serving containers will not be acceptable in any production area.

The following definitions apply to two types of warehouse areas:

1. Raw materials warehouse: A warehouse area that contains raw materials, including open containers and caps, where there may be any risk of contaminating the product through exposure of raw materials that could potentially expose the product to any microbiological, chemical, or physical hazard. This area may or may not be isolated from the production area.
2. Finished product warehouse: A warehouse area that contains product in sealed, ready to ship containers, and is physically separated from the production area or from open container or cap storage areas. This area may also serve as a staging area for 5-gallon returnable containers prior to washing and sanitizing.

Given the above warehouse definitions, placement of coolers ONLY in finished product warehouses will be acceptable.

	What constitutes double door construction for rest rooms in the production/processing areas? Is double door construction necessary or is it acceptable to have a partition in front of the door? How far away from the production area is this rule applicable?

It is IBWA’s and AUDITOR’s determination that double doors will be required in any area of the production area or in adjacent areas not physically isolated from the production or raw materials warehouse areas. A partition in front of the door will not be acceptable in these areas. Finally, IBWA and its auditors do not wish to establish an arbitrary criterion for distance from the production area.

	What documentation is acceptable as evidence of source approval? Will lack of available documentation or absence of a formal state or local source approval program result in citation of a plant for a critical deficiency?

The following documentation is acceptable as evidence of source approval:

- A permit or license from the state or local government for a specific well or spring.

- A letter from the appropriate state or local government agency(ies) stating that the well or spring has been inspected and meets all requirements for use as a source for bottled water.
- A current (two years or less) inspection report from any state or local health, agriculture, or environmental agency that addresses the source and indicates no problem with the source.
- A current license issued by any local, county, or state health, agriculture, or environmental agency, for operating a water bottling or food processing facility.
- Documented certification or approval of the source by a licensed or certified hydrogeologist accompanied by a sanitary survey or other technical information.

ANY ONE of the items in the above list is acceptable as documentation of source approval – it is not necessary to acquire two or more of the approvals.

A bottler will be cited for a critical deficiency under inspection item BG15 only if at least ONE of the above items has not been secured by the bottler. In cases where a source is approved, but the documentation is not available for inspection, inspection item BG15 will be marked “incomplete.” IBWA may request a copy of the source approval document(s) upon receipt of auditor’s inspection report.

	Should restrooms opening into production areas be cited as a deficiency, even if the door is self-closing and exhaust ventilation is provided? Would it be acceptable to open into a production area if a vestibule (double door) is provided?

Restroom doors must not open directly into production areas unless a vestibule (double door) is provided. Additionally, doors must be self-closing and exhaust ventilation, or an operable screened window provided. Production areas are those areas where there are exposed product, clean containers, and/or clean product contact surfaces.

	Can closures be left in an appropriate hopper for periods between bottling runs or during normal overnight or weekend down-time periods?

Closures may be left in the "Syntron" or an appropriate hopper during routine periods of down-time if the Syntron or hopper is adequately protected from contamination. During routine bottling room and equipment cleaning procedures the closures, where applicable, shall be removed from the hopper or Syntron bowl to protect against splash and spillage and to facilitate the cleaning and sanitizing of the hopper and/or Syntron bowl.

	What are the criteria to be used in requiring conveyor covers?

Conveyor lines are required to be covered where there is transport of clean sanitized bottles, whether outside the bottling room or inside prior to the filler. In some instances, by the design of either the filling or capping equipment, it may be necessary to cover the

conveyor between filler and capper to avoid contamination.

	Are fluoride tablets an acceptable method of producing fluoridated bottled water products?

Although IBWA strongly recommends against use of fluoride tablets added manually to bottled water final product, their use is not prohibited by FDA regulation. Manual addition of the tablets may compromise the microbiological integrity of the product, especially when handled without sanitized hands or gloves, and when bottles are capped manually. To minimize this risk, it is strongly recommended that plant employees use clean, sanitized gloves when handling fluoride tablets. Bottlers are also advised that sodium fluoride is a poison, and if handled improperly, may cause illness or other adverse health effects.

If tablets are used, it is advisable to use an automated dispensing system, followed by a mechanical capper. Since there is a risk that the tablets may not dissolve quickly or completely, some method of mixing the water should be used (inverting bottles, mechanical agitation, etc.).

	Must a sanitizer be used following a non-caustic detergent bottle washing operation?

Yes. Most regulatory authorities have established specific requirements for sanitizers in bottle washers following a detergent wash. Even though some local authorities may not specify these requirements, all IBWA members shall sanitize returnable containers. All sanitizing operations shall be used, as applicable, in accordance with Part 129.80 (b), (c), and (d) (1) (2) (3) (4) (5) of Title 21 of the Code of Federal Regulations.

	What is the need for, and proper procedure, to maintain carbon filters and other types of filters?

Filters can become contaminated from the build-up of organic material, the microorganisms filtered out of the water, and the change outs of cartridges. Periodic backwashing and/or sanitization is required when the pressure drop across the filter exceeds specifications, or the bacteria counts immediately downstream of the filter exceed standard. The preferred methods of sanitizing are steam or acids.

	Should the plant inspection include a review of the incoming city water supply backflow devices?

No. A backflow prevention device on an incoming city water supply is intended to protect the city water and is the responsibility of the local plumbing authority. Since this is governed by various local and national codes, it is outside the scope of the plant inspections.

	Are beard nets, as well as hair nets/caps, required? Must bottling room workers wear uniforms? When are hairnets required?

Uniforms, while not required, are recommended. Clean street clothes are permissible. Beard or hair nets/caps (i.e. hair restraints) are required in those production areas where there is an opportunity for loose hair to fall into the product or clean containers, and onto clean product contact surfaces.

	Should the presence of employees in the filling room be discouraged or not permitted?

Only authorized, properly attired personnel shall be permitted to enter the filling room to perform required tasks such as cleaning or operation of equipment, conducting certain tests, or collecting samples.

	Should the bottled water plant be operated under the supervision of a certified operator?

IBWA’s bylaws stipulate that the bottled water plant shall be operated under the supervision of a person holding a certificate attesting to completion of some form of a technical training course such as, but not limited to, IBWA's Technical Training Course, or a state's certified operator training course.

Appendix A IBWA Tier 1 Audit Checksheet

SECTION 1 General Good Manufacturing Practices (GMPs)

Checklist Item	*Ref. (21 CFR)*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
G1. **DISEASE CONTROL** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.	§117.10(a)	**Mn**	C / NC	
CLEANLINESS G2. Outer Garments: The methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.	§117.10(b)(1)	**Mn**	C / NC	
G3. Unsecured Jewelry and Other Objects: The methods for maintaining cleanliness include removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.	(b)(4)	**Mn**	C / NC	
G4. Gloves: The methods for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	(b)(5)	**Mn**	C / NC	
G5. Clothing and Other Personal Belongings: The methods for maintaining cleanliness include storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	(b)(7)	**Mn**	C / NC	
G6. Eating Food, Chewing Gum, Drinking Beverages, and Using Tobacco: The methods for maintaining cleanliness include confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.	§117.10(b)(8)	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
G7. Any Other Necessary Precautions: The methods for maintaining cleanliness include taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.	(b)(9)	**Mn**	C / NC	
PLANT GROUNDS, CONSTRUCTION, AND DESIGN				
G8. Management Responsibility for Maintaining Grounds: The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:	§117.20(a)(b)			
• Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.	(a)(1)	**Mn**	C / NC	
• Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.	(a)(2)	**Mn**	C / NC	
• Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.	(a)(3)	**Mn**	C / NC	
• Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.	(a)(4)	**Mn**	C / NC	
• If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in the rule, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.	(a)(4)	**Mn**	C / NC	
G9. Suitability of Plant Construction and Design: The plant buildings and structure must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).	§117.20(b)	**Mn**	C / NC	
G10. Placement of Equipment and Storage of Materials: The plant must provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.	(b)(1)	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
G11. Reduce Potential for Contamination and Allergen Cross-Contact Through Adequate Food Safety Controls and Operating Practices or Effective Design: Adequate precautions must be taken to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.	(b)(2)	**Mn**	C / NC	
G12. Food in Outdoor Bulk Vessels (including storage tanks and silos): Adequate precautions must be taken to protect food in installed outdoor bulk vessels by any effective means, including using protective coverings, controlling areas over and around the vessels to eliminate harborages for pests, checking on a regular basis for pests and pest infestation, and skimming fermentation vessels, as necessary.	(b)(3)	**Mn**	C / NC	
G13. Lighting: Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.	(b)(5)	**Mn**	C / NC	
G14. Ventilation: Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.	(b)(6)	**Mn**	C / NC	
G15. Adequate ventilation provided to minimize odors, noxious fumes, or vapors and condensate in processing, bottling, container washing and sanitizing rooms; ventilation equipment clean.	§129.20 (c)	**Mj/Mn**	C / NC	
G16. Screening: The plant must provide, where necessary, adequate screening or other protection against pests.	§117.20 (b)(7)	**Mn**	C / NC	
G17. Bottle washing/sanitizing in an enclosed room; positioned to minimize post-sanitization contamination.	§129.20 (d)	**Mn**	C / NC	
G18. Processing, washing, other rooms not directly connected to room(s) used for domestic household purposes.	§129.20 (e)	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
SANITARY OPERATIONS				
G19. General Maintenance: Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.	§117.35(a)	**Mj**	C / NC	
G20. Cleaning Compounds and Sanitizing Agents: Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: • Those required to maintain clean and sanitary conditions; • Those necessary for use in laboratory testing procedures; • Those necessary for plant and equipment maintenance and operation; and • Those necessary for use in the plant's operations.	(b)(1)	**Mn**	C / NC	
G21. Identification and Storage of Toxic Materials: Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.	(b)(2)	**Mn**	C / NC	
G22. Pest Control: Pests must not be allowed in any area of a food plant. Guard, guide, or pest detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.	§117.35(c)	**Mj/Mn**	C / NC	
G23. Sanitation of Food-Contact Surfaces: All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.	§117.35(d)	**Mj/Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
G24. Sanitation of Non-Food-Contact Surfaces: Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.	(e)	**Mn**	C / NC	
G25. Storage and Handling of Cleaned Portable Equipment and Utensils: Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.	(f)	**Mn**	C / NC	
SANITARY FACILITIES AND CONTROL				
G26. Water Supply: The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.	§117.37(a)	**Mj**	C / NC	
Plumbing: Plumbing must be of adequate size and design and adequately installed and maintained to:				
G27. Carry adequate quantities of water to required locations throughout the plant.	§117.37(b)(1)	**Mn**	C / NC	
G28. Properly convey sewage and liquid disposable waste from the plant.	(b)(2)	**Mn**	C / NC	
G29. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition	(b)(3)	**Mj**	C / NC	
G30. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.	(b)(4)	**Mn**	C / NC	
G31. Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing	(b)(5)	**Mn**	C / NC	
G32. Toilet facilities: Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.	(d)	**Mn**	C / NC	
G33. Hand-washing facilities: Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.	(e)	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
G34. Rubbish and offal disposal: Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.	(f)	**Mn**	C / NC	
G35. Operations water meets applicable regulatory standards and requirements.	§129.35 (a)(2)	**Mj**	C / NC	
G36. Source water approved by agency having jurisdiction or by certified or licensed professional geologist or hydrogeologist.	§129.35 (a)	**Mj**	C / NC	
G37. Air under pressure directed at product water or contact surfaces free of oil, dust, rust, excessive moisture; does not affect bacteriological quality.	§129.35 (b)	**Mn**	C / NC	
G38. Locker and lunch rooms separate from plant operations and storage areas; doors are self-closing; rooms are clean and sanitary; refuse container(s) provided; packaging, wrapping materials and processing supplies absent.	§129.35 (c)	**Mn**	C / NC	
G39. Product water contact surfaces (utensils, pipes, equipment) clean and adequately sanitized daily; records maintained.	§129.37 (a)	**Mn**	C / NC	
G40. Product water contact surfaces maintained free of scale, oxidation, and other residues. Presence of any unsanitary conditions corrected immediately.	§129.37 (a)	**Mn**	C / NC	
G41. Cleaned multi-service containers, utensils, disassembled piping, and equipment transported and stored in a sanitary manner.	§129.37 (b)	**Mj**	C / NC	
G42. Containers, closures, or seals purchased and stored in original containers in clean, dry place; examined before use; handled, dispensed in a sanitary manner. Washed, rinsed, and sanitized as needed.	§129.37 (c)	**Mj**	C / NC	
G43. Filling, capping, closing, sealing, and packaging done in a sanitary manner.	§129.37 (d)	**Mj**	C / NC	
EQUIPMENT AND PROCEDURES				
G44. Equipment suitable for intended use, designated, and of materials to be cleanable and properly maintained.	§129.40 (a)(1)	**Mn**	C / NC	
G45. Storage tanks can be closed to exclude all foreign matter; filtered vents provided; filters readily cleanable or replacement elements.	§129.40 (b)	**Mn**	C / NC	
G46. Product water separate from operations water to preclude contamination of product; either separate piping systems or suitable backflow prevention.	IBWA	**Mj**	C / NC	

Checklist Item	*Ref. (21 CFR)*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
PROCESSES AND CONTROLS				
Adequate Sanitation Principles:				
G47. All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.	§117.80(a)(1)	**Mn**	C / NC	
G48. Quality Control Operations: Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.	(a)(2)	**Mn**	C / NC	
G49. Supervising Overall Sanitation: Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.	(a)(3)	**Mn**	C / NC	
G50. Production Procedures: Adequate precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.	(a)(4)	**Mn**	C / NC	
G51. Chemical, Microbial, or Extraneous-Material Testing Procedures: Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.	(a)(5)	**Mn**	C / NC	
G52. Contaminated Food: All food that has become contaminated to the extent that it is adulterated be rejected, or if appropriate, treated or processed to eliminate the contamination.	(a)(6)	**Mj**	C / NC	
G53. Inspection, Segregation and Handling of Raw Materials and Other Ingredients: Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause increase the level of contamination of the food.	§117.80(b)(1)	**Mj**	C / NC	
G54. Levels of Microorganisms in Raw Materials and Other Ingredients: Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.	§117.80(b)(2)	**Mj**	C / NC	

Checklist Item	*Ref. (21 CFR)*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
G55. Holding Raw Materials, Other Ingredients, and Rework in Bulk: Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.	(b)(5)	**Mj**	C / NC	
G56. Liquid and dry raw materials and other ingredients: Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against contamination.	(b)(7)	**Mn**	C / NC	
G57. Treatment equipment processes and substances used preclude contamination or adulteration of product. Bottled water product shall not be transported, stored or processed through non-food equipment. If equipment is used for other foods, a documented cleaning/sanitizing procedure shall be made available.	§129.80 (a) MC 3(d) MC 3(f)	**Mj**	C / NC	
G58. Multi-service shipping cases maintained to assure they will not contaminate primary container or product.	§129.80 (b)(2)	**Mn**	C / NC	
G59. Records maintained of kind of product, volume produced, date produced, lot code used, and distribution to wholesale and retail outlets.	§129.80 (e)	**Mn**	C / NC	
MANUFACTURING OPERATIONS				
G60. Condition of equipment, utensils, and finished food containers: Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.	§117.80(c)(1)	**Mn**	C / NC	
G61. Conditions and controls for food manufacturing, processing, packing, and holding: All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.	(c)(2)	**Mj**	C / NC	
G62. Measures to destroy or prevent the growth of undesirable microorganisms: Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.	(c)(3) (c)(4)	**Mj**	C / NC	
G63. Work-in-Process and Rework: Work-in-process and rework must be handled in a manner that protects against contamination and growth of undesirable microorganisms.	(c)(5)	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments** (including opportunities for improvement and observations)*
G64. Equipment, containers, and utensils: Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against contamination.	(c)(7)	**Mn**	C / NC	
G65. Metal and other extraneous material: Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.	(c)(8)	**Mn**	C / NC	
G66. Disposal of adulterated food, raw materials, and other ingredients: Food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food; or if the adulterated food is capable of being reconditioned, it must be: 1. Reconditioned (if appropriate) using a method that has been proven to be effective; or 2. Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.	§117.80(c)(9)	**Mj**	C / NC	
G67. Filling, Assembling, Packaging and Other Operations: Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against contamination and growth of undesirable microorganisms.	(c)(13)	**Mn**	C / NC	
WAREHOUSING AND DISTRIBUTION / DEFECT ACTION LEVELS				
G68. Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.	§117.93	**Mn**	C / NC	
G69. The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.	§117.110	**Mn**	C / NC	

SECTION 2 Additional Bottled Water-Specific GMPs (21 CFR 129 and IBWA Code of Practice)

Checklist Item	*Ref. (21 CFR)*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
BG1. Product water from approved source; complies with applicable laws and regulations; documented; complies with GMPs and SOQs; source integrity verified; source free of surface water influence.	§129.35 (a)(1)	**Mj**	C / NC	
BG2. Source waters analyzed annually for chemical/physical parameters; every four years for radiological parameters. Non-PWS source waters analyzed weekly for microbiological contaminants.	§129.35 (a)(3)	**Mj**	C / NC	
BG3. Product water contact surfaces comply with FDA, Codex, or other applicable standards; are of nonabsorbent, nontoxic materials; can be adequately cleaned and sanitized.	§129.40 (a)(2)	**Mj**	C / NC	
BG4. Treatment process achieves intended purpose; inspection records maintained and reviewed.	§129.80 (a)	**Mn**	C / NC	
BG5. Product water samples taken after processing prior to bottling to verify effectiveness of treatment process; approved analysis methods.	§129.80 (a)	**Mn**	C / NC	
BG6. Unsanitary or defective containers reprocessed or discarded; multi-service containers cleaned, sanitized prior to filling and capping; records maintained.	§129.80 (b)	**Mj**	C / NC	
BG7. Mechanical washers inspected and records maintained for maintenance and performance.	§129.80 (b)(1)	**Mn**	C / NC	
BG8. Sanitizing operations comply with applicable regulations and manufacturer's directions; records maintained.	§129.80 (c)	**Mn**	C / NC	
BG9. Containers and closures nontoxic; comply with applicable regulations. Each product identified by production code. Code identifies particular batch or segment of continuous run and day produced.	§129.80 (c)/(f)	**Mj**	C / NC	
BG10. Filling, capping, and sealing monitored; filled containers inspected; records maintained.	§129.80 (f)	**Mn**	C / NC	
BG11. Containers and closures tested for microbiological contaminants at least quarterly; records maintained.	§129.80 (f)	**Mj**	C / NC	
BG12. Samples taken at least once per week for each product type; analyzed at an approved laboratory for microbiological contaminants; records maintained.	§129.80 (g)(1); MC 5(b)	**Mj**	C / NC	
BG13. Bottled water products tested daily for total coliform by an in-house laboratory or an approved laboratory.	MC 3(h)	**Mj**	C / NC	
BG14. Samples analyzed at least once per year for each product type for chemical and physical parameters by an approved laboratory	§129.80 (g)(2)	**Mj**	C / NC	
BG15. All records of certifications and approvals of source and operations water on file.	§129.80 (h)	**Mn**	C / NC	
BG16. All records retained for a minimum of two years.	MC 3,4,5	**Mn**	C / NC	

SECTION 3 PC Rule Hazard Analysis, Preventive Controls, and Food Safety Plan

Checklist Item	*Ref. (21 CFR)*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
FACILITY REGISTRATION: The facility is registered with FDA under the facility registration rule.		**Mj**	C / NC	
FOOD SAFETY PLAN: The facility has a written food safety plan (FSP). The FSP addresses the following:	§117.126(a)	**Mj**		
PC1. A written hazard analysis (HA);	§117.126(b)(1)	**Mj**	C / NC	
PC2. Written risk-based preventive controls (RPC);	(b)(2)	**Mj**	C / NC	
PC3. Written procedures for monitoring the implementation of the preventive controls;	(b)(3)	**Mj**	C / NC	
PC4. The written corrective action procedures;	(b)(4)	**Mj**	C / NC	
PC5. Written verification procedures;	(b)(5)	**Mj**	C / NC	
PC6. A written supply-chain program as required by subpart G of the Preventive Controls Rule;		**Mj**	C / NC	
PC7. A written recall plan.	(b)(6)	**Mj**	C / NC	
HAZARD ANALYSIS				
PC8. Biological Hazards Identified:	§117.130(b)(1)	**Mj**	C / NC	
PC9. Chemical (including Radiological) Hazards Identified:	(b)(2) (b)(4)	**Mn**	C / NC	
PC10. Physical Hazards Identified:	(b)(3)	**Mn**	C / NC	
PC11. Hazard Analysis Revisions: Hazard analysis is evaluated when changes to the facility or food safety plan occur, or at a minimum, every 3 years.	§117.130	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments*** *(including opportunities for improvement and observations)*
Preventive Controls: The written FSP addresses the following preventive controls:				
PC12. Process controls (e.g., operational controls for filters, UV units, ozone, RO). Note that as appropriate to the nature of the control and its role in the facility's food safety system, process controls must include parameters and the min/max value to which the parameter must be controlled.	§117.135 (d)(1)	**Mj**	C / NC	
PC13. Food allergen controls (e.g., protecting food from allergen cross contact during storage, handling and use; ensuring proper labeling).	(d)(2)	**Mn**	C / NC	
PC14. Sanitation controls (e.g., cleanliness of food contact surfaces; prevention of cross contamination).	(d)(3)	**Mj**	C / NC	
PC15. Any other controls employed by the facility. (including supply chain, recall plan, other controls)	(d)(5)	**Mn**	C / NC	
PC16. MONITORING REQUIREMENTS The bottling facility must establish and implement written procedures for monitoring preventive controls, including frequency. Monitoring must be performed at adequate frequency to ensure that the preventive controls are being performed consistently. Monitoring activities must be documented, but exception records are permitted. Monitoring records are also subject to verification, including records reviews.	§117.140	**Mj**	C / NC	
PC17. CORRECTIVE ACTIONS The bottling facility must establish and implement written corrective action procedures to be used if the preventive controls are not properly implemented. Corrective actions are, as FDA states, as appropriate to the nature of the hazard and the nature of the preventive control. Corrective action procedures must address product testing and environmental monitoring results.	§117.145	**Mn**	C / NC	

Checklist Item	***Ref. (21 CFR)***	***NC Type***	***Audit Result***	***Comments*** *(including opportunities for improvement and observations)*
VERIFICATION				
Verification activities must include "as appropriate to the preventive control and its role in the facility's food safety system:"				
PC18. The food safety plan has been validated; signatures document validation with date.	§117.150 (a)	**Mn**	C / NC	
PC19. Verification that monitoring is being conducted.	(b)	**Mn**	C / NC	
PC20. Where applicable, verification that appropriate decisions about corrective actions are being made.	(c)	**Mn**	C / NC	
PC21. Where applicable, verification of implementation and effectiveness of corrective actions and corrections.	(d)	**Mn**	C / NC	
PC22. Reanalysis of portions of the food safety plan, or the entire food safety plan are being completed at least once every three years.	(f)	**Mn**	C / NC	
PC23. All verification activities are documented, and records maintained for 5 years.	MC 3,4,5	**Mn**	C / NC	
Preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards via:				
PC24. Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)		**Mn**	C / NC	
PC25. Product testing (daily/weekly/quarterly/annually)		**Mj**	C / NC	
PC26. Environmental monitoring (containers and closures)		**Mj**	C / NC	
Records reviews				
PC27. Records of monitoring and corrective actions must be reviewed within 7 working days after the records are created, or within a reasonable timeframe provided that the preventive controls qualified individual prepares (or oversees preparation of) a written justification for a timeframe that exceeds 7 working days;	§117.175	**Mn**	C / NC	
PC28. Records of calibration, testing (e.g., product testing; environmental monitoring), supplier verification activities, and other verification activities must be reviewed within a reasonable time after the records are created.		**Mn**	C / NC	

SECTION 4 IBWA FOOD DEFENSE PLAN

IBWA Security Plan Checklist

Checklist Item	*Ref.*	*NC Type*	*Audit Result*	*Comments (including opportunities for improvement and observations)*
FD1. Does the company and facility have a documented food defense plan? Is there a designated person to oversee it?	CoP 2(c)	**Mj**	C / NC	
FD2. Is access to the facility limited? Is entry controlled?	FDA 2003	**Mn**	Y / N	
FD3. Are immediate supervisors aware of which employees should be on the premises and the area they are assigned to?	FDA 2003	**Mn**	Y / N	
FD4. Are all employees screened prior to hiring (e.g. reference checks OR criminal background check, etc.), including temporary employees?	FDA 2003	**Mn**	Y / N	
FD5. Has food defense training been provided to all employees?	FDA 2003	**Mn**	Y / N	
FD6. Is the security team for each facility identified and the member list current? Do they meet at least quarterly?	FDA 2003	**Mn**	Y / N	
FD7. Are employees aware of whom in management they should contact about potential security problems/issues?	FDA 2003	**Mn**	Y / N	
FD8. Does the company keep a current roster of employees, full time and temporary?	FDA 2003	**Mn**	Y / N	
FD9. Is there an employee identification system in place? Are uniforms, name tags or identification badges collected from employees prior to the termination of employment?	FDA 2003	**Mn**	Y / N	
FD10. Is there a system of traceability of computer transactions, and is computer access restrict	FDA 2003	**Mn**	Y / N	
FD11. Does the facility have a documented policy to prevent storage or holding of finished product in unsecured areas?	FDA 2003	**Mn**	Y / N	
FD12. Are routine security checks of the premises performed to identify signs of tampering, criminal or terrorist act?	FDA 2003	**Mn**	Y / N	
FD13. Is the security of points of entry monitored?	FDA 2003	**Mn**	Y / N	
FD14. Are keys to the facility monitored or tracked?	FDA 2003	**Mn**	Y / N	
FD15. Does the facility have an emergency lighting system?	FDA 2003	**Mn**	Y / N	
FD16. Is the delivery and off-loading of incoming materials supervised?	FDA 2003	**Mn**	Y / N	

Checklist Item	***Ref.***	***NC Type***	***Audit Result***	***Comments*** ***(including opportunities for improvement and observations)***
FD17.Does the facility have a program in place to inspect product returned to the facility for tampering?	FDA 2003	**Mn**	Y / N	
FD18.Are floor plans, product flow charts and/or segregation charts are in a secure location?	FDA 2003	**Mn**	Y / N	
FD19.Is there a documented contractor and visitor policy?	FDA 2003	**Mn**	Y / N	
FD20.Are visitors required to show ID? Is the purpose of the visitation verified before entry into the factory? Is there evidence the policy is being followed?	FDA 2003	**Mn**	Y / N	
FD21.Are visitors prohibited from sensitive areas in the plant (production, treatment etc.), unless accompanied by an authorized employee?	FDA 2003	**Mn**	Y / N	
FD22.Is there a policy in place stating where personal items are allowed and not allowed in the facility?	FDA 2003	**Mn**	Y / N	

Additional comments (include item no. and details):

Section 5 IBWA Membership Requirements

Checklist Item	***Ref. (IBWA)***	***NC Type ****	***Audit Result***	***Comments*** *(including opportunities for improvement and observations)*
IBWA Membership Requirements				
M1. Plant is operated under the supervision of a competent person qualified by experience, education, and training to operate and maintain the plant's facilities. Said person holds a certificate from IBWA or an applicable state agency.	Model Code Rule 3(p)	**MMj**	C / NC	
M2. IBWA member proprietary brands 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.	Model Code Rule 6(d)	**MMj**	C / NC	
M3. Written document containing analytical test results and any other pertinent water quality information for bottler's proprietary brands available for inspection during audit. Document is made available by company to consumers upon request.				
M4. Annual audit completed each year.	IBWA Bylaws	**MMj**	C / NC	
M5. Written policies and procedures designed to protect the integrity and security of their operations and products (bottled water facility security plan). Facility registered with the U.S. Food and Drug Administration.	Model Code Rule 2(d)	**MMj**	C / NC	

Additional comments (include item no. and details):

***MMj** = Membership Major: Membership requirement results are used only by IBWA staff to determine member facility compliance with specific requirements in IBWA's Bottled Water Code of Practice and IBWA's Bylaws. The results do not impact the audit score.

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Appendix B Corrective and Preventive Action Reports

IBWA Tier 1 Bottled Water Plant Audit Program

IBWA Tier 1 Major Nonconformance Corrective and Preventive Action Report (CAR-1)

Company:_____	Audit Date: ____/____/____
Plant Location (City/State/Country):	Inspector:_____
_____	Company Representative:_____

Auditor Finding (*Complete this section OR attach copy of electronic auditor finding report*)

Audit Form Item No.:_____

The finding has been classified as a ___ Major Nonconformance (Mj)

Description of Finding:

Auditor Name (Print):_____ Auditor Signature:_____ Date: ___/___/___

Root Cause Analysis By Company (include potential causes and assurance that problem does not occur elsewhere) (not required for OFI or Ob items)

Company Rep. Name:_____ Signature:_____ Date: ___/___/___

CORRECTIVE AND PREVENTIVE ACTION BY COMPANY (complete and submit to IBWA within 10 business days of audit date)

Based on the Root Cause Analysis above, the following action(s) has/have been planned/taken to correct the problem and to prevent its reoccurrence.

Company Rep. Name:_____ Signature:_____ Date: ___/___/___

Auditor Review of Company's Action(s)

Comments: _____

STATUS:_____ Auditor SIGNATURE:_____ DATE:___/___/___

IBWA Tier 1 Bottled Water Plant Audit Program

IBWA Tier 1 Minor Nonconformance Corrective and Preventive Action Report (CAR-2)

Company:_____ Plant Location (City/State/Country): _____	Audit Date: ____/____/____ Inspector:_____ Company Representative:_____

Auditor Finding (*Complete this section OR attach copy of electronic auditor finding report*)

Audit Form Item No.:_____

The finding has been classified as

Minor Nonconformance (Mn)

Description of Finding:

Auditor Name (Print):_____ Auditor Signature:_____ Date: ___/___/____

Bottler Description of Corrective and Preventive Action (complete and submit to IBWA within 10 business days of audit date)

Company Rep. Name:_____ Signature:_____Date: ___/___/____

Auditor Finding

Audit Form Item No.:_____

The finding has been classified as:

Minor Nonconformance (HMn)

Description of Finding:

Auditor Name (Print):_____ Auditor Signature:_____ Date: ___/___/____

Bottler Description of Corrective and Preventive Action (complete and submit to IBWA within 10 business days of audit date)

Company Rep. Name:_____ Signature:_____Date: ___/___/____

IBWA Tier 1 Bottled Water Plant Audit Program

Audit Assessment Summary

The IBWA Bottled Water Plant Audit Program has been revised, effective in 2019. The former program, based on Food and Drug Administration regulations, the IBWA Model Bottled Water Regulation ("Code of Practice"), and the principles of HACCP.

IBWA's new FSMA-based plant audit system incorporates the preventive controls principles as addressed in the company's food safety plan. A FSMA-based inspection focuses on areas that have the potential of directly or indirectly affecting the *safety* of food products. When developing this audit program, IBWA, in cooperation with its audit contractor, ruled that all FSMA-related items in the audit affect the effectiveness of the company's food safety program. Certain regulatory GMP requirements would also have an impact on food safety, and are enforceable through FDA regulations. Therefore, generally only these items are considered as major conformance issues. If not in compliance, a plant is cited for a major nonconformance (Mj or Mj). An example of a Mj is not addressing potential hazards in the food safety plan. Another example of a Mj is not performing the annual chemical and physical testing required by FDA in 21 CFR §129.80. Some items that were considered "critical" deficiencies in previous audit programs are now classified as minor nonconformances.

GMPs remain an integral part of the system, but the overall evaluation of the audit no longer includes calculation of a score. Rather, each item on the new audit check sheet is predetermined to be a **major nonconformance (HMj or GMj)** or a **minor nonconformance (HMn or GMn)**. The number of major and minor nonconformances are now used to determine the plant's qualification for the IBWA Excellence in Manufacturing award and Certificate of Compliance. HACCP-related nonconformances are weighted over GMP nonconformances. Therefore, the following system is used to determine a plant's qualification for the awards:

Excellence in Manufacturing:	*0 Mj AND <7 Mn*
Certificate of Compliance:	*0 Mj AND 8-17 Mn*

By not allowing any Mj nonconformances, the audit is weighted toward verification of the company's conformance with its own food safety plan and compliance with FDA food safety regulations. Audit findings that exceed the numbers of nonconformances listed above will disqualify the bottler from eligibility for the Excellence in Manufacturing award or the Certificate of Compliance.

Requirements for IBWA membership are reviewed in Section 5 of the audit. Nonconformance with the requirements for membership may result in ineligibility for Excellence in Manufacturing award and Certificate of Compliance.

Appendix C Audit Appeal Procedure

Policy and Procedure

IBWA Bottled Water Plant Audit Program
Appeal of Audit Findings

Objective

The IBWA Bottled Water Plant Audit Program was established to provide consultative services to IBWA member bottled water plants. It is also a requirement of IBWA membership that each domestic member plant be audited by IBWA's third party audit contractor, and that direct international bottler members be audited annually by an IBWA-approved audit agency. On occasion, a member plant may wish to appeal one or more of the auditor's findings. Through this policy and procedure, IBWA is establishing a structured and standardized means for appealing those audit findings.

Policy

It is the policy of the International Bottled Water Association that all U.S domestic and direct international bottler members participate in the annual Bottled Water Plant Audit Program. IBWA understands that there are occasions when a bottler disagrees with an auditor's finding(s). IBWA contracts with an independent, third party audit agency to provide audits services of IBWA's member plants. It is therefore NOT the policy of IBWA to "reverse" audit findings and modify audit reports. IBWA will serve as an arbiter in some cases to assist in resolving conflicts between the member and the audit agency. In most cases, it is preferred that the member consult directly with the audit agency to resolve conflicts.

Some conflicts lead to appeals of audit findings. To provide members a means for appealing those findings, IBWA is establishing a formal process, described in the following sections.

Procedure for U.S. Domestic Bottlers

When a U.S. domestic bottler member disagrees with an audit finding, the first course of action should be to complete and submit an audit appeal form directly to the auditor, or another designated representative at the audit company. The auditor will in turn consult with company colleagues, if necessary, auditor who conducted the audit and filed the disputed finding(s).

In the event that the conflict cannot be resolved, the bottler may appeal the finding(s) to IBWA. This can be accomplished by sending a copy of the audit appeal form (copy attached to this policy and procedure document) providing details about the disputed audit item, and submitting it to designated IBWA technical staff. Upon receipt, IBWA's technical staff will review the appeal. Staff will first review the IBWA *Audit Handbook* to determine if there is an applicable ruling on the situation surrounding the appealed audit item. This will include review of any gray areas ruled upon by the IBWA Audit Program Evaluation Team (APET). If the appealed item has already been addressed by the *Audit Handbook* or APET, the bottler will be notified in writing of that ruling. If the appealed item has NOT been addressed previously by

the Audit Handbook or APET, the bottler will be notified that the appeal is being forwarded to the third-party agency and APET for review, consideration and possible ruling. These types of appeals are commonly referred to as “gray area” items. IBWA technical staff will distribute the appeal to all members of APET, with all identification of the member bottler removed, with a request that they return their opinions on the matter. In many cases, IBWA technical staff and APET members will schedule a conference call to discuss groups of appeals. Such conference calls may also involve a representative of the third party, independent audit agency. Upon receiving a ruling from APET, IBWA technical staff will notify the bottler. If corrective action is required to correct any major nonconformances, staff will request such from the bottler.

When an appeal results in a change in an audit report, audit contractor staff will issue a revised audit report. The corrected report will be sent directly to the bottler by auditor.

It is the intent of this policy to address all appeals expeditiously. Therefore, once filed with auditor contractor, said audit contractor will have 10 business days to review the appeal and respond to the bottler with a finding. When the appeal is filed with IBWA’s technical staff, they will distribute the appeal anonymously to APET. APET will have 10 business days from the date of receipt of the appeal by IBWA’s staff to review the appeal and respond to IBWA technical staff with a ruling on the issue. APET’s rulings will require a minimum of 4 votes for approval. IBWA staff will respond to the bottler with the final APET ruling no later than 30 days after the date the bottler’s appeal was filed.

Direct International Bottler Members

“Direct International Bottler Members” are member companies based outside the United States that export to and sell bottled water products in the U.S. and are subject to U.S. regulations and standards for those products.

The same policy and procedure applies to direct international member plants. However, when reviewed by APET, they will take into consideration any local regulations that may have led to the nonconformance being cited by the auditor. When completing an appeal form, direct international bottler members are requested to submit evidence of such local regulations with the appeal form.

Document prepared by:	Bob Hirst, IBWA
Document reviewed by:	Bob Hirst, IBWA IBWA Audit Program Evaluation Team
Original Policy Date:	January 26, 2004
Revised:	February 7, 2020

IBWA TIER 1 BOTTLED WATER PLANT AUDIT PROGRAM

Appeal of Audit Findings

Name:_____ Company:_____

Plant Location: City:_____ State:_____

Audit Date:__/__/__ Auditor Name:_____

Audit Agency/Company:_____

Audit Form Item No. Appealed:_____

Auditor's Comments:_____

_____

_____

Reason for Appeal:_____

_____

_____

Audit Form Item No. Appealed:_____

Auditor's Comments:_____

_____

_____

Reason for Appeal:_____

Audit Form Item No. Appealed:_____

Auditor's Comments:_____

_____

_____

Reason for Appeal:_____

_____

_____

APPENDIX D U.S. FOOD AND DRUG ADMINISTRATION REGULATIONS FOR BOTTLED WATER

Title 21 - Food and Drugs
Chapter I - Food and Drug Administration, Department of Health and Human Services
Subchapter B - Food for Human Consumption

PART 117 - CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Source: 80 FR 56145, Sept. 17, 2015, unless otherwise noted.

Editorial Note: Nomenclature changes to part 117 appear at 81 FR 49896, July 29, 2016.

Subpart A - General Provisions

§ 117.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, F, or G of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2016]

§ 117.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Acid foods or *acidified foods* means foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Correction means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.,* foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 117.5(a).

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged food means packaged food that is not exposed to the environment.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.,* held for a fee).

Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Written procedures for receiving raw materials and other ingredients means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2016]

§ 117.4 Qualifications of individuals who manufacture, process, pack, or hold food.

(a) ***Applicability.***

(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.

(b) ***Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.*** Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 117.3 - *i.e.,* have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) ***Additional qualifications of supervisory personnel.*** Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

(d) ***Records.*** Records that document training required by paragraph (b)(2) of this section must be established and maintained.

§ 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subparts C and G of this part do not apply to a qualified facility. Qualified facilities are subject to the modified requirements in § 117.201.

(b) Subparts C and G of this part do not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if you are required to comply with, and are in compliance with, part 123 of this chapter with respect to such activities.

(c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities.

(d)

(1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subparts C and G of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g)

(1) The exemption in paragraph (g)(3) of this section applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the "farm" definition in § 1.227 of this chapter. Activities that are within the "farm" definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) For the purposes of paragraphs (g)(3) and (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (*i.e.,* coffee beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.

(i) ***Dried/dehydrated fruit and vegetable products*** includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(ii) ***Other fruit and vegetable products*** includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (g)(2)(i) of this section. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(iii) ***Peanut and tree nut products*** includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

(iv) ***Processed seeds for direct consumption*** include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(v) ***Dried/dehydrated herb and spice products*** includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(vi) ***Other herb and spice products*** includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (*e.g.,* essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph (g)(2)(v) of this section. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.

(vii) ***Grains*** include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(viii) ***Milled grain products*** include processed food products such as flour, bran, and corn meal.

(ix) ***Baked goods*** include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(x) ***Other grain products*** include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (g)(2)(viii) of this section or baked goods as described in paragraph (g)(2)(ix) of this section.

(3) Subparts C and G of this part do not apply to on-farm packing or holding of food by a small or very small business, and § 117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations - *i.e.,* packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(i) Baked goods (*e.g.,* bread and cookies);

(ii) Candy (*e.g.,* hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);

(iii) Cocoa beans (roasted);

(iv) Cocoa products;

(v) Coffee beans (roasted);

(vi) Game meat jerky;

(vii) Gums, latexes, and resins that are processed foods;

(viii) Honey (pasteurized);

(ix) Jams, jellies, and preserves;

(x) Milled grain products (*e.g.,* flour, bran, and corn meal);

(xi) Molasses and treacle;

(xii) Oils (*e.g.,* olive oil and sunflower seed oil);

(xiii) Other fruit and vegetable products (*e.g.,* flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);

(xiv) Other grain products (*e.g.,* dried pasta, oat flakes, and popcorn);

(xv) Other herb and spice products (*e.g.,* chopped or ground dried herbs, herbal extracts);

(xvi) Peanut and tree nut products (*e.g.,* roasted peanuts and tree nut flours);

(xvii) Processed seeds for direct consumption (*e.g.,* roasted pumpkin seeds);

(xviii) Soft drinks and carbonated water;

(xix) Sugar;

(xx) Syrups (*e.g.,* maple syrup and agave syrup);

(xxi) Trail mix and granola;

(xxii) Vinegar; and

(xxiii) Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (*e.g.,* bone meal) in powdered, granular, or other solid form).

(h)

(1) The exemption in paragraph (h)(3) of this section applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the "farm" definition in § 1.227 of this chapter. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the "farm" definition in § 1.227 of this chapter. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the "farm" definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the "farm" definition. Activities that are within the "farm" definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) The terms in paragraph (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (h)(3) of this section.

(3) Subparts C and G of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk manufacturing/processing activity/food combinations:

(i) Boiling gums, latexes, and resins;

(ii) Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (*e.g.,* cutting lemons and limes), baked goods (*e.g.,* slicing bread), dried/dehydrated fruit and vegetable products (*e.g.,* pitting dried plums), dried herbs and other

spices (*e.g.,* chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (*e.g.,* shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (*e.g.,* chopping roasted peanuts);

(iii) Coating dried/dehydrated fruit and vegetable products (*e.g.,* coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (*e.g.,* coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (*e.g.,* adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (*e.g.,* adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (*e.g.,* adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));

(iv) Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (*e.g.,* drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (*e.g.,* drying chopped fresh herbs, including tea);

(v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (*e.g.,* dried mint), fresh herbs (*e.g.,* fresh mint), fruits and vegetables (*e.g.,* olives, avocados), grains (*e.g.,* oilseeds), and other herb and spice products (*e.g.,* chopped fresh mint, chopped dried mint);

(vi) Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (*e.g.,* cut fruits and vegetables);

(vii) Grinding/cracking/crushing/milling baked goods (*e.g.,* crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.,* raisins and dried legumes), dried/dehydrated herb and spice products (*e.g.,* intact dried basil), grains (*e.g.,* oats, rice, rye, wheat), other fruit and vegetable products (*e.g.,* dried, pitted dates), other grain products (*e.g.,* dried cereal), other herb and spice products (*e.g.,* chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (*e.g.,* roasted peanuts);

(viii) Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens), coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (*e.g.,* corn meal) or that are single-ingredient foods (*e.g.,* wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (*e.g.,* snack chips made from potatoes or plantains), other grain products that do not contain food allergens (*e.g.,* popcorn), other herb and spice products (*e.g.,* chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (*e.g.,* roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food

that does not require time/temperature control for safety and that does not contain food allergens (*e.g.,* vitamins, minerals, and dietary ingredients (*e.g.,* bone meal) in powdered, granular, or other solid form);

(ix) Making baked goods from milled grain products (*e.g.,* breads and cookies);

(x) Making candy from peanuts and tree nuts (*e.g.,* nut brittles), sugar/syrups (*e.g.,* taffy, toffee), and saps (*e.g.,* maple candy, maple cream);

(xi) Making cocoa products from roasted cocoa beans;

(xii) Making dried pasta from grains;

(xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;

(xiv) Making molasses and treacle from sugar beets and sugarcane;

(xv) Making oat flakes from grains;

(xvi) Making popcorn from grains;

(xvii) Making snack chips from fruits and vegetables (*e.g.,* making plantain and potato chips);

(xviii) Making soft drinks and carbonated water from sugar, syrups, and water;

(xix) Making sugars and syrups from fruits and vegetables (*e.g.,* dates), grains (*e.g.,* rice, sorghum), other grain products (*e.g.,* malted grains such as barley), saps (*e.g.,* agave, birch, maple, palm), sugar beets, and sugarcane;

(xx) Making trail mix and granola from cocoa products (*e.g.,* chocolate), dried/dehydrated fruit and vegetable products (*e.g.,* raisins), other fruit and vegetable products (*e.g.,* chopped dried fruits), other grain products (*e.g.,* oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;

(xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (*e.g.,* fruit wines, apple cider), and other grain products (*e.g.,* malt);

(xxii) Mixing baked goods (*e.g.,* types of cookies), candy (*e.g.,* varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (*e.g.,* dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (*e.g.,* dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (*e.g.,* flour, bran, and corn meal), other fruit and vegetable products (*e.g.,* dried, sliced apples and dried, sliced peaches), other grain products (*e.g.,* different types of dried pasta), other herb and spice products (*e.g.,* chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (*e.g.,* vitamins, minerals, and dietary ingredients (*e.g.,* bone meal) in powdered, granular, or other solid form);

(xxiii) Packaging baked goods (*e.g.,* bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (*e.g.,* flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (*e.g.,* pitted, dried fruits; sliced, dried apples; snack chips), other grain products (*e.g.,* popcorn), other herb and spice

products (*e.g.,* chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (*e.g.,* vitamins, minerals, and dietary ingredients (*e.g.,* bone meal) in powdered, granular, or other solid form);

(xxiv) Pasteurizing honey;

(xxv) Roasting and toasting baked goods (*e.g.,* toasting bread for croutons);

(xxvi) Salting other grain products (*e.g.,* soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and

(xxvii) Sifting milled grain products (*e.g.,* flour, bran, corn meal), other fruit and vegetable products (*e.g.,* chickpea flour), and peanut and tree nut products (*e.g.,* peanut flour, almond flour).

(i)

(1) Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subparts C and G of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k)

(1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:

(i) "Farms" (as defined in § 1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this chapter in accordance with § 1.226(f) of this chapter;

(iii) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(iv) Activities of "farm mixed-type facilities" (as defined in § 1.227 of this chapter) that fall within the definition of "farm"; or

(v) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).

(2) If a "farm" or "farm mixed-type facility" dries/dehydrates raw agricultural commodities that are produce as defined in part 112 of this chapter to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016]

§ 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food.

(a) ***Applicability of subparts C and G.*** Subparts C and G of this part do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) ***Applicability of subpart D.*** A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities.

Except as provided by § 117.5(k)(1), subpart B of this part applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in part 112 of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

[81 FR 3956, Jan. 25, 2016]

§ 117.9 Records required for this subpart.

(a) Records that document training required by § 117.4(b)(2) must be established and maintained.

(b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

Subpart B - Current Good Manufacturing Practice

§ 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) ***Disease control.*** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations

which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) ***Cleanliness.*** All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§ 117.20 Plant and grounds.

(a) ***Grounds.*** The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) ***Plant construction and design.*** The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (*i.e.,* manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 117.35 Sanitary operations.

(a) ***General maintenance.*** Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) ***Substances used in cleaning and sanitizing; storage of toxic materials.***

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) ***Pest control.*** Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) ***Sanitation of food-contact surfaces.*** All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) ***Sanitation of non-food-contact surfaces.*** Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) ***Storage and handling of cleaned portable equipment and utensils.*** Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§ 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) ***Water supply.*** The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) ***Plumbing.*** Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) ***Sewage disposal.*** Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) ***Toilet facilities.*** Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) ***Hand-washing facilities.*** Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) ***Rubbish and offal disposal.*** Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§ 117.40 Equipment and utensils.

(a)

(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 117.80 Processes and controls.

(a) ***General.***

(1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) ***Raw materials and other ingredients.***

(1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) ***Manufacturing operations.***

(1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§ 117.95 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

(c) Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

[80 FR 56337, Sept. 17, 2015]

§ 117.110 Defect action levels.

(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at*http://www.fda.gov/pchfrule* and at*http://www.fda.gov*.

Subpart C - Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Food safety plan.

(a) ***Requirement for a food safety plan.***

(1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.

(b) ***Contents of a food safety plan.*** The written food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written supply-chain program as required by subpart G of this part;

(4) The written recall plan as required by § 117.139(a); and

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a);

(6) The written corrective action procedures as required by § 117.150(a)(1); and

(7) The written verification procedures as required by § 117.165(b).

(c) ***Records.*** The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

[80 FR 56145, Sept. 17, 2015, as amended at 84 FR 12491, Apr. 2, 2019]

§ 117.130 Hazard analysis.

(a) ***Requirement for a hazard analysis.***

(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

(2) The hazard analysis must be written regardless of its outcome.

(b) ***Hazard identification.*** The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) ***Hazard evaluation.***

(1)

(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (*e.g.,* weather-related) nature of some hazards (*e.g.,* levels of some natural toxins).

§ 117.135 Preventive controls.

(a)

(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) ***Process controls.*** Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) ***Food allergen controls.*** Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) ***Sanitation controls.*** Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) ***Supply-chain controls.*** Supply-chain controls include the supply-chain program as required by subpart G of this part.

(5) ***Recall plan.*** Recall plan as required by § 117.139.

(6) ***Other controls.*** Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) ***Circumstances.*** If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of food (*e.g.,* raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(B) Will only sell to another entity that agrees, in writing, it will:

(*1*) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart); or

(*2*) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.

(b) ***Records.*** You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including:

(1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016]

§ 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).

A facility that provides a written assurance under § 117.136(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 117.139 Recall plan.

For food with a hazard requiring a preventive control:

(a) You must establish a written recall plan for the food.

(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food - *e.g.,* through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 117.140 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 117.145;

(2) Corrective actions and corrections in accordance with § 117.150; and

(3) Verification in accordance with § 117.155.

(b) The supply-chain program established in subpart G of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 117.165(a)(4); and

(3) Reanalysis in accordance with § 117.170.

(c) The recall plan established in § 117.139 is not subject to the requirements of paragraph (a) of this section.

§ 117.145 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system:

(a) ***Written procedures.*** You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and

(b) ***Monitoring.*** You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c) ***Records.***

(1) ***Requirement to document monitoring.*** You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

(2) ***Exception records.***

(i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016]

§ 117.150 Corrective actions and corrections.

(a) ***Corrective action procedures.*** As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) ***Corrective action in the event of an unanticipated food safety problem.***

(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) ***Corrections.*** You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) ***Records.*** All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).

§ 117.155 Verification.

(a) ***Verification activities.*** Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) ***Documentation.*** All verification activities conducted in accordance with this section must be documented in records.

§ 117.160 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)

(A) Prior to implementation of the food safety plan; or

(B) When necessary to demonstrate the control measures can be implemented as designed:

(*1*) Within 90 calendar days after production of the applicable food first begins; or

(*2*) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards; and

(c) You do not need to validate:

(1) The food allergen controls in § 117.135(c)(2);

(2) The sanitation controls in § 117.135(c)(3);

(3) The recall plan in § 117.139;

(4) The supply-chain program in subpart G of this part; and

(5) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

§ 117.165 Verification of implementation and effectiveness.

(a) ***Verification activities.*** You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and

(ii) Records of calibration, testing (*e.g.,* product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) ***Written procedures.*** As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

§ 117.170 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the food;

(3) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required (§ 117.160(c)(5));

(5) Review of records (§ 117.165(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan (§ 117.170(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(b) A qualified auditor must conduct an onsite audit (§ 117.435(a)).

(c)

(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.190 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 117.136(b), of the basis for not establishing a preventive control in accordance with § 117.136(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D - Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

(a) ***Attestations to be submitted.*** A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)

(i) An attestation that you have identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) ***Procedure for submission.*** The attestations required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) ***Electronic submission.*** To submit electronically, go to *http://www.fda.gov/furls* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) ***Submission by mail.***

(i) You must use Form FDA 3942a. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from *http://www.fda.gov/pchfrule*;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c) ***Frequency of determination of status and submission.***

(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from "not a qualified facility" to "qualified facility" based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from "qualified facility" to "not a qualified facility" based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.

(d) ***Timeframe for compliance with subparts C and G of this part when the facility status changes to "not a qualified facility."*** When the status of a facility changes from "qualified facility" to "not a qualified facility," the facility must comply with subparts C and G of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) ***Notification to consumers.*** A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f) ***Records.***

(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016]

§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.

(a) If a facility that is solely engaged in the storage of unexposed packaged food stores any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if you cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E - Withdrawal of a Qualified Facility Exemption

§ 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 117.254 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA Division Director in whose division the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

[80 FR 56145, Sept. 17, 2015, as amended at 85 FR 16553, Mar. 24, 2020]

§ 117.257 Contents of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption under § 117.5(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and G of this part on the date that is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287;

(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;

(h) The mailing address, telephone number, email address, fax number, and name of the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016; 85 FR 16553, Mar. 24, 2020]

§ 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

(a) If you receive an order under § 117.254 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the modified requirements in § 117.201.

§ 117.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or fax number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), you may include a written request for an informal hearing as provided in § 117.267.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016; 85 FR 16553, Mar. 24, 2020]

§ 117.267 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 117.264 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

§ 117.270 Requirements applicable to an informal hearing.

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1-calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material

issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2-calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) of this chapter does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3) and (a)(5) of this chapter and 117.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

[80 FR 56145, Sept. 17, 2015, as amended at 85 FR 16553, Mar. 24, 2020]

§ 117.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16553, Mar. 24, 2020]

§ 117.277 Timeframe for issuing a decision on an appeal.

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2-calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within 10-calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 117.280 Revocation of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10-calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 117.284 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 117.287 Reinstatement of a qualified facility exemption that was withdrawn.

(a) If the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his or her own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA Division Director in whose division your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 117.251(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 117.5(a), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 117.251(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a) in accordance with the requirements of paragraph (b) of this section.

[80 FR 56145, Sept. 17, 2015, as amended at 85 FR 16553, Mar. 24, 2020]

Subpart F - Requirements Applying to Records That Must Be Established and Maintained

§ 117.301 Records subject to the requirements of this subpart.

(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart.

(b) The requirements of § 117.310 apply only to the written food safety plan.

(c) The requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201.

§ 117.305 General requirements applying to records.

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the plant or facility (*e.g.,* the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 117.310 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

(a) Upon initial completion; and

(b) Upon any modification.

§ 117.315 Requirements for record retention.

(a)

(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.,* because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.155(b))));

(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 117.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

§ 117.325 Public disclosure.

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

§ 117.330 Use of existing records.

(a) Existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 117.335 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) The applicable assurance under:

(i) Section 117.136(a)(2);

(ii) Section 117.136(a)(3);

(iii) Section 117.136(a)(4);

(iv) Section 117.430(c)(2);

(v) Section 117.430(d)(2); or

(vi) Section 117.430(e)(2);

(b) A written assurance required under § 117.136(a)(2), (3), or (4) must include:

(1) Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and

(2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

Subpart G - Supply-Chain Program

§ 117.405 Requirement to establish and implement a supply-chain program.

(a)

(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to food that is supplied for research or evaluation use, provided that such food:

(i) Is not intended for retail sale and is not sold or distributed to the public;

(ii) Is labeled with the statement “Food for research or evaluation use”;

(iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and

(iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.,* when a non-supplier applies controls to certain produce (*i.e.,* produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

[80 FR 56145, Sept. 17, 2015; 81 FR 3956, Jan. 25, 2016]

Effective Date Note: At 80 FR 56145, Sept. 17, 2015, § 117.405 was added, effective Nov. 16, 2015, except for paragraph (a)(2). FDA will publish a document in the FEDERAL REGISTER announcing the effective date for this paragraph.

§ 117.410 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:

(1) Using approved suppliers as required by § 117.420;

(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425;

(3) Conducting supplier verification activities as required by §§ 117.430 and 117.435;

(4) Documenting supplier verification activities as required by § 117.475; and

(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)

(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 117.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

§ 117.415 Responsibilities of the receiving facility.

(a)

(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 117.410(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435.

§ 117.420 Using approved suppliers.

(a) ***Approval of suppliers.*** The receiving facility must approve suppliers in accordance with the requirements of § 117.410(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b) ***Written procedures for receiving raw materials and other ingredients.***

(1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

§ 117.425 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 117.410(d).

§ 117.430 Conducting supplier verification activities for raw materials and other ingredients.

(a) Except as provided by paragraph (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 117.410(b), as determined under § 117.410(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)

(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans:

(i) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.

§ 117.435 Onsite audit.

(a) An onsite audit of a supplier must be performed by a qualified auditor.

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (*e.g.,* Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)

(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

Effective Date Note: At 80 FR 56145, Sept. 17, 2015, § 117.435 was added, effective Nov. 16, 2015, except for paragraph (d). FDA will publish a document in the FEDERAL REGISTER announcing the effective date for this paragraph.

§ 117.475 Records documenting the supply-chain program.

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 117.165(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

Effective Date Note: At 80 FR 56145, Sept. 17, 2015, § 117.475 was added, effective Nov. 16, 2015, except for paragraph (c)(2). FDA will publish a document in the FEDERAL REGISTER announcing the effective date for this paragraph.

Title 21 - Food and Drugs
Chapter I - Food and Drug Administration, Department of Health and Human Services
Subchapter B - Food for Human Consumption

PART 129 - PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

Authority: 21 U.S.C. 342, 348, 350k, 371, 374, 42 U.S.C. 264.

Source: 42 FR 14355, Mar. 15, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 129.1 Current good manufacturing practice.

The applicable criteria in parts 110 and 117 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

[80 FR 56167, Sept. 17, 2015]

§ 129.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) ***Approved source*** when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.

(b) ***Bottled drinking water*** means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) ***Lot*** means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(d) ***Multiservice containers*** means containers intended for use more than one time.

(e) ***Nontoxic materials*** means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

(f) ***Operations water*** means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) ***Primary container*** means the immediate container in which the product water is packaged.

(h) ***Product water*** means processed water used by a plant for bottled drinking water.

(i) ***Shall and should.*** "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) ***Shipping case*** means a container in which one or more primary containers of the product are held.

(k) ***Single-service container*** means a container intended for one time usage only.

(l) ***Unit package*** means a standard commercial package of bottled drinking water, which may consist of one or more containers.

[42 FR 14355, Mar. 6, 1977, as amended at 44 FR 12175, Mar. 6, 1979]

Subpart B - Buildings and Facilities

§ 129.20 Plant construction and design.

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

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

§ 129.35 Sanitary facilities.

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) ***Product water and operations water*** -

(1) ***Product water.*** The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) ***Operations water.*** If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) ***Product water and operations water from approved sources.***

(i) Samples of source water from each source in use by the plant are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for total coliform at least once each week. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. This sampling is in addition to any performed by government agencies having jurisdiction. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for use in bottled water by paragraph (a)(1) of this section. Before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Records of approval of the source water by government agencies having jurisdiction, records of sampling and analyses for which the plant is responsible, and records describing corrective measures taken in response to a finding of *E. coli* are to be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (*e.g.,* Environmental Protection Agency (EPA) and State-certified laboratories), except that the analysis of the five samples from the same sampling site that originally tested positive for *E. coli,* as required by paragraph (a)(3) of this section, must be conducted under part 1, subpart R of this chapter.

(4) ***Source water testing exemptions.***

(i) Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants (40 CFR parts 141 and 143), for the testing requirements of § 129.35(a)(3).

(ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).

(iii) Firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H) of this chapter. Firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment.

(iv) The finished bottled water must comply with bottled water quality standards (§ 165.110(b) of this chapter) and section 402(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act dealing with adulterated foods.

(b) ***Air under pressure.*** Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

(c) ***Locker and lunchrooms.*** When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

[42 FR 14355, Mar. 15, 1977, as amended at 44 FR 12175, Mar. 6, 1979; 60 FR 57123, Nov. 13, 1995; 66 FR 16865, Mar. 28, 2001; 74 FR 25664, May 29, 2009; 86 FR 68831, Dec. 3, 2021]

§ 129.37 Sanitary operations.

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

Subpart C - Equipment

§ 129.40 Equipment and procedures.

(a) ***Suitability.***

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

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) ***Design.*** Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

Subpart D [Reserved]

Subpart E - Production and Process Controls

§ 129.80 Processes and controls.

(a) ***Treatment of product water.*** All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) ***Containers.***

(1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) ***Cleaning and sanitizing solutions.*** Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) ***Sanitizing operations.*** Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57 °F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57 °F or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) When containers are sanitized using a substance other than one provided for in § 178.1010 of this chapter, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.

(e) ***Unit package production code.*** Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

(f) ***Filling, capping, or sealing.*** During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

(g) ***Compliance procedures.*** A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli.*

(2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

(h) ***Record retention.*** All records required by §§ 129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

[42 FR 14355, Mar. 15, 1977, as amended at 44 FR 12175, Mar. 6, 1979; 60 FR 57124, Nov. 13, 1995; 74 FR 25665, May 29, 2009]

Title 21 - Food and Drugs
Chapter I - Food and Drug Administration, Department of Health and Human Services
Subchapter B - Food for Human Consumption

PART 165 - BEVERAGES

Authority: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

Source: 60 FR 57124, Nov. 13, 1995, unless otherwise noted.

Subpart A - General Provisions

§ 165.3 Definitions.

(a) A *lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B - Requirements for Specific Standardized Beverages

§ 165.110 Bottled water.

(a) *Identity* -

(1) ***Description.*** Bottled water is 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 § 165.110(b)(4)(ii). 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 part 129 of this chapter.

(2) ***Nomenclature.*** The name of the food is "bottled water," "drinking water," or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is "artesian water" or "artesian well water." 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.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is "ground water." Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be "mineral water." 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.

(iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of "purified water" in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*), may be "purified water" or "demineralized water." Alternatively, the water may be called "deionized water" if the water has been processed by deionization, "distilled water" if it is produced by distillation, "reverse osmosis water" if the water has been processed by reverse osmosis, and "_____ drinking water" with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., "purified drinking water" or "deionized drinking water").

(v) The name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source may be "sparkling bottled water."

(vi) The name of water derived from an underground formation from which water flows naturally to the surface of the earth may be "spring water." Spring water shall be collected only at the spring or through a bore hole 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. 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 bore hole.

(vii) The name of water that meets the requirements under "Sterility Tests" <71>in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51. (Copies may be obtained from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.), may be "sterile water." Alternatively, the water may be called "sterilized water."

(viii) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be "well water."

(3) ***Other label statements.***

(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."

(4) ***Label declaration.*** Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) ***Quality.*** The standard of quality for bottled water, including water for use as an ingredient in beverages (except those described in the labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water"), is as follows:

(1) ***Definitions.***

(i) ***Trihalomethane*** (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(ii) ***Total trihalomethanes (TTHM)*** means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane, and tribromomethane), rounded to two significant figures.

(iii) ***Haloacetic acids*** (five) (HAA5) means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

(2) ***Microbiological quality.***

(i) Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in paragraph (b)(2)(ii) of this section, meet the following standards of microbiological quality:

(A) ***Total coliform*** -

(*1*) ***Multiple-tube fermentation (MTF) method.*** Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(*2*) ***Membrane filter (MF) method.*** Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(B) ***E. coli.*** If *E. coli* is present, then the bottled water will be deemed adulterated under paragraph (d) of this section.

(ii) Analyses conducted to determine compliance with paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section and § 129.35(a)(3)(i) of this chapter shall be made in accordance with the multiple-tube fermentation (MTF) or the membrane filter (MF) methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 21st Ed. (2005), American Public Health Association. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA). You may inspect a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993,

301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) ***Physical quality.*** Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies may be obtained from the American Public Health Association, 800 I St. NW., Washington, DC 20001, 202-777-2742 (APHA), or a copy may be examined at the National Archives and Records Administration (NARA), or at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, for information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*), meet the following standards of physical quality:

(i) The turbidity shall not exceed 5 units.

(ii) The color shall not exceed 15 units.[1]

(iii) The odor shall not exceed threshold odor No. 3.[1]

(4) ***Chemical quality.***

(i)

(A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in milligrams per liter
Chloride[1]	250.0
Iron[1]	0.3
Manganese[1]	0.05
Phenols	0.001
Total dissolved solids[1]	500.0
Zinc[1]	5.0

[1] Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(B) Analyses conducted to determine compliance with paragraph (b)(4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 15th Ed. (1980), or

[1] Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

"Methods for Chemical Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory (EMSL), EPA-600/4-79-020, March 1983, U.S. Environmental Protection Agency (EPA), both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by the appropriate methods set forth below. The methods in paragraphs (b)(4)(i) (C)(*1*) and (C)(*2*) of this section are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and are described in "Standard Methods for Examination of Water and Wastewater," 15th Ed. (1980). Copies may be obtained from the American Public Health Association, 800 I St. NW., Washington DC 20001, and examined at the National Archives and Records Administration (NARA) , or the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The methods in paragraphs (b)(4)(i)(C)(*3*) and (C)(*4*) are cross-referenced in 40 CFR part 141, subpart C, appendix C.

(*1*) "Methods for Organochlorine Pesticides in Industrial Effluents;"

(*2*) "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973;

(*3*) "Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method;" which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(*4*) "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," which is cross-referenced in 40 CFR part 141, subpart C, appendix C;

(ii)

(A) 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

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

(C) Bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(D) Imported bottled water to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(iii) Having consulted with EPA as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F), and (b)(4)(iii)(G) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Arsenic	0.010
Antimony	.006
Barium	2
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Copper	1.0
Cyanide	0.2
Lead	0.005
Mercury	0.002
Nickel	0.1
Nitrate	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate and Nitrite	10 (as nitrogen)
Selenium	0.05
Thallium	0.002

(B) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71-43-2)	0.005
Carbon tetrachloride (56-23-5)	0.005
o- Dichlorobenzene (95-50-1)	0.6
p- Dichlorobenzene (106-46-7)	0.075
1,2-Dichloroethane (107-06-2)	0.005
1,1-Dichloroethylene (75-35-4)	0.007
cis-1,2-Dichloroethylene (156-59-2)	0.07
trans-1,2-Dichloroethylene (156-60-5)	0.1

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Dichloromethane (75-09-2)	0.005
1,2-Dichloropropane (78-87-5)	0.005
Ethylbenzene (100-41-4)	0.7
Monochlorobenzene (108-90-7)	0.1
Styrene (100-42-5)	0.1
Tetrachloroethylene (127-18-4)	0.005
Toluene (108-88-3)	1
1,2,4-Trichlorobenzene (120-82-1)	0.07
1,1,1-Trichloroethane (71-55-6)	0.20
1,1,2-Trichloroethane (79-00-5)	0.005
Trichloroethylene (79-01-6)	0.005
Vinyl chloride (75-01-4)	0.002
Xylenes (1330-20-7)	10

(C) The allowable levels for pesticides and other synthetic organic chemicals (SOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Alachlor (15972-60-8)	0.002
Atrazine (1912-24-9)	0.003
Benzo(a)pyrene (50-32-8)	0.0002
Carbofuran (1563-66-2)	0.04
Chlordane (57-74-9)	0.002
Dalapon (75-99-0)	0.2
1,2-Dibromo-3-chloropropane (96-12-8)	0.0002
2,4-D (94-75-7)	0.07
Di(2-ethylhexyl)adipate (103-23-1)	0.4
Di(2-ethylhexyl)phthalate (117-81-7)	0.006
Dinoseb (88-85-7)	0.007
Diquat (85-00-7)	0.02
Endothall (145-73-3)	0.1
Endrin (72-20-8)	0.002
Ethylene dibromide (106-93-4)	0.00005
Glyphosate (1071-53-6)	0.7
Heptachlor (76-44-8)	0.0004
Heptachlor epoxide (1024-57-3)	0.0002
Hexachlorobenzene (118-74-4)	0.001
Hexachlorocyclopentadiene (77-47-4)	0.05
Lindane (58-89-9)	0.0002

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Methoxychlor (72-43-5)	0.04
Oxamyl (23135-22-0)	0.2
Pentachlorophenol (87-86-5)	0.001
PCB's (as decachlorobiphenyl) (1336-36-3)	0.0005
Picloram (1918-02-1)	0.5
Simazine (122-34-9)	0.004
2,3,7,8-TCDD (Dioxin) (1746-01-6)	3×10^{-8}
Toxaphene (8001-35-2)	0.003
2,4,5-TP (Silvex) (93-72-1)	0.05

(D) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations (40 CFR part 143) are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1
Sulfate[1]	250.0

[1] Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

(E) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(A) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(E)(*1*) through (b)(4)(iii)(E)(*14*) of this section and described, unless otherwise noted, in "Methods for Chemical Analysis of Water and Wastes," U.S. EPA Environmental Monitoring and Support Laboratory (EMSL), Cincinnati, OH 45258 (EPA-600/4-79-020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*1*) Antimony shall be measured using the following methods:

(*i*) Method 204.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*iii*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method D-3697-92 - "Standard Test Method for Antimony in Water," contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*2*) Barium shall be measured using the following methods:

(*i*) Method 208.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 208.1 - "Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of

Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*3*) Beryllium shall be measured using the following methods:

(*i*) Method 210.2 - "Atomic Absorption; Furnace Technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*4*) Cadmium shall be measured using the following methods:

(*i*) Method 213.2 - "Atomic Absorption; Furnace Technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June

1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*5*) Chromium shall be measured using the following methods:

(*i*) Method 218.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*6*) Copper shall be measured as total recoverable metal without filtration using the following methods:

(*i*) Method 220.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 220.1 - "Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and

Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*7*) Cyanide shall be measured using the following methods:

(*i*) Method 335.1 - "Titrimetric; Spectrophotometric" which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 335.2 - "Titrimetric; Spectrophotometric" which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 335.3 - "Colorimetric, Automated UV," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iv*) Method D-2036-91 - "Standard Test Methods for Cyanides in Water," contained in the Annual Book of ASTM Standards, vols. 11.01 and 11.02, 1995, American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*8*) Lead shall be measured as total recoverable metal without filtration using the following methods:

(*i*) Method 239.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*9*) Mercury shall be measured using the following methods:

(*i*) Method 245.1 - "Manual cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 245.2 - "Automated cold vapor technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*10*) Nickel shall be measured using the following methods:

(*i*) Method 249.1 - "Atomic Absorption; direct aspiration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 249.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7 - "Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*11*) Nitrate and/or nitrite shall be measured using the following methods:

(*i*) Method 300.0 - "The Determination of Inorganic Anions in Water by Ion Chromatography - Method 300.0," EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*ii*) Method 353.1 - "Colorimetric, automated, hydrazine reduction," for nitrate only, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 353.2 - "Colorimetric, automated, cadmium reduction," for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iv*) Method 353.3 - "Spectrophotometric, cadmium reduction," for both nitrate and nitrite, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*12*) Selenium shall be measured using the following methods:

(*i*) Method 270.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 270.3 - "Atomic Absorption; gaseous hydride," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*13*) Thallium shall be measured using the following methods:

(*i*) Method 279.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*ii*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iii*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and

Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*14*) Arsenic shall be measured using the following methods:

(*i*) Method 200.8 - "Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Revision 5.4, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.8 is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples - Supplement 1," EPA/600/R-94/111, May 1994. Copies of this publication are available from the National Technical Information Service (NTIS), PB95-125472, U.S. Department of Commerce, 5825 Port Royal Rd., Springfield, VA 22161, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*ii*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption," Revision 2.2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Method 200.9 is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples - Supplement 1," EPA/600/R-94/111, May 1994. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*14*)(*i*) of this section.

(F) Analyses to determine compliance with the requirements of paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (b)(4)(iii)(F)(*1*) through (b)(4)(iii)(F)(*22*) of this section and described, unless otherwise noted, in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, EMSL, EPA/600/4-88/039, December 1988, or in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1," Office of Research and Development, EMSL, EPA/600/4-90/020, July 1990, or in "Methods for the Determination of Organic Compounds in Drinking Water, Supplement III," EPA National Exposure Research Laboratory, Office of Research and Development, EPA/600/R-95/131, August 1995, including Errata, November 27, 1995. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of these publications are available from National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. You may inspect a copy at the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860 or at the National Archives and Records Administration (NARA). Hearing-impaired or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339. For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(*1*) Method 502.1 - "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*2*) Method 502.2 - "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*3*) Method 503.1 - "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," Rev. 2.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*4*) Method 524.1 - "Measurement of Purgeable Organic Compounds in Water by Packed Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*5*) Method 524.2 - "Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 3.0, 1989, (applicable to VOC's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*6*) Method 504 - "1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*7*) Method 505 - "Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Microextraction and Gas Chromatography," Rev. 2.0, 1989, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, hexachlorocyclopentadiene, simazine, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*8*) Method 506 - "Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection," applicable to di(2-ethylhexyl) adipate which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*9*) Method 507 - "Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector," Rev. 2.0, 1989, (applicable to alachlor, atrazine, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*10*) Method 508 - "Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector," Rev. 3.0, 1989, (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, endrin, hexachlorobenzene, and as a screen for PCB's), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*11*) Method 508A - "Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography," Rev. 1.0, 1989, (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508 in paragraph (b)(4)(iii)(F)(*7*) or (b)(4)(iii)(F)(*9*) of this section, respectively, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*12*) Method 515.1 - "Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector," Rev. 5.0, 1991, (applicable to 2,4-D, 2,4,5-TP (Silvex), pentachlorophenol, dalapon, dinoseb, and picloram), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*13*) Method 525.1 - "Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 2.2, May 1991, (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, pentachlorophenol, benzo(a)pyrene, di(2-ethylhexyl) adipate, endrin, hexachlorobenzene, hexachlorocyclopentadiene, and simazine), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*14*) Method 531.1 - "Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization," Rev. 3.0, 1989, (applicable to carbofuran and oxamyl (vydate)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*15*) Method 547 - "Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection HPLC, Post-Column Derivatization, and Fluorescence Detection," (applicable to glyphosate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*16*) Method 548 - "Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron-Capture Detection," (applicable to endothall), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*17*) Method 549 - "Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid Extraction and HPLC with Ultraviolet Detection," (applicable to diquat), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*18*) Method 550 - "Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*19*) Method 550.1 - "Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection," (applicable to benzo(a)pyrene and other polynuclear aromatic hydrocarbons), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(F) of this section.

(*20*) Method 1613 - "Tetra- through Octa- Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS," Rev. A, 1990, EPA, Office of Water Regulations and Standards, Industrial Technology Division, (applicable to 2,3,7,8-TCDD (Dioxin)), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from USEPA-OST, Sample Control Center, P.O. Box 1407, Alexandria, VA 22313, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(*21*) Method 506, Rev. 1.1 - "Determination of phthalate and adipate esters in drinking water by liquid/liquid extraction or liquid/solid extraction and gas chromatography with photoionization detection," EPA/600/R-95/131, 1995, (applicable to di(2-ethylhexyl)phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*22*) Method 525.2, Rev. 2.0 - "Determination of organic compounds in drinking water by liquid-solid extraction and capillary column gas chromatography/mass spectrometry," EPA/600/R-95/131, 1995, (applicable to di(2-ethylhexyl)phthalate), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(G) Analyses to determine compliance with the requirements of paragraph (b)(4)(iii)(D) of this section shall be conducted in accordance with an applicable method and applicable revisions to the methods listed in paragraphs (b)(4)(iii)(G)(*1*) through (b)(4)(iii)(G)(*3*) of this section and described, unless otherwise noted, in "Methods of Chemical Analysis of Water and Wastes," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*1*) Aluminum shall be measured using the following methods:

(*i*) Method 202.1 - "Atomic Absorption; direct aspiration technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 202.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E).

(*iii*) Method 200.7 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*2*) Silver shall be measured using the following methods:

(*i*) Method 272.1 - "Atomic Absorption; direct aspiration technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*ii*) Method 272.2 - "Atomic Absorption; furnace technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(*iii*) Method 200.7 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry," Rev. 3.3, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*iv*) Method 200.8 - "Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," Rev. 4.4, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*v*) Method 200.9 - "Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," Rev. 1.2, April 1991, U.S. EPA, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4-91/010), June 1991, which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E)(*1*)(*ii*) of this section.

(*3*) Sulfate shall be measured using the following methods:

(*i*) Method 300.0 - "The Determination of Inorganic Anions in Water by Ion Chromatography - Method 300.0," EPA, EMSL (EPA-600/4-84-017), March 1984, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(E)(*11*)(*i*) of this section.

(*ii*) Method 375.1 - "Colorimetric, Automated, Chloranilate," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iii*) Method 375.3 - "Gravimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or

(*iv*) Method 375.4 - "Turbidimetric," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporation by reference is given in paragraph (b)(4)(iii)(E) of this section.

(H) The allowable levels for residual disinfectants and disinfection byproducts are as follows:

Substance	Concentration in milligrams per liter
Disinfection byproducts	
Bromate	0.010
Chlorite	1.0
Haloacetic acids (five) (HAA5)	0.060
Total Trihalomethanes (TTHM)	0.080
Residual disinfectants	
Chloramine	4.0 (as Cl_2)
Chlorine	4.0 (as Cl_2)
Chlorine dioxide	0.8 (as ClO_2)

(I) Analysis to determine compliance with the requirements of paragraph (b)(4)(iii)(H) of this section shall be conducted in accordance with an applicable method listed in paragraphs (b)(4)(iii)(I)(*1*) through (b)(4)(iii)(I)(*7*) of this section and described in "Method 300.1, Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118; "Methods for the Determination of Inorganic Substances in Environmental Samples," U.S. EPA, August 1993, EPA/600/R-93/100; "Methods for the Determination of Organic Compounds in Drinking Water-Supplement II," U.S. EPA, August 1992, EPA/600/R-92/129; "Methods for the Determination of Organic Compounds in Drinking Water-Supplement III," U.S. EPA, August 1995, EPA/600/R-95/131; "Standard Methods for the Examination of Water and Wastewater," 19th Ed., American Public Health Association, 1995; and "Annual Book of ASTM Standards," vol. 11.01, American Society for Testing and Materials, 1996, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the following publications are available from the National Technical Information Service (NTIS): EPA/600/R-95/131 (NTIS number

PB95-261616), EPA/600/R-92/129 (NTIS number PB92-207703), EPA/600/R-93/100 (NTIS number PB94-121811), and EPA/600/R-98/118 (NTIS number PB98-169196). NTIS can be contacted at NTIS, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, 1-800-553-6847 or 703-605-6000, *www.ntis.gov*. Copies of the publication EPA/600/R-98/118 are also available from the Chemical Exposure Research Branch, Microbiological and Chemical Exposure Assessment Research Division, National Exposure Research Laboratory, U.S. EPA, Cincinnati, OH 45268, 513-569-7757, (FAX) 513-569-7757. Copies of "Standard Methods for the Examination of Water and Wastewater," 19th Ed., are available from the American Public Health Association, 1015 15th Street, NW., Washington, DC 20005. All of the publications cited in paragraph (b)(4)(iii)(I) of this section may be examined at the National Archives and Records Administration (NARA), or at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies of "Annual Book of ASTM Standards," 1996, vol. 11.01, are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohoken, PA 19428, or may be examined at the Office of the Federal Register. Copies of the methods incorporated by reference in paragraph (b)(4)(iii)(I) of this section may also be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039.

(*1*) Bromate shall be measured using the following method: Method 300.1 - "Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*2*) Chlorite shall be measured using the following methods:

(*i*) Method 300.0 - "Determination of Inorganic Anions by Ion Chromatography," Rev. 2.1. The revision is contained in the manual entitled "Methods for the Determination of Inorganic Substances in Environmental Samples," U.S. EPA, August 1993, EPA/600/R-93/100, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 300.1 - "Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Rev. 1.0, U.S. EPA, 1997, EPA/600/R-98/118, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*3*) HAA5 shall be measured using the following methods:

(*i*) Method 552.1 - "Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion Exchange Liquid-Solid Extraction and Gas Chromatography with Electron Capture Detection," Rev. 1.0. The revision is contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water-Supplement II," U.S. EPA, August 1992, EPA/600/R-92/129, which is

incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 552.2 - "Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Extraction, Derivatization and Gas Chromatography with Electron Capture Detection," Rev. 1.0. The revision is contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water-Supplement III," U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iii*) Method 6251 B - "Disinfection By-Products: Haloacetic Acids and Trichlorophenol," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*4*) TTHM shall be measured using the following methods:

(*i*) Method 502.2 - "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series," Rev. 2.1. The revision is contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water-Supplement III," U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 524.2 - "Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry," Rev. 1.0. The revision is contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water-Supplement III," U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iii*) Method 551.1 - "Determination of Chlorination Disinfection Byproducts, Chlorinated Solvents, and Halogenated Pesticides/Herbicides in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron-Capture Detection," Rev. 1.0. The revision is contained in the manual entitled "Methods for the Determination of Organic Compounds in Drinking Water-Supplement III," U.S. EPA, August 1993, EPA/600/R-95/131, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*5*) Compliance with the chloramine standard can be determined by measuring combined or total chlorine. The following methods shall be used to measure chloramine:

(*i*) ASTM Method D1253-86 - " Standard Test Method for Residual Chlorine in Water," which is contained in the book entitled "Annual Book of ASTM Standards," 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 4500-Cl D - "Amperometric Titration Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iii*) Method 4500-Cl F - "DPD Ferrous Titrimetric Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iv*) Method 4500-Cl G - "DPD Colorimetric Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*v*) Method 4500-Cl E - "Low-Level Amperometric Titration Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*vi*) Method 4500-Cl I - "Iodometric Electrode Technique," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*6*) Compliance with the chlorine standard can be determined by measuring free or total chlorine. The following methods shall be used to measure chlorine:

(*i*) ASTM Method D1253-86 - "Standard Test Method for Residual Chlorine in Water," which is contained in the book entitled "Annual Book of ASTM Standards," 1996, vol. 11.01, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 4500-Cl D - "Amperometric Titration Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iii*) Method 4500-Cl F - "DPD Ferrous Titrimetric Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*iv*) Method 4500-Cl G - "DPD Colorimetric Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*v*) Method 4500-Cl E - "Low-Level Amperometric Titration Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*vi*) Method 4500-Cl I - "Iodometric Electrode Technique," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*vii*) Method 4500-Cl H - "Syringaldazine (FACTS) Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*7*) Chlorine dioxide shall be measured using the following methods:

(*i*) Method 4500-ClO_2 D - "DPD Method," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(*ii*) Method 4500-ClO_2E - "Amperometric Method II," which is contained in the book entitled "Standard Methods for the Examination of Water and Wastewater," 19th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(4)(iii)(I) of this section.

(5) ***Radiological quality.***

(i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.

(ii) Analyses conducted to determine compliance with the requirements of paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of "Standard Methods for the Examination of Water and Wastewater," 20th Ed., may be obtained from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005. Copies of the methods incorporated by reference in this paragraph (b)(5)(ii) may also be examined at the National Archives and Records Administration (NARA), or at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039. For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(A) Combined radium-226/-228 shall be measured using the following methods:

(*1*) Method 7500-Ra B - "Precipitation Method," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500-Ra D - "Sequential Precipitation Method," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(B) Gross alpha particle radioactivity shall be measured using the following method: Method 7110 C - "Coprecipitation Method for Gross Alpha Radioactivity in Drinking Water," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(C) Beta particle and photon radioactivity shall be measured using the following methods:

(*1*) Method 7500-Sr B - "Precipitation Method," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500-^{3}H B - "Liquid Scintillation Spectrometric Method," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*3*) Method 7120 B - "Gamma Spectroscopic Method," which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(D) Uranium shall be measured using the following methods:

(*1*) Method 7500-U B - "Radiochemical Method" which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500-U C - "Isotopic Method" which is contained in "Standard Methods for the Examination of Water and Wastewater," 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(c) ***Label statements.*** When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in § 130.14(a) the following statement(s) shall be used:

(1) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of paragraph (b)(2)(i)(A) of this section.

(2) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.

(3) "Contains Excessive _____," with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes") except that "Contains Excessive Chemical Substances" may be used if the bottled water is not mineral water.

(4) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) ***Adulteration.*** Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If *E. coli* is present in bottled water, then the bottled water will be deemed adulterated under section 402(a)(3) of the act.

[60 FR 57124, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769, May 11, 1998; 66 FR 16865, Mar. 28, 2001; 66 FR 17359, Mar. 30, 2001; 66 FR 35373, July 5, 2001; 66 FR 56035, Nov. 6, 2001; 58 FR 15355, Mar. 31, 2003; 68 FR 9881, Mar. 3, 2003; 70 FR 33700, June 9, 2005; 74 FR 25665, May 29, 2009; 76 FR 64813, Oct. 19, 2011; 81 FR 5591, Feb. 3, 2016; 87 FR 23441, Apr. 20, 2022]

APPENDIX E GUIDANCE FOR PREVENTIVE CONTROLS RULE

INTERNATIONAL BOTTLED WATER ASSOCIATION

BOTTLED WATER AND THE FOOD SAFETY MODERNIZATION ACT

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
("Preventive Controls Rule")

February, 2016

1700 DIAGONAL ROAD,
SUITE 650
ALEXANDRIA, VA 22314

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BOTTLED WATER AND THE FDA FOOD SAFETY MODERNIZATION ACT

CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD ("PREVENTIVE CONTROLS RULE")

International Bottled Water Association
Alexandria, Virginia

February, 2016

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PREFACE

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law on Jan. 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

The following are among FDA's key new authorities and mandates. Specific implementation dates specified in the law are noted in parentheses.

PREVENTION

For the first time, FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- Mandatory preventive controls for food facilities: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise.
- Mandatory produce safety standards: FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables.
- Authority to prevent intentional contamination: FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points.

INSPECTION AND COMPLIANCE

The FSMA recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge. FSMA provides FDA with important new tools for inspection and compliance, including:

- Mandated inspection frequency: The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- Records access: FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.

RESPONSE

The FSMA recognizes that FDA must have the tools to respond effectively when problems emerge despite preventive controls. New authorities include:

- Mandatory recall: The FSMA provides FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by FDA.
- Expanded administrative detention: The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- Suspension of registration: FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food.

IMPORTS

The FSMA gives FDA unprecedented authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include:

- Importer accountability: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.
- Third Party Certification: The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports in two situations:
    - Certification for high risk foods: FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.
    - Voluntary qualified importer program: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.

- Authority to deny entry: FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

IBWA submitted a substantial volume of comments on most of the FSMA proposed rules, but our focus was on the Preventive Controls Rule, as it will have more of an impact on bottled water than any other upcoming FSMA final rule.

The final Preventive Controls Rule illustrated demonstrated that the comments submitted by IBWA and other trade associations were very successful in convincing FDA to move in certain directions on the revise the final rule to reflect our input.

TOP TEN ACCOMPLISHMENTS OF COMMENTS ON THE PREVENTIVE CONTROLS RULE

1. Preventive controls are general and flexible, and not necessarily critical control point (CCP)-based.
2. Oversight of preventive controls is also flexible, incorporating a "sliding scale."
3. Recognition that finished product testing is not mandatory in all facilities – just "where appropriate."
4. No mandatory Zone 1 environmental testing.
5. Supply chain management focuses on both ingredient risk and supplier risk.
6. No Part 11 compliance, remote access to records, or facility profiles.
7. No requirement to review consumer complaints.
8. Third-party audits for supplier verification do not trigger the "bells and whistles" of the accredited third-party certification rule.
9. Warehouse exemption for most packaged foods, and modified requirements for products requiring time/temperature control for safety.
10. Staggered compliance date based on entity size.

Despite these successes, there are issues that, bottlers will need to be alert to other issues. For example, records and documentation requirements are extensive throughout the regulations and will be a major focus of FDA inspections. The rules of thumb regarding recordkeeping are:

- If you didn't document it, it didn't happen!
- If you did document it, it happened just that way!

Additionally, the supply chain management regulations are very detailed and will likely need additional attention by food companies.

OVERVIEW OF THE PREVENTIVE CONTROLS RULE

On September 17, 2015, FDA published the final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food ("Preventive Controls Rule"). The long-awaited rule, which was first proposed on January 16, 2013, will be the most impactful of the seven major FSMA rules for bottled water, and is the first of those rules to be finalized.

The two principal areas of the final rule that will impact bottled water are:

1. New requirements for domestic and foreign facilities registered with FDA as food "facilities" to establish and implement hazard analysis and risk-based preventive controls for human food. This, of course, includes bottled water facilities. This portion of the rule requires these registered food facilities to establish and maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of certain identified hazards, unless an exemption applies. Facilities must also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these actions. The requirements of the final rule, in many respects, follow the principles of HACCP.
2. This rule modernizes FDA's long-standing current good manufacturing practice (CGMP) regulations regarding the manufacturing, processing, packing, or holding of human food. FDA has updated, revised, and otherwise clarified certain requirements within the CGMP regulations, which were last updated in 1986. Note that FDA has not amended the bottled water-specific CGMP regulations, which remain in effect unchanged.

The final rule implements the requirements of the original FSMA legislation for facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the rule establishes requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections;
- Verification;
- Supply-chain program;
- Recall plan; and
- Associated records.

The last three items are new HACCP/food safety plan items for bottlers who have, since 2002, developed and maintained a HACCP program at their bottling facilities. FDA will now require assurance through written supplier programs that food additives and contact materials are safe by requiring that bottlers consider any hazards associated with those

materials and engage in supplier verification when those hazards are controlled by their suppliers. Recall plans, which have long been a requirement by FDA and IBWA's Bottled Water Code of Practice, are now to be integral parts of every facility's food safety plan. Finally, FDA has established extensive new recordkeeping requirements under the Preventive Controls Rule.

COMPLIANCE DATES AND MODIFIED REQUIREMENTS

The compliance dates are as follows:

- All other businesses: September 19, 2016
- Small businesses (under 500 employees): September 18, 2017
- Very small businesses (under $1,000,000 in sales): September 17, 2018

For compliance purposes, FDA defines "small business" as a business, including subsidiaries, with fewer than 500 employees. Those employees must work at least 2,080 hours per year, or be "full time equivalent." Small businesses do not qualify for any exemptions from any part of the preventive controls rule, and must be in full compliance with the rule by September 18, 2017.

A "very small business" (including any subsidiaries and affiliates) must average less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). Unlike small businesses, very small businesses are subject to modified requirements under the preventive controls rule as so-called "qualified facilities"—but such facilities will NOT be exempt from the revised CGMPs portion of the final rule. Of course, facilities may voluntarily comply with the entire final rule. Also, FDA has established in the final rule a procedure for withdrawal of that exemption should your product become involved in a contamination incident and/or recall, at which time full compliance would again be required.

If a facility wants to take advantage of the modified requirements for a "qualified facility", it must notify FDA about its status through submission of an attestation; and either:

- Notify FDA that it is addressing hazards through preventive controls and monitoring performance of those controls to ensure they are effective; or
- Notify FDA that it complies with applicable non-Federal food safety laws, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.

Upon request, the company must present to FDA or state equivalent inspectors financial evidence to support the company's exemption qualification.

The FDA exemption notification is in the form of an attestation, and must be submitted every two years, at the same time the facility is required to update its facility registration. The next facility registration period is scheduled for late-2016.

Businesses with 500 or more full-time equivalent employees must be in compliance with the rule by September 19, 2016.

CURRENT GOOD MANUFACTURING PRACTICES

FDA has transferred its current good manufacturing practice (CGMP) regulations from 21 C.F.R. Part 110 to a new 21 C.F.R. Part 117. Most CGMP subsection numbers from part 110 have been re-designated in the new part 117. For example, subsection 110.3 (Definitions) is now subsection 117.3 (Definitions).

It is important to recognize that FDA has not made any revisions to the bottled was CGMP regulations in 21 C.F.R. Part 129. Those regulations are unchanged and remain in effect. The revisions only affect the requirements currently codified in 21 C.F.R. Part 110.

Because of the detail of the final rule, we will focus here on a general discussion of CGMP changes made to part 110 in the new part 117 with a focus on what will likely apply to bottled water. Future IBWA publications will focus more on details. We will also identify which sections were REVISED (R) and which sections were NOT REVISED (NR) from part 110. Look for "R" and "NR" for each section discussed below.

First, let's look at some general new items and revisions in the new part 117. A number of terms have been changed to harmonize part 117 with other recent FDA rules, such as FDA's facility registration and recordkeeping regulations. These terms include:

- Manufacturing/processing.
- Packing.
- Holding.
- You, which now refers to the owner, operator, or agent in charge of a facility.
- Food and food-contact substances are now referred to as food-packaging materials. For the purposes of the provisions that require protection against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials, the term "food-packaging materials" does not include shipping containers such as cartons and crates that pose no risk of introducing contaminants or food allergens into food.

FDA is also revising the current part 110 to make five editorial changes: (1) Refer to the "Federal Food, Drug, and Cosmetic Act" rather than to "the act"; (2) replace the term "shall" with the term "must"; (3) replace the phrase "includes, but is not limited to" with "includes"; (4) replace the phrase "adulteration within the meaning of the act" with the single term "adulteration"; and (5) replace the term "whenever" with "when."

As noted above in (2), FDA is replacing the term "shall" with the term "must." This is part of the general effort by FDA to eliminate non-binding provisions and suggestions that were incorporated into part 110. These will now be part of a forthcoming guidance document for the Preventive Controls Rule.

Throughout the new part 117 are new provisions for "cross-contact" of packaging materials, food contact surfaces, and food products by common allergens. The former CGMP regulations did not address allergens. The term "cross-contact" is intended to differentiate contamination by allergens from other food contaminants, referred to as "contamination" or "cross-contamination."

Part 117 contains new requirements for training of plant personnel, requiring everyone to be a "qualified individual." Each individual engaged in manufacturing, processing, packing, or holding food must have the education, training, or experience (or combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. That training must include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the individual's assigned duties. There are additional training requirements for supervisory personnel, and requirements for maintaining records of personnel training. IBWA is developing a webinar platform through which we can assist you with FSMA education requirements by providing more education on FSMA and other issues. We will advise you when that is available.

NOTE: Some CGMPs have been transferred from part 110 to part 117 without change. REVISED CGMPs are indicated with an "R." CGMPs that were NOT REVISED are indicated with "NR."

DISEASE CONTROL (NR)

There are no revisions to the requirement that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel must be instructed to report such health conditions to their supervisors.

CLEANLINESS

Outer Garments (R): The methods for maintaining cleanliness include wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials and to protect against the cross-contact of food.

Unsecured Jewelry and Other Objects (NR): The methods for maintaining cleanliness include removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

Gloves (R): The methods for maintaining cleanliness include maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. FDA also deleted a recommendation that gloves should be of an impermeable material. As discussed above, FDA is deleting those non-binding recommendations of part 110 that they are not establishing as requirements.

Clothing and Other Personal Belongings (R): The methods for maintaining cleanliness include storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

Eating Food, Chewing Gum, Drinking Beverages, and Using Tobacco (NR): The methods for maintaining cleanliness include confining the following to areas other than where food

may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

Any Other Necessary Precautions (R): The methods for maintaining cleanliness include taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin) and to protect against cross-contact of food.

PLANT AND GROUNDS

Management Responsibility for Maintaining Grounds (R): The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

1. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.
2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
3. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
4. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
5. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in the rule, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

Suitability of Plant Construction and Design (NR): The plant buildings and structure must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).

Placement of Equipment and Storage of Materials (R): The plant must provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

Reduce Potential for Contamination and Allergen Cross-Contact Through Adequate Food Safety Controls and Operating Practices or Effective Design (R): Adequate precautions must be taken to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

Food in Outdoor Bulk Vessels (including storage tanks and silos) (R): Adequate precautions must be taken to protect food in installed outdoor bulk vessels by any effective means, including using protective coverings, controlling areas over and around the vessels to

eliminate harborages for pests, checking on a regular basis for pests and pest infestation, and skimming fermentation vessels, as necessary.

Lighting (R): Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

Ventilation (R): Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

Screening (NR): The plant must provide, where necessary, adequate screening or other protection against pests.

SANITARY OPERATIONS

General Maintenance (R): Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

Cleaning Compounds and Sanitizing Agents (R): Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. We also proposed that mechanisms to comply with provisions related to cleaning compounds and sanitizing agents must be safe and effective and provided examples of ways to achieve such compliance. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- Those required to maintain clean and sanitary conditions;
- Those necessary for use in laboratory testing procedures;
- Those necessary for plant and equipment maintenance and operation; and
- Those necessary for use in the plant's operations.

Identification and Storage of Toxic Materials (R): Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. We also proposed to remove a recommendation for following all relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of toxic cleaning compounds, sanitizing agents, and pesticides.

Pest Control (R): Pests must not be allowed in any area of a food plant. Guard, guide, or pest detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on

the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

Sanitation of Food-Contact Surfaces (R): All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

Food-Contact Surfaces Used for Manufacturing/Processing or Holding (R): Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

Wet Cleaning (R): In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

Single-Service Articles (R): Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

Sanitation of Non-Food-Contact Surfaces (R): Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

Storage and Handling of Cleaned Portable Equipment and Utensils (R): Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

SANITARY FACILITIES AND CONTROLS

Water Supply (R): The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

Plumbing (NR/R): Plumbing must be of adequate size and design and adequately installed and maintained to:

- Carry adequate quantities of water to required locations throughout the plant (NR).
- Properly convey sewage and liquid disposable waste from the plant (NR).
- Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition (NR).

- Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor (NR).
- Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing (R).

Sewage disposal (R): Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

Toilet facilities (R): Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

Hand-washing facilities (R): Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

Rubbish and offal disposal (R): Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

DESIGN, CONSTRUCTION, USE, INSTALLATION, AND MAINTENANCE OF EQUIPMENT AND UTENSILS

Design of Plant Equipment and Utensils (NR):

1. All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
2. Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
3. Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
4. Food-contact surfaces must be corrosion-resistant when in contact with food.
5. Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
6. Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

Seams on Food-Contact Surfaces (R): Food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms and cross-contact.

Construction of Equipment (R): Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

Holding, Conveying, and Manufacturing Systems (R): Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

Compressed Air or Other Gases (NR): Compressed air or other gases mechanically introduced into food or used to clean food contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

GENERAL PROCESSES AND CONTROLS

Adequate Sanitation Principles (NR):

- All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
- Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
- Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
- Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
- Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
- All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

Quality Control Operations (NR): Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Supervising Overall Sanitation (NR): Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

Production Procedures (R): Adequate precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.

Chemical, Microbial, or Extraneous-Material Testing Procedures (R): Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.

Contaminated Food (NR): All food that has become contaminated to the extent that it is adulterated be rejected, or if appropriate, treated or processed to eliminate the contamination.

Processes and Controls for Raw Materials and Other Ingredients

Inspection, Segregation and Handling of Raw Materials and Other Ingredients (R): Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

Levels of Microorganisms in Raw materials and Other Ingredients (R): Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

Natural Toxins in Raw Materials and Other Ingredients (R): Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

Pests, undesirable microorganisms, and extraneous material in raw materials and other ingredients (R): Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

Holding Raw Materials, Other Ingredients, and Rework in Bulk (R): Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

Frozen Raw Materials and Other Ingredients (NR): Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

Liquid and dry raw materials and other ingredients (R): Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

Raw materials and other ingredients that are food allergens (R): Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

MANUFACTURING OPERATIONS (R)

Condition of equipment, utensils, and finished food containers: Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

Conditions and controls for food manufacturing, processing, packing, and holding: All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

Food that can support the rapid growth of undesirable microorganisms: Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

Measures to destroy or prevent the growth of undesirable microorganisms: Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

Work-in-Process and Rework: Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

Finished food: Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.

Equipment, containers, and utensils: Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

Metal and other extraneous material: Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

Disposal of adulterated food, raw materials, and other ingredients: Food, raw materials, and other ingredients that are adulterated:

- Must be disposed of in a manner that protects against the contamination of other food; or
- If the adulterated food is capable of being reconditioned, it must be:
    - Reconditioned (if appropriate) using a method that has been proven to be effective; or

- Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.

Manufacturing operations: Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

Heat blanching, and growth and contamination by thermophilic microorganisms, during manufacturing operations: Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

Batters, breading, sauces, gravies, dressings, and other similar preparations: Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

Filling, Assembling, Packaging and Other Operations: Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

Food that relies on the control of water activity (aw) for preventing the growth of undesirable microorganisms: Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

Food that relies on the control of pH for preventing the growth of undesirable microorganisms: Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.

Requirements for ice used in contact with food: When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

Food-manufacturing areas and equipment: Deleted.

WAREHOUSING AND DISTRIBUTION (R)

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

DEFECT ACTION LEVELS (R)

The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at http://www.fda.gov/pchfrule and at http://www.fda.gov.

HAZARD ANALYSIS

HARPC OVERVIEW

The first requirement of this section of the Preventive Controls Rule is that every facility that is required to register with FDA under the facility registration rule (unless specifically exempted) must prepare, or have prepared, and implement a food safety plan. The food safety plan must be prepared, or its preparation overseen, by one or more "preventive controls qualified individuals." The written food safety plan must include:

1. A written hazard analysis (HA);
2. Written risk-based preventive controls (RPC);
3. Written procedures for monitoring the implementation of the preventive controls;
4. The written corrective action procedures;
5. Written verification procedures;
6. A written supply-chain program as required by subpart G of the Preventive Controls Rule; and
7. A written recall plan.

THE WRITTEN HAZARD ANALYSIS

The development of a food safety program and plan under the Preventive Controls Rule begins with a hazard analysis of the entire food processing system. In the case of bottled water, the process begins at the water source. (The hazard analysis must address hazards in additives to bottled water, such as mineral salts or fluoride, but we'll cover that later in the section on supplier programs.) Bottlers will be required to identify and evaluate, based on experience, illness data, scientific reports, and other information "known or reasonably foreseeable hazards" for each type of food manufactured, processed, packed, or held at your facility to determine whether there are "any hazards requiring a preventive control."

The hazard analysis must be written regardless of the outcome of the hazard analysis. In other words, even if no hazards are identified, you must retain written evidence in support of that conclusion. However, especially in the case of natural water sources, such as springs and artesian wells, IBWA points out that FDA regulates bottled water sources for total coliform and E. coli. We suggest you not overlook these regulated microbial issues as possible hazards.

To further clarify the different types of hazards covered in the Preventive Controls Rule, the flowing definitions are offered:

> "Hazard" is any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
>
> "Known or Reasonably Foreseeable Hazard" is a biological, chemical (including radiological), or physical hazard that is known to be or has the potential to be associated with the facility or the food.

"Hazard Requiring a Preventive Control" is a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (including an assessment of the severity of illness or injury if the hazard were to occur and the probability that it will occur in the absence of preventive controls), establish one or more preventive controls to SMOP (significantly minimize or prevent). The proposed versions of the Preventive Controls Rule referred to these hazards as "Significant Hazards."

Hazards may be:

- Naturally occurring or unintentionally introduced.
- Intentionally introduced for economic gain (EMA). FDA only is focused here on situations where there are known past instances of EMA that can affect public health (e.g., melamine in dairy powder). This is not about issues relating to pecuniary gain-alone (e.g., passing off conventional as organic).

Hazards to be evaluated include:

- Biological, including microbiological hazards (e.g., parasites, environmental pathogens, and other pathogens);
- Chemical, including radiological hazards, pesticide residues, drug residues, natural toxins, decomposition, unapproved food and color additives, and food allergens; and
- Physical, such as stones, glass, metal fragments.

The hazards identified must be evaluated to assess:

- The severity of the illness or injury if the hazard would occur, and
- The probability that the hazard will occur in the absence of preventive controls

Environmental pathogens must be evaluated whenever a ready-to-eat food is exposed to the environment before packaging, when a lethality treatment is not applied to the packaged food. Bottled water has minimal exposure to environmental pathogens in processing, but bottlers already monitor containers and closures for these pathogens. Containers and closure analysis is a form of environmental monitoring. We'll address that in more detail in future communications.

The hazard evaluation must also consider the effect of each of the following on the safety of the finished food for the intended consumer:

- The formulation of the food;
- The condition, function, and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;

- Sanitation, including employee hygiene; and
- "Any other relevant factors" (such as unexpected hazards).

PREVENTIVE CONTROLS

Preventive controls must be identified and implemented to SMOP those hazards requiring a preventive control (i.e., make sure the food is not adulterated and does not contain any undeclared allergens). FDA defines preventive controls as "Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about [food safety] would employ to [SMOP] the hazards identified under the hazard analysis…." Preventive controls, unlike preventive measures in a HACCP system, are not limited to CCPs. Preventive controls include controls at CCPs, if any, AND at points other than CCPs.

FDA cites many forms of preventive controls in the final rule. Types of preventive controls addressed in the final rule include:

- Process controls (e.g., operational controls for filters, UV units, ozone, RO).
    - Note that as appropriate to the nature of the control and its role in the facility's food safety system, process controls must include parameters and the min/max value to which the parameter must be controlled.
- Food allergen controls (e.g., protecting food from allergen cross contact during storage, handling and use; ensuring proper labeling).
- Sanitation controls (e.g., cleanliness of food contact surfaces; prevention of cross contamination).
- Any other controls employed by the facility.

Technically, supply-chain controls and the recall plan also are types of preventive controls, but conceptually these activities are distinct because they do not control hazards in the same way as the other types of controls.

MANAGEMENT COMPONENTS OF PREVENTIVE CONTROLS

Preventive controls are subject to the following management components, "as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system"

- Monitoring
- Corrective actions and corrections
- Verification
- Validation

Each management component is applied "as appropriate to [the nature of] the preventive control and its role in the facility's food safety system"

MONITORING REQUIREMENTS

The bottling facility must establish and implement written procedures for monitoring preventive controls, including frequency. Monitoring must be performed at adequate frequency to ensure that the preventive controls are being performed consistently

Monitoring activities must be documented, but exception records are permitted. Monitoring records are also subject to verification, including records reviews.

CORRECTIVE ACTIONS

The bottling facility must establish and implement written corrective action procedures to be used if the preventive controls are not properly implemented. Corrective actions are, as FDA states, as appropriate to the nature of the hazard and the nature of the preventive control. Corrective action procedures must address product testing and environmental monitoring results.

CORRECTIONS

FDA defines "correction" to mean an action to identify and correct a problem without other actions associated with corrective action procedures. Corrections can be taken for sanitation and food allergen controls, but also for "minor and isolated problems that do not directly impact product safety." Corrections are not required to be documented.

VERIFICATION

Verification activities must include "as appropriate to the preventive control and its role in the facility's food safety system:"

- Validation of the food safety plan.
- Verification that monitoring is being conducted.
- Verify that appropriate decisions about corrective actions are being made.
- Verification of implementation and effectiveness of corrective actions and corrections.
- Reanalysis of portions of the food safety plan, or the entire food safety plan at least once every three years.

As is required for most other parts of the Preventive Controls Rule, all verification activities must be documented in records.

As appropriate to the facility, the food, the nature of the control and its role in the facility's food safety system, the bottling facility must verify the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards via:

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)
- Product testing

- Environmental monitoring
- Records reviews
    - Records of monitoring and corrective actions must be reviewed within 7 working days after the records are created, or within a reasonable timeframe provided that the preventive controls qualified individual prepares (or oversees preparation of) a written justification for a timeframe that exceeds 7 working days;
    - Records of calibration, testing (e.g., product testing; environmental monitoring), supplier verification activities, and other verification activities must be reviewed within a reasonable time after the records are created.

Note that there is no requirement in the final rule to review consumer complaints as an official verification activity, but you should expect FDA to ask about complaints during inspections. FDA will want to know that you have a systematic way to review any complaints alleging consumer illness or injury.

TESTING

FSMA requires each facility to determine what degree of environmental and finished product testing, if any, is needed to verify that the preventive controls are working effectively. . For bottled water, compliance with existing FDA requirements for testing of bottled water products under the bottled water regulations should meet FSMA requirements. For environmental testing, container and closure testing at bottled water facilities will probably suffice, but companies need to be able to justify why the external environment will not infiltrate the "closed" system of water filtration and filling. Also, IBWA strongly recommends that plant quality management staff consider more frequent container and closure testing to avoid additional FDA requirements for environmental testing, or at least be able to demonstrate how quarterly testing is sufficient for your operation.

Although the final rule does not dictate which laboratories must be used for product and environmental testing, FDA's requirement for bottled water to be tested at "approved laboratories" remains in 21 CFR 129. The final rule requires testing procedures to be "scientifically valid," but not formally validated.

VALIDATION

General requirements for validation require scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the hazards identified in the hazard assessment. This requirement applies to process controls. Bottled water facilities will particularly need validation for their disinfection systems (e.g., ozone, UV). This is particularly important because, if you do not have a validated disinfection system, and you find the presence of E. coli in your source, then FDA may require a recall of product already in commerce. Validation of your disinfection system needs to be a high priority.

Consideration should also be given to reverse osmosis systems as a preventive control.

You do not need to validate:

- Food allergen controls.
- Sanitation controls.
- The recall plan.
- The supply chain program.
- Other preventive controls, if you have a written justification for no validation being necessary.

REANALYSIS

Reanalysis is required for the whole food safety plan at least every three years, regardless of whether or not revisions are made. Even determinations not to revise the plan must be documented. Additionally, reanalysis (and revision, if appropriate) of the whole plan or applicable portion of the plan must be conducted:

- Whenever a significant change is made in the activities at the facility affecting the hazard analysis.
- Whenever the facility becomes aware of new information about potential hazards.
- Whenever appropriate after an "unanticipated food safety problem."
- Whenever a preventive control, combination of PCs, or the plan as a whole is found ineffective.

As mandated by FDA in response to new hazards and developments in scientific understanding.

SUPPLY-CHAIN

Supply-chain controls are a type of preventive control. New requirements for supply chain programs are addressed under Subpart G of the Preventive Controls Rule. The rule takes a linear approach to supply chain management, includes very detailed requirements, and is very record intensive.

FDA defines a supplier as the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility (i.e., your bottling facility) without further manufacturing/processing by another establishment, except for manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature. For bottled water, our suppliers include spring sources, municipal water sources, and the companies providing inputs like food contact packaging and mineral salt ingredients.

Entities like brokers, distributors, or aggregators can engage in supplier verification as a service to the receiving facility. In these cases, the receiving facility must review and assess that entity's applicable documentation, and document this review and assessment. Receiving facilities must establish and follow written procedures for receiving raw materials, and must document use of these procedures

Bottlers will need to identify hazards controlled earlier in the supply chain (i.e., before receipt), if any, and the suppliers that control those hazards. Supplier verification is required when your suppliers control hazards requiring preventive controls. For such hazards, you need to conduct an analysis of the risk presented by the raw material or ingredients and the supplier, in order to determine appropriate verification activities and frequency of activities for each supplier. For example, you "must" consider specified factors, including the supplier's performance, food safety history, and compliance with FDA food safety regulations.

Based on the outcome of this analysis, you must engage in verification activities. Verification activities can include audits (second- or third-party), testing (by the supplier or receiving facility), and records reviews (e.g., reviewing the supplier's food safety plan). Generally, annual audits will be required for hazards identified as presenting "Serious or Adverse Health Consequences or Death to Humans or Animals" (SAHCODHA) (i.e., the risk of a Class I recall) to verify that preventive controls for those hazards are effective. There is no requirement to keep complete audit reports. However, the documentation must include the conclusions of the audit and corrective actions taken in response to significant deficiencies identified during the audit. When the hazards are observed, you must take prompt corrective actions, as needed. As with other parts of the Preventive Controls Rule, all records must be verified, and all decisions and activities must be documented.

In determining the need for a supplier program, you should ask "Do any of these suppliers have hazards that need to be controlled? If yes, what level of supplier oversight is reasonably required?" For bottled water, the primary incoming ingredients are primarily water, mineral salts, and food contact packaging. It may not be necessary to implement supply-chain controls for, e.g., mineral salts in bottled water, provided that there are no hazards requiring preventive controls identified in these ingredients. Additionally, there are separate supplier verification requirements under the Foreign Supplier Verification Program

regulation, which affect imports of finished products such as bottled water produced outside of the U.S.

For food packaging (bottles and caps), the food packaging suppliers need to supply bottlers with clean materials, and the required quarterly testing of incoming caps and containers under the FDA standards of quality (SOQ) in 21 CFR § 165.110 provides a basis for meeting this new FSMA requirement. FSMA specially lists "testing" as an acceptable supplier verification activity.

Additionally, bottled water companies should secure written certification from their suppliers that the plastics used in the bottled and caps have been cleared by the FDA under the food contact substance program.

RECORD KEEPING AND TRAINING

RECORD KEEPING

Nearly every activity required by the regulation must be documented under the Preventive Controls Rule. Records must:

- Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities
- Be accurate, indelible, and legible
- Be created concurrently with performance of the activity documented
- Be as detailed as necessary to provide the history of the work performed
- Include:
    - Information adequate to identify the plant/facility
    - The date and, when appropriate, the time of the activity documented
    - The signature or initials of the person performing the activity
    - Identity of the product and lot code (if any), where appropriate

Required records must be retained for at least 2 years after the date they were prepared. Records relating to the general adequacy of equipment/processes being used by the facility (e.g., results of scientific studies used for validation) must be retained for 2 years after their use is discontinued. All records, except for the food safety plan, can be stored offsite so long as they can be retrieved and provided onsite within 24 hours. Records are exempt from Part 11, which provides electronic recordkeeping system validation requirements.

All required records must be made "promptly available" for official review and copying upon oral or written request. FDA intends to copy records on a case-by-case basis—and primarily when conducting an inspection for cause (e.g., outbreak investigation).

Most records obtained or delivered to FDA are subject to disclosure under the Freedom of Information Act (FOIA), subject to the law's exemptions such as those for trade secrets or privileged or confidential commercial information. IBWA raised a concern at a public meeting earlier in 2015 about the confidentiality of facility food safety plans. FDA is expected exempt food safety plans from public release as a "trade secret." Disclosure of verification records, such as the results of product testing and environmental monitoring, would be evaluated on a case-by-case basis. Despite the protections in FOIA, companies would be well-served to always mark their records as "CONFIDENTIAL" when allowing FDA to make copies.

TRAINING

All employees at a bottled water plant must be "qualified individuals." This essentially means that employees must be qualified to do their jobs. The specific training and recordkeeping requirements for "qualified individuals" are discussed above in the section on CGMPs.

Additionally, certain activities must be conducted by a "preventive controls qualified individual" (PCQI), which is a qualified individual who has successfully completed training

in the development of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience. This person must prepare or oversee certain preventive controls functions

More specifically, a PCQI must engage in the following activities, or oversee those engaging in these activities:

1. Prepare the food safety plan
2. Validate preventive controls
3. Justify validation timeframes
4. Justify why determining validation is not required
5. Review records
6. Justify the timeframe for reviewing monitoring and corrective action records
7. Reanalyze the food safety plan
8. Determine the timeframe for reanalysis and validation of additional preventive controls

IBWA has a plan to assist members with satisfying the training requirements under the PC Rule. First, Bob Hirst will be trained as a trainer under the FSPCA Lead Instructor Program. As a Lead Instructor, he can then provide trainings to members to become Preventive Controls Qualified Individuals (PCQIs). The proposed program may become an extension of the existing IBWA CPO Program.

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Although the Preventive Controls Rule is the most significant regulation for the bottled water industry, it is important to bear in mind that there are other FSMA regulations that also will affect our industry:

- Foreign Supplier Verification Programs – Published November 27, 2015 (80 Fed. Reg. 74226)
- Accreditation of Third-Party Certification Bodies – Published November 27, 2015 (80 Fed. Reg. 74570)
- Sanitary Food Transportation – expected early April 2016
- Food Defense – expected early June 2016

We will provide additional guidance documents, such as this publication, as appropriate for these additional regulations.

TOP TEN AREAS OF FOCUS FOR BOTTLED WATER MANUFACTURERS

1. Update HACCP plan to be sure it contains a written hazard analysis that addresses all of the new hazard identification and evaluation requirements.

2. Be sure any CCPs are properly documented.

3. Ensure that you have defined procedures for monitoring and corrective actions, and that you follow them.

4. Validate your disinfection process(es). This is critical, both for FSMA and to avoid product recall in the event of a positive E. coli finding at the source.

5. Recognize that the bottled water Standards of Quality should generally satisfy the FSMA provisions on product and environmental testing (although, you may want to consider testing bottles and caps more frequently than quarterly).

6. Develop a supplier verification program. The verification activities for incoming caps and bottles may be satisfied by testing already required under the FDA Standards of Quality, but you still need a written program and justification for this approach to link the SOQ to FSMA. Also, verify that your suppliers use FDA-cleared plastics.

7. Train your employees in FSMA-related responsibilities, and be sure you have a Preventive Controls Qualified Individual (PCQI).

8. Recordkeeping is critical. Ensure that all required documents are complete, maintained, and accessible. Train your employees in good recordkeeping practices.

9. Update your inspection manual to reflect FDA's broader records access and the new recordkeeping requirements.

10. Develop/maintain a written recall plan.

FSMA READINESS CHECKLIST

1. Conduct hazard analysis (§ 117.130)
    - Identify known or reasonably foreseeable hazards:
        - Biological
        - Chemical
        - Physical
    - Evaluate hazards to assess severity and probability
        - Consider the effect of several specific factors listed in the regulations (§ 117.126(c))

2. Identify and implement preventive controls (§ 117.135), including:
    - Process controls
    - Sanitation controls

3. Develop monitoring procedures (§ 117.145)

4. Develop corrective action procedures (§ 117.150), including to address:
    - The presence of a pathogen or indicator organism in finish product
    - The presence of an environmental pathogen or indicator organism

5. Develop verification procedures (§ 117.155), including procedures for:
    - Product testing
    - Environmental monitoring
    - Calibration

6. Validate process controls (§ 117.160)

7. Develop supply-chain program (§ 117, Subpart G)

8. Engage in records review of records related to (§ 117.165):
    - Monitoring
    - Corrective action
    - Calibration
    - Product testing
    - Environmental monitoring
    - Supplier and supply-chain verification activities
    - Other verification activities

9. Prepare recall plan (§ 117.139)

10. Ensure records meet basic requirements (e.g., are signed and dated) (§ 117.305)

11. Compile Food Safety Plan (§ 117.126)
    - Hazard Analysis
    - Preventive Controls
    - Supply-Chain Program
    - Recall Plan
    - Monitoring Procedures
    - Corrective Action Procedures
    - Verification Procedures

12. Sign and date Food Safety Plan (§ 117.310)

13. Conduct a reanalysis at least every 3 years and when required by the regulations (§ 117.170)

14. Ensure that a "preventive controls qualified individual" prepares or oversees preparation of the plan and other specific activities (§ 117.180)

15. Ensure all employees are qualified individuals (i.e., trained for their specific jobs) (§ 117.4)

IBWA TO OFFER FSPCA TRAINING FOR PREVENTIVE CONTROLS QUALIFIED INDIVIDUALS

FDA's final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food ("Preventive Controls Rule" or "PC Rule") includes a requirement for Preventive Controls Qualified Individuals ("PCQIs") that states:

> *"Many activities required by the final rule must be conducted (or overseen) by a preventive controls qualified individual, a new term we are coining here. A preventive controls qualified individual is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system."*

The details of the new requirement are found throughout the final rule. However, in summary, FDA states in § 117.180(a) that the responsibilities of a PCQI are:

> (a) One or more preventive controls qualified individuals must do or oversee the following:
>
> 1. Preparation of the food safety plan (§ 117.126(a)(2));
> 2. Validation of the preventive controls (§ 117.160(b)(1));
> 3. Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;
> 4. Determination that validation is not required (§ 117.160(c)(5));
> 5. Review of records (§ 117.165(a)(4));
> 6. Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;
> 7. Reanalysis of the food safety plan (§ 117.170(d)); and
> 8. Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

To facilitate compliance with this new requirement, FDA worked with the Food Safety Preventive Controls Alliance (FSPCA) to develop a curriculum to be used by FSPCA-trained Lead Instructors to educate, and recognize, individuals as preventive controls qualified individuals, herein referred to as "PCQIs." The FSPCA is an alliance of government, academia, and industry whose mission is to assist with implementation of FSMA in the food industry. As was mentioned above, the final rule also provides for PCQI approval for those "otherwise qualified through job experience to develop and apply a food safety system."

However, FDA has not yet defined the process for becoming a PCQI through job experience. IBWA will make that information available once FDA has published guidelines for approval through job experience.

The FSPCA began offering a "train-the-trainer" program in late-2015 to make Lead Instructors available to the food industry. IBWA's Vice President for Education, Science, and Technical Relations, Bob Hirst, completed a FSPCA training session in January, 2016 to become a Lead Instructor. Bob will begin offering PCQI training sessions for IBWA bottler members in 2016. As several IBWA members are required to comply with the PC Rule beginning in 2016 and 2017, this is important to note.

IBWA will offer a new PCQI certificate under our current Certified Plant Operator (CPO) program. Current CPOs may become PCQIs by completing the IBWA PCQI training program. An additional certificate will be made available to IBWA CPOs upon completion of the PCQI training course. However, IBWA members need not be CPOs to complete the training to attend IBWA's workshops to become a PCQI.

IBWA is working to schedule regional PCQI workshops throughout the U.S. beginning in 2016. These workshops, which will be scheduled over 2½ days, will provide anyone in the bottled water industry an opportunity to become a PCQI for their facility(ies), in compliance with the new Preventive Controls Rule. The 2.5 day course will include:

- Food Safety Plan Overview
- GMPs and Prerequisite Programs
- Biological Food Safety Hazards
- Chemical, Physical and Economically Motivated Food Safety Hazards
- Preliminary Steps
- Resources for Preparing a Food Safety Plan
- Hazard Analysis and Preventive Control Determination
- Process Preventive Controls
- Food Allergen Preventive Controls
- Sanitation Preventive Controls
- Supplier Preventive Controls
- Verification and Validation Procedures
- Recordkeeping Procedures
- Recall Plan
- FSMA Regulatory Overview

IBWA will release additional information about this training program in early-2016. A fee, to be determined, will be assessed to cover the expenses of travel and training materials for the workshops. A separate fee will be established for non-IBWA members as well. IBWA is aware of member concerns over the cost of travel and training, and will schedule the workshops at low cost venues as much as possible given that attendance will involve multiple days with possible overnight stays at hotels.

Watch IBWA's News Splash and other communications for workshop details as well as dates and locations for this and other workshops.

If you have any questions, please feel free to contact Al Lear at alear@bottledwater.org.

APPENDIX F IBWA BOTTLED WATER CODE OF PRACTICE

Bottled Water Code of Practice

Revised November, 2024
Effective January 1, 2025

International Bottled Water Association
Alexandria, VA 22314
(703) 683-5213
http://www.bottledwater.org

INTERNATIONAL BOTTLED WATER ASSOCIATION
Bottled Water Code of Practice

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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.

NOTE: The November 2020 revision of the Code of Practice included revisions resulting from the Food Safety Modernization Act (FSMA). The final rule for Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food ("Preventive Controls Rule") was published on August 30, 2015, and was effective beginning August 30, 2016. The October 2022 revision updated the FDA Standard Of Quality for added fluoride in bottled water.

INTERNATIONAL BOTTLED WATER ASSOCIATION
Bottled Water Code of Practice

Foreword

The IBWA Bottled Water Code of Practice 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 Code of Practice 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 Code of Practice 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 Code of Practice. 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. With the final FDA Preventive Controls Rule in 2015, IBWA prepared for implementation of a new audit program to accommodate the new food safety regulations.

The IBWA Code of Practice has also 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 Code of Practice, 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 Code of Practice 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 FDA's Good Manufacturing Practices (GMPs) and preventive controls regulations and provides the basis for food safety in the bottled water industry.

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 meet or exceed 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 under contract with IBWA. 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 principles 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 §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, mitigation, and response procedures required in 21 CFR §129.35(a)(3).

(c) IBWA bottler members believe that consumers have a right to know what is in the bottled water they drink. To demonstrate their commitment to openness and cooperation, IBWA bottler members shall, upon request, provide consumers meaningful information about their bottled water brands. The bottler shall provide consumers information that demonstrates compliance with applicable federal, state, and IBWA Standards of Quality. Bottlers must provide analytical testing data results for all substances listed in Appendix A of the IBWA Code of Practice that were provided during their most recent IBWA Code of Practice 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 IBWA plant audit. IBWA members are free to determine how information is provided to consumers (e.g., via regular mail, email, web site, phone, etc.) but shall provide the information in written form, upon request.

This IBWA Code of Practice 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. This IBWA Code of Practice amendment becomes effective on January 1, 2021.

(d) IBWA bottler members shall adopt written policies and procedures designed to protect the integrity and security of their operations and products. The companies' food safety 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 two 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 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulations (21 CFR Part 117) and in Processing and Bottling of Bottled Drinking Water (21 CFR Part 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 comprehensive food safety program in compliance with Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR Part 117). As a part of the program, the plant shall develop and write a food safety Plan that addresses product safety as defined by the U.S. Food and Drug Administration. The plan shall address, but is not limited to, the following:

(1) A hazard analysis.

(2) Establishment of preventive controls.

(3) Establishment of parameters and values (critical limits).

(4) Detail of the monitoring program.

(5) Description of corrective actions or corrections to be taken by the plant should a critical limit be exceeded.

(6) Description of the plant's verification system for process controls.

(7) Description of the plant's recordkeeping system. Plants shall maintain food safety records for a period of two years.

(8) Development of a recall plan to address any hazards requiring a preventive control.

In support of the plan's food safety program, a sanitization standard operating procedure (SSOP) and other appropriate supporting standard operating procedures (SOPs) shall be

[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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-security-preventive-measures-guidance-food-producers-processors-and.

developed and maintained. Appropriate documents and records will be made available to IBWA and government agency inspection staff upon request.

(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 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.

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 food safety plan, and shall include provisions for monitoring, critical limits, appropriate corrective action, and records.

(h) Bottled water that originates from a source that is not protected from surface contamination shall be subjected to ozonation, filtration rated at one micron, or another effective process that 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 may be unnecessary, with concurrence by the regulatory agency having jurisdiction. 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, GMPs, food safety, 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 and in Appendix A of this Code of Practice. Such monitoring shall be at least annually, except as is noted in Appendix A of this Code of Practice.

(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.

(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 two 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.

(c) (b)(1)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 two 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.

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) For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.006	0.006	0.006
Arsenic		0.01	0.01	0.01
Barium		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, Total		0.05	0.1	0.1
Chromium, Hexavalent (6)		0.01	NA	NA
Cyanide (1)		0.2	0.2	0.2
Fluoride		0.7 (3)	0.7 (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) For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.03	0.2	0.2
1,1,2-Trichloroethane		0.003	0.005	0.005
1,1-Dichloroethylene		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		0.002	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 listed is for bottled water to which fluoride is added. SOQ for bottled water to which no fluoride is added dependent upon temperature and other factors. See fluoride section on page 24 in 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.
(6) If total chromium results are <0.005 mg/l (5 ug/l), then monitoring for hexavalent chromium is waived.

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.

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) For items with footnote (2), see *FDA D/DBP Rule Monitoring Requirements on page 21.*	0.001	0.005	0.005
Toluene		1	1	1
Trichloroethylene		0.001	0.005	0.005
Vinyl chloride		0.002	0.002	0.002
Xylenes (total)		1	10	10
Bromodichloromethane		(7)	(7)	(7)
Chlorodibromomethane		(7)	(7)	(7)
Chloroform		(7)	(7)	(7)
Bromoform		(7)	(7)	(7)
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	0.006	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		0.002	NA	0.002
Aldicarb sulfoxide		0.004	NA	0.004
Atrazine		0.003	0.003	0.003
Carbofuran		0.04	0.04	0.04
Chlordane		0.0005	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)(8)	Product: Every 3 years Source: Annually	$3x10^{-8}$	$3x10^{-8}$	$3x10^{-8}$
Diquat (1)(8)		0.02	0.02	0.02
Endothall (1)(8)		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)(8)	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.
(7) No SOQs or MCLs established for individual trihalomethane contaminants. The sum of the 4 THMs is regulated as total trihalomethanes (TTHMs).
(8) FDA requires that the four synthetic organic chemicals (SOC) listed must be tested quarterly for four consecutive quarters for each type of finished bottled water (e.g., spring, purified, etc.). If none of the SOCs are detected, then once every three years for each type of finished product. If SOCs are detected, maintain monitoring for four consecutive quarters in each three-year period. New products and new companies must do an initial round of quarterly monitoring in the first year of operation.

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

Appendix A
2025 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)		
Additional 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
Perchlorate		0.002	NA	NA
Phenols (Total Recoverable Phenolics)		0.001	0.001	NA
m-Dichlorobenzene		0.6	NA	NA
1,1-Dichloroethane		0.05	NA	NA
1,1,2,2-Tetrachloroethane		0.001	NA	NA
Per- and Polyfluoroalkyl Substances (PFAS) (US EPA Method 537.1) (10) SEE SECTION IN APPENDIX A	(Product)	(10)	NA	(10)
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)) PRODUCT: daily (IBWA Code of Practice Rule 5 (a)(1)	No *Escherichia 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.	**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.

(10) SEE SECTION IN APPENDIX A FOR PFAS REQUIREMENTS.

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
2025 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
2025 MONITORING MATRIX
IBWA Code of Practice 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.

Appendix A
2025 MONITORING MATRIX
IBWA Code of Practice Monitoring Requirements

Per- and Polyfluoroalkyl Substances

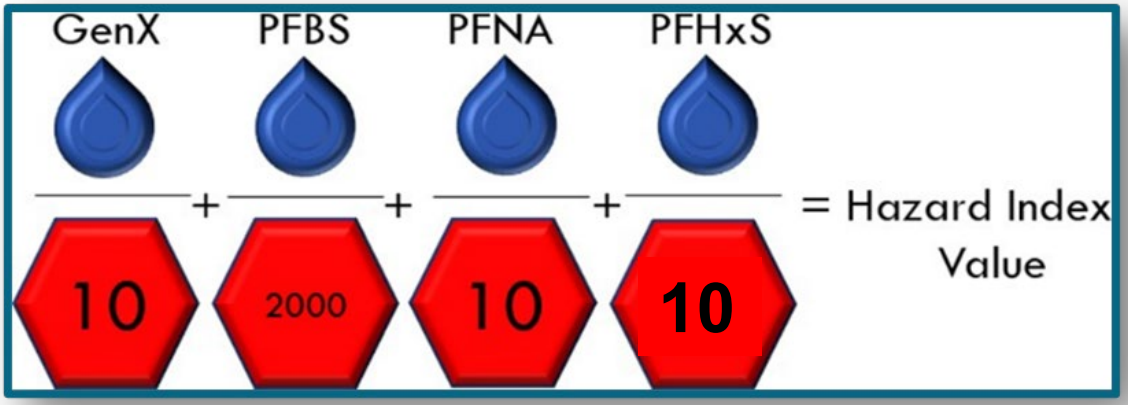
The following guidance is based on the drinking water standards and requirements for monitoring in the US EPA final rule for per- and polyfluoroalkyl substances (PFAS), published in the Federal Register on April 26, 2024.

Per- and Polyfluoroalkyl Substances	**SEE BELOW**	**IBWA SOQ**	**FDA SOQ**	**EPA MCL**
PFOA	EACH PRODUCT TYPE: Annually	4.0 ng/L (ppt)	TBD	4.0 ng/L (ppt)
PFOS		4.0 ng/l (ppt)	TBD	4.0 ng/l (ppt)
HFO-DA (Gen X) (1)		10 ng/l (ppt)	TBD	10 ng/l (ppt)
PFHxS (1)		10 ng/l (ppt	TBD	10 ng/l (ppt
PFNA (1)		10 ng/l (ppt)	TBD	10 ng/l (ppt)
Mixtures containing any combination of HFO-DA, PFHxS, PFNA, and PFBS		HI $\leq$ 1	TBD	HI $\leq$ 1
Remaining 12 PFAS compounds from EPA Method 537.1		Single detect 5 ng/l (ppt) Multiple detects 10 ng/l (ppt)	NA	NA

ng/l = nanogram per liter / ppt = parts per trillion
(1) Four (4) PFAS compounds whose test results are used to calculate Hazard Index, a unitless measure. The MCL for HI is 1.
(2) TBD = To be determined.
(3) HI = Hazard Index

Hazard Index Calculation

Hazard Index = ([HFPO-DAwater ng/l]/[10 ng/l]) + ([PFBSwater ng/l]/[2000 ng/l]) + ([PFNAwater ng/l]/[10 ng/l]) + ([PFHxSwater ng/l]/[10 ng/l])



Sample Calculation

Assume the following test results for a source water sample:

GenX	PFBS	PFNA	PFHxS
2 ppt	120 ppt	3 ppt	3 ppt

Applying the formula illustrated above, the following calculation is made:

GenX /10	PFBS /2000	PFNA /10	PFHxS /10	HAZARD INDEX
0.2	0.06	0.3	0.3	0.86

In the above example, the HI for the four PFAS compounds (0.86) would be compliant with the unitless standard in the proposed EPA rule.

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. Mitigation shall be accomplished as required in 21 CFR §129.35(a)(3).

Appendix D

List of State Regulatory Contacts (revised (September), 2020)
(This section is under revision at the time of publication of the Code of Practice. Some information may be inaccurate or outdated.)

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Environmental & Health Facility Standards Administration
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ALASKA (042604)
Dept. of Environmental Conservation
Division of Environmental Health
Food Safety & Sanitation Program
555 Cordova
Anchorage, AK 99501
CONTACT: Ms. Nancy Napolilli
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Arizona Dept. of Health Services
Food Safety & Environmental Services
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ARKANSAS (042604)
Arkansas Dept. of Health
Food Protection Services
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California Dept. of Health Services
Food and Drug Branch (MS-7602)
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Fax: (916) 440-5369
e-mail: CLee1@dhs.ca.gov

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

FLORIDA (051804)
Dept. of Agriculture & Consumer Services
Division of Food Safety
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Food & Rural Resources
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State Board of Health
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