

Imported Bottled Water Interim Standard

Regarding Section 11.1, Water Supply Rule, March 17, 2020

Issued January 30, 2024

Based on review of the Water Supply Rule and current oversight of the imported bottled water program by the State of Vermont, the Agency of Natural Resources is issuing this interim standard for Approvals to Sell Bottled Water in Vermont.

In assessing the imported bottled water program, the State determined that current requirements for imported bottled water create potential obstacles to bottled water access. This interim standard formally establishes Approval guidelines consistent with or more stringent than recent oversight practices, while reflecting requirements more attainable than those in the Water Supply Rule to ensure an adequate ongoing supply of bottled water in Vermont.

The measures set out in this interim standard meet or exceed minimum standards set by the United States Food and Drug Administration (FDA), ensuring that Vermont's requirements are at least as public health protective as the federal standard. This interim standard comports with the statutory requirements for selling imported bottled water under 10 V.S.A. § 1673(f) and falls under the Secretary's authority to regulate drinking water quality in Vermont under 10 V.S.A. § 1672(b)(1).

As specified in the Water Supply Rule, an Approval applies to a single bottling facility and all products produced by that facility. Systems seeking Approval to sell in Vermont are required to certify that they meet all applicable standards set forth in rule and statute, except where identified below.

To qualify for an Approval, the bottling facility owner or legal representative must certify that the water, sources, and bottling system are regulated by drinking water standards or requirements that are substantially equivalent to or more stringent than the standards or requirements established by the Secretary pursuant to 10 V.S.A., §1672(b). They must also certify that the Bottled Water System operates in accordance with the FDA's Good Manufacturing Practice Regulations (GMPRs) as found in 21 CFR Parts 110 & 129.

This standard reflects an interim policy and does not take the place of existing regulation. The standard will be reviewed and formally encoded in a future revision of the Water Supply Rule.

Water Quality Monitoring

Per Section 11.1.2(a)(4) of the Water Supply Rule, *"In the application for the Approval to Sell Bottled Water in Vermont: The Imported Bottled water system shall submit monitoring results for all contaminants identified in Tables 6-1 and 6-2 of Subchapter 21-6 that is measured at locations*

representative of each source prior to treatment and from each finished bottled water product type and package size to be distributed or sold in Vermont.”

Per Section 11.1.2(b) of the Water Supply Rule, *“Imported Bottled water systems shall submit monitoring results for the contaminants identified in Table 6-1 of Subchapter 21-6, at the sampling frequency and for the number of samples identified in Table 11-1, measured at locations representative of each source prior to treatment and from each finished bottled water product type and package size distributed or sold in Vermont. “*

Under the interim standard, bottling facilities seeking to obtain or maintain an Approval shall submit monitoring results for representative samples from each finished bottled water product type but are *not* required to submit monitoring results for a representative sample from each package size. The package size requirement has not been consistently implemented or enforced in the history of the State’s oversight of imported bottled water Approvals. Moreover, this requirement could significantly reduce the number of bottling facilities seeking Approvals in Vermont, posing a risk to the adequate supply of bottled water.

Product type will be defined using standards of identity in 21 CFR § 165.110 (a) and will include “purified water”, “purified water with mineral mix [X]”, “distilled water”, “mineral water”, “spring water”, and any other distinct type defined by source type, treatment type, and/or added minerals. For example, one product type may be purified water with mineral mix A and another may be spring water. One representative sample will be required per product type regardless of the number of package sizes associated with that product type. Also, one representative sample will be required per product type regardless of the number of labels applied for its distribution.

Bottling Facility and Source Labeling

Per Section 11.1.1(d) of the Water Supply Rule, *“All bottled water labels shall contain the following information:*

- (1) The name of the person or company bottling the water;*
- (2) Town and state in which the water is bottled;*
- (3) Town and state where the source is situated; and*
- (4) Source, i.e. private spring, private well or the name of the Public water system supplying the water.”*

Bottling Facility Labeling

Under the interim standard, requirements for 11.1.1(d)(1) and (2) will be implemented as follows:

All bottled water labels shall contain the following information:

- (1) The name of manufacturer, packer, or distributor; and*
- (2) The place of business of the manufacturer, packer, or distributor (which may be a corporate location in lieu of the bottling facility location).*

This is consistent with the standard set by the FDA. Per 21 CFR § 101.5, labels must include the “**name and place of business of the manufacturer, packer, or distributor**”, where “the label may state the **principal place of business** in lieu of the actual place where such food was manufactured or packed or is to be distributed”. This requirement will provide consumers with all necessary information to contact the bottling firm and acquire more detailed information about the bottling facility itself.

The Water Supply Rule as written would require many bottling firms to produce labels exclusively for distribution in Vermont, a barrier which could pose a risk to Vermont's bottled water supply. This interim standard maintains a minimum standard of public health protection while ensuring sufficient access to bottled water in Vermont.

Source Labeling

Under the interim standard, requirements for 11.1.1(d)(3) and (4) will be implemented as follows:

All bottled water labels shall contain the following information:

- (1) *For private springs and wells:*
 - a. *The type of source (i.e., private spring, private well); and*
 - b. *The location of the source.*
- (2) *For water from a Public water system that does not meet the definition of "purified water" or "sterile water" per 21 CFR § 165.110(a)(2)(iv) and (a)(2)(vii):*
 - a. *A statement reading, "from a community water system" or, alternatively, "from a municipal source" as appropriate; and*
 - b. *The name and location of the water system.*
- (3) *For water from a Public water system that meets the definition of "purified water" or "sterile water" per 21 CFR § 165.110(a)(2)(iv) and (a)(2)(vii) and is labeled as such:*
 - a. *No source information shall be required.*

Relative to the current Water Supply Rule, this standard adjusts labeling requirements for water that is already regulated in another capacity and has undergone a standardized level of treatment (purified or sterile water from a Public water system), while maintaining specificity for sources that (a) are most commonly associated with misleading labeling language, (b) are not regulated in other capacities, and/or (c) may warrant further investigation of water treatment standards by a consumer.

These requirements are the result of a survey of other northeastern states' bottled water regulations. The State identified Massachusetts' application of its bottled water source labeling regulations (105 CMR 500.090) as more attainable than the current State standard while maintaining a high degree of public health protection. This interim standard reflects those attainable practices, as applicable to Vermont. The requirements exceed the minimum standard set by the FDA. Per 21 CFR § 165.110, the location of a source must only be identified for spring water. Federal regulation does not require bottled water labels to include source information for private wells. For water from a community water system that does not meet the definition of "purified water" or "sterile water" per 21 CFR § 165.110(a)(2)(iv) and (a)(2)(vii), the only additional source information required by the FDA is a statement reading, "from a community water system" or, alternatively, "from a municipal source" as appropriate.

Approved by: _____

Ben Montross, Drinking Water Program Manager
Drinking Water and Groundwater Protection Division

_____ Date