

## Article - Health - General

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§21–336.1.

- (a) Except as permitted under subsection (b) of this section, bottled water shall:
- (1) Be obtained from an approved source; and
  - (2) Undergo:
    - (i) Ozonation or an equivalent disinfection process approved by the Department; and
    - (ii) When required by the Department, filtration or any other treatment that is necessary for the water to comply with the standards adopted by the Department under § 21–336(e)(1)(ii) of this subtitle.
- (b) The Department may grant to a bottler a waiver of the filtration and disinfection treatment required under subsection (a) of this section if the Department is satisfied that the filtration and disinfection treatment are not necessary to assure that a bottled water product will consistently comply with the microbiological standards under this subtitle.
- (c) (1) Based on the bottler’s demonstration of long-term baseline microbiological data that monitors the source and the product, the nature and extent of source monitoring, and source protection and bottling sanitation procedures instituted by the bottler, a waiver may be granted if:
- (i) The product and source are in compliance with the Codex Alimentarius standard for natural mineral water, CAC/RS 108, as amended, and the requirements under § 21–336(a)(2) and (e) of this subtitle;
  - (ii) The product and source are in compliance with the Code of Hygienic Practice of the Codex Alimentarius, Alinorm 85/13A, as amended, for the collection, processing, and marketing of natural mineral water; and
  - (iii) The bottler has submitted a basic hydrogeological survey of the source, a hydrogeological assessment that demonstrates that the source is not under the direct influence of surface water, and an annual sanitary survey, all of which have been prepared by a professionally qualified hydrogeologist and which demonstrate the integrity of the source.
- (2) The annual sanitary survey required under paragraph (1)(iii) of this subsection shall include:
- (i) Watershed surveillance that includes an inspection of those portions of the drainage area necessary to identify and evaluate actual and probable

sources of contamination;

(ii) Evaluation of source construction and protection, and, when appropriate, intake structures and transmission facilities; and

(iii) Evaluation of finished water storage facilities.

(d) Once a waiver has been granted under this section:

(1) A bottler shall renew the waiver of the filtration and disinfection treatment provided under subsection (b) of this section on an annual basis if a continuation of operations is desired by submitting a letter of compliance with subsection (c) of this section from a representative of the bottler to the Department.

(2) The representative of the bottler shall certify under personal knowledge and penalty of perjury that the conditions under subsection (c) of this section on which the waiver was granted have not changed.

(3) The representative of the bottler shall have a continuing obligation to notify the Department of any change of a condition under subsection (c) of this section not later than 5 days from the date of the change.

(4) The product shall be bottled:

(i) In an enclosed filling room or chamber that is under positive pressure of filtered purified air; and

(ii) At a facility and with good manufacturing practices that comply with the requirements of 21 C.F.R. Part 129.

(e) If a bottled water product is not in compliance with any requirement under subsection (c) or (d) of this section:

(1) The Department shall revoke the waiver; and

(2) The product shall be subject to the filtration and disinfection treatment requirements under subsection (a) of this section.

(f) Except for filtration and disinfection treatment, this section may not be construed to waive any requirement that is applicable under this subtitle to a bottled water product.

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