

401 KAR 8:700. Bottled water.

RELATES TO: KRS 224.10-100, 224.10-110, 21 C.F.R. 129.35, 165.110

STATUTORY AUTHORITY: KRS 224.10-100, 224.10-110

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-110 requires the cabinet to enforce the administrative regulations adopted by the secretary for the regulation and control of the purification of water for public and semipublic use. This administrative regulation establishes provisions to assure the purity of water placed in bottles that will be resold as a food for human consumption or other consumer use. U.S. EPA does not have a federal regulation relating to bottled water. Certain provisions of this administrative regulation are more stringent than the FDA requirements. The cabinet requires that plans, reports, and monitoring results be submitted to the cabinet to ensure that compliance with all public health standards is achieved without more frequent, costly on-site inspections, and that systems monitor for chlorite more frequently to ensure that public health standards are met for any disinfectant residuals.

Section 1. Applicability.

- (1) A bottled water system that bottles water within the Commonwealth shall comply with the provisions of 401 KAR Chapter 8 except:
 - (a) Distribution system monitoring and compliance applicable to public water systems, including provisions for chlorine residual and disinfection by-products; and
 - (b) The public notification requirements of 401 KAR 8:070 and the reporting requirements of 401 KAR 8:075; and
- (2) Water bottled outside the Commonwealth shall not be subject to this administrative regulation, regardless of its source.

Section 2. Disinfection and Treatment.

- (1) Disinfection shall be by chlorination, ultraviolet light, ozonation, or chlorine dioxide.
- (2) "Filtration", as defined by 40 C.F.R. 141.2, shall be used for all sources identified as "surface water" or "groundwater under the direct influence of surface water", as defined by 40 C.F.R. 141.2.
- (3) A bottled water system that uses a surface water source may use treatment techniques that are different from other surface water users if equivalent treatment is provided.
- (4) Water located in the line after bottling operations cease shall be flushed before bottling is resumed.

Section 3. Sampling, Monitoring, and Reporting.

- (1) Analysis shall be performed with a method established in 401 KAR Chapter 8 in a laboratory that shall be certified to conduct testing pursuant to 401 KAR 8:040.
- (2) Monitoring results, including the Monthly Operating Report, shall be received by the cabinet no later than the tenth day of the month following the end of the reporting period.
- (3) If no treatment or bottling of water occurred during the reporting month, the bottled water system shall notify the cabinet in its Monthly Operating Report established in 401 KAR 8:020, Section 2(7), no later than the tenth day of the following month.
- (4) Microbiological Sampling and Monitoring. A bottled water system shall conduct microbiological sampling and testing as established in 401 KAR 8:200.
 - (a) Each sample shall be taken after water disinfection and prior to the water being placed in a bottle, with no intervening stagnant storage; or
 - (b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant.
- (5) Turbidity Sampling and Monitoring.

- (a) A bottled water system shall conduct turbidity sampling once every four (4) hours the system is in operation, regardless of source. The system may substitute continuous monitoring for grab sampling as established in 401 KAR 8:150, Section 3(2), and may use the average turbidity value for each four (4) hour increment to determine compliance with turbidity performance criterion in paragraph (b) of this subsection.
- (b) The turbidity level of the system's product water shall be less than or equal to three-tenths (0.3) nephelometric turbidity units (NTU) in not less than ninety-five (95) percent of the measurements taken each month, and shall never exceed one (1) NTU.
- (6) Disinfectant Sampling and Monitoring. Monitoring for disinfectants shall occur after disinfection but prior to bottling, with no intervening stagnant storage.
- (a) Chlorine dioxide. A bottled water system that uses chlorine dioxide shall monitor daily for chlorine dioxide.
1. The Maximum Residual Disinfection Level (MRDL) for chlorine dioxide shall not exceed 0.8 mg/L.
 2. No two (2) consecutive daily samples shall exceed the MRDL for chlorine dioxide.
 3. A bottled water system shall immediately take steps to lower the level of chlorine dioxide in finished water if the MRDL for chlorine dioxide is exceeded.
- (b) Chlorite. A bottled water system that uses chlorine dioxide as a disinfectant shall monitor for chlorite annually. The Maximum Residual Disinfection Level (MRDL) for chlorite shall not exceed 1.0 mg/L.
- (c)
1. Ozone. A bottled water system that uses ozone shall monitor:
 - a. Monthly for bromate; or
 - b. Annually for bromate if the system demonstrates that the average bromate concentration is less than 0.0025 mg/L calculated as a running annual average of monthly bromate samples.
 2. The Maximum Contaminant Level (MCL) for bromate shall not exceed 0.010 mg/L.
- (7) Chemical contaminants.
- (a) A bottled water system shall monitor for chemical contaminants after treatment but before bottling, with no intervening stagnant storage.
- (b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant.
- (c) A bottled water system shall monitor for chemical contaminants:
1. Annually for inorganic and organic contaminants established in 401 KAR 8:250, including sodium;
 2. Annually for secondary contaminants established in 401 KAR 8:600, except that a bottled water system may exceed maximum secondary contaminant levels for purposes of bottling mineral water or other water if:
 - a. Each consumer is informed by labeling as established in 902 KAR 45:050; and
 - b. The system obtains written cabinet approval after:
 - (i) Submitting secondary contaminant results before and after treatment; and
 - (ii) Providing justification for any exceedances;
 3. Annually for lead and copper as established in 401 KAR 8:300;
 4. Annually for total trihalomethanes and haloacetic acids established in 401 KAR 8:510; and
 5. Every four (4) years for radiological contaminants established in 401 KAR 8:550.
- (d) Exception. A bottled water system that uses as its source a public water system as defined in 40 C.F.R. 141.2 and is subject to 401 KAR Chapter 8 may substitute the monitoring results of the public water system to satisfy the requirements of this

subsection if the bottled water system submits a letter to the cabinet postmarked no later than January 30 of each year stating that it shall:

1. Use the annual results of their public water system source for that calendar year; and
2. Conduct monitoring established in this subsection that has not been conducted by the public water system source.

Section 4. Failure to Comply.

(1) A bottled water system that exceeds a MCL or MRDL or otherwise fails to comply with this administrative regulation shall:

- (a) Immediately cease operations;
- (b) Notify the cabinet as established by 401 KAR 8:020, Section 2(7)(c), and the Cabinet for Health and Family Services, Department for Public Health; and
- (c) Not resume operations without the written approval of the cabinet and the Cabinet for Health and Family Services, Department for Public Health.

(2) Enforcement of this administrative regulation shall be pursued for bottled water systems in the same manner as other public water systems.

(401 KAR 008:70. 17 Ky.R. 645; eff. 11-15-1990; 23 Ky.R. 2614; eff. 5-14-1997; 31 Ky.R. 211; 780; eff. 1-4-2005; 41 Ky.R. 320; 1051; eff. 12-5-2014; Crt eff. 10-3-2018; Crt to Am; filing deadline 4-1-2027.)