

1 ENVIRONMENTAL AND PUBLIC PROTECTION CABINET

2 Department for Environmental Protection

3 Division of Water

4 (Amendment)

5 401 KAR 8:700. Bottled water.

6 RELATES TO: KRS 224.10-100, 224-110, 21 C.F.R. 165.110 [~~Chapter 224~~]

7 STATUTORY AUTHORITY: KRS 224.10-100, 224.10-110, 21 C.F.R. 165.110

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-110 directs the cabinet to
9 enforce the administrative regulations adopted by the secretary for the regulation and control of the
10 purification of water for public and semipublic use. The purpose of this administrative regulation is
11 to set out provisions to assure the purity of water, placed in bottles, that will be resold as a food for
12 human consumption or other consumer use. The U.S. Environmental Protection Agency has no
13 federal regulation relating to bottled water; [;] therefore, this administrative regulation it is not more
14 stringent than federal requirements. The U.S. Food and Drug Administration regulates the labeling
15 of bottled water and requires some testing but does not require reporting of the test results. This
16 administrative regulation requires testing of bottled water and that those results be reported to the
17 cabinet.

18 Section 1. A [~~AH~~] bottled water system [~~systems~~] shall comply with the provisions of 401
19 KAR Chapter 8 [~~8:010 through 8:700, inclusive,~~] with the following exceptions and provisions:

20 (1) Distribution systems and free chlorine.

21 (a) Administrative regulations pertaining to distribution systems of a public water system,

1 including provisions for a free chlorine residual, shall not apply.

2 (b) The requirements of 401 KAR 8:160 and 401 KAR 8:510 shall not apply to a bottled
3 water system, unless specifically included by this administrative regulation.

4 (c) Administrative regulations for the packaging and distribution of water after placement in a
5 bottle may be found at 902 KAR Chapter 45 and in other applicable administrative regulations.

6 (2) Microbiological sampling. A [~~AH~~] bottled water system [~~systems~~] shall conduct
7 microbiological sampling and testing at least once a week. Tests shall otherwise conform to the
8 administrative regulations in 401 KAR Chapter 8 relating to microbiological sampling and testing.

9 (3) Samples location. (a) Except as provided in paragraph (b) of this subsection, [~~AH~~]
10 samples shall be taken after the disinfection of the water and prior to the water being placed in the
11 bottle, with no intervening stagnant storage.

12 (b) A sample may be taken from a bottle immediately after bottling and before the bottle
13 leaves the plant, if all other sampling procedures are met.

14 (c) Water located in the line after bottling operations cease shall be flushed before bottling is
15 resumed.

16 (4) Turbidity sampling. For all bottled water systems, regardless of source, turbidity sampling
17 shall be conducted once every four (4) hours the system is in operation. The system may substitute
18 continuous monitoring for grab sampling, with cabinet approval, and may use the turbidity value for
19 every four (4) hours to determine compliance with the turbidity performance criterion. The
20 turbidity level of the system's product water shall be less than or equal to three-tenths (0.3)
21 [~~five-tenths (0.5)~~] nephelometric turbidity units, [~~(~~] NTU, [~~)~~] in at least ninety-five (95) percent of
22 the measurements taken each month, and shall never exceed one (1) NTU.

23 (5) [~~Other~~] Sampling, MCL, and MRDL for other contaminants.

1 (a) MCLs. 1. Except for lead and copper, the MCL for a contaminant for which testing is
2 required in this subsection shall be as specified in 401 KAR 8:250, 401 KAR 8:400, 401 KAR
3 8:420, and 401 KAR 8:510.

4 2. Lead and copper. The MCL shall be:

5 a. Lead: 0.005 mg/L; and

6 b. Copper: one and zero-tenths (1.0) mg/L.

7 3. Within twenty-four (24) hours of receiving the test results, a bottled water system shall
8 report to the cabinet violations of the MCL for chlorite and bromate and shall immediately stop
9 bottling operations.

10 (b) MRDLs. 1. Except as provided in subparagraph 2 of this subsection, the MRDL for
11 disinfectants shall be as specified in 401 KAR 8:510.

12 2. The MRDL for chlorine dioxide shall be as specified in 401 KAR 8:510, Section 3. No
13 two (2) consecutive daily samples shall exceed the MRDL, monitored at the treatment plant after
14 treatment.

15 3. A bottled water system shall report to the cabinet a violation of the MRDL for chlorine
16 dioxide as soon as possible after learning of the exceedance, and shall immediately take steps to
17 lower the level of chlorine dioxide in the system.

18 (c) Sampling. 1. A bottled water system shall monitor annually for the following:

19 a.(i) Contaminants specified in 401 KAR 8:250, 401 KAR 8:400, and 401 KAR 8:420, except
20 as provided in subclause (ii) of this clause.

21 (ii) A bottled water system that uses as its source a public water system subject to 401 KAR
22 Chapter 8 may, with written approval from the cabinet, substitute the monitoring results of the
23 public water system for the monitoring required by clause a of this subparagraph. The bottled water

1 system shall submit a letter by January 30 of each year, stating that they will use the annual results
2 of their purchasing system; the system shall include the PWSID of the purchasing system.

3 b. Lead;

4 c. Copper;

5 d. Total trihalomethanes, or TTHMs; and

6 e. Haloacetic acids, or HAAs;

7 2. A bottled water system shall monitor for radionuclides every four (4) years pursuant to
8 401 KAR 8:550. [All other sampling for maximum contaminant levels and unregulated
9 contaminants shall be conducted on the same schedule as community water systems.]

10 (6) Disinfection [~~methods~~]. (a) Disinfection shall [~~may~~] be by chlorination, ultraviolet light,
11 ozonation, chlorine dioxide, or other method approved by the cabinet that provides equivalent
12 treatment.

13 (b) A bottled water system that uses:

14 1. Chlorine dioxide shall monitor for chlorite daily in the treatment plant; or

15 2. Ozone shall monitor monthly for bromate in the treatment plant, or may, with written
16 approval from the cabinet, reduce bromate monitoring in accordance with 401 KAR 8:510, Section
17 6, except that the system shall continue to monitor for bromide.

18 (7) Surface water treatment. Bottled water systems using surface water sources may, with
19 cabinet approval, use treatment techniques that are different from other surface water users, if
20 equivalent treatment is provided.

21 (8) Maximum contaminant level exception labeling. With approval of the cabinet, bottled
22 water systems may exceed maximum contaminant levels for secondary contaminants for purposes
23 of bottling “mineral water” or other water, if [~~provided~~] consumers are informed by proper labeling.

1 (9) Water bottled outside Commonwealth. Water bottled outside Kentucky shall not be
2 subject to [is not covered by] this administrative regulation, regardless of its source.

3 (10)(a) Analyses shall be performed in accordance with methods approved by 401 KAR
4 Chapter 8 or 21 C.F.R. 165.110, in laboratories that are certified to conduct testing pursuant to 401
5 KAR Chapter 8.

6 (b) Monitoring results shall be received by the cabinet no later than the tenth day of the month
7 following the end of the reporting period.

8 (11) The public notification requirements of 401 KAR 8:070 and the reporting requirements of
9 401 KAR 8:075 shall not apply to a bottled water system.

10 Section 2. Failure to Comply. A [Any] bottled water system that exceeds a maximum
11 contaminant level or MCL, or a maximum residual disinfectant level or MRDL, or otherwise
12 [which] fails to comply with the [any of these] administrative regulations in 401 KAR Chapter 8
13 shall:

14 (1) Immediately cease operations; [~~shall~~]

15 (2) Notify the cabinet and the Cabinet for Health and Family Services, Department for Public
16 Health; [~~;~~] and [~~shall~~]

17 (3) Not resume operation without the written approval of the cabinet.

401 KAR 8:700 Approved for promulgation:

Date

LaJuana S. Wilcher, Secretary
Environmental and Public Protection Cabinet

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on July 21, 2004 at 1:00 p.m. (Eastern time) in Conference Room D-16 at the Department of Surface Mining, #2 Hudson Hollow, Frankfort, Kentucky. Individuals interested in being heard at this hearing shall notify this agency in writing by July 14, 2004, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. If you request a transcript, you may be required to pay for it. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until August 2, 2004. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

PARKING NOTE: Persons interested in attending the public hearing, other than those with handicap parking plates or placards, are asked to park in the "upper" parking lot on Hudson Hollow, next to the Little Lamb Preschool behind the hedge, and not in the visitor parking lot or main parking lot.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 401 KAR 8:700

Contact Person: Jeffrey W. Pratt, Director

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation prescribes the requirements for public water systems that bottle water in Kentucky for sale to customers.
- (b) The necessity of this administrative regulation: KRS 224.10-100(30) and 224.10-110 authorize the cabinet to promulgate administrative regulations for the regulation and control of the purification of water for public and semipublic use. This administrative regulation is necessary to prescribe requirements for public water systems that bottle water in Kentucky for public sale, thus protecting their public health.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation is one aspect of the overall program for the regulation and control of the purification of water for public and semipublic use.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides for the control of bottled water systems, which provide water for public use to the citizens of the Commonwealth.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: This administrative regulation is being amended to more correctly prescribe the requirements for bottled water systems. Many of the newer administrative regulations elsewhere in this chapter relate to the distribution system of a public water system. Those requirements are not applicable to a bottled water system. Also, several other requirements apply to individual filters; those requirements also are not applicable to a bottled water system. This administrative regulation is being amended to clarify that those requirements do not apply to bottled water systems. These requirements are consistent with those prescribed by the Food and Drug Administration and the International Bottled Water Association. In addition, although a bottled water system will still monitor for contaminants, the number of tests may not be the same that for a surface water system, and the tests may be performed less frequently.
- (b) The necessity of the amendment to this administrative regulation: These amendments are necessary because some of the requirements throughout Chapter 8 are not applicable to bottled water systems. However, the public still needs to be assured that the water it purchases in bottles is tested similar to other water systems and meets the maximum contaminant levels and maximum residual disinfectant levels for contaminants that are applicable to a bottled water system.
- (c) How the amendment conforms to the content of the authorizing statutes: These amendments will ensure that this aspect of the Cabinet's program for the control and purification of water for public and semipublic use is appropriate for bottled water systems.
- (d) How the amendment will assist in the effective administration of the statutes: This

amended regulation will be a part of the Cabinet's program for the purification of water for public or semipublic use.

- (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation applies to public water systems that bottle water in Kentucky. This administrative regulation does not apply to a bottled water system that bottles water outside the Commonwealth. There are ten bottled water systems in Kentucky to which this administrative regulation applies, all of which are owned by private entities. There are no state or local governments that own or operate a bottled water system.
- (4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment: These amendments clarify what portions of the new requirements are applicable to a bottled water system. In some respects, the amendments represent deleting some requirements. However, those requirements that are being deleted are not applicable to bottled water systems, therefore these amendments merely represent a clarification of the Cabinet's intent for bottled water systems.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: There are no initial costs; bottled water systems would not have to provide exactly the same type of monitoring that other water systems provide.
 - (b) On a continuing basis: There are no continuing costs as a result of these amendments.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Monies allocated by the Kentucky General Assembly in its biennial budget will be used to implement and enforce the administrative regulations throughout 401 KAR Chapter 8, including this administrative regulation.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase in fees or funding will be necessary to implement this administrative regulation on bottled water systems.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or directly or indirectly increase any fees.
- (9) TIERING: Is tiering applied? Yes. Tiering is applied because this administrative regulation applies only to bottled water systems. This administrative regulation prescribes fewer monitoring requirements for bottled water systems than for other public water systems.

FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation#: 401 KAR 8:700

Contact Person: Jeffrey W. Pratt, Director

1. Federal statute or regulation constituting the federal mandate. There is no federal mandate for bottled water systems.
2. State compliance standards. 401 KAR 8:700.
3. Minimum or uniform standards contained in the federal mandate. There is no federal mandate.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements than those required by the federal mandate? There is no federal mandate.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. There is no federal mandate.

FISCAL NOTE ON LOCAL GOVERNMENT

Administrative Regulation#: 401 KAR 8:700

Contact Person: Jeffrey W. Pratt, Director

Telephone: (502) 564-3410

1. Does this administrative regulation relate to any aspect of a local government, including any service provided by that local government? Yes _____ No X

2. State what unit, part, or division of local government this administrative regulation will affect. This administrative regulation will not affect any local government.

3. State, in detail, the aspect or service of local government to which this administrative regulation relates, including identification of the applicable state or federal statute or regulation that mandates the aspect or service or authorizes the action taken by the administrative regulation. This administrative regulation will not affect any local government.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a local government for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): There is no anticipated effect on current revenues since this administrative regulation does not affect local governments.

Expenditures (+/-): There is no anticipated effect on current expenditures since this administrative regulation does not affect local governments.

Other explanation: None.