

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 8. DEPARTMENT OF HEALTH SERVICES FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

PREAMBLE

1. Sections Affected

R9-8-201
R9-8-202
R9-8-202
R9-8-203
R9-8-203
R9-8-204
R9-8-204
R9-8-205
R9-8-205
R9-8-206
R9-8-206
R9-8-207
R9-8-208
R9-8-209

Rulemaking Action

Amend
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
Repeal
Repeal

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-132(A)(13) and 36-136(H)(6)

3. The effective date of the rules:

November 23, 2004

4. A list of the previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 9 A.A.R. 4670, October 31, 2003

Notice of Proposed Rulemaking: 10 A.A.R. 616, February 27, 2004

5. The name and address of the agency personnel with whom persons may communicate regarding the rulemaking:

Name: Will Humble, Bureau Chief

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or

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Notices of Final Rulemaking

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6. An explanation of the rule, including the agency's reasons for initiating the rule:

This rulemaking is authorized under A.R.S. § 36-136(H)(6), which requires the Department to make rules for the inspection and certification of bottled drinking water sources, plants, processes and transportation. In addition, this rulemaking is authorized under A.R.S. §§ 41-1072 through 41-1079, which requires the Department to establish licensing time-frames for applications acted upon by the Department. The Department is amending the rules for bottled water that are in A.A.C. Title 9, Chapter 8, Article 2. R9-8-201 is amended to reflect the changes made to the definitions in the Article. R9-8-202 is amended to explain the general requirements necessary for an approval of a source. R9-8-203 is amended to include the application requirements for an approval of a source. R9-8-204 contains the time-frame requirements as authorized under A.R.S. §§ 41-1072 through 41-1079. R9-8-205 explains the source quality testing requirements for bottled water processed and sold in Arizona and R9-8-206 contains the labeling requirements for bottled water processed and sold in Arizona. The Department is repealing R9-8-207 through R9-8-209. The amended rules conform to current statutory authority, rulemaking format and style requirements, industry practice, and departmental policy.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not to rely on in its evaluation of or justification for the rule, where the public may obtain or review the study, all data underlying each study, and any analysis of the study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The purpose of this rulemaking is to amend the rules for bottled water contained in A.A.C. Title 9, Chapter 8, Article 2, to include quality standards for bottled water that is processed and sold in Arizona. The U.S. Food and Drug Administration (FDA) is responsible for regulating bottled water that is sold into interstate commerce. The FDA has specific regulations for bottled water in Title 21 of the Code of Federal Regulations (21 CFR). The current rules for bottled water cite CFR provisions that no longer contain the quality standards for bottled water. The proposed rules cite to the CFR that contains the current quality standards for bottled water.

Annual cost/revenues are designated as minimal when less than \$1,000.00, moderate when between \$1,000.00 and \$10,000.00, and substantial when greater than \$10,000.00.

This rulemaking directly impacts any person that processes and sells bottled water, county health departments, and the Department. The cost to a person processing and selling bottled water will depend on the amount of quality testing the person is performing on the bottled water that the person is producing and selling. The cost to county health departments to inspect the quality of the bottled water is expected to be moderate. In 2002, there were 35 food establishments processing and selling bottled water in Arizona. The statewide goal is to inspect each of the food establishments processing and selling bottled water at least twice a year. The Department and county health departments conducted 79 inspections under A.A.C. Title 9, Chapter 8, Article 1, but were unable to inspect the quality of the bottled water because the current rules cite CFR provisions that no longer contain the quality standards for bottled water. Under the proposed rules, the county health departments will be able to inspect the quality of the bottled water being processed and sold. The cost to the county health departments to inspect for quality purposes includes the additional time needed to review the quality testing records maintained by the plant operator.

The Department will incur minimal costs for making and enforcing the rules. Costs for making the rules include staff time to write, review, and direct the rules through the rulemaking process and to create an approval of source application form to reflect the amended rules. The cost of enforcing the rules includes staff time to track the source approval time-frames and draft written notices.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

A Notice of Proposed Rulemaking was published on February 27, 2004. The Department held an oral proceeding on the proposed rules on April 1, 2004 and received written and oral comments during the comment period. The Department made the following changes in response to the written and oral comments:

R9-8-201. Definitions

In the definition of "Processes", the Department changed the word "make" to "ensure".

In the definition of "Spring", the Department is correcting the CFR citation. The proposed rule contained the correct CFR subpart but the incorrect subsection reference.

Notices of Final Rulemaking

11. A summary of the comments made regarding the rule and the agency response to them:

The following table summarizes the comments received by the Department and provides the Department's response to each comment.

Public Comment	ADHS Response
<p>One commenter noted that the Department incorporates by reference definitions from the FDA. The commenter is concerned that these incorporations by reference will not be updated in a timely manner if the FDA definitions are changed because the incorporation language includes the phrase, "and including no future editions or amendments". The commenter urges the Department to make changes in the bottled water rules as quickly as possible to reflect any changes made to the FDA definitions.</p>	<p>The Department appreciates the concerns raised by the commenter. The commenter is correct in its conclusion that if the FDA definitions change, the bottled water rules will also have to be changed through the regular rulemaking process governed by the Arizona Administrative Procedure Act. The language used in the incorporation by reference is the language prescribed by the Arizona Secretary of State's Office. The Department will monitor the FDA definitions to ensure that if any changes are made, the changes will be addressed as quickly as possible within the regular rulemaking process.</p>
<p>One commenter recommended that the Department change the proposed definition in R9-8-201(17) to reference 21 CFR 165.110(a)(2)(vi), which is the FDA regulatory definition of "spring water".</p>	<p>The Department is clarifying the proposed definition in R9-8-201(17) to read "“Spring” has the same meaning as “spring water” in 21 CFR 165.110(a)(2)(vi) incorporated by reference, on file with the Department, including no future editions or amendments, available at http://www.gpoaccess.gov/cfr/index.html and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401." The term “spring” is defined within 21 CFR 165.110(a)(2)(vi), which is the FDA definition of “spring water”. The proposed rule contained the correct CFR subpart but the incorrect subsection reference.</p>
<p>One commenter recommended that the Department incorporate the entire FDA definition of “bottled water” under 21 CFR 165.110(a), which also includes the standards of identity for bottled water in 21 CFR 165.110(a)(2) and would provide for a uniform nomenclature that describes the various types of bottled water.</p>	<p>The Department recognizes the need for uniform nomenclature that describes the various types of bottled water. However, the Department considers the need for uniform nomenclature terms a labeling issue and covered by the Arizona Food Code in A.A.C. Title 9, Chapter 8, Article 1, and the proposed R9-8-206. Under A.A.C. Title 9, Chapter 8, Article 1, any individual who processes and sells bottled water in Arizona is required to be licensed as a food establishment. The labeling of food is addressed in R9-8-107. Additional labeling requirements specific to bottled water are in the proposed R9-8-206. The Department is not making changes in response to this comment.</p>
<p>One commenter recommended changing the word “make” in R9-8-201(13) to “assure” to clarify that specific treatment or disinfection in the processing of source water into bottled water is not required.</p>	<p>The Department is modifying R9-8-201(13) to read “Processes” means the steps taken to ensure source water meets the quality standards for bottled water in 21 CFR 165.110(b), incorporated by reference, on file with the Department, including no future editions or amendments, available at http://www.gpoaccess.gov/cfr/index.html and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.”</p>
<p>One commenter supported the testing of finished bottled water to ensure the product received by the consumer meets the standards of quality and the good manufacturing practices of FDA regulations.</p>	<p>The Department appreciates the support.</p>

Notices of Final Rulemaking

<p>One commenter recommended the Department add language to the proposed rulemaking that restricts the use of multi-purpose equipment in the processing and sale of bottled water. The commenter recommended using the following provision as a substitute for the current language in R9-8-207 of the Arizona bottled water rules:</p> <p><i>“Water intended for bottling shall not be stored, transported, processed, or bottled through equipment or lines used for milk, other dairy products, and non-beverage foods. 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 HACCP plan, and shall include provisions for monitoring, critical limits, appropriate corrective action, and records.”</i></p> <p>The Department is repealing R9-8-207 in the proposed rulemaking.</p>	<p>The Department acknowledges the concern of the commenter with regard to the use of multi-purpose equipment in the processing and sale of bottled water. However, there are current sanitary requirements for the use of multi-purpose equipment in the Arizona Food Code in A.A.C. Title 9, Chapter 8, Article 1. Under A.A.C. Title 9, Chapter 8, Article 1, any individual who processes and sells bottled water in Arizona is required to be licensed as a food establishment. The sanitary requirements for multi-purpose equipment are addressed in R9-8-107. Therefore, the Department is not making changes in response to this comment.</p>
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12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

The following is incorporated by reference in R9-8-201(4):

21 CFR 165.110(a)(1) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

The following is incorporated by reference in R9-8-201(13):

21 CFR 165.110(b) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

The following is incorporated by reference in R9-8-201(17):

21 CFR 165.110(a)(2)(vi) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

The following is incorporated by reference in R9-8-203(B):

21 CFR 165.110(b) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

The following is incorporated by reference in R9-8-205(A):

21 CFR 129.80(g) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

The following is incorporate by reference in R9-8-206:

21 CFR 129.80(e) (2003), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

ARTICLE 2. BOTTLED WATER

Section

R9-8-201.	Definitions
R9-8-202.	Water quality and source <u>General Requirements</u>
R9-8-203.	Processing practices <u>Application for an Approval of a Source</u>
R9-8-204.	Labeling requirements <u>Time-frames</u>
R9-8-205.	Source water sampling <u>Quality Testing Requirements</u>
R9-8-206.	Finished Product Monitoring <u>Labeling Requirements</u>
R9-8-207.	Transportation Vehicles <u>Repealed</u>
R9-8-208.	Certification and Inspection <u>Repealed</u>
R9-8-209.	Public Nuisance <u>Repealed</u>

ARTICLE 2. BOTTLED WATER

R9-8-201. Definitions

In this Article, unless the context otherwise requires:

1. ~~“Approved source”, when used in reference to a plant's water product 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, municipal water supply or any other source that has been inspected by the Arizona Department of Environmental Quality and issued a certificate or notification of approval.~~
1. “Applicant” has the same meaning as in R9-8-101.
2. “Aquifer” means a layer of underground sand, gravel or porous rock where water collects.
- 2-3. ~~“Artesian well water” means natural water from a drilled well tapping that accesses an aquifer in which the water level will stand that stands above the bottom of the confining bed of the aquifer, and in which the hydraulic pressure of the water in the aquifer is greater than the force of gravity.~~
3. ~~“Bottled water” means water that is from an approved source and is placed by a food establishment in a sealed container or package for human consumption or other consumer uses and has been produced by any of the processes described in R9-8-203 or which has undergone minimum treatment consisting of filtration (activated carbon and/or particulate) and ozonation or an equivalent process.~~
4. “Bottled water” has the same meaning as in 21 CFR 165.110(a)(1) incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.
5. “Bottled water plant” means a food establishment that processes and sells bottled water.
4. ~~“Carbonated water” means bottled water containing carbon dioxide. It is also known as “sparkling water” or “soda water”.~~
5. ~~“Cleaning in place” means the automatic or mechanical cleaning and/or sanitizing of a stationary piece of equipment.~~
6. ~~“CFR” means the Code of Federal Regulations.~~
7. “Confining bed” means a layer of ground that resists water penetration.
- 7-8. ~~“Department” means the Arizona Department of Health Services or a local health department designated by the Director.~~
9. “Drilled well” means a hole bored into the ground to reach underground water.
10. “Food establishment” has the same meaning as in A.A.C. Title 9, Chapter 8, Article 1.
8. ~~“Distilled water” means water which has been produced by a process of distillation and meets the definition of purified water on page 1124 of The United States Pharmacopoeia (21st rev.) dated 1985, Mack Publishing Company, Easton, Pennsylvania 18042, incorporated herein by reference and on file with the Office of the Secretary of State.~~
9. ~~“Drinking water” means water obtained from an approved source for purposes of human consumption.~~
10. ~~“Filler equipment” means a machine used for the purpose of bottling or packaging liquids.~~
11. ~~“Fluoridated water” means water containing naturally occurring or added fluoride of not less than 0.8 milligram per liter fluoride ion and complying with the Food and Drug Administration quality standards set forth in 21 CFR 103.35(d)(2) (4-1-89 Ed.), incorporated herein by reference and on file with the Office of the Secretary of State~~
12. ~~“Mineral water” means “natural water” that contains not less than 500 parts per million dissolved mineral solids and whose source is approved by the Department of Environmental Quality.~~
13. ~~“Mineralized water” means water which has been modified by mineral addition or deletion and contains not less than~~

Notices of Final Rulemaking

500 parts per million dissolved mineral solids and whose source is approved by the Department of Environmental Quality.

14. "Natural water" means spring, artesian well or well water, derived from an underground formation, which is unmodified by blending with water from another source or by mineral addition or deletion but may be treated to reduce the concentration of any substance, except minerals, to meet the safe drinking water standards established by the Arizona Department of Environmental Quality.
15. "Naturally carbonated" or "naturally sparkling" means water that contains carbon dioxide and that emerges from the source and is bottled directly with its entrapped gas or from which the gas is mechanically separated from the water and later reintroduced into the water at the time of bottling.
16. "Purified water" means water produced by distillation, deionization or reverse osmosis and meets the definition of purified water on page 1124 in The United States Pharmacopoeia (21st rev.) dated 1985, Mack Publishing Company, Easton, Pennsylvania 18042, incorporated herein by reference and on file with the Office of the Secretary of State.
17. "Soda water" means bottled water containing carbon dioxide.
11. "Licensed laboratory" means a laboratory licensed by the Department under A.R.S. Title 36, Chapter 4.3, Article 1.
12. "Plant operator" means an individual designated by the applicant to operate a specific bottled water plant.
13. "Processes" means the steps taken to ensure source water meets the quality standards for bottled water in 21 CFR 165.110(b), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.
14. "Public water system" has the same meaning as in A.A.C. R18-4-101.
15. "Source" means an artesian well, drilled well, public water system, or spring.
16. "Source water" means water from an artesian well, drilled well, public water system, or spring.
18. "Sparkling water" means bottled water containing carbon dioxide.
17. "Spring" has the same meaning as "spring water" in 21 CFR 165.110(a)(2)(vi) incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.
19. "Spring water" means water other than artesian that is derived from a natural underground stratum that flows naturally or by external enhancement to the surface through a natural orifice or from a bore hole adjacent to the natural orifice and which meets the requirements of "natural water".
20. "Well water" means water from a hole bored into the ground which taps the water of the aquifer and which meets the requirements of "natural water".

R9-8-202. ~~Water quality and source~~ General Requirements

- A.** All bottled water processed in Arizona shall be obtained from a source whose quality is approved by the Director of the Department of Environmental Quality in accordance with the provisions of the A.A.C. Title 18, Chapter 4, Article 2.
- B.** With the exception of mineral water, mineralized water and carbonated water, bottled water processed or sold in Arizona shall meet or exceed the minimum quality standards prescribed by 21 CFR 103.35 (4-1-89 Ed.), incorporated herein by reference and on file with the Office of the Secretary of State.

A food establishment that processes and sells bottled water in Arizona shall use a source approved by the Department.

R9-8-203. ~~Processing practices~~ Application for an Approval of a Source

- A.** All bottled water processed or sold in Arizona shall be processed and packaged in accordance with the U.S. Food and Drug Administration's Good Manufacturing Practice regulations for bottled water beginning at 21 CFR 129 (4-1-89 Ed.), incorporated herein by reference and on file with the Office of the Secretary of State.
- B.** Bottled water shall not be processed or bottled through a line or other equipment used for any other purpose, except that filler equipment used to bottle liquids intended for human consumption may also be used to bottle water, provided:
 1. Filler and processing equipment, unless specifically designed for cleaning in place, shall be completely disassembled and cleaned after each use and sterilized after assembly.
 2. A separate set of gaskets, O-rings and similar flexible material is used for bottling water.
 3. A physical break exists between all processing lines at the filler inlet.
- C.** The provisions of R9-8-203(B) shall not apply to soft drink bottling operations processing carbonated water.
- A.** An applicant shall complete and submit to the Department, an application for an approval of a source on a form provided by the Department that includes:
 1. The name, mailing address, and telephone number of the applicant;
 2. The name, street address, and telephone number of the bottled water plant;
 3. The location of the source used at the bottled water plant;
 4. The applicant's signature; and
 5. The date the application is signed.
- B.** With the completed application, an applicant shall include test results from a licensed laboratory that has tested the bottled water according to the quality requirements for bottled water in 21 CFR 165.110(b), incorporated by reference, on file

with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

C. An applicant shall comply with subsections (A) and (B) for each source used at the bottled water plant.

R9-8-204. Labeling requirements Time-frames

A. All bottled water processed or sold in Arizona shall conform to the requirements established in A.R.S. § 36-906 and shall be labeled in compliance with one of the following standards:

1. Mineral water shall be labeled "mineral water" or "natural mineral water".
2. Mineralized water shall be labeled "mineralized water".
3. Spring water shall be labeled "spring water" or "natural spring water".
4. Naturally carbonated or naturally sparkling water shall be labeled with the words "naturally carbonated" or "naturally sparkling".
5. Bottled water which contains carbon dioxide, other than "naturally carbonated or naturally sparkling", shall be labeled with the words "carbonated" or "sparkling" or "soda water".
6. Well water shall be labeled "well water" or "natural well water".
7. Artesian well water shall be labeled "Artesian well water", "natural artesian well water" or "natural well water".
8. Purified water shall be labeled "purified water" and the method of preparation shall be stated on the label except that purified water produced by distillation may be labeled "distilled water".
9. Drinking water shall be labeled "drinking water".

B. Any bottler, distributor, or vendor of bottled water whose corporate name, brand name or trademark contains the words "well" "artesian well", "natural" or any derivation of these words shall label each bottle with the source of the water in typeface at least equal to the size of the typeface of the corporate name or trademark if the actual source of the bottled water is different from the source stated in the corporate name, brand name or trademark.

C. The use of words "spring", "spring fresh", "spring brand", "spring type" or other language containing the word "spring" in a corporate name, brand name or trademark, or in describing water, is prohibited unless the water is "spring water" as defined in R9-8-201.

D. Supplemental printed information and graphics concerning recognized uses of the water may appear on the label but shall not imply properties of the product or preparation methods which are not accurate.

A. The overall time-frame described in A.R.S. § 41-1072 for the Department to act on an application for an approval of a source is 60 days. The applicant and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame by no more than 25% of the overall time-frame.

B. The administrative completeness review time-frame described in A.R.S. § 41-1072 for an application for an approval of a source is 30 days and begins on the date the application is received.

1. The Department shall mail notice of administrative completeness or deficiencies to the applicant within the administrative completeness review time-frame.

a. A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the application.

b. If the Department issues a notice of deficiencies within the administrative completeness review time-frame, the administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice is issued until the date the Department receives the missing information from the applicant.

c. If the applicant fails to submit to the Department all the information and documents listed in the notice of deficiencies within 60 days of the date the Department mailed the notice of deficiencies, the Department deems the application for approval of a source withdrawn.

2. If the Department issues an approval of a source to the applicant during the administrative completeness review time-frame, the Department does not issue a separate written notice of administrative completeness.

C. The substantive review time-frame described in A.R.S. § 41-1072 is 30 days and begins on the date the notice of administrative completeness is mailed to the applicant.

1. The Department shall mail an approval of a source or a written notification of denial of approval to the applicant within the substantive review time-frame.

2. If the Department issues a comprehensive written request or supplemental request for information, the substantive review time-frame and the overall time-frame are suspended from the date the Department issues the request until the date the Department receives all of the information.

3. If the Department denies approval of a source, the Department shall send the applicant a written notice of disapproval that lists the reasons for disapproval and all other information required in A.R.S. § 41-1076.

D. If a time-frame's last day is on a Saturday, Sunday, or legal holiday, the Department considers the next business day as the time-frame's last day.

R9-8-205. Source water sampling Quality Testing Requirements

A. Samples shall be taken of approved sources of water by plant operators or their agents according to the schedule established in A.A.C. R18-4-223.

Notices of Final Rulemaking

- ~~B.~~ Sampling and analyses shall be by laboratories certified in accordance with A.A.C. R9-14-602 and shall be in addition to any sampling performed by the Department.
- ~~C.~~ Original laboratory records of bacteriological analyses shall be kept by the bottler for five years. Records of chemical analyses shall be kept ten years.
- ~~A.~~ To maintain approval of its source, a plant operator shall have a licensed laboratory test the quality of the bottled water at the times stated in 21 CFR 129.80(g), incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.
- ~~B.~~ A plant operator shall maintain records of the quality testing of the bottled water on the bottled water plant premises for two years from the date the bottled water is tested and ensure that the records are readily available for inspection by the Department.

R9-8-206. ~~Finished product sampling~~ Labeling Requirements

- ~~A.~~ To assure that the plant's production of bottled water is in compliance with 21 CFR 103.35 (4-1-89 Ed.), incorporated herein by reference and on file with the Office of the Secretary of State, the plant shall have the following analyses performed by a laboratory certified according to the provisions of A.A.C. R9-14-602:
 - 1. A representative sample from a batch or segment of a continuous production for each type of bottled water produced by the plant shall be analyzed weekly for microbiological purposes.
 - 2. A representative sample from a batch or segment of a continuous production for each type of bottled water produced by the plant shall be analyzed annually for chemical, physical and radiological compliance.
- ~~B.~~ The representative samples required in subsection (A) above shall be derived from the bottled product.
- ~~C.~~ Records of the sampling and analyses shall be maintained on file at the place of operation for a period of two years and shall be made readily available to the Director.

In addition to the labeling requirements in A.A.C. Title 9, Chapter 8, Article 1, a plant operator shall ensure the bottled water processed and sold is labeled according to 21 CFR 129.80(e) incorporated by reference, on file with the Department, including no future editions or amendments, and available at <http://www.gpoaccess.gov/cfr/index.html> and from U.S. Government Printing Office, 732 N. Capital Street, NW Washington, DC 20401.

R9-8-207. ~~Transportation vehicles~~ Repealed

- ~~A.~~ Bottled water shall be transported in vehicles used only for the transportation of food and other non-toxic products.
- ~~B.~~ All vehicles transporting bottled water shall be clean and shall protect the bottled water from dust, dirt, insects and other vermin.

R9-8-208. ~~Certification and inspection~~ Repealed

- ~~A.~~ Upon application by an establishment, pursuant to R9-8-119, a bottled water processing certificate shall be issued prior to the establishment's operation and shall be valid for a period of one year. An establishment shall apply for renewal of its certificate no later than 60 days prior to its expiration.
- ~~B.~~ A bottled water processing certificate shall be issued when the bottler has complied with all provisions of this Article and has in its possession a certificate form the Department of Environmental Quality approving the water source.
- ~~C.~~ All bottled water processors shall be inspected prior to licensure and once every six months thereafter for compliance with the minimum standards of this Article.

R9-8-209. ~~Public nuisance~~ Repealed

- ~~A.~~ Any water supply, label, premises, equipment, process or vehicle which does not comply with the minimum standards of this Article shall be considered a public nuisance.
- ~~B.~~ All bottled water public nuisances shall be abated by revocation of the bottling establishment's permit or through the procedures established in A.R.S. § 36-601 or by any other means permissible by law.