#### ARTICLE 2. BOTTLED WATER

#### R9-8-201. Definitions

In this Article, unless the context otherwise requires:

- 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.
- 3. "Artesian well" means a drilled well that accesses an aquifer with a water level that stands above the bottom of the confining bed of the aquifer.
- 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. Capitol Street, N.W. Washington, D.C. 20401.
- 5. "Bottled water plant" means a food establishment that processes and sells bottled water.
- 6. "CFR" means the Code of Federal Regulations.
- 7. "Confining bed" means a layer of ground that resists water penetration.
- 8. "Department" means the Arizona Department of Health Services.
- 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.
- 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. Capitol Street, N.W. Washington, D.C. 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.
- 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. Capitol Street, N.W. Washington, D.C. 20401.

## **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Amended by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

#### **R9-8-202.** General Requirements

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

### **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed; new Section made by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

## R9-8-203. Application for an Approval of a Source

- 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 <a href="http://www.gpoaccess.gov/cfr/index.html">http://www.gpoaccess.gov/cfr/index.html</a> and from U.S. Government Printing Office, 732 N. Capitol Street, N.W. Washington, D.C. 20401.
- C. An applicant shall comply with subsections (A) and (B) for each source used at the bottled water plant.

### **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed; new Section made by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

#### R9-8-204. Time-frames

- 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.

#### **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed; new Section made by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

## **R9-8-205.** Quality Testing Requirements

- 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. Capitol Street, N.W. Washington, D.C. 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.

## **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed; new Section made by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

### **R9-8-206.** Labeling Requirements

In addition to the labeling requirements in 9 A.A.C. 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. Capitol Street, N.W. Washington, D.C. 20401.

## **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed; new Section made by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

# **R9-8-207. Repealed**

#### **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

## R9-8-208. Repealed

### **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).

# **R9-8-209. Repealed**

# **Historical Note**

Adopted effective August 6, 1990 (Supp. 90-3). Section repealed by final rulemaking at 10 A.A.R. 4178, effective November 23, 2004 (Supp. 04-3).