



## WATER BOTTLING PLANT (IN-STATE & OUT-OF-STATE) LICENSE APPLICATION PROCEDURES



California Health and Safety Code (H&SC) Section 111120 requires in-state operators of water bottling plants to obtain a Water Bottling Plant License issued by the California Department of Public Health, Food and Drug Branch (FDB).

H&SC Section 111125 requires operators of out-of-state or foreign bottlers to obtain Water Bottling Plant License to sell or distribute bottled water products in California.

The Water Bottling Plant License for in-state or out-of-state firms is non-transferrable and must be renewed annually.

“Bottled water” means any water that is placed in a sealed container to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

A “Water bottling plant” means any facility in which bottled water is produced.

This document will provide you with guidance on how to apply for a new and renewal Water Bottling Plant license. Use the links below to navigate directly to the desired topic.

# I. How to apply for a New IN-STATE Water Bottling Plant License

## A. Application form completion and handling information.

1. Obtain a Water Bottling Plant license application (CDPH 8603) by calling the Water program desk at (916) 324-2170, or by downloading the form online.
2. Complete the application in type or legible print and sign the form. Make sure each section is completed fully. **Incomplete applications will be returned to the applicant.**
3. Source water Information (Items 26 and 27 of the application form):
  - a) If your source water is Public Drinking Water (municipal)
    - You must indicate the name, address and phone number of the public (municipal) water source on the application form. You are not required to analyze the source water, but must obtain a copy of the most recent chemical, physical and microbiological analysis test results for the water.
  - b) If your source water is an FDB licensed Private Water Source Operator ,
    - You must indicate the name of the Private Water Source operator (PWSO) on the application. Provide the source location and the operator's name, phone number, and FDB Private Water Source Operator license number on the application form. **A copy of your purchase agreement with the PWSO can facilitate the application process.**

**Note:** All private water sources, such as wells or springs, **MUST** be licensed. If a well or spring is located on the same property as is the bottling plant, it still **MUST** be licensed as a private water source by FDB.

You may obtain a Private Water Source Operator license application (CDPH 8594) by calling the FDB Water program desk at (916) 650-6500, or by downloading the form online.

*FDB may waive the Private Water Source Operator license **fee** if the private water source is based and operated at the same location as the bottling plant.*

4. Make sure you include a valid telephone number on the application. FDB staff may contact you at the provided number to request clarification or additional information regarding your water bottling plant, labeling, Bottled Water Report, and/or application.
5. Submit your completed application and the non-refundable license fee (check or money order) to the address listed in the application instructions.
6. Submission of the following items is recommended to expedite the licensing process.
  - Copies of water quality test reports
  - Plant schematic diagram and/or process flow
  - Labeling
  - Bottled Water Report

These items will ultimately be required as part of the inspection process. For more details refer to “Water Bottling Plant – Inspection Procedures and Operating Requirements” document located online.

7. After your application is processed you will be contacted by FDB to schedule a licensing inspection. If your water bottling plant is found to be in substantial compliance with all applicable laws and regulations, your license will be processed for issuance.
8. The Water Bottling Plant License is valid for one calendar year. It is your responsibility to renew the license prior to the expiration date printed on the license. See Procedures for renewal of your Water Bottling Plant License for more details.

## II. How to apply for a New OUT-OF-STATE Water Bottling Plant License (including bottlers located in foreign countries)

### A. Application form completion and handling information.

1. Obtain a Water Bottling Plant license application (CDPH 8603) by calling the FDB Water program desk at (916) 650-6500, or by downloading the form online.
2. Complete the application in type or legible print and sign the form. Make sure each section is completed fully. **Incomplete applications will be returned to the applicant.**
3. Source Water Information (items 26 and 27 of the application form):

Source water must be from an approved source. Water from an unapproved source cannot be bottled for importation into California.

- a) If your source water is from a **public water source** (public potable drinking water source):

You must indicate the name, address, and phone number of the public water source on the application form. You must have a copy of the most recent chemical, physical, and microbiological analysis test results for the water. You are allowed to obtain a copy the analysis test results from the public water source supplier.

- b) If your source water is from a **private water source**:

As part of the requirements for licensure, FDB must approve the source from which water is extracted for processing bottled water to import, distribute, or offer for sale in California. In order to evaluate your private water source you must prepare and submit additional information listed in the section titled "Supplemental Application Information."

4. Make sure you include a valid telephone number on the application. FDB staff may contact you to request additional information regarding your OUT OF STATE water bottling plant, water source, labeling, bottled water reports, etc.
5. Submit your completed application, supplemental application information, and the non-refundable license fee (check or money order), per mailing instructions on application.

**PLEASE SUBMIT THE REQUESTED INFORMATION IN ONE COMPLETE PACKAGE TO AVOID DELAYS IN THE APPLICATION REVIEW PROCESS.**

## B. Supplemental Application Information

The items listed below must be included with each out-of state Water Bottling Plant License application form.

### 1. **Source water information**

Submit the following information from a licensed (or certified) Hydrogeologist, Geologist, Engineering Geologist or Hydrogeological Engineer.

- a) Description of the exact source location and a detail map (or drawing) showing the boundary and the location of the natural spring (if applicable), bore hole (if applicable) or well (if applicable) and buildings, storage tanks, and piping.
- b) Review of the hydrogeology surrounding the site including a description of the vertical and horizontal extent of the surface aquifer.
- c) Information on the recharge area or zone of influence of the subject source and documentation that identifies and evaluates actual and potential sources of contamination.
- d) Details of the source development: description and/or diagrams of the method of construction, collection and catchment of source water, storage facility, conveyance and loading systems, underground piping map and treatment systems used. All equipment must have documented proof that it has been approved for potable water use.
- e) Copies of well (borehole) driller's report and/or well (borehole) log; well (borehole) sealing diagram.
- f) If ground water (e.g., spring water, artesian well water, well water), evidence (e.g., microscopic particulate analysis) that it is not under the direct influence of surface water as defined in 40 CFR 141.2.
- g) Substantiating information that the designation of source water (e.g., "spring water", artesian well water", "well water") meets the definition for the terms as specified in H&SC Section 111175 and 21 CFR Part 165.110 (a).
- h) A copy of a permit or an inspection report from a governmental agency which has jurisdiction over the source.
- i) Photographs showing the source, source development (e.g., extraction system), delivery system (e.g., pipes), storage tank(s), etc.

### 2. **Water quality analysis reports**

You must provide water quality analysis reports for both source water and finished product water. The substances to be tested are shown in the "Bottled water and vended water, Source and Product water analysis" document located online.

- a) For public water sources you may obtain water quality analysis reports from your supplier.

- b) For private water sources you must make arrangements with a certified laboratory to conduct the water quality analysis testing.
- c) The source water sample must be collected after completion of the water collection, delivery, and storage system.
- d) If you have multiple sources or multiple water extraction systems, water from each source or extraction system must be analyzed separately.
- e) The water quality of each bottled water type must be analyzed separately. Each bottled water product with a differing mineral profile (e.g. TDS, key minerals), is considered a different bottled water type.

### 3. Water Bottling Plant permits and operation information

Submit legible copies of the following items

- a) A copy of the permit or an inspection report of your bottling facility from a governmental agency which has jurisdiction over the facility.
- b) Schematic or diagram of the water treatment and bottling process.
- c) Evidence of whether the facility has a separate bottling room that complies with 21CFR 129.20(a).
- d) Evidence that the bottling room is operated in a sealed system under pressure.
- e) Specifications of equipment. State on the top of the first page of each specification sheet whether the equipment has been approved for food use and/or potable water use. Include the name of the approval organization. **Equipment advertisements or promotional materials are not acceptable.**
- f) Sanitation procedures.
- g) Information on the “unit package production code” as required by 21CFR Part 129. We suggest that a copy of your “recall plan”, which includes the production code information, be submitted.
- h) Copies of records that are (or will be) maintained as required by 21CFR Part 129. We suggest that a copy of the “product quality control procedure”, which includes the record keeping information, be submitted.
- i) Photographic evidence showing the bottling equipment and facility.

### 4. Product Labels

- a) Provide a label (copies/photographs are acceptable) for each bottled water product you intend to sell or distribute in California.
- b) Labels must comply with both federal and state labeling laws and regulations for bottled water. Refer to 21CFR Part 101 and H&SC Section 111170 to review bottled water labeling requirements..
- c) H&SC Section 111170(f) requires your label to include the following information:
  - i. Contact information. You must provide a telephone number and one other means of contact for the bottled water company, including but not limited to a full mailing address, e-mail address or website address where information can be requested or

obtained. If your firm's website is listed as one of the two contact methods, your bottled water reports must be available on that website.

- ii. Source of the bottled water
- iii. A clear and conspicuous statement that informs consumers about how to access water quality information contained in the bottled water report.

## **5. The Bottled Water Report**

Pursuant to H&SC 111071 all water bottling plants must annually prepare a bottled water report. The report must be prepared in English, and Spanish and you must submit a copy of both bottled water reports (English and Spanish language versions) with your application.

You may review more information regarding the required bottled water report on the "Water Bottling Plant: The Bottled Water Report" guidance document located online.

### III. Procedures for renewal of your Water Bottling Plant License (applicable to in-state & out-of-state water bottlers)

- A. Once licensed, you will receive a Renewal Notice and Application 60 days prior to the expiration date of your license.

Application form sections 1-5 will be pre-filled on the Water Bottling Plant License application. Verify the information, make any corrections, and complete the remaining sections. Make sure each section is completed fully. **Incomplete applications will be returned to the applicant.**

If you do not receive your renewal notice, please contact the Water program desk at (916) 324-2170, or you may download a blank form online.

Submit your renewal application, non-refundable license fee (check or money order), water quality test results, and other required information (see below) to FDB per the mailing instructions.

- B. Water quality analysis test results
- a. **In-State bottlers** are required to submit finished product water analysis reports.
  - b. **Out-of-State bottlers** (including bottlers in foreign countries) must provide the water analysis reports for both source water and finished product water.
- The substances to be analyzed are listed in the “Bottled Water and Vended Water, Source and Product Water Analysis” document.
  - If multiple sources or multiple water extraction systems feed into a common distribution system (e.g. storage tank), you may sample from the common system.
  - Each bottled water product with a differing mineral profile (e.g. TDS, key minerals), is considered a different bottled water type. You must submit the required analysis report for each type of bottled water product.
- C. Product labels
- a. Submit copies or images of all product labels
- D. The Bottled Water Report
- a. Submit an English and Spanish version of your report.