



## California Department of Public Health Food and Drug Branch



### PROCEDURE FOR OBTAINING AN IN-STATE or OUT-OF STATE WATER BOTTLING PLANT LICENSE

(Revised, 6/20/2008)

#### License Application Form: CDPH 8603

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

H&SC Sections 111120 and 111125 requires out-of-state or foreign bottlers to obtain a Water Bottling Plant License issued by FDB to sell or distribute bottled water products in California.

#### LICENSE APPLICATION

Submit a fully completed Water Bottling Plant License Application form with the required fee. To obtain an application form, you may call FDB at (916) 650-6500 or download the form from the FDB website (<http://www.cdph.ca.gov/pubsforms/forms/Pages/FoodandDrug.aspx>; click "Form CDPH 8603").

Important points regarding completion of the application form:

- Include the firm name
- For RENEWAL licenses, include the license number
- Write the phrase "PCA Code 76215" on your check or money order.
- The business address must be that of the bottling plant, not that of the corporate headquarters.
- The mailing address can be that of the plant, corporate headquarters or the firm's branch office.
- Licenses and renewal notices will be sent to the mailing address listed on the application form.
- Proper telephone numbers must be provided to expedite scheduling of inspection appointments.
- **IN-STATE BOTTLERS:** All water sources must be identified on the application form. Only water from a public drinking water supply or from a private water source licensed by FDB can be processed for bottling.
  - Public Drinking Water
    - You must indicate the name, address and phone number of the public (municipal) Water District on the application form. You are not required to analyze the source water, but must obtain a copy of the Water District's most recent chemical, physical and microbiological analysis data for the water.
  - Licensed Private Water Source
    - **You must indicate the name of the private water source on the application. Provide the source location and the operator's name, phone number, and license number on the application form. Include a copy of the purchase contract.**
    - Note: **An unlicensed well or spring, whether owned by the water bottler or not and regardless of whether it is located on the same premise as the bottling plant, cannot be used as a source unless it has already been licensed as a private water source by FDB. Contact FDB at 916-950-6500 to obtain a Private Water Source (PWS) Operator's License Application and the Procedures for Obtaining the PWS Operator's License. FDB may waive the PWS License fee if the private water source is based and operated at the same location as the bottling plant. However, a valid PWS Operator's License is mandatory and all PWS licensing requirements must be met.**
- Keep copies of the source water analytical data in your files. You will need to provide this information to FDB during inspections or as otherwise requested.

- **OUT-OF-STATE (OR FOREIGN) BOTTLERS**

- If Public or Municipal Water is Used as A Source: Provide the name of the water district, address, telephone number and a copy of the water district's most recent chemical, physical, radiological and microbiological analysis for the water.
- If a Private Well or Spring is the Source of the Water:
  - Submit information from a licensed (or certified) Hydrogeologist, Geologist, Engineering Geologist or Hydrogeological Engineer:
    - 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.
    - Review of the hydrogeology surrounding the site including a description of the vertical and horizontal extent of the surface aquifer.
    - 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.
    - 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.
    - 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.
    - 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).
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  - Information from the State, Local Health Agency or Other Approval Authority:
    - Copies of well (borehole) driller's report and/or well (borehole) log; well (borehole) sealing diagram; certificate or permit for satisfactory well construction from the pertinent state or local agency.
    - Sanitary appraisal report for the well or spring
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  - If your source is a spring and the spring water is extracted from a bore hole using external force, you must provide the following information as well:
    - An explanation why a bore hole(s) is used;
    - Evidence, including actual data that:
      - Water flows naturally to the surface of the earth at the natural spring (a copy of the inspection report from the pertinent government agency);
      - Spring water collected from the bore hole is from the same underground stratum as the natural spring, as shown by a measurable hydraulic connection between the bore hold and natural spring. The hydraulic connection must be shown by a hydrogeologically valid method such as the pumping test or dye test).
      - Water from the bore hole has all the physical properties, before treatment, and is of the same composition and quality as the water that flows naturally to the surface of the earth (i.e., natural springs).

- Samples for Testing:
  - All testing must be done on samples collected after completion of the entire system (e.g., well drilling, piping, installation of storage tanks, loading system).
  - If multiple sources or multiple water extraction systems feed into a common distribution system (e.g., storage tank), only the sample from the common system (rather than from each source or extraction system) can be tested, provided that the sources/extraction systems have already been approved. **For a NEW LICENSE, each source (or each water extraction system) must be analyzed separately.**

Any incomplete and/or illegible applications will be RETURNED to the applicant. **License fees are non-refundable. Water Bottling Plant Licenses are non-transferrable to new owners or other locations.** A change of ownership or a change in facility location will require submittal of a NEW application.

The Bottled Water Plant License is valid for one year. It is your responsibility to renew the license prior to the expiration date printed on the license. You will receive a renewal notice from FDB approximately two months before the expiration date of your license. Follow the instructions on the renewal notice and submit the completed application form, a check or money order for the license fee payment, and a copy of water quality tests for the upcoming licensing year (coliform (bacteria), chemical, physical and radiological). If you bottle more than one type of product at the facility, you must submit one set of analysis results for each product. If you do not receive a renewal notice, please contact the FDB Water Desk at (916) 650-6500.

#### INSPECTION and OPERATING REQUIREMENTS

FDB will perform an on-site inspection of **in-state bottling plants** prior to issuance of the license. FDB will also conduct periodic inspections once the license has been issued. Inspections are conducted to ensure that the facility is in compliance with the applicable state and federal laws and regulations.

A. Water Quality Testing: Maintain copies of all water quality test results in your files.

1. Source Water Quality: Maintain copies of current source water quality analysis data in your files. You will need to submit copies of the source water quality analysis data to the FDB investigator during licensing inspections and/or routine inspections.
2. Product Water Quality: Please contact the Water Licensing Desk at 916-650-6500 to obtain a copy of the list of substances to be analyzed. Or, you may download the list at: <http://www.cdph.ca.gov/pubsforms/forms/Pages/FoodandDrug.aspx> (click on "Water Analysis")
  - a. General chemical, physical and radiological quality of water as required by the federal quality standards of bottled water and H&SC Sections 111080 and 111155. See the List of Substances to be Analyzed – Group I, II, III, IV, V and VII) for specific substances.
    - i. You must test each of your product waters for quality at least once every year. The laboratory report must clearly identify your firm name, address and license number.
    - ii. Take four samples for each product and send all samples to the testing laboratory. The laboratory will make a composite of the four samples and test for the substances, except for volatile organic chemicals (VOC's). For VOC's, the laboratory will randomly select one of the four samples from each product to test.
  - b. Bacteriological quality of water as required by the federal quality standards of bottled water. See the List of Substances to be Analyzed – Group VI.
    - i. You must test all product waters for total coliforms at least once every week. The laboratory report must clearly identify your firm name, address and license number.
    - ii. Take four samples for each product and send all samples to the testing laboratory. The laboratory will randomly select one of the four samples (from each product) for testing.
    - iii. The laboratory can use the presence/absence (P&A) test for coliform analysis. Only negative (absence) test results are acceptable. **If a sample tests positive (presence), you just resample the water within 24 hours and test**

**using the multiple tube-fermentation method. If the test results show that the water contains more than 2.2 MPM/100ml, you must immediately stop distributing the water, notify the FDB Water Licensing Desk, investigate the cause of the problem; take corrective actions and resample/retest the water. You must not resume distribution of the water until the test shows that the water contains total coliforms of less than 2.2 MPN/100m..**

- c. All testing must be done by a California laboratory that has been certified for testing water or by a laboratory certified by the United States Environmental Protection Agency (USEPA). For a list of certified laboratories, please contact the California Environmental Laboratory Accreditation Program (ELAP) at (510) 620-3155 or <http://www.cdph.ca.gov/certlic/labs/Pages/ELAP.aspx>. Testing done by a laboratory approved by the primary enforcement authority in states which have been granted primacy by the USEPA is also acceptable pursuant to H&SC 111165.
  - d. If more than one type of product is bottled at the facility, separate sets of analysis must be submitted and/or maintained for each type of product.
  - e. Any test results are valid for one year from the date of analysis.
  - f. [Note: Pursuant to H&SC Section 111155, FDB may ask you to test for other contaminant(s) if FDB suspects the substance(s) may be present in the water.]
3. **Bottling Operation:** You will need to submit copies of the following documents, specification sheets and/or information to the FDB investigator during the licensing inspection and/or routine inspections and to maintain copies for your files.
- a. Schematic site (facility) diagram;
  - b. Schematic water treatment/bottling process diagram;
  - c. Evidence of whether the facility has a separate bottling room that complies with 21 CFR 129.20 (a). Photographs are acceptable;
  - 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. Please do not send equipment advertisements or promotional materials.
  - f. Sanitation procedure;
  - g. Information on the "unit package production code" as required by 21 CFR 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 12 CFR Part 129. We suggest that a copy of the "product quality control procedure", which includes the record keeping information, be submitted.
  - i. Photographs showing the bottling equipment and facility
  - j. Original labels and original advertising and promotional materials for your products.
    - i. Typed or photocopied labels may be submitted with prior FDB approval **only if** the labels are: (1) printed or embossed directly in the bottles or (2) large labels (greater than 100 square inches in label size) and are printed directly onto large boxes.
    - ii. Labels, advertising and promotional materials must meet the requirements of H&SC Section 109875 et. seq. and applicable federal regulations, including those for nutrition labeling if nutrient content or health claims are made or if nutrition information which necessitates nutrition labeling is provided.
4. **Bottled Water Report:** Beginning January 1, 2009, bottlers are required to submit two sets of "bottled water reports" (one in English and one in Spanish). For details, refer to H&SC Section 111071. H&SC Section 111071 can be downloaded from the following: <http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection+hsc&codebody=&hits=20>
5. **Record Keeping:** Title 21, Code of Federal Regulations Part 129.80 (h) requires RWF to maintain records for at least 2 years. Refer to Part 129.80 (h) regarding the types of records that must be maintained.
6. **Design or Construction Changes:** You must inform FDB when changes are made to:
- a. Bottling operation,
  - b. Design or construction of your plant,
  - c. Sanitary operation,

- d. Equipment,
- e. Water source – Any new drilling or redeveloping of a source under this license will automatically trigger the re-evaluation of the source. FDB must re-evaluate the source prior to you using the source.
- f. Types of water produced
- g. Product Labels

7. Recalls: You must notify FDB if any of your products are recalled.

Other Agency Requirement: Your firm may have to register with the California Department of Conservation (CDC) in compliance with the California Beverage Container Recycling Act. We suggest that you contact CDC to obtain information about registration:

California Department of Conservation  
Division of Recycling, Client Service Section  
810 K Street, 17<sup>th</sup> Floor  
Sacramento, CA 95814  
Phone number: 1-800-RECYCLE or 1-800-732-9253  
Web address: <http://www.conservation.ca.gov/dor/Pages/Index.aspx>