



TOMÁS J. ARAGÓN, M.D., Dr.P.H.
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

February 11, 2022

Dear Retail Water Facility Licensee,

The California Department of Public Health (Department), Food and Drug Branch (FDB) has become increasingly aware of retail water facilities pre-filling and bottling water. The purpose of this letter is to clarify that retail water facilities are prohibited from pre-filling water into sealed single-use or multi-service bottles/containers without a **Water Bottling Plant license issued by FDB**.

The California Health and Safety Code (HSC) Section 111120(a) provides in part, *no person shall operate a water-bottling plant in this state except pursuant to a license issued by the department (FDB)*. HSC Section 111120(c) provides in part, *Any bottled water or vended water dispensed by a retail water facility that is not licensed in compliance with this article is misbranded and may be embargoed*.

Examples of single-use and multi-service bottled water containers that must not be produced in a retail water facility include, but are not limited to the following:



Single Use

Multi-service Use

Below are specific definitions found in the HSC:

- HSC Section 111070(a) *“Bottled water,” means any water that is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. Bottled water shall not include water packaged with the approval of the department for use in a public emergency.*



- HSC Section 111070 (c) *“Water-bottling plant” means any facility in which bottled water is produced.*
- HSC Section 111070 (h) *“Bottled water distributor” means any person, other than an employee or representative of a bottled water plant, who delivers bottled water directly to customers.*

Requirements to Bottle Water

A water bottling plant must comply with all applicable laws and regulations found in California Law (HSC 111070-111198); Title 21 of the Code of Federal Regulations (CFR) Part 129; Title 21 CFR Part 101; and Title 21 CFR Part 165.110. These laws and regulations can be found on our [webpage](#). Water bottling requirements include (but are not limited to):

- Submission of application and fee to FDB
- Annual physical, bacteriological, chemical, and radiological water analyses for both source water and product water found in Title 21 CFR Part 165.110(b)
- Enclosed filling room with tight walls, ceiling, and self closing doors to protect against contamination, that is separate from other plant operations or storage areas, and dedicated to filling operations only
- Washing of returnable multi-service bottles
- Quarterly testing of caps for bacteriologicals
- Bottled water reports in English and Spanish
- Product labels in compliance to state law and federal regulations

Requirements to **Distribute** Multi-Service Water That Was Bottled By A Licensed Bottler

If a business wants to distribute water packed in multi-service containers, the water must be obtained from a licensed Water Bottling Plant **and**, the business distributing the water must obtain a **Bottled Water Distributors License** issued by FDB.

A bottled water distributor must comply with all applicable laws and regulations found in the HSC; Title 21 CFR Part 129, Title 21 CFR Part 101, and Title 21 CFR Part 165.110. Licensing requirements include, but are not limited

- Submission of application and fee
- Review of records
- Review of product label(s)
- Verification that the water was produced by a company with a valid Water Bottling Plant License

Please note **it is unlawful to bottle water without a valid Water Bottling Plant License issued by FDB**. Violations may result in enforcement action including, but not limited to, embargo, assessment of an administrative penalty, and/or referral to a prosecuting attorney for civil or criminal prosecution.

If you have questions about this notification, the **Water Bottling Plant license** and/or **Bottled Water Distributors license**, please visit our Bottled and Vended Water [webpage](#) or contact the FDB Bottled and Vended Water License Desk at (916) 650-6500 or FDBFood@cdph.ca.gov.

Sincerely,

A handwritten signature in blue ink that reads "Travis You". The signature is written in a cursive style.

Travis You, MPH
Senior Environmental Scientist Specialist
Specialized Expertise and Technical Support Section

Attachment:

1. California Health and Safety Code 111070 – 111198
Bottled, Vended, Hauled, and Processed Water