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Water quality standards and licensing requirements to sell or distribute bottled water or carbonated non-alcoholic beverages in Massachusetts

The following information is provided to assist municipalities, regulators, bottling plants and other interested parties in meeting the Massachusetts licensing requirements for compliance with MDPH regulations 105 CMR 500.000 (Good Manufacturing Processes for Food) and any applicable sections of federal regulations 21 CFR Part 129 (Processing and Bottling of Bottled Drinking Water) and 21 CFR 165 (Beverages). Additional information is available on our webpage at https://www.mass.gov/how-to/apply-for-a-permit-to-sell-or-distribute-bottled-water-or-carbonated-nonalcoholic-beverages or by contacting the **Food Protection Program at (617) 983-6712 or fpp.dph@state.ma.us**.

Sections **105 CMR 500.090** through **500.094** list specific licensing requirements that must be met for the manufacture, collection, bottling, and labeling of bottled water and carbonated non-alcoholic beverages sold in Massachusetts. The requirements listed in **105 CMR 500.000** apply to firms whether they are based in Massachusetts or in other states or countries. The information below is intended to promote the uniform application of **105 CMR 500.000**, which can be accessed here: 105 CMR 500.000, "Good Manufacturing Practices for Food".

Applications

1. Firms that sell bottled water or carbonated non-alcoholic beverages in Massachusetts are required to submit an annual application for review by the Massachusetts Department of Public Health (MDPH) under **MGL Ch. 94, s.10A**.

    - If a bottling plant is located within Massachusetts, the application is reviewed by MDPH, and recommendations for licensing are made to the local Board of Health of the town where the plant is located.
    - If a bottling plant is located outside of Massachusetts, then the plant is licensed by MDPH in accordance with applicable sections of MDPH regulations 105 CMR 500.000, "Good Manufacturing Practices for Food".

2. Applications are reviewed for compliance with drinking water standards established by:
    - Massachusetts Department of Environmental Protection (MassDEP) regulations 310 CMR 22.00 (Drinking Water)
    - US Environmental Protection Agency (EPA) regulations 40 CFR Parts 141 (National Primary Drinking Water Regulations) and 143 (National Secondary Drinking Water Regulations), and
    - US Food and Drug Administration (FDA) regulations 21 CFR Part 129 (Processing and Bottling of Bottled Drinking Water) and 21 CFR 165 (Beverages).

    In cases where state and federal regulatory programs have different standards, MDPH will review applications for compliance with the stricter standard. **[105 CMR 500.005(D) and 500.092]**

Water Quality Standards

All untreated (raw) source water used for bottled water and carbonated non-alcoholic beverages licensed to be sold in Massachusetts must meet the federal drinking water standards established by the EPA as well as any additional requirements set for drinking water by the MassDEP. Finished bottled water must also meet the federal standards established by FDA. **[105 CMR 500.092(A)-(B)]**

In 2020, MassDEP amended its Massachusetts Drinking Water Regulations (**310 CMR 22.00**) to implement a Maximum Contaminant Level (MCL) for Per-and polyfluoroalkyl substances (PFAS). In accordance with section **105 CMR 500.092** MDPH regulations now require laboratory results for source and finished water to be no more than 20 parts per trillion (ppt) for six PFAS chemicals combined (sum): PFOA (Perfluorooctanoic acid), PFOS (Perfluorooctanesulfonic acid), PFNA (Perfluorononanoic acid), PFHxS (Perfluorohexanesulfonic acid), PFHpA (Perfluoroheptanoic acid), and PFDA (Perfluorodecanoic acid).

1. Table 1 lists the current water quality standards (WQS) used by MDPH to review permit applications submitted by bottling plants. Table 1 also lists the minimum testing frequency required for raw water from private sources and treated water from public water supplies. **[105 CMR 500.093(A)(1)]**

2. If source water comes from a public water system, and the source water is used without treatment or with only minimal treatment, then compliance with water quality standards may be satisfied by either:
    a. Submitting a copy of the public water system testing results, or
    b. Submitting copies of certificates showing full compliance with the relevant provisions of **40 CFR Parts 141**. **[105 CMR 500.093(A)(1)(c)]**

3. If source water from a public water system is treated, then compliance with water quality standards must be met:
    a. For bottled water only – **105 CMR 500.093(A)(1)(d)**
    b. For non-alcoholic carbonated beverages – **105 CMR 500.093(A)(1)(a) and (b).**

4. For bottled water, manufacturers are required to submit test results for finished products annually. For carbonated non-alcoholic beverages, manufacturers are also required to test finished products as

frequently as necessary to ensure that no product is adulterated and submit results to MDPH upon request. **[105 CMR 500.093(D)]**

Laboratory Testing Requirements

1. Laboratories certified by MassDEP must be used when testing in-state water sources, raw water from in-state private sources, treated water from in-state public water supplies, and finished products bottled in Massachusetts. In-state bottling firms must use testing methods specified under MassDEP regulations. Water originating from sources in other states must be tested by laboratories that are certified by the appropriate agency within the state where the laboratory is located. Water from sources outside the U.S. must be tested by laboratories certified by the EPA. **[105 CMR 500.091(A) and (C)]**

2. Section **105 CMR 500.093** of MDPH regulations requires applications for all new and renewal permits to include copies of original laboratory reports for, as applicable, source water, treated source water, bottled water, and carbonated non-alcoholic beverages. The following information is required for MDPH review of laboratory reports:
    - Client's name and address.
    - Sample identification (indicating "Source" water, "Finished" water (for bottled water), or “Treated” water (for bottled water and non-alcoholic carbonated beverages)); the name of the "Source" or “Treated”, or brand of "Finished" water, and either the date water was bottled, or best buy/expiration date.
    - Sample collection date.
    - Sampler's name.
    - Laboratory name, address and certification number.
    - Laboratory Director's signature and date.
    - Lab Sample ID #
    - Laboratory Reference #
    - For each contaminant:
        - Result in specified units;
        - Maximum contaminant level (MCL) in specified units;
        - The method detection limit in specified units;
        - Analytical method;
        - Date analyzed;
        - Space for notation if an analysis was subcontracted to another lab. Include the name, address and certification number of the sub-contracted lab;
        - A copy of the subcontracted laboratory analysis on the letterhead or report form of the subcontracted laboratory.

3. In addition to submitting original laboratory reports, applicants must provide the information outlined in Table 2 for each sample in the application.*

Table 1 - Water Quality Standards for Source and Bottled Water

Parameter	WQS (mg/L)[1]	Sampling Frequency
Microbiology		
E. coli	1 per 100 mL	monthly
Total Coliforms	1 per 100 mL	monthly
Radionuclides		
Gross Alpha Activity	15 pCi/L	annually
Radium 226 and 228	5 pCi/L	annually
Gross Beta Particle Activity	50 pCi/L	annually
Uranium	0.03	annually
Inorganic Compounds		
Aluminum	0.2[2]	annually
Antimony	0.006	annually
Arsenic	0.01	annually
Asbestos (fiber length > 10 µm)	7 MFL	annually[3]
Barium	2	annually
Beryllium	0.004	annually
Cadmium	0.005	annually
Chloride	250[2,4]	annually
Chromium (total)	0.1	annually
Copper	1.0[2]	annually
Cyanide (as free CN)	0.2	annually
Fluoride	0.8	annually
Iron	0.3[2,4]	annually
Lead	0.005	annually
Manganese	0.05[2,4]	annually
Mercury (inorganic)	0.002	annually
Nickel (salts)	0.1	annually
Nitrate (as N)	10	annually
Nitrite (as N)	1	annually[5]
Nitrate/Nitrite (Total)	10	annually
Perchlorate	0.002	annually
Selenium	0.05	annually
Silver	0.1[2]	annually
Sodium (Required to determine if sodium labeling or nutritional labeling is required.)	20	annually
Sulfate	250[2,4]	annually
Thallium	0.002	annually
Total Dissolved Solids	500[2,4]	annually

[1] All concentrations in mg/L, unless otherwise specified
[2] Secondary Maximum Contaminant Level
[3] If no asbestos is detected in first round of testing, frequency of testing may be reduced to once every nine years.
[4] Not applicable to mineral water.
[5] Sampling requirement will increase if nitrite is $\geq$ 50% of the MCL

Zinc	5[2,4]	annually
Organic Compounds		
Alachlor (Lasso)	0.002	annually
Atrazine (Atranex, Crisazina)	0.003	annually
Benzo(a)pyrene	0.0002	annually
Carbofuran (Furadan 4F)	0.04	annually
Chlordane	0.002	annually
Dalapon	0.2	annually
Di(2-ethylhexyl)-adipate	0.4	annually
Di(2-ethylhexyl)-phthalate	0.006	annually
1,2-Dibromo-3-chloropropane (DBCP)	0.0002	annually
2,4-Dichlorophenoxyacetic acid (2,4-D)	0.07	annually
Dinoseb	0.007	annually
Diquat	0.02	annually
Endothall	0.1	annually
Endrin	0.002	annually
Ethylene dibromide (EDB)	0.00002	annually
Glyphosate	0.7	annually
Heptachlor	0.0004	annually
Heptachlor epoxide	0.0002	annually
Hexachlorobenzene	0.001	annually
Hexachlorocyclopentadiene	0.05	annually
Lindane	0.0002	annually
Methoxychlor (DMDT, Marlate)	0.04	annually
Oxamyl	0.2	annually
Pentachlorophenol	0.001	annually
Per- and polyfluoroalkyl substances (PFAS)[6]	0.000020	annually
Picloram	0.5	annually
Polychlorinated biphenyls (PCBs) (Arochlor)	0.0005	annually
Simazine	0.004	annually
2,3,7,8-TCDD (Dioxin)	3×10^{-8}	annually
Toxaphene	0.003	annually
2,4,5-TP (Silvex)	0.05	annually
Volatile Organic Compounds		
Benzene	0.005	annually
Carbon Tetrachloride	0.005	annually
1,2-Dichlorobenzene (0-DCB)	0.6	annually
1,4-Dichlorobenzene (p-DCB)	0.005	annually
1,2-Dichloroethane	0.005	annually
1,1-Dichloroethylene	0.007	annually

[6] Includes perfluorooctanesulfonic acid or perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), perfluoroheptanoic acid (PFHpA), perfluorodecanoic acid (PFDA); sum must not exceed WQS for PFAS. Also see: https://www.mass.gov/info-details/per-and-polyfluoroalkyl-substances-pfas

1,2 *(cis)*-Dichloroethylene	0.07	annually
1,2 *(trans)*-Dichloroethylene	0.1	annually
Dichloromethane	0.005	annually
1,2-Dichloropropane	0.005	annually
Ethylbenzene	0.7	annually
Monochlorobenzene	0.1	annually
Phenols (Recoverable Phenolics, Total)	0.001	annually
Styrene	0.1	annually
Tetrachloroethylene	0.005	annually
Toluene	1	annually
1,2,4-Trichlorobenzene	0.07	annually
1,1,2-Trichloroethane	0.005	annually
1,1,1-Trichloroethane	0.2	annually
Trichloroethylene	0.005	annually
Vinyl Chloride	0.002	annually
Xylenes (total)[7]	10	annually
Disinfectant By-Products in Finished Water		
Bromate	0.01	annually
Chlorite	1	annually
Haloacetic Acids (HAA5)	0.06	annually
Chloramines	4	annually
Chlorine (Total chlorine residual)	4	annually
Chlorine Dioxide	0.8	annually
Total Trihalomethanes (TTHM)[8]	0.08	annually

KEY

MFL = Million Fibers per Liter (for fiber length greater than 10 microns)
mg/L = milligrams per liter
pCi/L = picocuries per liter
WQS = Water Quality Standard

[7] Includes *o*-xylene (1,2-dimethylbenzene), *m*-xylene (1,3-dimethylbenzene), *p*-xylene (1,4-dimethylbenzene), *m/p*-xylene
[8] Includes chloroform, bromoform, chlorodibromomethane, bromodichloromethane

***Table 2** in the application requests the following laboratory and sample information in Tables 2a and 2b.

Table 2a (Laboratory Required Information) asks applicants to provide:

- Laboratory Report Name
- Laboratory Certification #
- Lab Reference #

Table 2b (Samples in Application Package) contains 6 sub-tables:

1. Source water chemical sampling results (including PFAS) less than 12 months old
2. Source water radiological sampling results less than 12 months old
3. Source water microbiological contaminants results less than 4 weeks old
4. Finished water chemical sampling results (including PFAS) less than 12 months old
5. Finished water radiological sampling results less than 12 months old
6. Finished water microbiological contaminants results less than 4 weeks old

Each sub-table in 2b asks applicants to provide:

- Source name
- Laboratory Report Name
- Sample description on report
- Lab Sample ID(s)
- Sample date
- Sampler's Name