

Consolidating Food Manufacturing, Processing and Distribution Regulations

**Public Health Council
October 8, 2014**



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I. Background – The Administration’s Regulatory Streamlining Initiative



- In 2011, Governor Patrick launched a review of state regulations with an emphasis on consolidation and streamlining
- In response to the Governor’s directive, the Department of Public Health (DPH) is promulgating regulations related to food manufacturing, food processing, and food distribution.
- 2 sets of rules will be deleted, while 9 are consolidated and replaced with a single, modernized set of food safety regulations

Background (cont'd)

- Over the past few years, the Bureau of Environmental Health's Food Protection Program (FPP) and the Office of General Counsel (OGC) worked to consolidate multiple sets of regulations
- The consolidated regulations being proposed for final promulgation will:
 - Provide uniform sanitation standards for food products
 - Standardize procedural requirements for licensure and enforcement
 - Incorporate federal requirements into the state regulations
 - Update safety requirements for food manufacturing

II. Overview of Regulatory Amendments

- The nine sets of current regulations that will be consolidated into a single regulation include:
 1. 105 CMR 500.000: Good Manufacturing Practices for Food
 2. 105 CMR 520.000: Labeling
 3. 105 CMR 530.000: Sanitation in Meat and Poultry Processing Establishments
 4. 105 CMR 531.000: Inspection of Meat Slaughtering and Processing
 5. 105 CMR 532.000: Inspection of Poultry and Poultry Products
 6. 105 CMR 533.000: Fish and Fishery Products
 7. 105 CMR 541.000: Milk and Milk Products, Grade A Condensed and Dry Milk Products, Grade A Condensed and Dry Whey, and Milk Pasteurization Plants
 8. 105 CMR 561.000: Frozen Desserts and Frozen Dessert Mixes
 9. 105 CMR 570.000: The Manufacture, Collection, and Bottling of Water and Carbonated Non-Alcoholic Beverages

Overview of Regulatory Amendments (cont'd)

- The two sets of current regulations that will be deleted because they are outdated are:
 1. 105 CMR 510.000: Standards of Identity and Definitions of Purity and Quality of Food
 2. 105 CMR 565.000: Dietetic Foods

III. Effects of Amendments

- Simplification of terms and definitions.
 - Basic definitions will be added that apply to all types of food manufacturing and do not differ by food product (e.g. “Imminent Danger to the Public Health” replaces inconsistent definitions in current regulations.)
 - Currently, in seafood regulations, 105 CMR 533, “Imminent Danger to Public Health” means that a condition or a combination of conditions exist that, in the opinion of the Department, would place the public at risk for a foodborne related illness or other similar hazard, if not immediately corrected.
 - In milk regulations, 105 CMR 541, the term “Imminent Health Hazard” is defined as any violation by a milk pasteurization plant, or any other occurrence or condition in a milk pasteurization plant, that has the potential to pose an imminent threat to public health. Such violation, condition or occurrence shall include, but not be limited to: an extended loss of water supply, an extended power outage, a severe backup into pasteurization plant, or any condition which is defined elsewhere as an imminent health hazard .
 - The proposed regulations would define an “Imminent Danger to the Public Health” as any regulatory violation or occurrence or condition with “the potential to pose a serious threat to public health.”

Effects of Amendments (cont'd)

- Addressing existing gaps:
 - Providing consistent sanitation standards for all food products to enhance public health protection and simplify requirements for the regulated community (e.g. certain current regulations specify that a plant must have a safe source of water, while others do not)
 - The combined regulation provides sub-sections containing specific requirements, where necessary (e.g. specific subsections applicable to manufacturers of bottled water, for example. Bottled water must be tested for the same suite of chemicals/environmental contaminants that DEP requires for public drinking water but such chemical tests do not apply to frozen desserts)

Effects of Amendments (cont'd)

- Clarifying the appeal process
 - The proposed consolidation creates one set of administration and enforcement procedures (currently each separate set of regulations has its own, which are not worded uniformly)
 - The appeal process takes into account different statutory and federal model ordinance requirements (e.g. interstate shellfish and milk shipping requirements) while incorporating provisions that apply to all areas, such as administrative hearings through the Division of Administrative Law Appeals

V. Public Comments

Proposed amendments were initially presented to PHC on April 9, 2014. A public hearing was held in Boston on May 30, 2014.

- No oral testimony presented
- Written comments were submitted by the International Bottled Water Association (IBWA), the trade association for the bottled water industry.

Public Comments (cont'd)

All of IBWA's comments related to existing provisions governing bottled water, which DPH had not proposed to amend.

IBWA Comment	DPH Response
Supports DPH's efforts to maintain regulations for multi-use equipment that refer to federal requirements at 21 CFR 129.	DPH appreciates this support. No changes necessary.
Objected to requirement that if the word "spring" is used in a company's name but source of water is not a spring, the words designating type of source must be no smaller than one half the size of the word "spring" in company name.	DPH agreed as some companies bottle spring water as well as other types of water. Deleted the provision regarding wording size on the label.
Questioned MA DEP jurisdiction for recommendations on water source approval.	DEP's involvement in water source review for the Commonwealth is long-standing and subject to MOU between DPH and DEP. DPH does not propose making a change.

Public Comments (cont'd)

IBWA Comment	DPH Response
<p>Questioned requirement that source water meet state and federal drinking water standards established by DEP and EPA.</p>	<p>DPH believes these standards are appropriately protective of public health. This standard applies only to in-state sources of bottled water, as DEP standards do not apply out of state.</p> <p>Additionally, M.G.L. c. 111, § 160B provides that where any DPH order concerning water quality standards conflicts with a DEP order, the DPH order shall take precedence; as such, public health considerations are protected under the current framework.</p>
<p>Clarify language regarding minimal treatment of water sources.</p>	<p>Added “beyond mechanical filtration and disinfection” in two places in the regulations.</p>
<p>Reference to a specific number of approved methods of analysis for bottled water products is too narrow, as FDA allows use of any FDA-approved method.</p>	<p>Regulations currently require that methods shall be as specified in 21 CFR § 165.110(b). Those specified methods include Inductively Coupled Plasma-Mass Spectrometry, direct aspiration, and Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry, among several other methods used for detecting trace elements. DPH agrees, and has made changes allowing use of any FDA-approved method of analysis.</p>
<p>IBWA disagreed with allowing DPH to require any bottler to test and submit results whenever DPH has “reason to believe” that harmful substances may be present in a product. IBWA argued that compliance should be based on confirmed tests instead of potential threats.</p>	<p>This requirement is intended to <i>prevent</i> potential problems. For example, a spill of a toxic substance near a water source would require immediate testing. DPH will keep this section in the regulations.</p>

VI. Summary / Next Steps

The consolidated regulations provide uniformity and consistency for the regulated industry

- Provides specific requirements for certain industries in sub sectors
- Addresses current and future impacts to food supply (e.g. climate change)
- Enhances consistency with federal rules

Next steps:

- Approval of the proposed final amendments by the Public Health Council
- Final regulations will then be published in the Massachusetts Register in February 2015, with an effective date of March 1, 2015.

VIII. Questions

