

# Consolidating Food Manufacturing, Processing and Distribution Regulations

**Public Health Council  
April 9, 2014**



# Outline

- I. Background
- II. Description of regulatory amendments
- III. Overview of stakeholder involvement and outreach efforts
- IV. Summary
- V. Next Steps
- VI. Questions



# I. Background - The Administration's Regulatory Streamlining Initiative



- In 2011, Governor Patrick launched a review of state regulations with an emphasis on the need for consolidation and streamlining
- In response to the Governor's directive, the Department of Public Health (DPH) is proposing consolidation of 9 separate sets of rules (and deletion of 2) related to food manufacture, food processing, and food distribution, and replacing them with a single, modernized set of food safety regulations

# Background

- 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 will:
  - Adopt generic sanitation standards for food products
  - Standardize procedural requirements for licensure and enforcement
  - Incorporate required federal requirements into the state regulations
  - Update safety requirements for food manufacturing

# II. Description of Regulatory Amendments - Overview

- 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

# Description of Regulatory Amendments - Overview

- The two sets of current regulations that will be deleted because they are outdated are: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

# Description of Regulatory Amendments – Effects of Amendments

- The proposed consolidation will provide:
  - Simplification
    - Basic definitions 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.)
      - 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 of 105 CMR 541.00 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 and 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 in 105 CMR 541.00 as an imminent health hazard

# Description of Regulatory Amendments – Effects of Amendments

- The proposed consolidation will:
  - Address existing gaps:
    - Consistent sanitation standards for all food products will 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 will provide 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)

# Description of Regulatory Amendments – Effects of Amendments

- The proposed consolidation will also:
  - Clarify appeal process
    - The proposed consolidation will create 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
    - Sections include licensure (500.201), inspections (500.203) and correction orders (500.204), grounds for enforcement (500.207), and procedures for appeal (500.208)

# Description of Regulatory Amendments – Effects of Amendments (cont'd)



- The proposed consolidation will provide:
  - Updated Food Safety Standards
    - Some of the current food manufacturing regulations are outdated, especially the codes for meat and poultry which became law in the late 1960s and early 1970s
    - 500.030 “Meat and Poultry” cross-references to federal exemptions, and replaces 248 pages of regulations with five (5) focused and streamlined pages.
    - The proposed draft of the single, comprehensive regulation contains updated provisions for all food types



» 500.006(J) “Emergency Action Plan” requires all firms to develop a plan for continued operation during emergencies (i.e., power outage, floods, ice storms, etc.) This is particularly important given the significant impacts of climate change we have already realized.

- The format will more easily allow for future amendments if needed to accommodate improvements in food safety.
  - » Since all MA food industries are covered by one regulation, all industries will benefit from any proposed amendments

# Description of Regulatory Amendments – Effects of Amendments (cont'd)

- The proposed consolidation will provide:
  - Inter-state Equivalency
    - Like other state agencies, DPH has an obligation to compare its food-related regulations to federal laws and regulations with the goal of equivalency.
    - The proposed consolidation will help Massachusetts achieve the equivalency required by the U.S. Food and Drug Administration.
      - » 500.005(B) “Food Labeling” adopts FDA criteria for, among other things, acceptable market names for seafood under 21 CFR 101
      - » 500.005 (C) “Standard of Identity” adopts definitions established by FDA for all food
  - Consolidate food labeling requirements
    - Food labeling is no longer a stand-alone regulation, but is integrated in 105 CMR 500.
    - This will provide further clarity to food manufacturers, processors and distributors as to proper food labeling in conformance with federal standards.

# III. Overview of Stakeholder Involvement and Outreach Efforts

- FPP worked with an industry task force to develop these proposed amendments. The task force included representatives from:
  - Food processors;
  - The dairy industry;
  - The bottled water industry;
  - The meat industry;
  - A major food testing laboratory;
  - Consulting firms representing seafood and milk providers.
- Local Health and others were also consulted in Food Establishment Advisory Committee meetings
- Task force members discussed issues associated with regulatory amendments and provided industry perspective on the impact that possible changes would have on businesses, in accordance with the Administration's focus on the effect of regulatory amendments on business operations.

# IV. Summary

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

# V. Next Steps

- Following preliminary approval, DPH will schedule public hearings
- DPH will analyze comments and return to PHC for a vote on the proposed final amendments
- Final regulations will then be published in the Massachusetts Register

# VI. Questions

