The Impact that FSMA regulations are having on the Pasteurized Milk Ordinance (PMO)

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History of the PMO

• In 1924 the **Standard Milk Ordinance** was created by United States Public Health Service (USPHS)
• In 1927 the **Code** was published
• Includes fluid milk, cream products, yogurt, cottage cheese, eggnog, buttermilk and some dried dairy products
• Developed with assistance from Milk Regulatory and Rating Agencies at every level of Federal, State and local governments

• Source: PMO
History of the PMO

• Basic standard used by all 50 states

• National Conference on Interstate Milk Shipments (NCIMS) holds biennial conferences and recommends changes or modifications to the PMO

• Source: PMO
History of the PMO

• Designed for:
  – Procurement of milk and milk products
  – Sanitary regulation for milk and milk products found on interstate carriers
  – Recognized by many as the national standard for milk sanitation
  – Will continue to provide effective public health protection without being unduly burdensome to regulatory agencies or the dairy industry
  – Represents current knowledge and experiences for milk sanitation standards for the nation

Source: PMO
PMO Compliance

- Grade A milk and milk product facilities operating under the Pasteurized Milk Ordinance (PMO) have until **September 17, 2018** to implement new changes that will align the PMO with the Food and Drug Administration’s final Preventive Controls rule under the Food Safety Modernization Act (FSMA)

- Source: FDA
PMO Compliance

• Will incorporate regulatory requirements of the preventive controls into a new *Appendix T*.

• **Requirements:**
  – Written hazard analysis plan
  – Description of food safety preventive controls
  – Testing programs showing effectiveness of the controls

  – Source: FDA
PMO Compliance

- FDA regulators will conduct inspections every **36 months**
- State regulators will still conduct quarterly inspections to verify compliance with the main parts of the PMO. May include checks on control of allergen-containing ingredients
- Regulators must attend training of the Preventive Controls before inspecting facilities

Source: FDA
**PMO and FSMA Requirements**

- **Section 103** (Hazard Analysis and risk-based Preventive Controls) does not exempt dairy facilities

- **What is needed:** written hazard analysis, food allergens, environmental monitoring in the production area

- Source: FDA
PMO and FSMA Requirements

- Farms who meet the definition are not required to register under section 415 (FD&C Act requires additional registration information to FDA).

- However, farms that manufacture products must meet the requirements of the Preventive Controls rule

Source: FDA
PMO and FSMA Requirements

• Must have an environmental monitoring program in place and finished product testing as a verification activity

• For example: if you making a soft cheese that was exposed to the environment you must have an environmental monitoring program for *Listeria* spp.

• Source: FDA
References


- https://www.fda.gov/Food/GuidanceRegulation/FSMA/

- https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm

- https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm
Questions?