

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)



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



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



PMO and FSMA Requirements

- Section 103 (Hazard Analysis and riskbased Preventive Controls) does not exempt dairy facilities
- What is needed: written hazard analysis, food allergens, environmental monitoring in the production area



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



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.



References

- https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocum entsRegulatoryInformation/Milk/UCM513508.pdf
- 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?