

August 2014

Issues relating to the regulation of the milk food chain: Pasteurized Milk Ordinance (PMO) versus Food Safety Modernization Act (FSMA) rules

Authors: Ana Ebbert, School of Public Health, University of Minnesota (UMN) and Kaylee Myhre Errecaborde, College of Veterinary Medicine, UMN.

Brief reviewed by a multidisciplinary, multi-sector team of experts.

Summary of Findings

- The complex process of collecting raw milk from a dairy cow and transforming it into a safe, palatable, consumer-ready milk product has been considered at high risk for accidental or intentional contamination.
- The production of Grade A, consumer-ready milk products has been regulated by the Pasteurized Milk Ordinance (PMO) in the United States (US) since 1927 to prevent accidental contamination of the product.
- While other industries have been exempted from some of the new legislation under the Food Safety Modernization Act (FSMA), the dairy industry has been included in a rule established to prevent intentional contamination of food.
- Controversy exists over whether the dairy industry should be required to comply with this regulation in FSMA since the PMO has been protecting the US milk supply to date.

Background

Assuring the Safety of Milk

The United States Public Health Service (USPHS) has worked with states and municipalities since 1924 to develop and maintain effective programs to prevent milk-borne disease.¹ Model regulations and details for their administration were published in 1927 as the *Grade "A" Pasteurized Milk Ordinance* (or PMO). The PMO is reviewed every two years and was most recently updated in 2013.^{2,3} Nevertheless, the United States (US) Government Accountability Office (GAO) released a report in 1990 about the questionable safety of the US milk supply chain, calling the product high risk for both accidental and intentional contamination.¹ The process of collecting raw milk from dairy cows and transforming it into a milk product consists of multiple steps before reaching the consumer. The GAO report emphasized that the length of time required and complexity of this process may allow for accidental or intentional "adulteration" (the legal term for contamination).¹ While intentional milk adulteration has never been recognized in the US, it has been reported in China, India, Brazil, Thailand, and other countries.⁴ Most notably, the intentional economically motivated adulteration of milk with melamine in China caused the death of six infants, sickened over 300,000 people, and drew intense international criticism.⁴ As a result of the 1990 GAO report, federal vulnerability assessments, and overall heightened awareness of the potential for intentional contamination, the Food Safety Modernization Act (FSMA) has proposed additional requirements for milk processing.⁵

Pasteurized Milk Ordinance and the Dairy Industry

The PMO is a comprehensive regulatory framework that is jointly written by the US Food and Drug Administration (FDA) and the USPHS.^{2,3} All "Grade A" dairy products (i.e., milk produced specifically to be consumed in its fluid state or, as applicable, dried or condensed milks) must come from dairy farms and dairy plants that meet the requirements of the PMO.³ Milk that is used in butter, cheese, and other dairy production does not count as "Grade A" and thus is not covered by the PMO.^{2,3} The "Grade A" standards outlined within the PMO have been recommended by the National Conference on

Interstate Milk Shipments (NCIMS), which is made up of local and state regulatory agencies within the US dairy industry.⁶ While the PMO focuses on protection against *accidental* contamination and the mislabeling or misbranding of milk and other “Grade A” dairy products, it does not specifically address *intentional* tampering.^{2,3}

Food Safety Modernization Act and the Dairy Industry

FSMA was signed into law in January of 2011.⁵ The main goal of FSMA is to provide the FDA with a better ability to protect the US food supply. While other industries, such as seafood, juice, and canned goods, are exempt from most of FSMA, the dairy industry has been included specifically under the “focused mitigation strategies to protect food against intentional adulteration” rule.⁵ The other industries were excluded due to already having in place hazard analysis and critical control point (HACCP) programs regulated by the FDA.⁵ It should be noted that HACCP programs are in place to prevent hazards in the production process that may cause food to be unsafe; HACCP programs are not designed to specifically prevent intentional adulteration, though the process should mitigate much of this as well. As stated in the FDA Guidelines for Application of HACCP Principles, “Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan.”⁷

Why include dairy farmers in FSMA when they already comply with the PMO?

The International Dairy Foods Association (IDFA), which is composed of the Milk Industry Foundation, the National Cheese Institute, the International Ice Cream Association, and other marketing industries and suppliers, wrote an official letter in November 2013 to the FDA regarding FSMA and the non-exemption of the dairy industry.⁶ They argue that the FDA should exempt the dairy industry on the grounds that the PMO, which is also regulated by the FDA, is very similar to HACCP programs by which other “FSMA-exempt” industries must abide.⁶ The IDFA also states that having milk producers follow both FSMA and the PMO would be taxing in terms of finance, time, employee input, and other types of resources, and could result in confusion and a decrease in product safety.⁸ Moreover, many stakeholders argue that adulteration of milk, as seen with the melamine incident in China, will likely come from those working within the supply chain, and no amount of regulation from the PMO or FSMA will prevent this.⁹

FSMA is intended to protect the integrity of the US food system and to proactively prevent against *accidental and intentional* product adulteration.⁵ While other industries that are exempt from FSMA have HACCP programs that control for adulteration, the dairy industry does not. Because milk is deemed such a high risk product, the FDA has stated a need to move forward with the intentional adulteration rule in FSMA to fill a gap in the PMO and prevent intentional adulteration, which the PMO does not address.^{2,3} Some argue the debate should be simply to include intentional adulteration in the PMO or work to reduce duplication in incremental efforts between the intentional adulteration rule and the PMO.

The “focused mitigation strategies to protect food against intentional adulteration” rule applicable to the dairy industry is currently advancing through the federal rule-making process. The comment period was closed as of June 30, 2014.⁵ Once the rule is made final, large dairy farmers will have one year, small business farmers (<500 employees) will have two years, and any businesses that make less than \$10 million in sales per year will have three years to comply.⁵ Specifically, the rule will target activities that are most vulnerable to adulteration (i.e., bulk liquid receiving and loading, liquid storage and handling, and secondary handling and mixing).⁵ As the rule stands for comment, farmers and producers with any of the activities listed above will need to complete their own vulnerability assessment and maintain a food defense plan.⁵ They will then need to identify actionable process steps, which are points, steps, or procedures, that will require focused mitigation strategies.

References

1. U. S. Government Accountability Office. 1990. FDA surveys not adequate to demonstrate safety of milk supply. Retrieved from <http://www.gao.gov/products/RCED-91-26> (Accessed on 8/14/2014).
2. U.S. Department of Health and Human Services, Public Health Service and the Food and Drug Administration. 2011. Pasteurized milk ordinance. Retrieved from <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf> (Accessed on 8/14/2014).
3. U.S. Department of Health and Human Services, Public Health Service and the Food and Drug Administration. 2013. Pasteurized milk ordinance. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm389905.htm> (Accessed on 8/14/2014).
4. Moore, J. C., Spink, J., & Lipp, M. 2012. Development and application of a database of food ingredient fraud and economically motivated adulteration from 1980 to 2010. *Journal of Food Science*; 77(4): 8118-8126.
5. Food and Drug Administration. 2014. FDA food safety modernization act. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm> (Accessed on 8/14/2014).
6. National Milk Producers Federation and the International Dairy Foods Association. 2013. Comments on the pasteurized milk ordinance and the food safety modernization act. Retrieved from <http://www.nmpf.org/files/file/Issues%20Watch%20Food%20Safety/2013%20PMO%20Comments%20Submitted%20to%20FDA.pdf> (Accessed on 8/14/2014).
7. U.S. Food and Drug Administration. Guidelines for application of HACCP. Updated 2014. Retrieved from: Principles <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#princ>. (Accessed on 8/14/2014).
8. National Milk Producers Federation. 2014. Food safety modernization act. Retrieved from http://nmpf.org/washington_watch/standardsandsafety/foodsafetylegislation (Accessed on 8/14/2014).
9. National Milk Producers Federation and the International Dairy Foods Association. 2013. General comments on current good manufacturing practice and hazard risk analysis and risk-based preventative controls for human food: Food safety modernization act. Retrieved from <http://www.nmpf.org/files/file/Issues%20Watch%20Food%20Safety/2013%20Final%20Preventive%20Controls%20%20Comments%2011%2015%202013.pdf> (Accessed on 8/14/2014).