Proposal 101 Adulteration Study Committee Report to the 2025 National Conference on Interstate Milk Shipments

Submitted:

Charge to the Committee: Proposal 101 was passed at the 2023 NCIMS and stated the following:

> The assigned committee is charged to identify and develop appropriate strategies to prevent contamination of Grade "A" milk and/or milk products with chemical sanitizers after the CIP process. In developing prevention strategies, the assigned committee will, at least, consider:
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> - Which Grade "A" milk and/or milk products should be addressed through the prevention strategies;
> - Potential means to minimize contamination: regulatory activities (including guidance, Conference proposals); communication/outreach to industry stakeholders; training gaps (including operator training, food safety plan training); industry best practices; etc.

Committee Activity: The Adulteration Study Committee first convened in September 2023, consisting of six members from regulatory, five members from industry, four non-voting members from industry, and FDA representation.

Committee members are as follows:

Committee Members		
Regulatory	**Industry**	**Non-Voting Members**
Sofia Stifflemire – Chair (TX)	Brad Suhling- Vice Chair (Prairie Farms)	Dr. Nicole Martin- Cornell University
Eric Glaude (NY)	Roger Hooi (DFA)	John Allan- IDFA
Dustin Cox (NM)	Sabina Alexander (Hiland)	Brook Sherman- EcoLab
Nathan Campbell (IN)	Violet Martin (General Mills)	Clay Detlefsen- NMPF
Brian Wise (OH)	Denise DuFrense (Saputo)	
Shannon Maloney (MO)		**FDA**: Dr. Beth Briczinski and Clint George

The committee deliberated the charge of Proposal 101 and discussed issues industry has been facing since the 2020 COVID-19 outbreak. Lack of employees and high rate of employee turnover was discussed heavily the first couple of meetings. To help the committee determine which milk and/or milk products to focus on, FDA shared their incident reports on the multiple adulteration events and the committee performed a risk assessment.

The risk assessment tool provided by industry, along with historical data helped to narrow down the focus of the type of products and packaging that were the most common sources of concern. The risk assessment looked at the historical risk, mechanical controls, intended consumer, preventive control type and presence, adulteration potential, and consumer consumption habits. This was applied to all major categories of Grade A products. The Study Committee determined that flavored and unflavored fluid milk products packaged in paperboard containers are at greatest risk for industrial chemical adulteration during packaging.

The processes and products identified in the risk assessment helped direct the committees focus on how to achieve the objectives outlined in Proposal 101. The committee determined the product most likely to become adulterated were the gable top school milk containers. The committee discussed the multiple reasons for this which included, the older N8 fillers, and the containers not being transparent to allow employees to notice the sanitizer in the product.

The committee determined a Best Practices document focusing on the adulteration of milk and dairy products with chemical sanitizer was the prevention strategies to fulfil the objectives of Proposal 101. The committee also discussed the option of submitting a conference proposal to address flavoring (sensory evaluation) of milk on the production floor however did not proceed because of the conflict with the CFR (21 CFR 117.10(b)(8)) cGMP.

Conclusion:

The committee created a six-page Best Practices document focusing on the adulteration of milk and dairy products with chemical sanitizer. The document starts with a background explaining the need for and importance of identifying and proactive measures to prevent accidental adulteration of milk and milk products. The document then provides several scenarios of how a product can become adulterated with chemical sanitizers. The document then provides recommended strategies to reduce the risk of adulteration with chemical sanitizers. Lastly, the document addresses the

crucial need for a comprehensive training program for employees. With the NCIMS Executive Board approval, the committee requests the Best Practices document be housed on the NCIMS website. Regarding the question on a proposal on sensory evaluation on the production floor and due to the conflict with cGMP in the CFR, the committee ultimately decided to seek further directions from the NCIMS Executive Board and collaborate with FDA in addressing this conflict.