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Milk Specialist Insights

Eastern Milk Seminar 2019

Curtis Griner, FDA Milk Specialist



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TOP 2 ISSUES

1. 12p. Cleaning And Sanitizing of Containers and Equipment (Specifically Extended Run Proposals)
2. 17p. Cooling of Milk and/or Milk Products (Specifically Cooling and Acidification Studies)

Extending Production Runs

- Extended Run Proposals shall be submitted to and approved by the Regulatory Agency prior to qualification period in consultation with FDA
- All finished product produced during the qualification period shall comply with the requirements of Section 7 of the PMO

Extending Production Runs

- Supporting information may include but is **not** limited to:
 - Statement of proposal, including desired cleaning frequency
 - Product and equipment description
 - Intended use and consumers
 - Distribution and storage temperatures of product
 - Diagram of process of interest
 - Process parameters, including temperatures and times
 - Hazard evaluation and safety assessment

Extending Production Runs

- Review of equipment for sanitary design
- A plan for initial qualification when warranted

Extending Production Runs

- Additional items to consider:
 - What effect will extending a production run have on the facilities ability to maintain a clean processing environment?
 - Should environmental surveillance be included within the qualification study to validate the plants SOPs for cleaning the processing environment?
 - Has the plan addressed hazards that are more likely to occur during extended production runs? For Example: Down time due to equipment malfunctions

Extending Production Runs

What are the issues that we as Milk Specialist encounter while conducting Check Ratings?

- Proposal accepted by the Regulatory Agency without FDA consultation.
- Plant has a proposal but no documentation that the Regulatory Agency has accepted the proposal.
- No qualification study to validate the proposal.
- Proposal is inadequate to demonstrate all hazards have been considered and are successfully being controlled by the firm.
- Plant is not following the process parameters within the extended run proposal or the plant needs to update the proposal.

Extending Production Runs

What happens when the Milk Specialist determines a firm is non compliant with this provision of 12p?

- The firm may be debited for Items 12a (5 points) and 12c (5 points)

Refer to the 2017 PMO 12p page 74

Extending Production Runs

Are there process steps that are not eligible for extended runs?

Yes, for example: Milk product flavoring injection slurry that contains milk and/or milk product is stored between 45 and 150 F must be cleaned every 4 hours. This is a temperature abuse issue and is located in 17p of the PMO and not 12p and therefore is not eligible for application of the extended run provision of 12p. Refer to the 2017 PMO 17p page 112, Appendix H page 231 #6, M-I-15-3 question 59.

Cooling Exemptions allowed within 17p

All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging in approved equipment, to a temperature of 45F or less, unless drying is commenced immediately after condensing:

1. Those to be cultured
2. Cultured Sour Cream*
3. Acidified Sour Cream*
4. All yogurt *
5. Cultured Buttermilk*
6. Cultured Cottage Cheese*
7. All condensed whey and whey products*

Cooling Exemptions

Note those items that have an * .

*Critical factors including, but not limited to, PH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Regulatory Agency.....

Cooling Exemptions

- Please be sure to refer to the 2017 PMO 17p pages 112-116. Other references include M-I-13-4 and M-I-15-3 questions 57 and 58.

Cooling Exemptions

- What we are encountering on Check Ratings:
 - Incomplete documentation; no acidification study or verification by the Regulatory Agency is not documented.
 - Inadequate documentation by the firm that continuous monitoring is occurring.
 - Firm changes packaging without additional cooling study.
 - Reformulation of product without additional acidification study.

Cooling Exemptions

- Firm fails to conduct a study on all necessary products. Such as those that may have ingredients that may negatively effect equilibrium PH.

What to expect when this is found to be substantially non compliant on a Check Rating: This would be a violation of 17p (5 points) of the PMO.

Cooling Exemptions

- Side Note: Proposal 111

All yogurt products at all milkfat levels, cultured in the cup after filling (cup set) and subsequently moved out of the culturing room when reaching a pH of 4.80 or below and a pH of 4.6 or below within 24 hours* and cooled to 45 F or below within 96 hours of being moved out of the culturing room**.

Cup set yogurt was previously interpreted to fall under 1. Those to be cultured and did not have an *. This would indicate that cooling and acidification studies are now required for cup set yogurt.

CHOMP FREE ZONE



Questions?

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