Best Practices: Preventing Accidental Adulteration of Milk and Dairy Products with Chemical Sanitizers

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This document shall serve as recommended best practices for the dairy industry to identify and implement proactive measures needed to address accidental sanitizer adulteration of Grade "A" dairy products.

Accidental sanitizer adulteration of milk products stands as a critical concern within the dairy industry, posing substantial risks to both consumer health and industry integrity. The failure to implement robust controls aimed at preventing cross-contamination of finished products has the potential to trigger injuries among consumers or necessitate extensive product recalls. Between 2021 and 2024, the dairy industry has had at least seven confirmed events of sanitizer adulteration of fluid milk products, resulting in recalls and/or injuries to consumers.

The gravity of these incidents is magnified by the fact that sanitizer adulteration not only jeopardizes consumer safety but also significantly impacts consumer trust and the reputation of dairy products. The potential repercussions include financial losses and can even extend to the erosion of consumer confidence in an essential dietary staple.

In addition to existing PMO and 21 CFR part 117 requirements, the need for stringent preventive measures is paramount, necessitating a comprehensive understanding of the risks posed by sanitizer adulteration in milk products. Such understanding is crucial to implement proactive measures, fortify existing controls, and drive collaborative efforts among stakeholders to safeguard the integrity and safety of dairy products in the market.

There are several ways product can become contaminated. Some scenarios detailing how contamination with sanitizer could occur are listed below:

1. **Incomplete Drainage of CIP Sanitizers:**

- If jumper lines, pipelines, silos, or filler bowls/nozzles aren't adequately drained of Cleaning in Place (CIP) solutions after the cleaning process, any remaining solution can mingle with the next batch. This residue might contain sanitizer or other cleaning agents, leading to contamination.

2. **Cross Connections Between CIP and Product Lines:**

   - When there are unintended connections or overlaps between the lines used for Cleaning in Place (CIP) and those used for product processing, there is a heightened risk of contamination. If these lines intersect or share components, cleaning agents could inadvertently enter the product stream. The Pasteurized Milk Ordinance (PMO) is a great reference document to prevent this from occurring.

3. **Lack of Communication in CIP Process Management:**

   - Employee oversight in communicating the status of equipment within the Cleaning in Place (CIP) process can lead to errors. If the current stage of CIP for a particular piece of equipment isn't adequately communicated, there might be confusion regarding its readiness for use. This miscommunication could result in residual sanitizer being present during product processing, causing contamination.

4. **Failure to Disconnect Lines When Transferring Between Pieces of Equipment When Cleaning Chemicals are Present:**

   - When transferring product or cleaning solution from one piece of equipment to another, such as an HTST without disconnecting the appropriate lines, residual sanitizer from the previous batch can mix with the subsequent product. Without proper line disconnection, these chemicals can inadvertently contaminate the new product.

Each of these scenarios underscores the critical importance of strict adherence to cGMPs, thorough cleaning procedures, and clear communication among employees involved in the production and sanitation processes to prevent inadvertent contamination in dairy product manufacturing.

Recommended Practices

To minimize the risk of contamination, below are some best practice recommendations. Any recommendations that are implemented should be tailored to the specific facility.

1. **First Sellable Carton Check and Dual Verification:**
    - Implement a protocol where the first sellable carton from each filler undergoes thorough inspection and a dual verification process. This ensures the initial product meets quality standards and provides a redundant check to maintain consistency and reliability. This is as simple as sensory evaluation or "flavoring" of the product by the line operator. The secondary check can be performed by another line operator, supervisor, lab personnel, etc. These checks should be documented and should be done on each filling machine and each type of product produced on that machine in each production cycle. This could include a check for bulk tanks, or tankers. It is important to have staff who are trained in sensory evaluations to perform this check at all hours of the production cycle.
2. **Hard Hold Until Laboratory Checks are Completed:**
    - Implement a written SOP to place products on a hard hold until all relevant laboratory checks are completed. This ensures no product is released for sale until it passes quality testing, mitigating the risk of contaminated or substandard products entering the market. While this can be achieved in products with longer shelf, unfortunately, for fresh dairy products with a short shelf life, holding for 1 or 2 days may not be feasible. An intermediary step could be to place the product on hold until lab personnel or management perform a sensory evaluation on the first sellable products.
3. **Inadvertent Packaging During non Production Times:**
    - A way to reduce the likelihood of communication errors when transitioning from production to CIP is to remove all of the packaging from the filler, filling area, or production room. This ensures that extra steps would need to be taken, with multiple employees involved, to bring the equipment back into production mode. A verification check could be put into place before packaging materials are brought back into place and before production can start again.

- Install physical barriers or locks on machines after production is completed and before the Cleaning in Place (CIP) process begins to prevent accidental filling operation. This is similar to the lockout tagout programs in maintenance operations, helping avoid potential cross-contamination and ensuring the safety and integrity of the production line. For example, physical guards can be placed on the machines packaging infeeds to prevent any inadvertent packaging material from being utilized until production is ready to resume. This can also be used if a piece of equipment is going to be down for a period for maintenance reasons. This eliminates any potential confusion about which filling equipment is ready for production.
- Another way to accomplish this may be to disable or disconnect any packaging infeeds into the filling system during the cleaning process. Adding a documented check that this is completed before production resumes can ensure this is done routinely.

4. **Use of Unlabeled Cartons at Production Start:**

- Use of unlabeled (blank) cartons initially to mitigate the risk of any sanitizers contaminating sellable cartons. Once the equipment is released by preoperational inspection or supervisory review, the plant can transition to labeled sellable cartons for the remainder of the production run. The unlabeled cartons can be discarded once finished product is in sellable cartons.

5. **Verification of Equipment and Line Cleanliness:**

- When a piece of equipment has been cleaned and is ready to be put back into service, the equipment should be visually inspected by a trained individual to look for any residual cleaning solution. This should be part of the preoperational process and a procedure of how to perform the activity should be available to anyone performing it. This should be documented daily.

6. **Use of Inline Sensors:**

- Incorporate sensors or monitoring systems to verify that the CIP wash or sanitizer is entirely clear from the equipment before introducing product. Real-time monitoring ensures the complete removal of sanitizers, minimizing the risk of unintended contamination. The sensors must be validated upon initial installation and calibrated regularly. If the sensors fail, and there is no secondary check behind them, product could

unintentionally become contaminated. Additionally, not all chemicals are able to be measured with common inline sensing equipment.

7. Physical Disconnects Between Functions:

- One of the best ways to prevent contamination from occurring is to have a physical break between the two pieces of equipment that are performing different functions. If one piece of equipment is cleaning and another has product in it, a physical break, mix proof valving, block bleed block valve arrangement, or other approved means of separation is required. For example, when processing equipment washes, it is very important to manually disconnect or properly valve out the lines, with a fail-safe valve going to the finished product tanks associated with that processor. This is a requirement in item 15p of the PMO. It is important that the operator conducting these activities understands their system and has been trained to separate the systems for different functions. An up-to-date detailed procedure is recommended to be available for all persons performing this check. A visual check is also recommended after connections are made and before CIP or production resumes.
- Some filling machines can have automated valving that prevents the filler from starting when the machine is in CIP mode. This can be an automatic failsafe to prevent accidental cleaning solution introduction into a product. It must be a double seated mix proof valve meeting the requirements of the PMO, or at least two automatically controlled valves.
- It is recommended to add a check to your preoperational procedure. This is likely a visual check to ensure equipment is ready for a different purpose to ensure no cross connections exist. A trained individual should perform this activity.
- Understanding the process at your given facility is very important to keep sanitizer contamination from happening. Sanitary design and separation of function should also be considered before new equipment is installed, or existing equipment is retooled. Item 15p in the PMO requires one fail safe valve or sanitary check valve to be installed on any water to product line to reduce cross contamination potential.

This is not an exhaustive list, and this should be coupled with the facilities' prerequisite programs and Training Programs. Additionally, compliance with 21 CFR part 117, strict GMPs, and the current version of the PMO are prerequisites to creating an effective program.

By implementing these best practices, plants can significantly reduce the likelihood of contamination, maintain stringent quality control, and ensure the safety and integrity of their products throughout the production process. A plant's preoperational inspections and practices are crucial to reducing this risk and should be used when implementing these suggestions. Some or all of these practices can be used in a given facility, but should be tailored to fit the need of each specific location. While automation and technology help eliminate some of the human error, it should not be solely relied upon to prevent these issues. The best strategies should have a two-party prevention system so that the final release of product is not left to one machine or person.

Training and Awareness

While best practice suggestions are important, one of the most critical pieces to ensuring no sanitizer adulteration in dairy products occurs is through effective training of employees. Most of the documented incidents of sanitizer solution in product has been related to human error. Lack of adequate on-the-job training and communication have been seen with recently increasing rates of employee turnover in the dairy industry. Employee awareness and engagement is crucial to having a successful operation and this situation is no different.

A comprehensive training program is essential to uphold high quality standards and ensure the safety of products. To achieve this, an annual training session should be conducted for all personnel, covering general hygiene practices, regulatory updates, and safety protocols. Job-specific training is a crucial component, focusing on the unique responsibilities of production room personnel, including machinery operation, Cleaning in Place (CIP) procedures, and sensory evaluation. Regular refresher training sessions should be implemented for applicable personnel to reinforce key concepts, address any procedural changes, and maintain a continuous commitment to best practices. Equipment-specific training can be facilitated by vendors, utilizing a combination of hands-on demonstrations, classroom-style discussions, and interactive online modules to comprehensively educate employees on machinery operation, maintenance, and safety. A unique approach involves a side-by-side procedure check training, where a trainer works alongside employees during routine tasks, providing immediate feedback and verification of adherence to protocols. Recognizing that employee awareness and engagement are paramount, these training methods cater to various learning styles, creating a culture of attentiveness and dedication to quality and safety throughout the dairy production process.