



DRY-GUD-015	Dairy
Revision: 1.1	Missing or Incomplete Pasteurization Records
Approved: 11/01/2022	Wisc. Stat. and/or Wis. Admin. Code: ATCP 65

SUBJECT: Reconciliation Procedures for Missing or Incomplete Pasteurization Records

Scope

To assist dairy plants with evaluating and documenting product safety when required pasteurization records are missing or incomplete. This guidance only applies to properly functioning and operating pasteurization systems. Pasteurization systems operating under a broken seal shall follow DATCP broken seal procedures.

Definitions

Pasteurization as defined under ATCP 65.01(50)

Corrective action: procedures followed when a deviation occurs.

Guidance

1. If required pasteurization records are missing or incomplete, a risk assessment is needed to verify pasteurization and product safety.
2. The licensed dairy plant shall take the lead responsibility in determining the safety of any implicated product, which may or may not be in their control.
3. The following are considerations for alternative evidence and/or documentation that may assist with evaluating a corrective action.
 - a. Corrective action in the event of an unanticipated food safety problem, 21 CFR 117.150(b)(2).
 - i. Take corrective action to identify and correct the problem.
 - ii. Take steps to reduce the likelihood that the problem will recur.
 - iii. All affected food is evaluated for safety.
 - iv. All affected food is prevented from entering into commerce.
 - v. Reanalyze food safety plan to determine whether modifications are required.
 - vi. Criteria (available science or evaluation by a recognized authority) used to evaluate the process and ensure food safety.
 - b. Supporting pasteurization documentation
 - i. What specific legal requirement is missing or incomplete?

- ii. Are electronic records readily accessible and in compliance with the applicable provision of Appendix H, sections IV and V of the PMO?
 - iii. Are related back-up (non-legal) records available to substantiate the legal record?
 1. Is back-up data accurate and how is it verified for accuracy?
 2. Is back up data available for all the missing public health record requirements; e.g., product temp, air space, flow, temperature and flow event pen traces, other?
 - c. Evaluation of pasteurization public health controls
 - i. Verify public health controls listed on DATCP pasteurizer test report are functioning correctly, e.g., time, temperature, pressure and/or flow.
 - ii. Controls that are compromised shall follow DATCP broken seal procedures.
4. If corrective action, alternative evidence and/or documentation can be verified by the dairy plant, the implicated product can be considered safe for distribution.
5. Alternative uses for dairy products that cannot be verified to assure food safety.
 - a. Aging for 60 days, where appropriate under 21 CFR Standard of Identity.
 - b. Further manufacturing with a lethal heat-treatment, e.g., pasteurized process cheese.
 - c. Animal feed under appropriate preventive controls as required by 21 CFR 117.
 - d. Disposal
 - e. Food diverted to other acceptable uses that ensure food safety, e.g., high pressure processing.
6. Documentation
 - a. All documentation regarding missing or incomplete pasteurization records shall be maintained by the licensed dairy plant and be accessible for regulatory review as appropriate.
7. Regulatory authority
 - a. It is recommended that an industry hold be placed while evaluating a corrective action.
 - b. If corrective action or documentation are insufficient DATCP may place implicated product on hold according to statute Chapter 97.12(2).

Contacts

Responsible; Environmental Health Sanitarian, Environmental Health Services Supervisor, Dairy Technical Specialist, and Environmental Health Services Supervisor – Technical.

References

ATCP 65
Pasteurized Milk Ordinance
3-A Sanitary Standards
Chapter 97 Food Regulation

Document History

The most recent changes to this controlled document are listed at the top of the table:

Revision	Author	Change Description	Approval Date
1.1	Tyson Villarreal	New	11/01/2022

Approval

Tasks

This workflow created the following tasks. You can also view them in [Approval \(New\) Tasks](#).

<input type="checkbox"/> Assigned To	Title	Due Date	Status	Related Content	Outcome
■ Millard, Amy M	Please approve DRY-GUD-015 Missing or Incomplete Pasteurization Records NEW	11/9/2022	Completed	DRY-GUD-015 Missing or Incomplete Pasteurization Records	Approved
■ Sprecker, Troy S	Please approve DRY-GUD-015 Missing or Incomplete Pasteurization Records NEW	11/9/2022	Completed	DRY-GUD-015 Missing or Incomplete Pasteurization Records	Approved