THE DAIRY PRACTICES COUNCIL®

GUIDELINE FOR CONDUCTING AND DOCUMENTING HACCP 'HACCP PRINCIPLE #6 & #7: ESTABLISH VERIFICATION ACTIVITIES & RECORDS'

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APPROVED COPY
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Guideline Preparation and Review Process

Guideline development within Dairy Practices Council (DPC) is unique and requires several levels of peer review. The first step in the process of guideline development starts with a Task Force subcommittee comprised of individuals from industry, regulatory and education interested in and knowledgeable about the subject to be addressed. Drafts, referred to as 'white copies,' are circulated until all members are satisfied with the text. The final white copy may then be distributed to the entire Task Force, DPC Executive Vice President and whoever the Task Force Director feels would add to the strength of the review. Following final white copy review and correction, the next step in the process requires a yellow cover draft that is circulated to the member Regulatory Agency representatives that are referred to as "Key Sanitarians." The Key Sanitarians may suggest changes and insert footnotes if their state standards and regulations differ from the text. After final review and editing the guideline is distributed in the distinctive DPC green cover to people worldwide. These guidelines represent the state of the knowledge at the time they are written.

Disclaimer

The DPC is not responsible for the use or application of the information provided in this Guideline. It is the responsibility of the user to ensure that the information addresses their needs and that any action taken complies with appropriate regulations and standards.

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INTRODUCTION

This guideline will focus on Hazard Analysis Critical Control Point (HACCP) Principle #6: Establish Verification Activities and HACCP Principle #7: Establish Records.

Remember that the principles of HACCP apply to food safety, NOT food quality. Effective monitoring of critical limits is essential so that any deviation from a critical limit(s) triggers prompt corrective action and resolution.

NOTE: Critical factors for aseptically processed Grade "A" milk and milk products, as determined by the process authority and listed on the scheduled process under 21 CFR Part 113 shall be managed separately from the NCIMS HACCP System, even if identified as a CCP in the hazard analysis. Critical factors shall be monitored under the operating supervision of an individual who has successfully completed an approved course of instruction in low-acid canned foods as required under 21 CFR 108.35. Compliance with the provisions of 21 CFR Part 113 shall satisfy the requirements of this Section, regardless of whether a critical factor has also been designated as a CCP.

DEFINITIONS

Verification – the verification of Critical Limits (CL) at Critical Control Points (CCP) is essential to a properly operating HACCP system. Verification is also conducted for Sanitation Standard Operating Procedures (SSOPs) or Prerequisite Programs (PP's), which serve as part of the foundation of the HACCP System. Verification has been defined by Appendix K of the PMO as being those "activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan." For example: You are doing what you say you will do.

Validation – the validation of Critical Limits (CL) at Critical Control Points (CCP) is essential to a properly operating HACCP system. Validation is also conducted for Sanitation Standard Operating Procedures (SSOPs) or Prerequisite Programs (PP's), which serve as part of the foundation of the HACCP System. Validation has been defined by Appendix K of the PMO as being "The element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards." For example: Is what you are doing the right thing.

Records – the monitoring piece that is tied to the process that documents what is happening at each step in the process. Records are the evidence reviewed during verification that shows "you did what you said you were going to do." A record is the documented evidence that an activity took place – i.e., CCP monitoring, training, etc.

GUIDELINE CONTENT

Establish Verification – HACCP Principle #6

Verification of the HACCP Plan

After monitoring activities (HACCP Principle #5) have been established for each critical control point identified (HACCP Principle #2), they must be verified to ensure compliance.

Every dairy facility shall verify that the HACCP System is being implemented according to design. Verification activities shall include, but not be limited to:

1. The calibration of CCP process-monitoring instruments, i.e., pasteurization tests, vitamin concentration, metal detection, or any other monitoring activity of CCP's established by the facility.
2. The performance of periodic end-product or in-process testing.
3. A review, including signing and dating of monitoring records by a trained individual. These records include:
    - The Monitoring of CCPs, PP's or SSOP's: The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the recorded document values are within the control limits (CLs). This review shall occur at a frequency that is appropriate to the importance of the record and as specified in the HACCP Program; You should always complete these steps before product leaves your control or will have a recall of the product.
    - The Taking of Corrective Action: The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective action(s) was taken in accordance with the corrective action requirements cited in DPC094, *HACCP Principles #4 & #5: Establish Monitoring Procedures & Corrective Actions*. This review shall occur at a frequency that is appropriate to the importance of the record. A deviation log is required; and
    - The calibrating of any process monitoring instruments used in the HACCP Program and the performance of any periodic end-product or in-process testing that is part of the dairy facilities verification activities.

    The purpose of these reviews is to ensure that the records are complete and that these activities occurred in accordance with the dairy facilities written procedures. These reviews shall occur at a scheduled frequency and within a reasonable time after the records are made.
4. The taking of corrective action procedures whenever any verification procedure establishes the need to take a corrective action.

Validation of the HACCP Plan

Every dairy facility shall validate that the HACCP Plan is adequate to control hazards that are reasonably likely to occur. This validation shall occur at least once within twelve (12) months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP Plan. Such changes may include changes in the following:

- raw materials or source of raw materials;
- product formulation;
- processing methods or systems, including computers and their software;

- packaging;
- finished product distribution systems;
- the intended use or intended consumers of the finished product; and
- consumer complaints.

The validation shall be performed by a qualified individual(s) trained in accordance with the requirements described in Appendix K of the PMO and shall be subject to the record keeping requirements cited below. The HACCP Plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this document.

Validation of the Hazard Analysis Plan

Whenever a dairy facility does not have a HACCP Plan, because a hazard analysis has revealed no hazards that are reasonably likely to occur, the dairy facility shall reassess the adequacy of the hazard analysis whenever there are any changes in the process that could reasonably affect whether a hazard exists. Such changes may include changes in the following:

- raw materials or source of raw materials;
- product formulation;
- processing methods or systems, including computers and their software;
- packaging;
- finished product distribution systems;
- the intended use or intended consumers of the finished product; and
- consumer complaints.

A qualified individual(s) trained in accordance with HACCP and Appendix K of the PMO shall perform the validation. The hazard analysis shall be maintained on site and reviewed at least annually.

Establish Records – HACCP Principle #7

It is essential that dairy facilities use consistent terminology to identify each piece of equipment, record, document, or other program throughout their written HACCP System.

Required Records

A dairy facility shall maintain the following records for their HACCP System:

1. Records documenting the ongoing application of the PP's or SSOP's, including a brief written description, monitoring and corrective records;
2. The written hazard analysis;
3. The written HACCP Plan;
4. Required HACCP documents and forms;
5. A Table of Contents;
6. A document change log;
7. Records documenting the ongoing application of the HACCP Plan that include:
   - Monitoring of CCPs and their CLs, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP Plan;
   - Corrective actions, including all actions taken in response to a deviation;
   - A deviation log (required); and
   - Plan validation dates and activities.
8. Records documenting verification and validation of the HACCP System, including the HACCP Plan, hazard analysis, and SSOPs.

General Requirements

Information required on all records shall include:

1. The identity and location of the dairy facility;
2. The date and time of the activity that the record reflects;
3. The signature or initials of the person(s) performing the operation or creating the record; and
4. Where appropriate, the identity of the milk or milk product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

Documentation

The records shall be signed and dated by a qualified individual onsite. This signature shall signify that these records have been accepted by the firm.

Record Retention

All records of monitoring activities shall be retained at the dairy facility for perishable or refrigerated products, for at least one (1) year after the date that such products were prepared per the PMO. In the case of frozen, preserved, or shelf-stable products, for two (2) years after the date that the products were prepared or the shelf-life of the product, whichever is greater, unless longer retention time is required by other regulations or customers.

Records that relate to the adequacy of equipment or processes used, such as commissioning or process validation records, including the results of scientific studies and evaluations, shall be retained at the dairy facility for at least two (2) years after the date that the dairy facility last used such equipment or process.

Revisions of the HACCP System will be maintained at the facility going back one revision.

Off-site storage of processing records is permitted after six (6) months following the date that the monitoring occurred if such records can be retrieved and provided on-site within twenty-four (24) hours of a request for official review. Electronic records are considered to be on-site if they are accessible from an on-site location. HACCP plans are required to remain on site.

If the processing facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location(s) but shall be immediately returned to the processing facility for official review upon request.

Official Review

All records shall be available for official review.

Records Maintained on Computers

The maintenance of the records on computers is acceptable as long as they are available for review upon request.

REFERENCES

- National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (1997). *Hazard Analysis and Critical Control Point Principles and Application Guidelines.* Executive Secretariat Office, Room 354, Aerospace Center, 1400 Independence Avenue SW, Washington DC 20250.

- NCIMS (Current Version). *Grade "A" Pasteurized Milk Ordinance.* Public Health Services, Food and Drug Administration Publication No. 229.

APPENDIX

None.

CURRENT ACKNOWLEDGEMENTS

**This guideline was developed by contributors who are of experienced individuals in a related field(s). The acknowledged persons are included with their professional affiliations and may be contacted via a DPC Officer(s) and/or Task Force Director(s) for questions or concerns.*

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