ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES

420-3-16-AK Appendix K - HACCP Program.

I. THE HACCP SYSTEM INTRODUCTION

HISTORY OF HACCP - The use of the HACCP System is not new to the dairy industry. HACCP is a logical, simple, effective, but highly structured system of food safety control.

The HACCP System was introduced to the food industry as a spin-off of the space program during the 1960s. The National Aeronautics and Space Administration (NASA) used HACCP to provide assurance of the highest quality available for components of space vehicles. This program to develop assurance of product reliability was carried over into the development of foods for astronauts.

The U.S. Army Natick Laboratories, in conjunction with NASA, began to develop the foods needed for manned space exploration. They contracted with the Pillsbury Company to design and produce the first foods used in space. While Pillsbury struggled with certain problems, such as how to keep food from crumbling in zero gravity, they also undertook the task to come as close as possible to 100 percent assurance that the foods they produced would be free of bacterial or viral pathogens.

Using traditional quality control methods for the food industry was soon proven to be unworkable for the task Pillsbury had undertaken. The degree of safety desired was not provided by the current programs, and the product sampling necessary to provide an adequate degree of safety would have been prohibitive to commercialization of space foods. Pillsbury discarded its standard quality control methods and began an extensive evaluation, in conjunction with NASA and Natick Labs, to evaluate food safety. They soon realized that to be successful they would have to have control over their process, raw materials, environment, and their people. In 1971, they introduced HACCP as a preventive system that enables manufacturers to produce foods with a high degree of assurance that the foods were produced safely.

BACKGROUND - HACCP is a management tool that provides a structured and scientific approach to the control of identified hazards. HACCP is a logical basis for better decision-making with respect to product safety. HACCP has

international recognition as an effective means of controlling food safety hazards and is endorsed as such by the joint Food and Agriculture Organization (FAO) of the World Health Organization (WHO) Codex Alimentarius Commission. The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has also endorsed it.

The HACCP concept will enable those operating and regulating under a HACCP Plan to move to a preventive approach, whereby potential hazards are identified and controlled in the manufacturing environment, i.e., prevention of product failure. HACCP allows for a preventive, systematic approach to food safety.

VOLUNTARY PARTICIPATION - This Appendix describes a NCIMS voluntary HACCP Program alternative to the traditional inspection system. A milk plant, receiving station, or transfer station may not participate in the NCIMS voluntary HACCP Program unless the Health Officer's responsible for the oversight of the facility agrees to participate with the milk plant(s), receiving station(s), and transfer station(s) in the NCIMS voluntary HACCP Program. Both parties shall provide written commitment to each other that the necessary resources to support participation in the NCIMS voluntary HACCP Program shall be made available.

Management responsible for both the Health Officer and the milk plant, receiving station, and/or transfer station shall be willing to provide the resources required to develop and implement a successful HACCP System.

HACCP PRINCIPLES - Following are the seven (7) HACCP principles to be included in a HACCP Plan:

1. Conduct a hazard analysis.
2. Determine the critical control points.
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

PREREQUISITE PROGRAMS (PPs) - Prior to the implementation of a HACCP Plan, there is a requirement for milk plants, receiving stations, and transfer stations to develop, document and implement written PPs. PPs provide the basic environment and operating conditions that are necessary for the production of

safe, wholesome food. Many of the conditions and practices are specified in federal and state regulations and guidelines.

PPs and the HACCP System in total, address public health concerns such as those identified in 21 CFR Part 7, Recalls; Part 110, Good Manufacturing Practices (GMPs); Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; Part 131, Milk and Cream; the Grade "A" PMO; and the current edition of the NACMCF HACCP Principles and Application Guidelines.

SUMMARY - The seven (7) principles of HACCP are also called the HACCP Plan. When combined with the PPs, they constitute a HACCP System. The NCIMS voluntary HACCP Program described in this Appendix includes the HACCP System and other prescribed Grade "A" PMO criteria, such as drug residue testing and trace back; use of milk only from supplies that have been awarded a milk sanitation compliance rating of 90 percent or better or from an acceptable IMS HACCP listed source; and the labeling requirements of Section 4. When properly implemented, the NCIMS voluntary HACCP Program described in this appendix will provide assurance of milk and milk product safety that is equivalent to that provided under the traditional inspection system.

II. IMPLEMENTATION OF A HACCP SYSTEM

PRELIMINARY STEPS - Preliminary steps as listed in the NACMCF document should be followed when producing a HACCP Plan. Complete, up-to-date process flow diagrams are required for all milk and milk products manufactured. Flow diagrams may be combined when processes, products, and hazards are similar.

PREREQUISITE PROGRAM - HACCP is not a stand-alone program, but is part of a larger control system. PPs are the universal procedures used to control the conditions of the milk plant environment that contribute to the overall safety of the milk or milk product. They represent the sum of programs, practices, and procedures that shall be applied to produce and distribute safe milk and milk products in a clean, sanitary environment. They differ from CCPs in that they are basic sanitation programs that reduce the potential occurrence of a milk or milk product safety hazard. Frequently, both HACCP Plan CCPs and PPs control measures are necessary to control a food safety hazard.

HACCP may be implemented only in a facility that is constructed and operated to provide a sanitary environment. Milk plant, receiving station, or transfer station premises, building construction, maintenance, and housekeeping shall be maintained in a manner sufficient to provide such an environment. These factors shall be controlled by effective milk plant, receiving station, or transfer station programs or

by PPs, as the milk plant, receiving station, or transfer station chooses.

The exact set of PPs will vary since their application is milk or milk product and process specific. The existence and effectiveness of PPs should be assessed during the design and implementation of each HACCP Plan. PPs should be documented and regularly audited. An audit review consists of verifying that the company has a program implemented that indicates how the company monitors and controls each of the PPs. PPs are established and managed separately from the HACCP Plan.

1. Required PPs - The following required PPs shall have a brief written description or checklist that the PPs can be audited against to ensure compliance. PPs shall include procedures that can be monitored; records that specify what is monitored; and how often it will be monitored.

Each milk plant, receiving station, or transfer station shall have and implement PPs that address conditions and practices before, during, and after processing. The PPs shall address:

a. Safety of the water that comes into contact with milk or milk products or product-contact surfaces, including steam and ice.

b. Condition and cleanliness of equipment product-contact surface.

c. Prevention of cross-contamination from insanitary objects and/or practices to milk or milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product.

d. Maintenance of handwashing, hand sanitizing, and toilet facilities.

e. Protection of milk or milk product, packaging material, and product-contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical, and biological contaminants.

f. Proper labeling, storage, and use of toxic compounds.

g. Control of employee health conditions, including employee exposure to high risk situations that could

result in the microbiological contamination of milk or milk products, packaging materials, and product-contact surfaces.

h. Pest exclusion from the milk plant.

In addition to the required PPs specified above, any other PPs that are being relied upon in the hazard analysis to reduce the likelihood of hazards such that they are not reasonably likely to occur, shall also be monitored, audited, and documented as required PPs.

2. Monitoring and Correction - The milk plant, receiving station, or transfer station shall monitor the conditions and practices of all required PPs with sufficient frequency to ensure conformance with those conditions and that are appropriate both to the milk plant, receiving station, or transfer station and to the safety of the milk or milk product being processed. Each milk plant, receiving station, or transfer station shall document the correction of those conditions and practices that are not in conformance. Devices such as indicating and recording thermometers that are used to monitor PPs shall be calibrated to assure accuracy at a frequency determined by the milk plant, receiving station, or transfer station.

3. Required Records - Each milk plant, receiving station, or transfer station shall maintain records that document the monitoring and corrections required by this appendix. These records are subject to the record keeping requirements of this appendix.

HAZARD ANALYSIS - Each milk plant, receiving station, or transfer station shall develop, or have developed for it, a written hazard analysis to determine whether there are milk or milk product hazards that are reasonably likely to occur for each type of milk or milk product processed or handled by the milk plant, receiving station, or transfer station and to identify the control measures that the milk plant, receiving station, or transfer station can apply to control those hazards.

The hazard analysis shall include hazards that can be introduced both within and outside the milk plant, receiving station, or transfer station environment, including hazards that can occur during handling, transportation, processing, and distribution.

A hazard that is reasonably likely to occur is one for which a prudent milk plant, receiving station, or transfer station operator would establish controls because experience, illness

data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the hazard will occur in the particular type of milk or milk product being processed. The hazard analysis shall be developed by an individual(s) trained in accordance with this appendix and shall be subject to the record keeping requirements as described in this appendix.

1. In evaluating what milk or milk product hazards are reasonably likely to occur, at a minimum, consideration should be given to the following:

a. Microbiological contamination.

b. Parasites.

c. Chemical contamination.

d. Unlawful drug and pesticide residues.

e. Natural toxins.

f. Unapproved use of food or color additives.

g. Presence of undeclared ingredients that may be allergens.

h. Physical hazards.

2. Milk plant, receiving station, or transfer station operators should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and milk plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished milk or milk product for the intended consumer.

HACCP PLAN

1. Every milk plant, receiving station, or transfer station shall have and implement a written HACCP Plan whenever a hazard analysis reveals one (1) or more hazards that are reasonably likely to occur. The HACCP Plan shall be developed by an individual(s) who has been trained and shall be subject to record keeping requirements in accordance with this appendix. A HACCP Plan shall be specific to each location and milk or milk product. The plan may group similar types of milk and milk products together, or similar types of production methods together, if the hazards, CCPs, CLs, and procedures required to be identified and performed by 2 of this section are essentially identical, provided that

any required features of the plan that are unique to a specific milk or milk product or method are clearly delineated in the plan and are observed in practice.

2. Contents of the HACCP Plan - The HACCP Plan shall, at a minimum:

a. Include complete up-to-date process flow diagrams for all milk and milk products manufactured. Flow diagrams may be combined when processes, milk and milk products, and hazards are similar.

b. List all hazards that are reasonably likely to occur as identified in the hazard analysis specified above, and that shall be controlled for each type of milk or milk product.

c. List the CCPs for each of the identified hazards, including the appropriate:

(1) CCPs designed to control hazards that could occur or could be introduced in the milk plant, receiving station, or transfer station environment.

(2) CCPs designed to control hazards introduced outside the milk plant, receiving station, or transfer station environment, including hazards that occur before arriving at the milk plant, receiving station, and/or transfer station.

(3) List the CLs that shall be met at each of the CCPs.

d. List the procedures and the frequency with which they are to be performed that will be used to monitor each of the CCPs to ensure compliance with the CLs.

e. Include any corrective action plans that have been developed in accordance with the corrective action requirements as described in this Appendix, and that are to be followed in response to deviations from CLs at CCPs.

f. List the verification and validation procedures, and the frequency with which they are to be performed, that the milk plant, receiving station, or transfer station will use in accordance with verification and validation requirements as described in this appendix.

g. Provide a record keeping system that documents the monitoring of the CCPs in accordance with the record

requirements as described in this appendix. The records shall contain the actual values and observations obtained during monitoring.

3. Sanitation - Sanitation controls may be included in the HACCP Plan. However, to the extent that they are monitored in accordance with the PPs, they need not be included in the HACCP Plan.

CORRECTIVE ACTIONS - Whenever a deviation from a CL occurs, a milk plant, receiving station, or transfer station shall take corrective action by following the procedures set forth in 1 or 2 of this section.

a. Milk plants, receiving stations, or transfer stations may develop written corrective action plans which become a part of their HACCP Plan(s) in accordance with this appendix. These corrective action plans may predetermine the corrective actions that milk plants, receiving stations, and transfer stations will take whenever there is a deviation from a CL. A corrective action plan that is appropriate for a particular deviation is one (1) that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

b. No milk or milk product is allowed to enter commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; or

c. If such milk or milk product has entered commerce, it is expeditiously removed; and

d. The cause of the deviation is corrected.

2. When a deviation from a CL occurs, and the milk plant, receiving station, or transfer station does not have a corrective action plan that is appropriate for that deviation, the milk plant, receiving station, or transfer station shall:

a. Segregate and hold the affected milk or milk product, at least until the requirements of paragraphs 2.b and 2.c of this section are met.

b. Perform or obtain a review to determine the acceptability of the affected milk or milk product for distribution. The review shall be performed by an individual or individuals qualified by training or experience to perform such a review.

c. Take corrective action, when necessary, with respect to the affected milk or milk product to ensure that no milk or milk product is allowed to enter commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

d. Take corrective action, when necessary, to correct the cause of the deviation.

e. Perform or obtain timely validation by a qualified individual(s), as required in this appendix, to determine whether modification of the HACCP Plan is required to reduce the risk of recurrence of the deviation, and modify the HACCP Plan as necessary.

3. All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification.

VERIFICATION AND VALIDATION

1. Every milk plant, receiving station, or transfer station shall verify that the HACCP System is being implemented according to design, except that the milk plant’s APPS or RPPS, respectively, as defined by these rules, shall be managed separately from the NCIMS HACCP System, even if identified as a CCP in the hazard analysis. The milk plant's APPS or RPPS, respectively, shall be inspected by the FDA, or the state regulatory agency when designated by the FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110, and 113 at a frequency determined by FDA.

a. Verification activities shall include:

(1) The calibration of CCP process-monitoring instruments, i.e., pasteurization tests, etc.

(2) At the option of the milk plant, receiving station, or transfer station the performance of periodic end-product or in-process testing.

(3) A review, including signing and dating by an individual who has been trained in accordance with the training requirements of this appendix, of the records that document.

(i) The Monitoring of CCPs - 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 CLs. This review shall occur at a

frequency that is appropriate to the importance of the record and as specified in the HACCP Plan.

(ii) 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 before. This review shall occur at a frequency that is appropriate to the importance of the record. A centralized deviation log is required.

(iii) The calibrating of any process monitoring instruments used at CCPs and the performance of any periodic end-product or in-process testing that is part of the milk plant, receiving station, or transfer station's verification activities.

The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the milk plants, receiving stations, or transfer stations written procedures. These reviews shall occur 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.

b. The calibration of CCP process-monitoring instruments, and the performance of any periodic end-product and in-process testing, in accordance with 1.a.(3)ii) and 1.a.(3)iii) of this section, shall be documented in records that are subject to the record keeping requirements in this appendix.

2. **Validation of the HACCP Plan** - Every milk plant, receiving station, or transfer station 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:

a. Raw materials or source of raw materials; product formulation; processing methods or systems, including

computers and their software; packaging; finished product distribution systems; or 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 this appendix 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.

3. **Validation of the Hazard Analysis** - Whenever a milk plant, receiving station, or transfer station does not have a HACCP Plan, because a hazard analysis has revealed no hazards that are reasonably likely to occur, the milk plant, receiving station or transfer station 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:

a. Raw materials or source of raw materials.

b. Product formulation.

c. Processing methods or systems, including computers and their software.

d. Packaging.

e. Finished product distribution systems; or

f. The intended use or intended consumers of the finished product.

g. Consumer complaints.

A qualified individual(s) trained in accordance with the training requirements of this appendix shall perform the validation.

RECORDS

1. Required Records - It is essential that milk plants, receiving stations, and transfer stations use consistent terminology to identify each piece of equipment, record, document, or other program throughout their written HACCP System. A milk plant, receiving station, or transfer station shall maintain the following records documenting

the milk plant, receiving station, or transfer station's HACCP System:

a. Records documenting the ongoing application of the PP, including a brief written description, monitoring, and correction records.

b. The written hazard analysis.

c. The written HACCP Plan.

d. Required HACCP documents and forms specified in 1a-c. of this section shall be dated or identified with a version number. Each page shall be marked with a new date or version number whenever that page is updated.

e. A Table of Contents and centralized list of the HACCP program records, by title, documenting the ongoing application of the HACCP System shall be maintained and provided for review.

f. A document change log.

g. Records documenting the ongoing application of the HACCP Plan that include:

(1) Monitoring of CCPs and their CLs, including the recording of actual times, temperatures, or other measurements as prescribed in the milk plant’s, receiving station’s, or transfer station’s HACCP Plan.

(2) Corrective actions, including all actions taken in response to a deviation.

(3) A centralized deviation log is required.

(4) Plan validation dates.

h. Records documenting verification and validation of the HACCP System, including the HACCP Plan, hazard analysis, and PPs.

2. **General Requirements** - Records required by this section shall include:

a. The identity and location of the milk plant, receiving station, or transfer station.

b. The date and time of the activity that the record reflects.

c. The signature or initials of the person(s) performing the operation or creating the record.

d. 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.

3. **Documentation**

a. The records in paragraphs 1a-c. of this section shall be signed and dated by the most responsible individual onsite at the milk plant, receiving station, or transfer station. This signature shall signify that these records have been accepted by the firm.

b. The records in paragraphs 1a-c. of this section shall be signed and dated:

(1) Upon initial acceptance.

(2) Upon any modification.

(3) Upon verification and validation in accordance with the requirements cited above.

4. Record Retention

a. All records required by this section shall be retained at the milk plant, receiving station, or transfer station for perishable or refrigerated products for at least one (1) year after the date that such products were prepared, and 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.

b. 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 milk plant, receiving station, or transfer station facility for at least two (2) years after the date that the milk plant, receiving station, or transfer station last used such equipment or process.

c. 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.

d. 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.

5. **Official Review** - All records required by this section shall be available for official review at reasonable times.

6. **Records Maintained on Computers** - The maintenance of records on computers, in accordance with the requirements cited above, is acceptable.

III. **EMPLOYEE EDUCATION AND TRAINING**

The success of a HACCP System depends on educating and training management and employees in the importance for their role in producing safe milk and milk products. This should also include information in the control of milk borne hazards related to all stages of dairy production and processing. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring specific CCPs and PPs.

IV. **TRAINING AND STANDARDIZATION**

HACCP training for industry and regulatory personnel will be based on the current "Hazard Analysis and Critical Control Point Principles and Application Guidelines" of NACMCF, the current FDA HACCP recommendations, and the regulatory requirements of this appendix and related sections of these rules.

The Health Officer personnel responsible for the evaluation, licensing, and regulatory audits of facilities using the NCIMS voluntary HACCP Program shall have equivalent training to the training required to perform traditional NCIMS functions. They shall also have specialized training in conducting HACCP System audits.

Industry, regulatory, rating, and FDA personnel should be trained together.

HACCP TRAINING

1. Core Curriculum - The Dairy HACCP Core Curriculum consists of:

a. Basic HACCP training.

b. An orientation to the requirements of the NCIMS voluntary HACCP Program.

Basic HACCP training consists of instruction in the application of the NACMCF Principles of HACCP to Food Safety. This training includes practical exercises in conducting a hazard analysis and evaluating potential hazards; in writing a HACCP Plan; and in the validation of the plan. It should be taught by experienced instructors.

The orientation component ideally is coupled with the basic HACCP training but can be taught separately. The content of the orientation will be conducted under the guidance of the NCIMS. It is intended to familiarize industry and regulatory personnel with specific dairy HACCP concerns and the regulatory requirements under the NCIMS voluntary HACCP Program. It is to be taught by instructors experienced in the application of HACCP under the NCIMS voluntary HACCP Program.

The industry individual(s) performing the functions identified in this Appendix requiring training or listed in Part 2 of this section shall have successfully completed appropriate training in the application of HACCP principles to milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

2. **Industry Personnel** - Only industry individuals who have met the requirements of Part 1 of this section shall be responsible for the following functions:

a. Developing PPs.

b. Developing the hazard analysis, including delineating control measures, as required.

c. Developing a HACCP Plan that is appropriate for the specific milk plant, receiving station, or transfer station, in order to meet these requirements.

d. Validating and modifying the HACCP Plan in accordance with the corrective action procedures and the validation activities as specified.

e. Performing required HACCP Plan records reviews.

3. **Regulatory Personnel** - Regulatory personnel performing HACCP audits shall have successfully completed appropriate training in the application of HACCP principles for milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum.

V. HACCP AUDITS AND FOLLOW-UP ACTIONS

REGULATORY AGENCY AUDITS, ENFORCEMENT AUDITS, ACTIONS AND FOLLOW-UP - Audits shall be conducted of the milk plant, receiving station, or transfer station facility, and the NCIMS voluntary HACCP Program to ensure compliance with the HACCP System and other associated NCIMS regulatory requirements.

The audit may be announced at the discretion of the auditor under certain circumstances, i.e., initial audit, follow-up audit, new construction, pasteurizer checks, etc. When unannounced audits are conducted, the audits shall not be completed until appropriate milk plant personnel have had an opportunity to make all pertinent records available for review by the auditor.

AUDITING PROCEDURES

1. Pre-Audit Management Interview - Review and discuss the milk plant HACCP System including:

a. Changes in the management structure.

b. The Hazard Analysis - Ensure that all milk and/or milk product hazards are addressed.

c. Changes in the HACCP Plan.

d. Changes in the PPs.

e. Changes in the flow diagram.

f. Changes in milk or milk products or processes.

2. Review past Audit Reports (AR) and corrections of deficiencies and non-conformities, if any.

3. In-milk plant review of the implementation and verification of the HACCP System.

4. Review records of the HACCP System.

5. Review compliance with other applicable NCIMS regulatory requirements*.

6. Discuss findings and observations.

7. Prepare and issue an AR based on findings of deficiencies and non-conformities. The AR shall include timelines for the correction of all identified deficiencies and non-conformities.

8. Conduct the exit interview.

Note: Examples of Other Applicable NCIMS Requirements:

1. Raw Milk Supply Source.

2. Labeling Compliance.

3. Adulteration.

4. Licensing Requirements.

5. Drug Residue Testing and Trace Back Requirements.

6. Regulatory Samples in Compliance.

7. Approved Laboratory Utilized for the Required Regulatory Tests.

8. Pasteurization Equipment Design and Installation.

THE HEALTH OFFICER ENFORCEMENT ACTION/FOLLOW-UP

The Health Officer shall:

1. Prepare and issue ARs based on findings of deficiencies and non-conformities and other NCIMS requirements.

2. Review the AR with the milk plant and establish time lines for the correction of all identified deficiencies and non-conformities and other NCIMS requirements.

3. Follow-up to ensure corrections are made as a result of the issuance of the AR.

4. Take immediate action when an imminent health hazard is observed to prevent further movement of milk and milk products until such hazards have been eliminated.

5. Initiate regulatory enforcement action such as permit suspension, revocation, hearings, court actions, and/or other equivalent measures when the milk plant, receiving station, or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies).

AUDIT TIMEFRAMES

First Year after Initial Regulatory Audit	Initial audit; next audit in thirty (30) to forty-five (45) days; and four (4) month intervals thereafter, unless the Health Officer determines that a greater frequency is warranted.
Subsequent Audits	Every six (6) months unless the Health Officer determines that a greater frequency is warranted*.
Compliance Follow-Ups	Compliance follow-ups shall be made as frequently as necessary to assure that problems observed by the Health Officer have been resolved.

*The Health Officer may elect to extend the minimum audit frequency from four (4) to six (6) months as long as the following conditions exist:

1. Item 12b on FORM FDA 2359m-MILK PLANT, RECEIVING STATION, OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT is not marked on the regulatory audit for the current HACCP audit.

2. No current two (2) out of four (4) warning letter(s) or three (3) out of five (5) violation letter(s) for finished milk and/or milk product, or violative water sample results.

3. No CLEs on the current or prior audit.

Audit Report Form (refer to Appendix M).

Author: G. M. Gallaspy, Jr.
Statutory Authority: Code of Ala. 1975, §§22-2-2, 22-20-7.
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