NOT MEASUREMENT SENSITIVE

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# DEPARTMENT OF DEFENSE HANDBOOK

# GUIDELINES FOR AUDITING FOOD ESTABLISHMENTS

This handbook is for guidance. Do not cite this document as a requirement.

AMSC N/A FSG 89GP

# FOREWORD

1. This handbook is approved for use by all Departments and Agencies of the Department of Defense.

2. This handbook cannot be cited as a requirement. If it is, the contractor does not have to comply.

3. This handbook contains guidelines for auditing manufacturing facilities.

4. Each appendix is based on controlling regulatory provisions, industry standards, or other DoD requirements.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Director, DoD Veterinary Service Activity, Office of The Surgeon General/HQDA, 5109 Leesburg Pike, Falls Church, VA 22041-3258, by using the Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document, or by letter.

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# 1. SCOPE

1.1 Purpose. This handbook provides guidance related to conducting sanitation audits of commercial food establishments. The requirements for these audits and related DoD policy are contained in MIL-STD-3006A and AR 40-657, respectively. This handbook is based on the Current Good Manufacturing Practices (CGMP) requirements, as provided in Title 21, Code of Federal Regulations (CFR), Part 110, as basic sanitation standards for food establishments. The handbook also provides specific commodity guidance within appendices for use in the sanitation auditing process.

1.2 Application. This handbook is applicable to all establishments supplying subsistence purchased with Appropriated and Non Appropriated Funds (NAF) for Armed Forces use. Detailed auditing guidelines relating to specific types of food establishments are located in the appendices of this handbook. This handbook is also applicable in military owned or leased facilities where foods are stored, utilizing Title 21 CFR, Part 110, General Provisions only. Compliance with MIL-STD-3006A is mandatory for listing of plants in the Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement (Directory). Approved establishments are listed in U.S. Army Veterinary Command (VETCOM) Circular 40-1 (*Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*) or locally approved lists.

1.3 Objectives. This handbook is intended to ensure that food establishments supplying subsistence, both within the Continental United States (CONUS) and Outside the Continental United States (OCONUS), are in compliance with CGMPs, thus reducing the risk of transmission of foodborne disease. It is also intended to verify the effectiveness of food security and protection programs.

1.4 Limitations. In OCONUS locations, the Major Command (MACOM) Veterinarian may supplement this document. This handbook is not used to determine an establishment's capabilities to comply with product specifications or other purchase requirements. In cases where CGMPs are provided in the CFR for specific subsistence items (i.e., acidified foods), the specific CGMPs for that item will be applied in addition to those found in Part 110. Good Manufacturing Practice (GMP) documents provided by industry and recognized by the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) or the United States Department of Commerce (USDC), may be used in conjunction with Title 21, CFR, Part 110, with MACOM approval.

# 2. APPLICABLE DOCUMENTS

2.1 General. The documents listed below are not necessarily all of the documents referenced herein, but are the ones that are needed in order to fully understand the information provided by this handbook.

2.2 Government documents.

2.2.1 Standard. The following standard is a part of this document to the extent specified herein. Unless otherwise specified, the issue of the document is as listed in the latest issue of the Department of Defense Index of Specifications and Standards (DoDISS), and supplements thereto, and are referenced for guidance only.

DEPARTMENT OF DEFENSE STANDARD

MIL-STD-3006A Sanitation Requirements for Food Establishments

(Unless otherwise indicated, copies of the above specifications, standards, and handbooks are available from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094, http://www.dodssp.daps.mil/.)

2.2.2 Other government documents and publications. The following other Government documents and publications comprise a part of this handbook to the extent specified herein.

CODE OF FEDERAL REGULATIONS (CFR)

Title 7, Agriculture.

Title 9, Animals and Animal Products.

Title 21, Food and Drugs.

Title 40, Protection of Environment.

Title 50, Wildlife and Fisheries.

(Application for copies should be addressed to Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402-0001, http://www.acess.gpo.gov/nara/cfr/index.html/)

U.S. PUBLIC HEALTH SERVICE (USPHS)

U.S. Public Health Service (USPHS) Publication Number 229, Pasteurized Milk Ordinance (PMO)

(Application for copies should be addressed to: US Department of Health and Human Services, US Food and Drug Administration, Milk Safety Branch, HFS-626, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204.)

U.S. Public Health Service (USPHS), FDA Food Code 1999

(Application for copies should be addressed to Department of Health and Human Services, Food and Drug Administration, Food Service Sanitation Branch, Washington, DC 20204. http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

ENVIRONMENTAL PROTECTION AGENCY

Environmental Protection Agency Regulations
(http://www.epa.gov/epahome/publications.htm/)

MILITARY PUBLICATIONS

Army Regulation (AR) 25-50, Preparing and Managing Correspondence.

AR 40-5, Preventive Medicine.

AR 40-657, Veterinary/Medical Food Inspection and Laboratory Service.

(Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 1-800-553-6847; or download from web site: http://www.usapa.army.mil/.)

## 3. DEFINITIONS

3.1 General. The definitions and interpretations of terms found in 21 CFR 110 are applicable to this handbook.

3.2 Sanitation Audit. An in-depth examination of the sanitation system to determine the effectiveness and compliance with predetermined reference standards. The sanitation audit examines and evaluates the sanitation system as it applies to an overall organizational element.

3.3 Critical Defect. Condition, practice, step or procedure which: a) presents a biological, chemical or physical property that causes food to be unsafe for consumption; and/or b) the food safety hazard cannot be prevented, eliminated or reduced by a subsequent practice, step or procedure.

3.4 Major Defect. Condition, practice, step or procedure which: a) is of less food safety concern yet affects the usability of the products; and/or b) due to loss or lack of control, may become a Critical Defect.

3.5 Observation. A condition or practice that is not in accordance with the CGMP requirements, but is not a Critical or Major Defect.

3.6 Acceptable. The rating given to an establishment that complies with the requirements of the sanitary audit.

3.7 Unacceptable. The rating given to an establishment that does not comply with the requirements of the sanitary audit.

3.8 Sanitation Audit Rating. A rating based upon the results of the sanitation audit, rated as either “Acceptable” or “Unacceptable”.

3.9 Initial Sanitation Audit. Initial Sanitation Audit determines the sanitary status of food establishments. This audit approves or disapproves the establishment as a source for the Armed Forces. It is comprised of a complete audit of the facility, sanitary control systems and procedures employed by the establishment.

3.10 Special Sanitation Audit. Special Sanitation Audits are performed at approved establishments to decide whether the establishment will remain an approved procurement source of subsistence for the Armed Forces. This audit is performed when an establishment is rated "Unacceptable" or it is suspected that the food provided by the establishment is a threat to health. The focus of this audit is normally limited to the problems found during a previous audit rated “Unacceptable”.

3.11 Routine Sanitation Audit. Routine Sanitation Audits are conducted to determine the current sanitary status of an approved establishment. These audits result in the continued approval, or in notice of the possibility of removal from the Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement, if sanitary deficiencies are not corrected.

3.12 Directed Routine Sanitation Audit. Conducted within establishments listed in the Worldwide Directory, at the discretion of the MACOM Veterinarian, when laboratory results or customer complaints indicate a need for further sanitation cognizance. The focus of this audit is normally limited to the areas of concern.

3.13 Sanitation Audit Report (SAR). A written record of the results from a sanitation audit.

3.14 Corrective Action Request (CAR). A written request for a management response upon completion of a routine or directed routine sanitation audit resulting in an “Unacceptable” rating.

3.15 Dual-Listed Establishments. Dual-Listed establishments are facilities listed in the Worldwide Directory and another recognized federal listing.

3.16 Veterinary Corps Officer (VCO). The term VCO, as used in this handbook, means a graduate veterinarian serving as a commissioned officer in the U.S. Army Veterinary Corps.

3.17 Warrant Officer (WO). The term WO, as used in this handbook, means a Veterinary Services Technician, (MOS 640A) Warrant Officer.

3.18 Functional Area. Areas within a food processing facility where food is received, stored, staged, prepared, processed, packaged, and packed.

3.19 Food Security Violation. An observation noted for an intentional or unintentional breach in food security measures that may compromise food safety. It can occur at any stage during receipt, storage, in-processing, packaging, packing, warehousing and distribution.

3.20 Working Papers. Figures 1thru 11 are designed to assist auditors before, during, and after an audit. The working papers may include written notes and instructions, checklists, questionnaires, matrixes, and/or over-typed reports. Working papers may be modified to meet electronic reporting needs, provided that the original intent of this handbook is met.

3.21 Pre-operational Sanitation. Verification of proper sanitation of functional areas and equipment before operation. This may or may not include visual verification of cleaning and sanitizing techniques.

3.22 Pasteurized Juice. A heat-treated juice processed to accomplish FDA mandated 5-log reduction standard.

3.23 Root Cause. A true cause of a defect based on an in-depth investigation.

4. GENERAL GUIDANCE

4.1 Auditing Personnel.

4.1.1 Routine Sanitation Audits. A VCO/WO may perform Initial, Special, Routine, and Directed Routine Sanitation Audits. A qualified Noncommissioned Officer (NCO) (MOS 91R, SSG or above) may perform routine sanitary audits under certain conditions (refer to AR 40-657).

4.1.2. Joint audits. Joint audits by a VCO/WO and enlisted inspector are necessary to advance training and prepare for independent enlisted personnel inspection assignments.

4.1.3. Reserve Component (RC) VCO/WO. Reserve Component VCO/WO may also perform all commercial sanitation audits. The Veterinary Commander must determine whether the RC VCO/WO is fully qualified. When used, the Commanders must ensure RC officers are credentialed and/or have current knowledge of procedures, military standards, documentation, etc. Reserve Component VCO/WO should perform a joint audit with active duty personnel before an independent audit assignment.

4.2 Off-post caterers and civilian restaurants.

4.2.1 Audit. Audit these or similar off-post establishments according to AR 40-657.

4.2.2 Commercial food establishments. Commercial food establishments providing home delivery service only on a cash basis to individuals residing on a military installation are exempt from sanitation audit and Directory or local list requirements of AR 40-657. Local medical command policy will apply in these instances.

4.2.3 Dinner theaters. Civilian caterers furnishing meals to a Non-Appropriated Fund (NAF) operated dinner theater on a military installation are required to be listed in local or Worldwide Directory according to AR 40-657.

4.2.4 Unit parties. A civilian caterer furnishing meals to a military unit for a unit party or picnic (using NAF morale and welfare funds) must have sanitary approval. For one-time occasions, one-time approval is appropriate and Directory or local listing is not necessary.

4.2.5 On-post retail grocery store, restaurant, and fast-food outlets. These or similar on-post establishments are subject to military sanitary inspection and approval. However, Worldwide

Directory or local listing is not required. Auditors will regard these establishments as similar to military facilities. Retail grocery stores are subject to the same sanitary standards as military commissary stores. The veterinary service will inspect on-post retail grocery stores. Usually, the preventive medicine service is responsible for sanitary evaluation of on-post food service type establishments. AR 40-5 contains sanitary standards for food service establishments. Resale grocery items and raw materials for restaurants and/or fast-food outlets must comply with the approved source requirements of AR 40-657.

4.2.6 Mobile canteens and/or snack trucks servicing military installations. These units, when performing under a Government contract, are subject to sanitation inspection and Worldwide Directory or local listing. When the mobile unit operates as an extension of a central food preparation establishment, audit the base of operations and the mobile unit. AR 40-5 contains sanitary standards for food service operations. Resale food items and raw materials must comply with the approved source requirements of AR 40-657. The mobile units operating on-post are subject to veterinary and/or preventive medicine service inspections. Coordination between veterinary and preventive medicine services is essential to establish responsibility for audits. When operating on-post permissively (without a Government contract), local command policy and requirements for audits and approval will govern. The veterinary service will coordinate with the preventive medicine service to carry out the local command policy. Whether these units are performing under a Government contract or permissively, the Veterinary Commander should maintain sanitary cognizance.

4.2.7 Privately prepared foods. Sanitation audits and Directory or local listing requirements do not apply to food prepared in military quarters or private residences for the following purposes:

(1) Direct sale to individuals.
(2) Donation to charitable organizations.
(3) Consumption at social gatherings not involving the use of Appropriated Funds (APFs) or NAFs. Local command policy will apply in these cases.
(4) Military quarters or private residences will not be approved as sources of food for purchase by APF or NAF activities. However, a food processing establishment adjacent or attached to a private residence must be completely separated by a wall or floor for approval as an acceptable source. The food-processing establishment must not be an integral part of the residence.

4.2.8 Commercial food storage warehouses. Warehouses storing or handling Government-owned perishable or semi-perishable subsistence must be Directory-listed. Commercial cold storage warehouses serving as Defense Supply Center Philadelphia (DSCP) perishable subsistence supply points or storing prepositioned war reserve material stocks will receive annual routine sanitation audits. Furnish a copy of each sanitation audit report to the Defense Subsistence Office Chief; the contractor; and DSCP, ATTN: DSCP-HROS. Forward a copy of all sanitation audit reports to HQ VETCOM, ATTN: MCVS-FA.

4.3 Thermally processed food. Establishments furnishing thermally processed foods in hermetically sealed containers are exempt from Directory or local listing when the products are known to possess little or no potential health hazard. This exemption does not apply to aseptically processed and packaged milk/milk products (as defined in the PMO), canned meat,

poultry, or fish items, unless the appropriate recognized federal agency inspects and lists the establishment.

4.4 Food handler's certificates. In the United States, assign a defect for failure to possess current food handler's certificates only when civil authorities require such certificates. Local medical command policy in overseas areas will govern requirements for food handler certificates.

4.5 Change in establishment's name or ownership. When an establishment's name or ownership changes (without relocation of the plant), notify the approval authority in writing. The approval authority will make the appropriate administrative changes to the Directory or local list.

4.6 Change in establishment location (relocation). Advise the management to follow procedures for requesting an Initial Sanitation Audit.

4.7 Frequency and type of sanitation audits. The frequency and type of audits will be in accordance with AR 40-657.

4.8 Use of documents. Appendix A, General Provisions, is the base document for evaluating an establishment, and covers general sanitation and food security requirements for all establishments. Use the General Provisions in conjunction with the appropriate commodity appendix located in this Handbook. When a product does not have a supporting appendix, use Appendix A. In addition, supporting documents are provided for general/dairy laboratory/Quality Control review (Figures 1 and 2), dairy equipment testing (Figure 3), and food security (Figure 11), as required. Additional documents incorporated by reference are authorized for use.

4.8.1 Checklist. The Appendix A Checklist is comprised of different subparts and paragraphs corresponding back to 21 CFR 110 (Subparts D and F within the CFR are not used). In establishments with mandatory HACCP programs, Appendix A, Subpart H must be used. Establishments that do not have mandated HACCP programs are not required to meet the entire provisions of Appendix A, Subpart H. However, if a HACCP plan is in place, it will be reviewed but not scored. EXCEPTION: Some appendices used for auditing establishments without a mandatory HACCP program may contain specific regulatory requirements that can only be scored under the Subpart H (e.g., "H8-All records are retained for two years."). This is authorized in all instances. On the reverse side (second page) of the Sanitation Audit Report, fully describe any defect(s) (Critical, Major and Observations) corresponding to the subpart/annex used.

4.8.2 Sanitation audit rating. A sanitation audit rating is either “Acceptable” or “Unacceptable”. The finding of one Critical Defect will result in an "Unacceptable" rating. Four or more Major Defect items in Appendix A will result in an "Unacceptable" rating. A sanitation audit will not be rated “Unacceptable” solely based upon Table VII, Food Security. Each item in Appendix A will only be scored once. Only the most severe deficiency identified for each item will be annotated on the checklist. Additional deficiencies applicable for that item will be documented in the narrative. Observations will not result in an "Unacceptable" rating. The cumulative effect of multiple observations indicating an out-of-control process may require an upgrade to one Major Defect due to the increased public health significance.

## 5. AUDIT PROCEDURES FOR SANITATION AUDITS

5.1 Planning, scheduling, and initiating the sanitation audit.

5.1.1 Scheduling the sanitation audit. Normally, sanitation audits are announced and scheduled. Refer to AR 40-657 for exceptions. For Initial Sanitation Audits, send the Pre-audit Questionnaire to the establishment’s representative prior to scheduling the audit. The auditor will schedule the audit by mail, telephonically or in person. At the time the audit is scheduled, determine the type of product the establishment produces, identify those destined for sale to the governmental agencies, and ensure the establishment is operational and producing requested products on the day of the audit. Upon receipt of the Pre-audit Questionnaire, review for completeness and any problem areas, and re-confirm audit date. Lack of a response to the Pre-audit Questionnaire will not preclude scheduling and conducting the audit.

5.1.2 Assemble and review all reference materials. References will include as a minimum: MIL-STD-3006A, MIL-HDBK-3006A procedures, applicable appendices, reference documents, prior audits, CAR(s), laboratory results, etc. Check with supporting veterinary laboratory for the quality history of the company if laboratory results are not available. Reference documents will be available in the Lotus Notes document library.

5.2 Performance of the sanitation audit.

5.2.1 Pre-audit meeting. The Auditor will notify management immediately upon arrival. Conduct the pre-audit meeting with management. During this meeting discuss and review:

- Scope of the visit.
- Contents of the Pre-audit Questionnaire.
- Applicable standards.
- Process methodology.
- The plan for conducting the audit.
- Areas to be visited.
- Sequence of areas to be audited.
- Previous sanitation audits if applicable.
- Results of other agencies’ audits/inspections.
- Food safety program/quality plan:
  - Sanitation Standing Operating Procedures (SSOP’s).
  - Pest management program.

- HACCP plan if available.

- Requirements for laboratory analysis.
- Interviews with various plant personnel to obtain objective evidence.
- Establishment representative's cognizance of all plant production operations.
- Pertinent rules of audit results:
  - Scoring methods (severity of defects, effect on rating of establishment and Directory listing).
- Corrective actions (immediate vs. post-audit):
  - Establish a time and location for the post-audit meeting and, if necessary, the requirement for the CAR.

5.2.2 Conducting the audit. Conduct the sanitation audit in the presence of management or a designated representative. Evaluate all phases of the system: pre-operational sanitation, production, and post operational clean-up.

- In the pre-operational phase, focus on the effectiveness of the cleaning and sanitizing program.
- In the production phase, consider: wholesomeness of the raw product and ingredients, product flow, employee/sanitary practices throughout the process, in-line process controls, and end item protection and disposition.
- In the post-operational clean-up phase, verify the establishment's system for cleaning and sanitizing: water temperatures, chemicals, methods, etc.
- Conduct a thorough review of the laboratory program at the end of the audit.
  - All establishments are subject to laboratory testing.
  - Auditing Laboratory/Quality Control Programs. Complete the laboratory working paper for those establishments that have laboratories within their facility. Review the laboratory reports for those establishments that utilize independent laboratories.
- Additional Auditor Guidance:
  - Once initiated, complete the sanitation audit regardless of deficiencies found when conducting the audit.
  - Keep the management representative fully aware of what is being observed and recorded.
  - Discuss positive as well as deficient conditions as you note them throughout the audit.
  - Document observations and obtain objective evidence to determine compliance or noncompliance.
  - If appropriate, reduce the severity of individual major deficiencies to observations when corrected immediately and not systemic. Collect objective evidence through interviews, examination of documents and observation of activities and conditions in the establishment.
  - Physical observations, measurements, and records will provide objective evidence to verify compliance or noncompliance, whether they are specifically required in the applicable appendix or not.

5.2.3 Post-audit meeting. Prior to departing the establishment, advise the food establishment of the sanitation audit results, to include:

- All defects noted, placing particular emphasis on defect(s) of public health concern.

- Auditors will not make specific recommendations for corrective actions. However, guidelines for the steps necessary to meet the standards may be discussed.
- Prepare a separate CAR for each Critical and/or Major Defect if the establishment has been rated "Unacceptable" during a routine or directed routine sanitation audit only.
  - Prepare and sign Part I, to include management signature, and leave the original CAR(s) with the establishment.
  - If management will not sign the CAR(s), leave an unsigned original.
- If the establishment is rated "Unacceptable" during an Initial or Special Audit, advise management of procedures for re-applying for Directory listing.
- If the establishment is rated "Unacceptable" during Routine or Directed Routine Audits, advise management of the requirement for a Special Audit and potential for de-listing from the Directory.
- When samples are drawn as a part of an initial audit, notify management that the disposition of laboratory results will be considered when determining the establishment's final rating.
- Advise management that a final audit report will be sent.
- Conclude the post-audit meeting with a positive finding (if possible) to ensure good relations are maintained between representatives of the government and industry.

## 6. REPORTING PROCEDURES

6.1. Initial, Special, and Directed Routine Sanitation Audit Reports. Signed and completed reports may be submitted by electronic mail or fax. Distribute the following forms from this handbook as follows:

- Sanitation Audit Report (Figure 4).
  - Establishment: leave hand-written copy; send final typed report.
  - MACOM Veterinary Laboratory: send final written report (if applicable).
  - Veterinary Commanders and higher HQ: send final report.
- Corrective Action Request(s) (Figure 5, if required) - leave a copy only if an establishment received an "Unacceptable" rating during a directed routine sanitation audit. Final disposition completed by auditor upon receipt will be retained at unit level.
- Cover Letter to Establishment (Figure 6).

6.2 Routine Sanitation Audit Reports. Complete and distribute the following forms from this handbook:

- Sanitation Audit Report (Figure 4) - leave a copy at the establishment.
- Corrective Action Request(s) (Figure 5, if required) - leave a copy. Auditor will complete a final disposition upon receipt of the response.

6.3 Corrective Action Request. Request a response to CAR(s) from any establishment that received an "Unacceptable" rating during a routine or directed routine sanitation audit. A CAR is used to address Critical and Major Defect(s).

6.4 Sanitation Audit Report.

6.4.1 Routine Audits. Complete the front and reverse of Sanitation Audit Report form at the end of each routine audit. Include the methodology only if changes have occurred. Provide CAR(s) to the management only if an establishment received an "Unacceptable" rating.

6.4.2 Initial, Special, and Directed Routine Audits. In addition to completing the front and reverse of the Sanitation Audit Report, include a detailed methodology and product flow.

## 7. NOTIFICATION GUIDANCE FOR UNACCEPTABLE SANITATION AUDITS

7.1 Immediate notification. The Veterinary Commander or designated representative will immediately telephone the Directory or local list approval authority when an establishment receives an "Unacceptable" rating. The Directory approval authority must authorize suspensions of any deliveries. Describe any Critical Defects and current contracts (e.g., purchasing agencies, contract, or purchase order numbers, expiration dates of the contracts, items being delivered, and destinations). If the approving authority concurs with the recommendation, the Veterinary Commander or designated representative will take the applicable actions described below

7.1.1 Unacceptable Routine or Directed Routine with delivery suspension.

7.1.1.1 Purchasing agency notification. Promptly notify the appropriate purchasing activity if the establishment is a subcontractor on a contract or an active bidder on current solicitations. Follow up all notifications in writing.

7.1.1.2 Delivery suspensions. Delivery suspensions will remain effective until completion of a Special Sanitation Audit. Special Sanitation Audits will determine approval or disapproval for continued listing in the Directory or local list.

7.1.1.3 Suspension letter. In addition to normal notification of products placed on suspension due to microbiological testing, provide a copy of the suspension letter to HQ, Army and Air Force Exchange Service (AAFES); HQ, Defense Commissary Agency (DeCA); and HQ, Defense Supply Center Philadelphia (DSCP) for the respective theater Command. Ensure that local procedures are in place to prevent the acceptance of products that have been suspended due to suspected pathogens.

7.1.1.4 Interstate Milk Shippers (IMS) List deletions. Delivery suspensions for IMS List deletions follow the policy and procedures contained in MEDCOM Regulation 40-28. The Food and Drug Administration (FDA) notifies VETCOM whenever an IMS listed dairy receives a revised rating that is less than 90. The dairy will not be re-audited for a minimum of fifteen (15) days. During this period, the dairy plant is in a non-approved status.

7.1.2 Unacceptable Routine without delivery suspension.

7.1.2.1 Official letter. Follow up the post-audit meeting with an official letter listing the sanitary deficiencies found (see Figure 6). The letter must clearly state that an auditor will perform a Special Sanitation Audit on or after a specific date. Also, explain that failure to pass this audit will result in a recommendation for the establishment's removal from the Directory or local approved list.

7.1.2.2 Purchasing agency notification. Promptly notify all purchasing activities (having a current contract with the establishment) of the impending Special Sanitation Audit. Advise the purchasing agencies of a possible supply failure if the establishment does not pass the audit. Also, notify the appropriate purchasing activities if the establishment is a subcontractor on a current contract or an active bidder on current solicitations.

7.1.2.3 State and local notification. Before conducting the Special Sanitation Audit, notify the appropriate state and local health agencies and invite them to participate in the audit.

7.1.3 Unacceptable Directed Routine Sanitation Audits. The Veterinary Commander or designated representative will immediately telephone the Directory or local list approval authority when an establishment receives an "Unacceptable" rating. Directory approval authority will provide further guidance.

## 8. STANDARDIZED FORMATS AND INSTRUCTIONS

8.1 Notification letter to the establishment of an upcoming sanitation audit. Figure 7 is a standardized format for a cover letter to the establishment informing them of the upcoming audit and requesting the information needed for the Pre-audit Questionnaire.

8.2 Pre-audit Questionnaire. Figure 8 lists the information necessary to process Initial Sanitation Audit requests and to update records prior to Special Sanitation Audits.

8.3 Letter to the establishment. Figure 6 is a standardized format and instructions for a letter informing an establishment of the results of all Initial, Special, and Directed Routine Sanitation Audits and Unacceptable Routine Sanitation Audits.

8.4 Request for removal from the Worldwide Directory. An establishment may be recommended for deletion or removal from a Directory or Locally Listed establishment due to other than unsanitary conditions. If an establishment has been inactive less than two years, the deletion must include a deletion request signed by the plant management (Figure 9). The auditor may omit the plant management's signed request if the plant has attained exempt status or has gone out of business and the auditor cannot contact plant management. (Refer to AR 40-657.) Use the format and instructions shown at Figure 10.

8.5 Sanitation Audit Report. Format used to report findings from audit. Figure 4.

8.6 Methodology format for Sanitation Audit Report. Standardized format providing descriptive methodology paragraphs appear on page 3 of the Sanitation Audit Report (Figure 4). The written methodology must correspond to the sections of the Pre-audit Questionnaire. The sections should contain summaries of information obtained from Pre-audit Questionnaire. The "PROCESS" section will contain detailed description of the manufacturing process, including identified Critical Control Points (CCP). The "SECURITY" section will provide a general overview of the assessment, but will not contain a detailed description of security measures which might compromise security efforts in the establishment. Page 4 of Sanitation Audit Report must accurately depict the product flow throughout the establishment.

8.7 Corrective Action Request. Format used to report Major and Critical Defects found during routine or directed routine sanitation audits rated “Unacceptable”. Figure 5.

8.8 Recommendation for deletion. Figure 10 is a standardized format and instructions for a letter recommending removal of an establishment from the Worldwide Directory.

8.9 General laboratory checklist. Figure 1.

8.10 Laboratory checklist for dairy products. Figure 2.

8.11 Milk plant equipment and testing working paper. Format for reporting findings from testing pasteurization equipment and controls. Figure 3.

8.12 Food security questionnaire. Figure 11.

GENERAL LABORATORY CHECKLIST

Not all food plants have in-plant laboratory analysis. Some establishments routinely send products to third party laboratories for analysis, or perform no analysis on the product. If the plant has in-plant laboratory capabilities, as a minimum the following areas should be discussed and reviewed. If requirements exist for bacteriological or chemical analysis of specific type product(s) these requirements must be met, whether at in-plant laboratory or contracted facility.

1. Analysis performed as required per product reference and applicable appendix in MIL-STD –3006A.

2. Analysis performed in-plant or sent to contract laboratory.

3. Other types of analysis performed (i.e., environmental sampling, additional bacteriological sampling for quality characteristics).

4. Availability of applicable reference documents for analysis performed and methods used.

5. Proficiency testing program and employee training program in place.

6. In-plant quality control program (in addition to required analysis) has established control limits and corrective action is taken when limits are exceeded.

7. If required (primarily overseas), employee health certification is current and records maintained.
   a. Tuberculosis
   b. Hepatitis A/Hepatitis A antigen
   c. Stool Exam for parasites/protozoa
   d. Enteropathogenic exam for *Salmonella*, Toxigenic E. Coli, Vibrio cholera

8. Products identified as nonconforming based on laboratory analysis should have procedures established for corrective action and records of the action taken.

9. Notes: Make any note of special circumstances not covered above, rapid kits used or other pertinent data.

FIGURE 1. General laboratory checklist.

DAIRY LABORATORY CHECKLIST

As a minimum, the auditor should verify the required laboratory analyses for the product being produced. While not completely inclusive, this checklist synopsizes the primary laboratory requirements and is useful when visiting dairy plant laboratories. Manufactured dairy product plants may not perform all the laboratory analyses listed.

1. Appropriate references for laboratory use available and current.
   a. Standard Methods for Examination of Dairy Products._____
   b. USPHS Publication No. 229 Grade "A" PMO._____
   c. Other._____

2. Herd Health Testing (Brucellosis, Tuberculosis, other)._____

3. Employee Health and Food Handler's Certification (if required)._____

4. Raw Milk Testing - Each Producer (see PMO for details).
   a. Bacterial Count (4X each 6 Months) NMT 100,000/ml._____
   b. Somatic Cell Count (4X each 6 Months) NMT 750,000/ml._____
   c. Temperature (collection and receipt) (4X each 6 Months) 7°C/2hrs._____
   d. Drug Testing (Beta Lactam Residues)._____
   e. Added Water Test._____
   f. Chlorinated Hydrocarbon Pesticides (4X each 6 Months)._____
   g. Other Pesticides (1 each route each 6 Months)._____
   h. DMC (No clear slides allowed)._____

5. Are there means available to segregate milk destined for US Forces procurement and commingled milk with greater than (>) 300,000 cfu/ml bacterial counts?_____

6. Antibiotic Testing.
   a. Qualitative Bacillus stearothermophilus Disk Assay performed._____
   b. Positive controls used have not expired._____
   c. No zone greater than 16mm is authorized when using the B. stearothermophilus Disk Assay method._____

7. Rapid Phosphatase Test.
   a. Performed each hour for each type/size produced._____
   b. Records are maintained for all tests performed._____
   c. Positive controls are used for each test performed._____

FIGURE 2. Dairy laboratory checklist.

8. Vitamin A and D Testing (as applicable).
   a. Vitamin A: NLT 2000 IU/QT, NMT 3000 IU/QT, Recall at ≥6000 IU/QT Records reviewed.

   _____

   b. Vitamin D: NLT 400 IU/QT, NMT 600 IU/QT, Recall at ≥800 IU/QT Records reviewed.

   _____

9. Microbiological criteria for frozen deserts:
   a. SPC: NMT 50,000 cfu/g._____
   b. E.Coli: NMT 10/g (Fruits, nuts or other bulky flavors added NMT 20/g)._____

10. Corrective Action
    a. Steps taken when laboratory analysis indicates product is not conforming._____

    _____

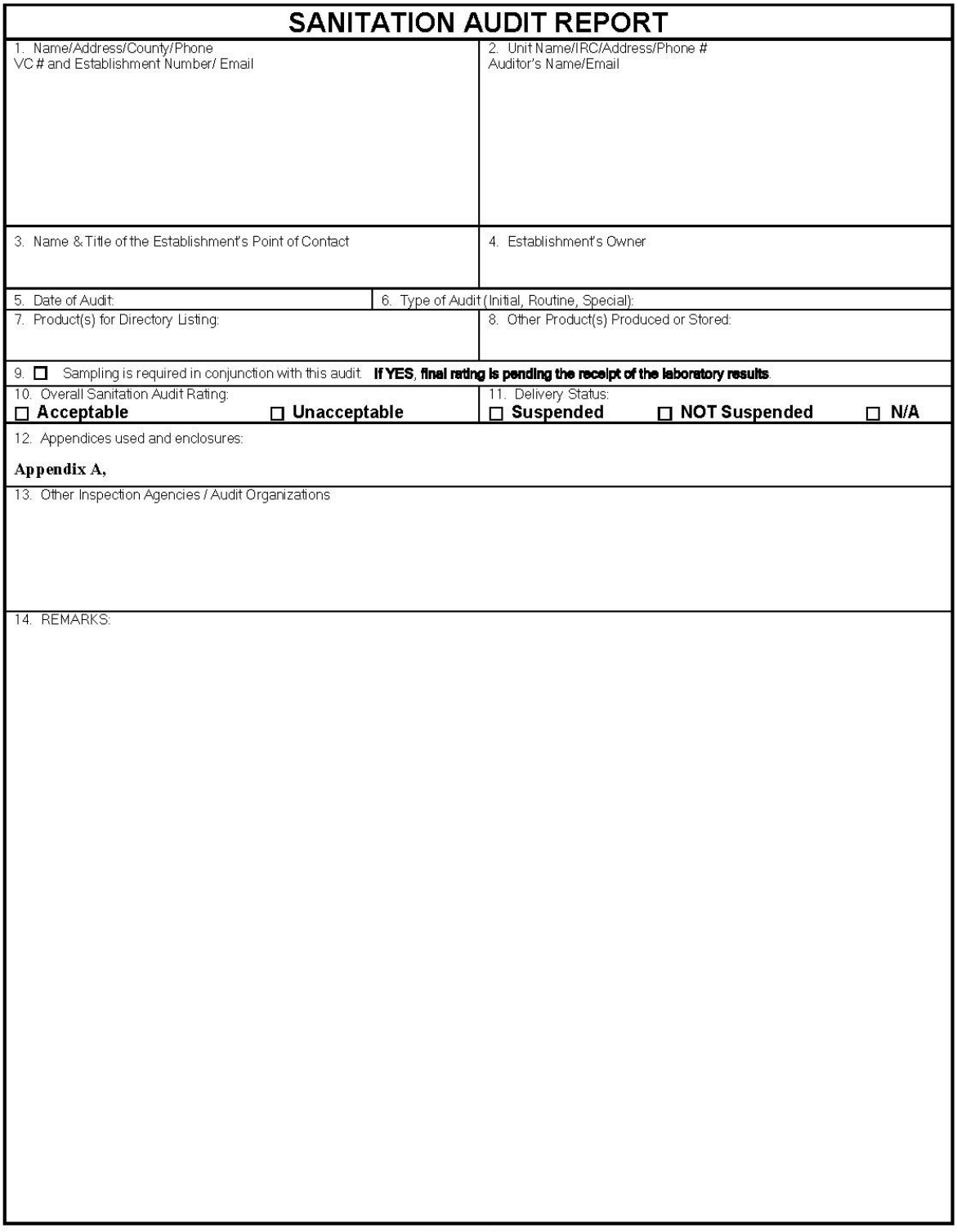
    _____

    _____

FIGURE 2. Dairy laboratory checklist - Continued.

| Department of Health and Human Services<br>Public Health Service / Food and Drug Administration | | | | MILK PLANT EQUIPMENT TEST REPORT | |
|---|---|---|---|---|---|
| TEST NO. | TEST | | TEST FREQUENCY | TESTED (X or NA) | RESULTS OF TEST (SEE REVERSE FOR WORKING NOTES) |
| 1. | Indicating thermometers (including air space): Temperature accuracy | | 3 months | | |
| 2. | Recording thermometers: Temperature accuracy | | 3 months | | |
| 3. | Recording thermometers: Time accuracy | | 3 months | | |
| 4. | Recording thermometers: Checked against indicating thermometer | | 3 months | | Daily by operator |
| 5. | Flow-diversion device: Proper assembly and function (HTST and HHST) | | | | |
| | 5.1 | Leakage past valve seat(s) | 3 months | | |
| | 5.2 | Operation of valve stem(s) | 3 months | | |
| | 5.3 | Device assembly (micro-switch) single stem | 3 months | | |
| | 5.4 | Device assembly (micro-switches) dual stem | 3 months | | |
| | 5.5 | Manual diversion - Parts (A,B, and C) (HTST only) | 3 months | | |
| | 5.6 | Response Time | 3 months | | |
| | 5.7 | Time delay interlock (dual stem devices) (Inspect) | 3 months | | |
| | 5.8 | Time delay interlock (dual stem devices) (CIP) | 3 months | | |
| | 5.9 | Leak Detect flush time delay (HTST only as applicable) | 3 months | | |
| 6. | Leak-protect valves: Leakage (Vats only) | | 3 months | | |
| 7. | Indicating thermometers in pipelines: Thermometric response (HTST only) | | 3 months | | |
| 8. | Recorder-Controller: Thermometric response (HTST only) | | 3 months | | |
| 9. | Regenerator Pressure Controls | | | | |
| | 9.1 | Pressure Switches (HTST only) | 3 months | | |
| | 9.2 | Differential pressure controllers | | | |
| | 9.2.1 | Calibration | 3 months | | |
| | 9.2.2 | Interwiring Booster Pump (HTST only) | 3 months | | |
| | 9.2.3 | Interwiring FDD (HHST and Aseptic) | 3 months | | |
| | 9.3 | Additional Booster Pump interwiring (HTST only) | | | |
| | 9.3.1 | With FDD | 3 months | | |
| | 9.3.2 | With Metering Pump | 3 months | | |
| 10. | Milk-flow controls: Cut-in and cut-out temperatures (10.1, 10.2, or 10.3) | | 3 months | | Daily by operator (HTST) |
| 11. | Timing System Controls | | | | |
| | 11.1 | Holding time (HTST except magnetic flow meters) | 6 months | | Adjusted holding time if applicable |
| | 11.2.a | Magnetic Flow Meters (HTST only) | 6 months | | |
| | 11.2.b | Flow alarm (HTST, HHST, and Aseptic) | 6 months | | |
| | 11.2.c | Loss of signal alarm (HTST, HHST, and Aseptic) | 6 months | | |
| | 11.2.d | Flow cut-in/cut-out (HTST only) | 6 months | | |
| | 11.2.e | Time delay (After divert) (HTST only) | 6 months | | |
| | 11.3 | HHST Indirect heating | 6 months | | |
| | 11.4 | HHST Direct Injection Heating | 6 months | | |
| | 11.5 | HHST Direct Infusion heating | 6 months | | |
| 12. | Controller: Sequence logic (HHST and Aseptic) (12.1 or 12.2) | | 3 months | | |
| 13. | Product pressure-control switch setting (HHST and Aseptic) | | 3 months | | |
| 14. | Injector differential pressure (HHST and Aseptic) (Injection heating) | | 3 months | | |
| Remarks | | | | | |

FIGURE 3. Milk plant equipment working paper.



**SANITATION AUDIT REPORT**

| | |
|---|---|
| 1. Name/Address/County/Phone<br>VC # and Establishment Number/ Email | 2. Unit Name/IRC/Address/Phone #<br>Auditor's Name/Email |
| 3. Name & Title of the Establishment's Point of Contact | 4. Establishment's Owner |
| 5. Date of Audit: | 6. Type of Audit (Initial, Routine, Special): |
| 7. Product(s) for Directory Listing: | 8. Other Product(s) Produced or Stored: |
| 9. ☐ Sampling is required in conjunction with this audit. **If YES, final rating is pending the receipt of the laboratory results.** | |
| 10. Overall Sanitation Audit Rating:<br>☐ **Acceptable** ☐ **Unacceptable** | 11. Delivery Status:<br>☐ **Suspended** ☐ **NOT Suspended** ☐ **N/A** |
| 12. Appendices used and enclosures:<br>**Appendix A,** | |
| 13. Other Inspection Agencies / Audit Organizations | |
| 14. REMARKS: | |

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FIGURE 4. Sanitation audit report.

| FINDINGS | | | |
|---|---|---|---|
| ESTABLISHMENT'S NAME: | | | DATE OF AUDIT: |
| SUBPART PARA | SCORE* | DESCRIPTION | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| | ----- | | |
| AUDITOR'S TYPED NAME & SIGNATURE | | COMMANDER'S TYPED NAME & SIGNATURE | |

* DEFECT: **C**-Critical, **M**-Major, **O**-Observation



FIGURE 4 Sanitation audit report (Findings) - Continued.

| METHODOLOGY | |
|---|---|
| ESTABLISHMENT'S NAME: | DATE OF AUDIT: |

**PERSONNEL/ADMINISTRATION:**

**GENERAL:**

**FACILITIES:**

**FOOD PROTECTION & SANITATION:**

**PROCESS:**

**STORAGE:**

**DISTRIBUTION:**

**SECURITY:**

Page 3 of 4

FIGURE 4. Sanitation audit report (Methodology) – Continued.

| PRODUCT FLOW | |
|---|---|
| ESTABLISHMENT'S NAME: | DATE OF AUDIT: |
| (description or graphical representation) | |



FIGURE 4. Sanitation audit report (Product flow) – Continued.

| CORRECTIVE ACTION REQUEST | |
|---|---|
| ESTABLISHMENT AND VC#: | POINT OF CONTACT: |
| **PART 1** | |
| **DEFICIENCY FOUND** | |
| Respond to the following deficiency by . | |
| AUDITOR'S NAME, SIGNATURE, AND DATE | MANAGEMENT'S NAME & SIGNATURE |
| **PART 2** | |
| **ROOT CAUSE OF DEFICIENCY** | |
| | |
| **ACTION TAKEN TO CORRECT AND PREVENT RECURRENCE OF DEFICIENCY** | |
| | |
| PERSON RESPONSIBLE FOR IMPLEMENTING CORRECTIVE ACTION: | SIGNATURE: |
| **PART 3** | |
| **AUDITOR'S EVALUATION OF CORRECTIVE ACTION(S)** | |
| DISPOSITION OF CORRECTIVE ACTION: | FOLLOW-UP AUDIT REQUIRED: |
| REMARKS: | |
| AUDITOR'S NAME & SIGNATURE: | DATE SIGNED: |

FIGURE 5. Corrective action request.

DEPARTMENT OF THE ARMY
HEADQUARTERS, NORTHEAST DISTRICT VETERINARY COMMAND
FORT MONMOUTH, NEW JERSEY 07703-5617
«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Name_Vendor»
«Address_Vendor»
«City_State_Zip_Vendor»

Gentlemen:

On «Civilian_Date_of_Inspection», «Name_Rank_Auditor» conducted an audit sanitation inspection of your establishment in accordance with Military Standard 3006A. During the audit, the inspector noted the following discrepancies requiring remedial action. The inspector discussed these discrepancies with «Name_Title_Plant_Representative». The discrepancies refer to the Code of Federal Regulation, Commercial Good Manufacturing Practices.

«Finding1»
«Finding2»
«Finding3»
«Finding4»
«Finding5»
(OPTIONAL) Refer to the enclosed Audit report.

Your establishment was rated «Acceptable_Unacceptable»; therefore, we «Have_HaveNot» recommended your establishment for listing in the Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement. You are approved for:

(OPTIONAL PARAGRAPH) If you wish to obtain another inspection, you must request it through procurement personnel. With your request, you must include a letter detailing all actions taken to correct each deficiency noted during this audit.

Sincerely,
«Auditor's_Name»
«Auditor's_Rank»
«Auditor's_Title»
«Enclosures»

FIGURE 6. Cover letter for initial sanitation audits.

DEPARTMENT OF THE ARMY
HEADQUARTERS, NORTHEAST DISTRICT VETERINARY COMMAND
FORT MONMOUTH, NEW JERSEY 07703-5617
«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment's_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

«Salutation»:

We have been notified that your establishment wishes to be listed in the "Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement." In order to be listed, your establishment must undergo a sanitation audit by a member of our Command.

(Alternate). After reviewing our records, it has been determined that a/an «Directed_Special» audit needs to be performed on your establishment in order for you to remain listed in the "Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement."

The audit will take place on «Date_of_Audit». Enclosed are reference documents that we will use to evaluate your processes. In order to receive an acceptable rating, no critical findings or no more than three (3) major findings can be annotated on the Code of Federal Regulation, Part 110, Checklist.

Enclosed you will find «Attached_Working_Papers». These are working papers that our auditor uses to prepare a methodology on how your product is processed. Please complete the enclosed checklists. Keep these working papers at your establishment and send a copy to the address listed below. Please fax directions to your facility from our audit center at «Audit_Center_Location». Our fax number is «Fax_Number».

«Name_of_Auditor» has been tasked to perform the sanitation audit of your establishment. Please feel free to contact him/her if you have any question(s) regarding this audit. «Name_of_Auditor»'s address is «Auditor_Address»; or he/she may be reached telephonically at «Auditors_Phone»

Sincerely,

Enclosure(s)

«Name»
«Grade_VC»
«Title»

FIGURE 7. Audit notification/letter to vendor.

## PRE-AUDIT QUESTIONNAIRE

**PERSONNEL/ADMINISTRATION**

1. What are the names of key personnel (owner, manager, and QA)?
2. What other agencies inspect your facility? What is the frequency?
3. What is the date of last inspection and the score received?
4. Is your facility identified by any Federal or State establishment number(s)?
5. Attach two copies of company letterhead or business card.

**GENERAL**

6. What is the daily output produced in either weight or number of products?
7. What is the recommended shelf life for your products?
8. List establishment number or address used on products.
9. Are your products closed-coded? Provide the interpretation.
10. What are the hours of operations?
11. How many employees (full and part-time) work in the establishment?

**FACILITIES**

12. Age of your facility:
13. What is the square footage of your facility?
14. Include a scaled floor plan of your building.
15. Building description, i.e., material(s) used in the construction of facility.

**FOOD PROTECTION & SANITATION**

16. Do employees receive a medical examination before employment?
17. What is the frequency of these examinations?
18. Are the employees trained in sanitation and hygiene? How often? Is the training documented?
19. What is the source of potable water?
20. Do you have a current (within 12 months) water potability certificate? Date.
21. What official, government, or independent laboratory performed the analysis?
22. Is there a written documented cleaning & sanitation program?
23. What schedule, chemicals, and methods are used?
24. Do you perform laboratory analysis of your product(s)? For what pathogens or chemical elements?
25. What laboratory performs the tests? What are the critical limits?
26. Who picks up the waste? What is the frequency?
27. Who performs pest control? What is the frequency? Do you have a layout plan of bait stations?
28. What chemicals are used/stored at the facility (excluding sanitation agents)?
29. Do you have a Hazard Analysis Critical Control Point Program (HACCP) in place?
30. What are the sources of raw materials?

(Continued on next page)

FIGURE 8. Pre-audit questionnaire.

**PROCESS**

31. Provide the flow diagram or describe processing steps from receipt of raw materials to the finished product. Note critical control points (CCP). Specific time, temperature, pressure, kill steps, etc. List major processing equipment, test controls (thermometers, testing strips, etc.), and quality control program (i.e., Statistical Process Control (SPC), In line Inspection Points, etc.).

**STORAGE**

32. Location/temperature/humidity of stored raw and finished product areas.

**DISTRIBUTION**

33. Describe product distribution and transportation system.
34. How and how often are your transportation assets cleaned and sanitized?

**FOOD SECURITY**

35. Are procedures in place to prevent product tampering (Upon Receipt, Storage, Processing, Distribution)? Refer to Food Security Questionnaire (Figure 11).

FIGURE 8. Pre-audit questionnaire - Continued.

(Date)

SUBJECT: Request for Removal from the Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement

TO: Commander, _____ District Veterinary Command,

_____

_____

As a representative of management, I request removal of the following establishment from the *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*.

Name of Company: _____

Location: _____

_____

_____

This letter serves as official notification of the company's decision for removal.

_____
(Signature)

_____
(Typed/Printed Name)

_____
(Title)

FIGURE 9. Vendor request for removal.

EXAMPLE OF A DIRECTORY OR LOCAL LIST
DELETION RECOMMENDATION

(Letterhead)

(Office Symbol) (Marks Number) (Date)

MEMORANDUM FOR (1)

SUBJECT: Recommendation for Deletion of (2)

We recommend deletion of subject establishment from listing in the (3), in accordance with AR 40-657.

(4).

Our point of contact is (5)

(Identify Enclosures, if any)

(6) SIGNATURE BLOCK

---

Use with Instructions for Preparing
a Worldwide Directory or Local List Deletion Recommendation

---

FIGURE 10. Recommendation for deletion.

INSTRUCTIONS FOR PREPARING A
WORLDWIDE DIRECTORY OR LOCAL LIST DELETION RECOMMENDATION

(DO NOT USE THIS FORMAT IF DELETION IS FOR CAUSE - SEE AR 40-657.

Address the recommendation FOR Commander, U.S. Army Veterinary Command, ATTN: MCVS-FA, 2050 Worth Road, Suite 5, Fort Sam Houston, TX 78234-6005; or FOR the Commander with approval authority for the local list.

Enter the complete name and address of the establishment as it appears in the Worldwide Directory or local list.

Enter "Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement" or "local list of sanitarily approved food establishments," as appropriate.

The request must include a justification, verification or concurrence of management, and an authority. Some possible examples follow.

The USDA Meat and Poultry Inspection Directory currently lists the subject establishment as establishment number 1322. Therefore, the establishment is exempt from Worldwide Directory listing in accordance with AR 40-657.

On 12 JAN 02, Mr. Johns, President, stated that the subject establishment has ceased production of all products at the present address and currently functions as a distribution point only. Therefore, the establishment is exempt from Worldwide Directory listing in accordance with AR 40-657.

The subject establishment no longer produces ice cream products. The Interstate Milk Shippers (IMS) List currently lists the establishment for milk and milk products. Mr. Johns, plant manager, stated that ice cream production ceased on 1 DEC 02. Therefore, the establishment is exempt from Worldwide Directory listing in accordance with AR 40-657.

During a routine sanitation audit on 11 DEC 02, Mr. Smith, Vice President of subject establishment, advised the auditor that they had no desire to continue Worldwide Directory listing. We enclose a request, signed by Mr. Smith, for removal from the Worldwide Directory.

The subject establishment has apparently gone out of business. The auditor has been unable to contact any management personnel and the building is now closed and appears to be empty.

Enter the name and telephone number of the point of contact.

Enter the appropriate signature block. The Commander should sign the memorandum whenever possible. Auditors designated by the commanders in writing can sign for the commander. Auditors not designated can sign the memorandum by addressing it THRU the Commander to the FOR addressee.

FIGURE 10. Recommendation for deletion - Instructions.

FOOD SECURITY QUESTIONAIRE

**PERSONNEL SCREENING**

1. Are employees screened for security purposes? (Scope of background checks, Prior employment history, References verified)
2. What is average length of employment?

**ACCESS TO PREMISES**

3. Is access to the facility limited? (Surveillance equipment (CCTV, alarm system), Physical barriers (fences, locked doors), Badges, time cards, sign-in rosters, Security personnel)

**ACCESS TO FUNCTIONAL AREAS**

4. Is access to functional areas restricted? (Uniforms/ ID badges, Access cards or keys, Visitors escorted, Supervisory monitoring)

**SECURITY OF RAW MATERIALS AND PACKAGING**

5. Are raw materials and packaging monitored? (QA program, Vehicle security (seals), Document verification)

**CONTROLS OF MANUFACTURING OPERATIONS**

6. Are products protected during manufacturing? (Closed/open systems, Control points for open systems, Unlabeled containers, Knowledge of product destination, Access control)

**WAREHOUSING AND DISTRIBUTION**

7. Are products protected during warehousing? (Access control (authorized personnel), Inventory control, Separation of returned products)
8. Are products protected during distribution? (Vehicle ownership , Vehicle security (seals), Vehicle tracking systems, Knowledge of product destination)

**RESPONSE TO FOOD SECURITY VIOLATIONS**

9. Are procedures in place to respond to food security violations? (Reporting requirements, Segregation & marking of suspect product, Recall program, Corrective action, Method of disposition)
10. Is training provided on food security? (Recognition of potential tampering, Reporting procedures, Handling of suspect foods, Frequency and scope of training)

FIGURE 11. Food security questionnaire.

## 9. NOTES

### 9.1 Intended use.

This handbook is intended to be used as guidance for auditing commercial food establishments.

### 9.2 Subject term (keyword) listing.

The following terms are to [may] be used to identify this handbook during retrieval searches:

Sanitation Audit Rating
Sanitation Audit Report
Corrective Action Request
Auditing Personnel
Initial Audits
Special Audits
Directed Sanitation Audits
Methodology
Merge Documents
Laboratory Checklist
Recommendation for Deletion
Request for Removal
Notification
Thermally Processed Food

### 9.3 Changes from previous issue.

Marginal notations are not used in this revision to identify changes with respect to the previous issue due to the extent of the changes.

# APPENDIX A - General Provisions

## A.1 SCOPE

A.1.1 Scope. This appendix contains guidelines for auditing food production facilities. The information contained herein is intended for guidance.

## A.2 APPLICABLE DOCUMENTS

A.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

A.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Title 21, Part 110.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

## A.3 DEFINITIONS

A.3.1 Definitions. Definitions are contained in the basic handbook.

## A.4 GUIDELINES

A.4.1 Checklists. Guidelines for auditing food production facilities are contained in the following checklists.

APPENDIX A Checklist

| TABLE I Subpart A - Personnel<br>GENERAL PROVISIONS<br><br>21 CFR 110 | |
|---|---|
| ITEM | REQUIREMENT |
| A1 | Adequate disease control measures are practiced. (Sec 110.10(a)). |
| A2 | Employees are wearing suitable clothing. (Sec 110.10(b)). |
| A3 | Employees are maintaining adequate cleanliness. (Sec 110.10(b)). |
| A4 | Employees are washing hands thoroughly after each absence from the workstation and at any other time the hands may have become soiled or contaminated. (Sec 110.10(b)). |
| A5 | Employees working in the processing area are free from unsecured jewelry or other objects. (Sec 110.10(b)). |
| A6 | Employees are using proper gloves and maintaining them in an intact, clean, and sanitary condition. (Sec 110.10(b)). |
| A7 | Employees are wearing effective hair or beard restraints. (Sec 110.10(b)). |
| A8 | Employees' belongings are being properly stored. (Sec 110.10(b)). |
| A9 | Employees are not eating food, chewing gum, drinking beverages or using tobacco where food is exposed or equipment and utensils are washed. (Sec 110.10(b)). |
| A10 | Precautions are taken to protect food from being contaminated by employees. (Sec 110.10(b)). |
| A11 | Employees are supervised by trained personnel and have clearly assigned responsibilities. (Sec 110.10 (9) (d)). |

# APPENDIX A

| TABLE II Subpart B - Buildings And Facilities<br>GENERAL PROVISIONS<br><br>21 CFR 110 | |
|---|---|
| ITEM | REQUIREMENT |
| B1 | Grounds are maintained in a condition that will protect against contamination or harborage of pests. (Sec 110.20 (a)). |
| B2 | Buildings and structure are suitable in size, construction, and design to facilitate maintenance and sanitary operations, to include food contact surfaces and food packaging materials. Potential for contamination reduced by effective separation of operations in which contamination is likely to occur. (Sec 110.20(b)). |
| B3 | Buildings (to include floors, walls, and ceilings), fixtures (to include those that allow dripping and condensation), utensils, and other physical facilities of the plant are maintained in a sanitary condition and in good repair. (Sec 110.20(b) & 110.35(a)). |
| B4 | Adequate protection against glass breakage over exposed foods. (Sec 110.20). |
| B5 | Adequate lighting, ventilation, and screening is provided. (Sec 110.20) |
| B6 | Substances used for cleaning, sanitizing and pest control are safe, adequate, used IAW instructions; and are properly marked and stored. (110.35(b)) |
| B7 | Adequate measures are taken to exclude pests from processing area and to protect against contamination of foods by pests, pesticides, and/or rodenticides. (Sec 110.35(c)). |
| B8 | Food contact surfaces are adequately cleaned and sanitized as frequently as necessary and are properly protected against contamination of food, to include single service articles (Sec 110.35(d)) |
| B9 | The water supply is sufficient and from a sanitary source. Water potability checked not less than annually by samples selected from within the plant. (Sec 110.37(a)). |
| B10 | The plumbing is adequate in size and is adequately installed and maintained. (Sec 110.37 (b)). |
| B11 | Sewage and rubbish are adequately disposed of. (Sec 110.37 (c) (f)). |
| B12 | Adequate toilet facilities are provided for employees. Sanitarily maintained, in good repair, and do not open into food processing areas. (Sec110.37 (d)). |
| B13 | Adequate hand-washing facilities are provided at convenient locations. (Sec 110.37 (e)). |

# APPENDIX A

| TABLE III Subpart C - Equipment And Utensils<br>GENERAL PROVISIONS<br><br>21 CFR 110 | |
|---|---|
| ITEM | REQUIREMENT |
| C1 | All pieces of equipment and utensils are adequately cleanable. (Sec 110.40(a)). |
| C2 | Food contact surfaces are corrosion resistant, made of nontoxic materials. (Sec 110.40(a)). |
| C3 | Equipment lubrication does not contaminate the product; only food grade lubricants are used in the food zone. (Sec 110.40(a)). |
| C4 | Seams on food-contact surfaces are smoothly bonded or maintained so as to minimize the growth of microorganisms. (Sec 110.40(b)). |
| C5 | Surfaces of equipment, other than food contact surfaces, maintained in the food handling area, are constructed so they can be kept in a clean condition. (Sec 110.40(c)). |
| C6 | Holding, conveying and manufacturing systems are designed and constructed so that they can be maintained in an appropriate sanitary condition. (Sec 110.40(d)). |
| C7 | Adequate indicating thermometers, temperature-measuring devices, temperature-recording devices, and temperature controls are in place. (Sec 110.40(f)). |
| C8 | Compressed air or other gases that are mechanically introduced into food or used to clean food-contact surfaces are free of indirect food additives. (Sec 110.40(g)). |
| C9 | Properly installed thermometers or temperature recording devices are required for freezers and cold storage areas that hold food capable of supporting microbial growth. (110.40(e)) |

# APPENDIX A

| TABLE IV Subpart E - Raw Materials And Operations<br>GENERAL PROVISIONS<br><br>21 CFR 110 | |
|---|---|
| ITEM | REQUIREMENT |
| E1 | Raw materials and other ingredients are purchased from an approved source, protected from contamination and adulteration at all times. (Sec 110.80(a)). |
| E2 | Manufacturing operations are conducted under conditions and controls necessary to minimize the potential growth of microorganisms or contamination of foods. (Sec 110.80(a)). |
| E3 | Foods are maintained under conditions during warehousing and distribution that will protect the food item and its container against physical, chemical, and microbial contamination, as well as against deterioration. (Sec 110.93). |
| E4 | Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible food contamination. Test results must meet the applicable requirements. (Sec 110.80). |
| E5 | Methods to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves, or other means). (Sec 110.80). |

| TABLE V Subpart G - Defect Action Levels<br>GENERAL PROVISIONS<br><br>21 CFR 110 | |
|---|---|
| ITEM | REQUIREMENT |
| G1 | Defect action levels are in compliance. (Sec 110.10). |

# APPENDIX A

TABLE VI Subpart H - Hazard Analysis And Record Keeping
GENERAL PROVISIONS

| ITEM | REQUIREMENT |
|---|---|
| H1 | Hazard analysis is performed, for all stages of production. |
| H2 | A Hazard Analysis Critical Control Point (HACCP) plan is written and implemented for each kind of product produced. |
| H3 | HACCP plan contains food safety hazards, critical control points, critical limits, monitoring procedures, corrective action plans, verification procedures and record keeping system. |
| H4 | Corrective action plan is followed and deviant product segregated. |
| H5 | Corrective actions are fully documented. |
| H6 | Records include all required information. |
| H7 | Records are reviewed, signed and dated as required. |
| H8 | Records are retained as required (per reference standard) and are available and subject to public disclosure limitations. |
| H9 | Internal reviews are performed as required. |
| H10 | Overall verification is performed by a trained individual annually or as a process change is made and when the HACCP plan is modified. |
| H11 | Sanitation control and monitoring is performed and documented with sufficient frequency to ensure compliance with Current Good Manufacturing Practices (CGMP) checklists as listed in Part 110. |

# APPENDIX A

| TABLE VII Subpart J – Food Security<br>GENERAL PROVISIONS<br><br>21 CFR 110.80 | |
|---|---|
| ITEM | REQUIREMENT |
| J1 | Appropriate measures taken to screen employees. (Sec 110.80) |
| J2 | Reasonable precautions taken to control physical access to premises. (Sec 110.80) |
| J3 | Reasonable precautions taken to control physical access to different functional areas of the establishment. (Sec 110.80) |
| J4 | Raw materials and packaging/packing materials received in original, intact containers and protected from potential tampering (contamination, adulteration, etc.). (Sec 110.80). |
| J5 | Manufacturing operations conducted under conditions and controls necessary to minimize the potential for tampering. (Sec 110.80). |
| J6 | End item(s) maintained under controls during warehousing and distribution that will protect the food item(s) and its container(s) against potential tampering. (Sec 110.80). |
| J7 | Protocols and training in place to recognize and respond to food security violations. (Sec 110.80) |

NOTE: Reference to the controlling 21 CFR 110 sections are identified in parentheses in Table I through V and Table VII above.

# APPENDIX B - Bakery

## B.1 SCOPE

B.1.1 Scope. This appendix contains guidelines for auditing bakery facilities. The information contained herein is intended for guidance.

## B.2 APPLICABLE DOCUMENTS

B.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

B.2.2 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

BAKING INDUSTRY SANITATION STANDARDS COMMITTEE

Sanitation Standards for the Design and Construction of Bakery Equipment and Machinery, January 1994

(Application for copies should be addressed to the Baking Industry Sanitation Standards Committee, 401 N. Michigan Avenue, Chicago, IL 60611, e-mail: bakesan@aol.com.)

## B.3 DEFINITIONS

B.3.1 Definitions. Definitions are contained in the basic handbook.

## B.4 GUIDELINES

B.4.1 General.

It is always beneficial to follow the flow of the product; however, some establishments might not want you to go from the dirty portion of their facility into the clean. Be sure to work out all details of the audit with management in the pre-audit meeting. Bulk deliveries can be railed or trucked in. If there is an unloading bay of some type at these establishments, be sure the product is protected during off-loading, and that piping is capped upon completion of the off-loading process. The bulk flour may, at this time, go through a sieve prior to being pumped into a silo. Ask if the establishment is testing any of their raw ingredients (e.g., ash testing for flour). Also, find out if the establishment is using any dairy products, egg products, liquid sugars, etc. Be cognizant of any hazards these items can bring. Establishments using bagged flour should be using pre-sifted flour. If they are not, be alert to the possibility of an insect problem.

The mixing area should be next in the product flow. It can either be completely automated, or ingredients metered out and added by dumping into the mixer. If there is a formulation room, be sure the product is protected until it is dumped into the mixer. (All ingredients should be covered when not in use.) After mixing, the dough may sit in troughs to rest. Be sure product is protected. Dough may then go into a proofer where it can rise. Proofers are hot, humid boxes with an environment conducive to mold growth. (Dough would have been formed prior to entering the proof box.)

The dough is then formed and baked. Although baking is usually at high heat, 500° F (260° C), be aware that the interior of the product never gets that hot. So, if mold is a problem in the establishment, it can be a problem in the finished product. The center of the item never reaches the temperature that the exterior of the product reaches. After exiting the oven, there are no other kill steps; therefore, auditors should increase their vigilance, looking for possible ways the product can be contaminated.

The product is usually cooled at this time by sitting on racks, or traveling along a conveyor with fans or other cooling instruments blowing on the product. Fans should be clean and there should be protection against condensation and other overhead contamination.

The product then may go through a slicer. Be aware of where the metal detection device(s) (if present) fit into the flow of the process. Some establishments have them prior to slicing. If this is the case, there is a potential that the knife blade of the slicer may break off in the product, thus physically adulterating the end item. After the metal detection device, product is packaged. (Many bakeries do this process by hand, so employees should have proper hand protection, and hand washing sinks should be present in this area.)

B.4.2 Checklist. Guidelines for auditing bakery facilities are contained in the following checklist:

# APPENDIX B

| BAKERY CHECKLIST<br>Baking Industry Sanitation Standards | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| C1 | Where equipment passes through walls, ceilings or floors, sufficient clearance is provided between the equipment and the wall, ceiling or floor, and the opening is finished to permit cleaning, or the equipment is sealed to the adjoining surface. (A6). |
| C5 | Product chutes at floor level are installed so that the rim is a minimum of 100mm (4 inches) above floor level. Such chutes are provided with overlapping covers. (A13). |
| C4 | Pans used to collect spillage or drip are readily accessible or readily removable, and are large enough to catch all spillage or drips. Also, fixed pans used to collect liquid spillage or drip are readily accessible, have drains, and are pitched to ensure complete drainage away from the product zone. (A14). |
| C5 | Liquid ingredient inlet pipes, valves and fittings are of sanitary take-apart type, unless designed for in-place cleaning, and are pitched for self-draining, back to the point where the line is continuously filled. (A21). |
| B2 | A concrete curb is built around all floor-mounted washing equipment to confine leakage. (A27). |
| C5 | Vents on equipment for handling and storing dry ingredients are protected against entry of foreign material, and are provided with readily removable filters to exclude particles of 5 microns or larger. (1-4.1.3). |
| C5 | Screw conveyor housings are hinged or removable so that the area around the helical flights can be cleaned from the outside. Sufficient clearance is provided between the bottom of the screw housing and the floor to permit sufficient exposure of the screw for cleaning. The screw housings are dust-tight and readily accessible. (1-4.1.8). |
| C5 | Straight run surfaces of pneumatic conveyors, valves and rotary feeders are smooth and readily accessible or removable, except that piping, tubing, valves or feeders which are self-purging are exempt from the requirements for accessibility. (1-4.3.1). |
| C8 | The air supply for blowers or compressors is filtered to exclude particles of 5 microns or larger. (1-4.3.4). |
| E2 | Dry product handling includes a sifter. (1-4.4.1). |
| C8 | Separate conveying air systems are provided before and after an atmospheric sifter in the system. (1-4.4.2). |
| C1 | A removable flexible connection is provided between the inlet to the hopper and the product delivery equipment. (1-4.5.1). |
| C5 | Discharge piping and unloading hoses are equipped with caps. (1-4.8.3). |
| C5 | Bearings are outside the product zone and are sealed or self-lubricated; and design and construction are such that lubricant cannot leak, drip or be forced into the product zone. (2-4.2.6). |
| C1 | Flexible tubing is transparent or translucent. Nozzles are readily removable. (5-4.1.3). |
| C1 | Pumps, valves, pipe fittings, including those used to insert thermometers and pressure gauge bulbs, are of the sanitary take-apart type and are readily accessible or removable. (5-4.1.10). |

BAKERY CHECKLIST - Continued.

| | |
|---|---|
| C5 | Stationary mixer bowls drain completely. Close-coupled sanitary drain valves which are accessible or removable are provided. (6-4.2.11). |
| C1 | The system for lubricating dough-contact surfaces, as distinct from the means of mechanical lubrication, has a reservoir readily accessible or removable for cleaning. Distribution lines, valves and pumps are removable for cleaning, or so designed as to permit Cleaning In Place (CIP). (8-4.2.6). |
| E2 | Proofing cloths are smooth, except they may be of absorbent material, but are readily removable for laundering. An extra set of proofing cloths are provided. (16-4.1.1). |
| C5 | Pumping, piping, valves and fittings used to dispense or convey frying fats, batter, glaze, icing, jellies and fillings are of sanitary take-apart type at least equal to 3A standards, and are accessible for inspection and cleaning. (16-4.1.16). |
| C1 | The icing and/or glazing reservoir return is readily accessible and self-draining. (32-4.1.1). |
| C5 | Drip or catch pans are provided under all product transfer points, as well as under cleaning attachments, and are readily removable. (32-4.1.6). |
| C4 | Drip or catch pans are provided between overhead trolleys and product zone, on suspended monorail type cooler. (33-4.2.5). |

NOTE: References to the controlling Baking Industry Sanitation Standards Committee are identified in parentheses

# APPENDIX C - Manufactured Dairy Products

## C.1 SCOPE

C.1.1 Scope. This appendix contains guidelines for auditing manufactured dairy products facilities. The information contained herein is intended for guidance.

## C.2 APPLICABLE DOCUMENTS

C.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

C.2.2 Government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

7 CFR, Part 58.

21 CFR, Parts 133, 173

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

National Institute of Standards and Technology, Handbook 44

(Application for copies should be addressed to National Institute of Standards and Technology, 110 Bureau Drive, Gaithersburg, MD 20899-0001, http://www.nist.gov/.)

C.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/ASHRAE 52.1-1992 Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter

(Application for copies should be addressed to American National Standards Institute, 11 West 42nd Street, New York, NY 10036, http://www.ansi.org/.)

C.3 DEFINITIONS

C.3.1 Definitions. Definitions are contained in the basic handbook.

C.4 GUIDELINES

C.4.1 General.

Making natural cheese is an art, not just a process. Removing most of the milk solids from the milk by coagulating with rennet or a bacterial culture, the curd is separated from the whey by heating, then drained and pressed. Both milk and cream may be used to make different varieties of cheese, and oftentimes skim milk is used. It is important to know and document the type of milk used in the process to understand the distinctive flavors, body and texture of the end product. The basic steps in cheese making include:

(a) Preparation of the milk or cream used based on type
(b) Method used for coagulating
(c) Cutting, cooking and forming the curd
(d) Type of culture used
(e) Salting
(f) Ripening conditions

After the cheese is formed and shaped, usually it is coated with a wax or wrapped and then aged for a specific period of time, depending on the sharpness desired. Cheese is then classified into four primary varieties: Very Hard, Hard, Semi-soft or Soft.

Basic terms used in cheese making:

Cured: Flavor and texture characteristics are determined by the amount of time enzymes and/or microorganisms are allowed to develop. The terms Mild, Medium or Sharp indicate ripening time and the expected flavor characteristic of the product. Mild cheese is cured for 2-3 months: softness and mild flavor. Medium cheese is cured for up to 6 months: mellow and smooth textured with a slightly nutty flavor; stronger flavor than mild cheese. Sharp or "Aged" cheese is cured over 6 months and has a rich-full bodied (strong) flavor.

Natural cheese: This cheese is comprised of the natural solids or casein portion of milk curd separated from whey and treated with microorganisms to impart flavor and cured over time.

Pasteurized process cheese: This cheese is a blend of fresh and already aged natural cheese. The aged cheese has been shredded, mixed with emulsifiers, and then heated. Pasteurization halts the ripening process and the heat allows the cheeses to blend smoothly, creating uniform body, flavor and texture. Blends may have one or more varieties of natural cheese and may also contain vegetable or meat (e.g., Jalapeno, Monterey Jack).

Pasteurized process cheese food: This cheese is prepared much the same as processed cheese, except that it contains less cheese and more nonfat milk or whey solids and water. Cheese food has higher moisture content and lower milk fat.

Pasteurized process cheese spread: Cheese spread is made in the same manner as processed cheese food, except that it contains less milk fat and has slightly higher moisture content.

Unripened fresh cheese: This cheese is not cured, thereby imparting a slight bland flavor. These cheeses are Cottage cheese, Cream cheese and Neufchatel cheese. The differences in Cream cheese and Neufchatel cheese are that Neufchatel contains less fat and more moisture. Both are made from milk and cream mixtures, pasteurized and coagulated with a lactic acid starter culture.

Common cheese varieties:

(a) Blue cheese - a semi-soft, made with whole milk; marbled with blue-green mold, white in color and spicy flavor.
(b) Brick - a semi-soft, made with whole milk; light yellow to orange color, shaped like a brick.
(c) Camembert - a semi-soft, made with whole milk; has an edible white crust, creamy yellow cheese interior and mild flavor.
(d) Cheddar (American) - a hard cheese made with whole milk; white to orange color, various shapes and wheel sizes; may be with a rind or without; mild to sharp aging.
(e) Colby - a hard cheese made with whole milk but slightly softer than Cheddar. Light yellow to orange in color; usually cylindrical, with mild flavor.
(f) Cottage - a soft, creamy cheese made from skim milk; moist with large or small curds throughout. This is a white cheese, packaged in cups or tubs, and slightly acidic in flavor.
(g) Cream - a soft cheese made from cream and whole milk. This cheese is white and usually packaged in foil blocks or in small tubs. The flavor is mild and slightly acidic.
(h) Edam - a hard type cheese, but softer than Cheddar, and made from partly-skimmed milk. Edam has a creamy yellow color and is most often found in red wax coated blocks or small balls or wheels. This is a mild flavored cheese.
(i) Farmers (Pressed Pot) - a soft cheese made from partly-skimmed milk. A white cheese, Farmers is a dry Cottage cheese pressed into paper packages. This is a mild flavored cheese.
(j) Gorgonzola - a semi-soft cheese made from whole milk. This cheese has a light tan color on the surface and light yellow interior. Similar to Blue cheese, this variety has blue-green mold marbling, a spicy flavor and usually is packaged in cylindrical shapes.
(k) Gouda - a hard cheese made from partly-skimmed milk, but softer than Cheddar. A creamy yellow-colored cheese, Gouda normally is packaged in red wax and is round, yet flat. This cheese is very similar to Edam.
(l) Limburger - a soft cheese made with whole or partly-skimmed milk. Limburger has a creamy white consistency with a highly aromatic property and robust flavor. This cheese is usually packaged in rectangular bricks.
(m) Monterey Jack - a semi-soft cheese made from whole milk. This is a creamy white colored cheese packaged in wheels or in rectangular bricks.

(n) Mozzarella - a semi-soft cheese made from whole or partly-skimmed milk. Another creamy white cheese, with mild and delicate flavor. Usually packaged in rectangular or spherical wheels.
(o) Muenster - a semi-soft cheese made from whole milk. This cheese has a yellow, tan or white surface with a creamy white interior. This cheese may be found packaged in small wheels or blocks and has a mild to mellow type flavor that varies between a Brick and Limburger cheese.
(p) Neufchatel - a soft cheese made from whole milk. White in color, this mild cheese is very similar to Cream cheese and is packaged in small foil bricks or tubs.
(q) Parmesan - a hard cheese designed for grating made from partly skimmed milk. A light yellow cheese, Parmesan is covered with a brown or black coating. In bulk, this cheese is usually cylindrical, with a very sharp flavor.
(r) Provolone - a hard cheese made from whole milk. This light golden brown cheese has a shiny surface and is tied (bound) with cord. The interior of the cheese is yellow-white; usually smoked and packaged in salami style shapes and packages.
(s) Ricotta - a soft cheese made from whey and whole or skim milk, or whole or partly-skimmed milk. This cheese may be moist and packaged in containers or tubs. Some varieties are dried for grating purposes. A bland flavor is expected, but often also referred to as semi-sweet.
(t) Romano - a hard grating type cheese made from partly-skimmed milk. This cheese has a black coating and usually is packaged cylindrically with flat ends. Romano is a sharp flavored cheese.
(u) Swiss - a hard cheese made from partly-skimmed milk. This cheese is rindless in blocks and comes with a rind in large wheels. This cheese has a mild, sweet nutty flavor.

Storage and shelf-life: Cured cheese will keep well in refrigerated storage for long periods of time. The longer in storage, the sharper the flavor may become. The recommended storage temperature for cheese is 40º F (4° C). Natural cheese may develop mold spots which can be easily removed without damage to the cheese. Should the mold penetrate to the deep crevices of the cheese, the entire wheel or block may have to be discarded. Mold is desirable in some cheeses, such as Blue cheese, where the strong flavor originates. Pasteurized processed cheese should always be refrigerated after opening. Most cheese may be stored in the freezer for short periods not exceeding two (2) months. Some varieties of cheese do not freeze well and will crumble after thawing. Pasteurized processed cheese can be stored in frozen conditions for up to four (4) months. Frozen storage of cheese should not exceed one pound block sizes and must be tightly wrapped to prevent drying.

Public health and cheese processing: The incidence of food-borne illness related to cheese is very low. Most often noted is the cheese processing and errors in manufacturing that contributed to the contamination of the product. Post-pasteurization contamination of the cheese is an area of great concern in the cheese manufacturing operations.

Variety cross comparison of soft cheeses:

(a) Alouette: Boursin.
(b) Boursault: Boursin, Brillat-Savarin, Caprice des Dieux, St. Andre or Excelsior.
(c) Boursin: Boursault or Alouette.

(d) Brie: Camembert, Paglietta, Limburger.
(e) Brillat-Savarin: see Boursault.
(f) Brinza: Feta cheese is a good comparison. Armenian cheese.
(g) California Chevre: Chevre.
(h) Camembert: Brie, Paglietta, Limburger.
(i) Caprini: Chevre.
(j) Carre de l'Est: Camembert or Brie.
(k) Chaource: Camembert or Brie.
(l) Chevre: Montrachet, Mascarpone or Feta.
(m) Coulommiers: Camembert or Brie.
(n) Feta: Shevre, Ricotta, Queso Fresco, or Romano
(o) Gorgonzola: Roquefort, Stilton or Sago Blue cheese.
(p) Hand: Mainz, Harz, or Limburger.
(q) Harz: Mainz, Hand, Limburger, Mariolles, Livarot, Brick or Liederkrantz.
(r) Maytag Blue: any other blue-veined cheese.
(s) Paglietta: Camembert or Brie.
(t) Petit-Suisse: Boursin or Camembert.
(u) Pont l'Eveque: Camembert.
(v) Queso Anejo: Feta or Queso Fresco (Mexican).
(w) Ricotta Salata: (Italian) Feta.
(x) Robiola: Mix equal parts Ricotta and Mascarpone, or Taleggio.
(y) Stracchino (Crescenza): Taleggio (unripened version of Stracchino).
(z) Taleggio: Stracchino (ripened version of Taleggio) or Fontina.
(aa) Teleme: Brie.

Variety cross comparison of semi-soft cheeses:

(a) Asadero (Queso Asadero): Muenster, Jack or Mozzarella.
(b) Beaumont: Reblochon, Havarti, or Port du Salut.
(c) Bel paese: Fontina, Gouda, Samsoe, Brick, Jack, Meunster or Mozzarella.
(d) Bleu de Bresse: Roquefort.
(e) Blue cheese: Gorgonzola.
(f) Brick: Lagerkaese, Liederkranz, Bel Paese, Limburger.
(g) Caciocavallo: Provolone, Scarmorza, or Mozzarella.
(h) Cantal: Monterey Jack.
(i) Danish Blue: Roquefort.
(j) Esrom: Havarti, Tilsit, Port Salut or Saint Paulin.
(k) Excelsior: Boursault or Brillat-Savarin.
(l) Farmer's cheese: Jack or Muenster.
(m) Gouda: Edam, Samsoe, Bel Paese, Jack, Muenster.
(n) Haloumi: Mozzarella.
(o) Havarti: Tilsit, Esrom or Port Salut.
(p) Jack: Monterey Jack, Sonoma Jack - Muenster, Gouda, Bel Paese or Samsoe.
(q) Lagerkaese: Brick or Limburger.
(r) Laguiole: Monterey Jack.
(s) Livarot: Maroilles, Limburger, Harz, Mainz, Hand, Brick, or Liderkranz.
(t) Morbier: any other semi-soft cheese.
(u) Mozzarella: Scarmorza, Cacciocavallo, string cheese, Queso Blanco, Provolone.

(v) Muenster: Jack, Brick, Port du Salut, Bel Paese.
(w) Oka: any other semi-soft cheese.
(x) Oregon Blue: other blue-veined cheese.
(y) Pipo Crem': other blue-veined cheese.
(z) Port Salut: Saint Paulin, Esrom, Havarti, Jack, Muenster, Brick, Bel Paese.
(aa) Provolone: Cacciocavallo, Scamoraza, Mozzarella.
(bb) Queso Blanco: Mozzarella, Meunster.
(cc) Reblochon: Beaumont, Esrom, Beaufort, Tomme, Raclette, Port Salut or Fontina.
(dd) Ricotta, solid: buffalo-milk Mozzarella.
(ee) Roquefort: Gorgonzola, Stilton.
(ff) Saint Paulin: Port Salut, Esrom or Havarti.
(gg) Samsoe: Gouda or Bel Paese.
(hh) Sarmorza: Mozzarella, Cacciocavallo, or Provolone.
(ii) String cheese: Mozzarella.
(jj) Syrian cheese: Jack or Muenster.
(kk) Tilsit: havarti, Esrom or Port Salut.
(ll) Tomme: Reblochon, Beaufort or Gruyere.

Variety cross comparison of semi-firm (hard) cheeses:

(a) Abondance: Fontina or Appenzell.
(b) American: Cheddar, Colby, Longhorn or Tallamook
(c) Appenzell: Emmentaler, Gruyere, Raclette, or Fontina.
(d) Asiago: any other semi-firm cheese.
(e) Beaufort: Emmenthal, Gruyere, Tomme or Reblochon.
(f) Caerphilly: Cheddar.
(g) Cantal: Cheddar, Gruyere or Monterey Jack.
(h) Cheddar: Colby, Tillamook, Cheshire, American.
(i) Chesire: Cheddar.
(j) Colby: Cheddar, Tillamook, American.
(k) Comte: Emmentaler.
(l) Coon: Cheddar.
(m) Danbo: Samsoe or Cheddar.
(n) Derby: Cheddar.
(o) Derby Sage: Vermont Sage.
(p) Double Gloucester: Cheddar.

C.4.2 Checklist. Guidelines for auditing manufactured dairy products facilities are contained in the following checklist:

# APPENDIX C

| MANUFACTURED DAIRY PRODUCTS CHECKLIST<br><br>7 CFR, Part 58, 21 CFR Parts 133, 173 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E2 | Graded product is marked, labeled, and handled in accordance with Part 58. |
| B2, B3 | Building and facilities are maintained for laboratory, starter rooms, grading rooms, etc., in accordance with 58.126. |
| C5 | All CIP systems, weighing and receiving tanks comply with 3-A accepted practices, in accordance with 58.128. |
| C7, C8 | If applicable, all can washers, associated water and steam lines are equipped and maintained for proper temperature and pressure controls. Steam pressure is not less than 80 lbs and the final rinse is an automatically controlled system, and does not exceed 140º F (60° C). (58.128 (c)). |
| C7, H6 | All scales comply with the National Institute of Standards and Technology Handbook 44 (latest version) and are accurate to the specifications of 58.128 (m). |
| E1, E4, H6 | Raw milk conforms to basic quality and classification specifications of 58.132 - 133 and is tested at the frequencies required, and records are maintained in accordance with 58.134 - 139. |
| C5 | Receiving, holding, and processing of milk and cream and the manufacturing, handling, packaging, storing, and delivery of dairy products are in accordance with Part 58. |
| H8 | Records are maintained for all required tests and analyses in accordance with 58.148. |
| C5 | Sanitary seal assemblies are removable on all agitators, pumps, and vats, and are inspected at regular intervals and kept clean. (58.146 (a)). |
| E4, H6 | Packaging room atmosphere is practically free from mold and verified in accordance with 58.151. |
| E1 | Salt is free flowing, white, refined sodium chloride, and meets the requirements of Food Chemical Code 58. |
| E1 | Color additives approved by US FDA. (58.329, 58.719). |
| B2, B4, H6 | Separate starter rooms or properly designed starter tanks with satisfactory air movement are provided. The air supply is filtered to 90% efficiency in accordance with ASHRAE Synthetic Dust Arrestance Test. (58.406). |
| E4, H6 | Mold counts for make rooms are not more than 15 colonies per plate/15 minutes. (58.407). |
| B2 | Brine room is separately constructed, with minimum corrosion. (58.408). |
| B2 | Adequate shelving, air circulation, temperature and humidity control are provided and maintained in drying rooms. (58.409) (cheese plants only). |
| B2 | Separate rooms are provided for packaging and boxing; maintained at proper temperature to prevent sweating prior to paraffining. (58.410) (cheese plants only). |

MANUFACTURED DAIRY PRODUCTS CHECKLIST - Continued.

| | |
|---|---|
| B2 | Separate rooms are provided for preparation of bulk cheese to be cut and wrapped into smaller packages. Air movement is outward moving. (58.413) (cheese plants only). |
| C6 | Bulk starter vats are equipped with tight fitting lids and have adequate temperature controls and indicating/recording devices. (58.414). |
| C1, C2, C3 | Vats, tanks, and drain tables are constructed of 16 gauge steel or equally corrosion resistant metal, properly pitched, welded, and fitted with sanitary outlets and valves for maintenance of heat to the lines. Auto curd makers, cyclone separators, conveying systems, and curd fillers are properly constructed and maintained. |
| C1 | Mechanical agitators, shields, shafts, hubs, blades, forks, and stirrers are in accordance with 3-A Accepted Standards. |
| C1, C8 | Automatic salters meet the specific requirements (salting method, design, and steam quality) of 58.418 (cheese plants only). |
| B4 | Hoop and barrel washing equipment is vented to the outside. (cheese plants only). |
| C1, C2, C3 | All hand utensils, knives, racks, shovels, scoops, paddles, strainers and other miscellaneous equipment meets 3A Sanitary Standards. Wires in curd knives are stainless steel, tight, and replaced as necessary. (58.419). |
| C1 | Reuse of single service press cloths is prohibited. (58.421) (cheese plants only). |
| E2 | Brine tanks, vacuumizers, and monorail systems do not contribute to the contamination of the product. (58.422, 423, and 424). |
| C7, E2 | Cheese wax is kept clean. Paraffin tanks are of adequate size, fitted with wooden racks, and have heat controls and an indicating thermometer. (58.427) (cheese plants only). |
| E1, H6 | Hydrogen peroxide, catalase, cheese cultures, calcium chloride, and other authorized ingredients comply with requirements. (21 CFR Part 133, 7 CFR Parts 58.431, 58.432, and 58.433) |
| E1 | Rennet, pepsin, and other milk clotting/flavor enzymes meet the requirements of 58.436, (21 CFR, Parts 133, 173). |
| E4 | Each vat and representative sample of finished product is analyzed for milk fat, moisture, and weight/volume control. |
| E2 | Based on the variety of products produced, the stated quality, identity, and analytical requirements of Part 58 are met. (21 CFR, Parts 133, 173) |
| E1 | Nonfat dry milk and whey will be USDA Extra grade except for moisture (Processed cheese). (7 CFR 58.716, 58.717) |
| B8 | Conveyors, grinders/shredders, and cookers maintained and cleaned to prevent contamination. (7 CFR Part 58.707, 58.708, 58.709) |
| E2 | Fats/oils used on the surface of the cheese will be food grade. (21 CFR, Parts 133) |

NOTE: Reference to the controlling CFR Title 7, Chapter 1, Part 58 sections are identified in text or parentheses above.

# APPENDIX D - Fluid Dairy

## D.1 SCOPE

D.1.1 Scope. This appendix contains guidelines for auditing fluid dairy facilities. The information contained herein is intended for guidance.

## D.2 APPLICABLE DOCUMENTS

D.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

D.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

Grade "A" Pasteurized Milk Ordinance (PMO), 1999

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

CODE OF FEDERAL REGULATIONS (CFR)

Title 21, Part 173.

(Application for copies should be addressed to Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/cfr-table-search.html - page1)

U. S. FOOD AND DRUG ADMINISTRATION

IMS List, Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (This publication is available at http://vm.cfsan.fda.gov/~ear/ims-toc.html)

U. S. DEPARTMENT OF AGRICULTURE

Dairy Plants Surveyed and Approved for USDA Grading Service (This publication is available at http://vm.cfsan.fda.gov/~ear/ims-toc.html)

D.3 DEFINITIONS.

D.3.1 Definitions. Definitions are contained in the basic handbook.

D.4 GUIDELINES

D.4.1 General. Vat Pasteurization Systems. The following are areas that need to be evaluated when determining if the vat pasteurization systems meet PMO standards 16p(A):

- Outlet Valves -
  - Constructed of solid stainless steel.
  - Leak protector type - designed to prevent leakage past the valve body.
  - Leak detector groove - at least 3/16 inch in width and 3/32 inch in depth.
  - Stop - required to ensure complete closure during operation.
  - Outlet - close coupled to prevent the accumulation of non-pasteurized milk when closed.
  - All valves must be kept closed during filling, heating, and holding periods.
- Covers -
  - Designed to prevent the entrance of surface contamination.
  - Openings must have raised lips and the covers must overlap.
  - Pipes, agitator shafts, thermometer, etc. must have aprons that divert condensation.
- Agitators –
  - Must insure each particle of milk is heated (not to exceed 1°F (0.5° C)) between two product locations in the vat).
  - Agitator shaft opening must be large enough to allow shaft removal and cleaning.
- Indicating and Recording Thermometers –
  - Compared to each other daily and results recorded on the recording chart.
  - Recording thermometer does not read higher than the indicating thermometer.
  - Should not read less than the pasteurization temperature throughout the holding time.
- Airspace Heater and Thermometer -
  - Air space thermometer bulb 1 inch/25 millimeters or more above product during processing.
  - Record the airspace temperature on the recording thermometer chart each batch.
- Recording Chart (retained for three months) –
  - Date.
  - Number and location of recorder when more than one is used.
  - Extent of holding time including filling and emptying times.
  - Reading of airspace thermometer, within the holding period, at a given time and reference point.
  - Reading of indicating thermometer, within the holding period, at a given time and reference point.
  - Quarterly, the initials of the regulatory agency opposite the required readings of the indicating and airspace thermometers.
  - Quarterly, time and accuracy of the recorder, as determined by the regulatory agency.
  - Amount and name of product represented by batch or run.

  - Any unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.
- General –
  - If at any time during pasteurization the process is interrupted, the timing process must be restarted.
  - No ingredients are added during pasteurization.
  - At no time during or after pasteurization may piping be attached to the vat that is also attached to a line or vessel containing raw milk or any other potentially contaminating substance.

High Temperature Short Time (HTST) Pasteurization Systems. The following are areas that need to be evaluated when determining if the HTST pasteurization systems meet PMO standards 16p(B):

- Constant Level Supply Tank (Balance Tank) –
  - Overflow level below the lowest level of raw milk in the regenerator.
  - All re-circulation lines, divert lines, and leak detect lines must have an air gap.
  - NLT twice the size of the line coming into the balance tank.
- Flow Promoting Devices –
  - Must be located upstream from the holding tube unless a vacuum breaker is installed between the end of the holding tube and the flow promoting device.
  - Air break must rise NLT 30 cm/1 ft higher than any raw milk downstream from the balance tank.
  - Flow promoting device controlling the holding time is connected to the metering pump and sealed.
  - When a homogenizer is used as the timing pump it will be sealed (see specific requirements).
  - Metering or timing pump; positive displacement type or comply with the magnetic flow meter system.
  - Manual switches for pumps that produce flow through the holding tube must be wired so they only operate when the milk is above pasteurization temperature.
  - Booster pump must shutdown in divert flow.
- Plate Heat Exchanger (Regenerator) –
  - Designed to be self-draining back to the balance tank during shutdown.
  - Designed so that the pasteurized product is under higher pressure than raw milk and other mediums in the system.
  - Gauges installed at the raw milk/medium inlet and pasteurized product outlet.
  - If a 1 psi differential is not maintained, system diverts, inter-wired with the flow diversion device.
- Design of pressure gauges (pressure differential gauges installed and a scale NMT 13.8 kPa/2 lbs per sq inch on the working scale NMT 138 kPa/20 lbs per sq inch per 25.4 ml/inch).
- Holding Tube –
  - Diameter of 17.8 cm/7 inches or less and free of fittings.
  - Continuous upward slope NLT 2.1 cm per meter/0.25 inches per foot.

  - No devices installed that can alter the holding time.
  - No portion of the holding tube may be heated, wrapped, or otherwise enclosed.
  - High viscosity products; holding time is calculated at twice the length required (laminar flow).
  - When steam injection is used, a pressure indicator/pressure switch is required.
  - (pressure below 69 kPa/10 psi, the system will divert, inter-wired with flow diversion device.)
- Indicating and Recording Thermometers –
  - Indicating thermometer is located as near as possible to the recording thermometer (indicating thermometer is first in the line).
  - The two thermometers are compared and recorded daily by the plant operator.
  - Recording thermometer does not read higher than indicating thermometer.
  - Recording thermometer inter-wired with the flow diversion device.
  - For specific thermometer scale, accuracy, etc., see Appendix H of the PMO.
- Flow Diversion Device –
  - Located NMT 46 cm/18 inches downstream from the recording thermometer.
  - Designed and installed so that when power is lost the system diverts (spring closure).
  - Leak escape installed on the forward flow side of the valve seat (no back pressure).
  - Leak escape installed between two valve seats or two portions of the same seat (back pressure).
  - When the leak escape line goes to the balance tank; an air break at the end and a sight glass in the line.
  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording Chart (retained for three months) –
  - Date.
  - Number or location of recorder, when more than one is used.
  - Reading of indicating thermometer, within the holding period.
  - Quarterly, the initials of the regulatory agency opposite the reading of the indicating thermometer.
  - Record of the time during which the flow diversion device is in the forward flow position.
  - Cut-in and cut-out temperature recorded daily at the beginning of the run (initialed quarterly by the regulatory agency).
  - Quarterly, time accuracy of the recorder.
  - Amount and name of pasteurized product represented by the chart.
  - Record of unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.

High Heat Short Time (HHST) and Aseptic Pasteurization Systems. The following are areas that need to be evaluated when determining if the HHST and Aseptic pasteurization systems meet PMO standards 16p(C):

- Constant Level Supply Tank (Balance Tank) –

  - All re-circulation lines, divert lines, and leak detect lines must be have an air gap.
  - NLT twice the size of the line coming into the balance tank
- Flow Promoting Devices –
  - Must be located upstream from the holding tube unless a vacuum breaker is installed between the end of the holding tube and the flow promoting device.
  - * The requirement for an air break rising NLT 30 cm/1 ft above the highest raw milk downstream from the balance tank may be eliminated if a differential pressure controller is used. All product contact surfaces between the holding tube and the diversion device are held at or above pasteurization temperature for at least the required pasteurization time.
  - Flow promoting device controlling the holding time is connected to the metering pump and sealed.
  - When a homogenizer is used as the timing pump it will be sealed (see specific requirements).
  - Metering or timing pump; positive displacement type or comply with the magnetic flow meter system.
  - Manual switches for pumps that produce flow through the holding tube must be wired so they only operate when the milk is above pasteurization temperature.
  - * Booster pump can run during divert flow.
- Plate Heat Exchanger (Regenerator) –
  - Designed to be self-draining back to the balance tank during shutdown.
  - Designed so that the pasteurized product is under higher pressure than raw milk and other mediums in the system.
  - Gauges at the raw milk/medium inlet and pasteurized product outlet.
  - If 1 psi differential is not maintained system diverts, inter-wired with the flow diversion device.
  - * Design of pressure gauges (pressure differential gauges installed and a scale NMT 13.8 kPa/2 lbs per sq inch on the working scale NMT 138 kPa/20 lbs per sq inch per 25.4 ml/inch).
  - * Raw product booster pump may be permitted to run in divert flow if the metering pump is operating.
- Holding Tube –
  - Diameter of 17.8 cm/7 inches or less and free of fittings.
  - Has a continuous upward slope NLT 2.1 cm per meter/0.25 inches per foot.
  - No devices installed that can alter the holding time.
  - No portion of the holding tube may be heated, wrapped, or otherwise enclosed.
  - * High viscosity products; holding time is calculated at twice the length required (laminar flow).
  - * Holding time must be calculated rather than measured.
  - * When forward flow can be maintained with less than 518 kPa/75 psi pressure the holding tube is equipped with a pressure limit indicator/pressure switch (to ensure product remains in liquid state).
  - Inter-wired with the flow diversion device.
  - * Steam injection process requires a differential pressure indicator across the injector (inter-wired with the flow diversion device to divert if pressure is less than 69 kPa/10 psi).

- Indicating and Recording Thermometers –
  - Each aseptic system has at least one mercury-in-glass thermometer or equivalent.
  - Indicating thermometer is located as near as possible to the recording thermometer.
  - Indicating thermometer is first in the line.
  - The two thermometers' readings are compared and recorded daily by the plant operator (recording thermometer does not read higher than the indicating thermometer).
  - Recording thermometer inter-wired with the flow diversion device.
  - For specific thermometer scale, accuracy, etc. see Appendix H of the PMO.
- Flow Diversion Device –
  - Located NMT 46 cm/18 inches downstream from the recording thermometer.
  - Designed and installed so that when power is lost the system diverts (spring closure).
  - Leak escape installed on the forward flow side of the valve seat (no back pressure).
  - Leak escape installed between two valve seats or two portions of the same seat (back pressure).
  - If leak escape goes to the balance tank, an air break at the end and a sight glass in the line are required.
  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording chart (retained for three months) –
  - Date.
  - Number or location of recorder, when more than one is used.
  - Reading of indicating thermometer, within the holding period.
  - Quarterly, the initials of the regulatory agency opposite the reading of the indicating thermometer.
  - * Record of the time during which the flow diversion device is in the forward flow position.
  - Quarterly, time accuracy of the recorder.
  - Amount and name of pasteurized product represented by the chart.
  - Record of unusual occurrences.
  - Signature or initials of the operator.
  - Name of plant.
  - * NMT 1 working day after processing, a member of management reviews, signs or initials, and dates the recording thermometer chart.
- General –
  - If heating by direct addition of steam, the steam boiler is equipped with a de-aerator.
  - * All product surfaces from the holding tube to the flow diversion device must be at pasteurization temperature for the required time to get into forward flow.
  - * Vacuum breaker not required after the pasteurization side of the regenerator.

Note:
* Indicates issues only related to HHST and aseptic systems.

D.4.2. Sources of manufactured and processed Dairy products. Establishments listed in the "Dairy Plants Surveyed and Approved for USDA Grading Service" may serve as sources of manufactured or processed dairy products as listed by product code. Those operations denoted

with "P" codes (packaging and processing) must be Directory-listed when providing ungraded manufactured or processed dairy products. When auditing personnel inspect "P" coded establishments providing ungraded products, the inspector must verify the source of raw materials being processed and packaged. (This publication is available at http://www.ams.usda.gov/dairy/dypubs.htm)

D.4.3. Sources of milk and milk products. Establishments listed in the "Sanitation Compliance and Enforcement Rating of Interstate Milk Shippers (IMS) List" may serve as sources (as listed) of milk and milk products. Listing in another approved source document is mandatory to serve as a source of other milk and milk products and/or frozen dessert items. In addition, the IMS List must include establishments producing both fresh milk products and frozen desserts before military sanitary inspection for frozen desserts. If the IMS List does not include the facility, the inspector must cover both processing operations. If the Food and Drug Administration (FDA) removes a Directory of locally-listed frozen dessert establishment from the IMS List, the Commander will recommend the establishment for removal from the Directory or local list. A commercial establishment previously listed in the IMS List and delisted for cause, or initially disapproved for listing, will not be inspected for listing in the Directory. Verify the status of the establishment by calling the State Grade A Milk Sanitation Regulatory official. (This publication is available at http://vm.cfsan.fda.gov/~ear/ims-toc.html)

D.4.4. Commercial dairies located outside the United States.

- Dairy plants outside of the United States will not be approved if they do not provide public health protection equivalent to the U.S. Public Health Service Pasteurized Milk Ordinance (PMO)/3-A Sanitary Standards.
- Dairy farm inspections are not required in Australia and New Zealand. Both countries are free of Bovine Brucellosis and Tuberculosis and have good farm inspection programs.

D.4.5 Deviations from the PMO: The following are issues that may be encountered in dairy plants where the PMO is normally not applied (primarily overseas). The deviations discussed below are intended to meet the food safety concerns of the PMO even though they do not meet the PMO exactly. No deviation can be accepted automatically and must be evaluated as it relates to the entire process and the final product. The auditor must ensure that authorized deviations do not (at the point of the change or elsewhere in the system) violate the intent of the PMO. At first glance a deviation from the PMO in one area may seem harmless, however most systems are highly interactive, and an unacceptable effect may result elsewhere in the system.

D.4.5.1 Issue: As part of the dairy plant audit, the raw milk source must be evaluated.

Deviations: The approval of the raw milk source(s) will be based on a review of the host nation farm inspection program, herd health issues, testing of the raw milk supplies, etc. Antibiotics require special mention here. Traditional residue tests are only sensitive for penicillin and its relatives because those have been the only drugs approved in most western countries. However, aminoglycosides, macrolids, and other potentially dangerous classes of drugs are often the drugs of choice in developing countries because they are usually cheaper and more effective. Currently, the Charm II system is recommended for the detection of chloramphenicol, kanamycin, and other prohibited antibiotic residues. PenZyme and Delvo tests are not sensitive

enough to detect therapeutic levels of these drugs. Similarly, insecticide use is a concern. DDT and other dangerous organochlorides are in daily use in much of the developing world. Farm visits provide a good opportunity to check for prohibited antibiotics and pesticides, but most overseas dairies buy from a milk shed. In most cases, this practice will prohibit the approval of a dairy who packages milk procured from a shed or collective because it is impossible to verify farm practices. Australia and New Zealand are exceptions because farm practices are tightly regulated by skilled, independent auditors. After it has been determined that all the raw milk is coming from a country/area that has been deemed acceptable, then the dairy plant can be audited.

D.4.5.2 Issue: The highest level of raw milk in the constant level must be lower than the lowest point of raw milk in the regenerator. The regenerator must be set up so that the raw milk in the regenerator drains freely back to the raw milk constant level tank during shutdown (holes drilled in the bottoms of the plates).

Deviation: The entire regeneration system must be Cleaned-In-Place (CIP) in the event of a shutdown for any reason, prior to resuming processing (going into forward flow).

D.4.5.3. Issue: All lines (such as re-circulation lines) that go from the pasteurized side of the system to the non-pasteurized side must have a physical break to ensure raw milk is not pulled back in the system on the pasteurized side. For example, re-circulation lines that run from the pasteurized side of the system to the constant level tank can allow raw product to be sucked into the pasteurized system. This can occur if the re-circulation line is not cut off above the overflow on the constant level tank and there is a drop in pressure on the pasteurized side of the system.

Deviation: Re-circulation lines (and other such lines) can have a hole drilled in them at a level above the overflow on the constant level tank. The hole must be of adequate size as to ensure product is not drawn back into the pasteurized side of the system should a pressure drop occur on the pasteurized side of the system.

D.4.5.4. Issue: The flow diversion valve should not be more than 46 centimeters (18 inches) down stream from the recording thermometer.

Deviation: When the flow diversion valve is more than 46 centimeters down stream from the recording thermometer, the system must have a delay sufficient enough to ensure all sub-legal product is past the flow diversion valve prior to the valve going into forward flow. The time delay must be part of the routine testing of the system. In addition, the minimum temperature (cut-out) should be raised by 4º F (2º C) to ensure proper temperature for pasteurization. The time delay does not apply to the valve going into divert flow; the PMO standard of not more than 1 second stands.

D.4.5.5. Issue: The PMO does not authorize the use of computers as a sole means of operating public health controls on pasteurization systems.

Deviation: All public health controls on the pasteurization system will be required to be hardwired and tested as indicated in the PMO. However, the computer can be used to operate the pasteurization system using more restrictive settings. This would allow the computer to control the system prior to hardwired controls taking place. The hardwired controls will need to be tested per the PMO.

D.4.5.6. Issue: The majority of tests required by the PMO are performed every three months.

Deviation: In areas where auditors are not assigned/located, quarterly testing may not be possible. Dairy plants are required to have their own PMO equivalent test equipment. And a minimum of one employee must be trained in performing the PMO tests. That person(s) will perform the tests (if an auditor is not available) when there is a change in equipment or procedures that affects a portion of the process that would normally be sealed by a regulatory agency. They may also test the equipment if there is a three-month period when an auditor is unable to perform the testing. However, at a minimum, an auditor will perform or assist in the performance of the testing every other three-month period. It is highly recommended that more than one person per dairy plant be trained in performing the PMO tests. Only those dairy personnel trained and approved will be authorized to test equipment in the absence of an auditor.

D.4.5.7. Issue: Any time there is a change to the pasteurizing system that affects a portion of the equipment that would normally be sealed, that portion of the system must be tested prior to further processing. This is not possible in locations where an auditor is not readily available.

Deviation: Equipment will not be sealed; however, dairies will be required to test their own equipment in accordance with the PMO if there are changes to the system. The testing must be done by a trained/approved plant employee and prior to any further processing. All equipment changed, adjustments, and test results (to include the name of the person performing the test) will be documented. This information will be made available to the auditor during the next audit.

D.4.5.8. Issue: On a daily basis the plant operator is required to compare the recording thermometer to the indicating thermometer and check the cut-in and the cut-out temperatures. The results are written on the recording thermometer chart along with the initials of the plant operator that performed the checks. This may not be possible for systems without recording charts that can be written on.

Deviation: If the recording thermometer chart can not be written on at the time of the checks, a log with all the necessary information may be used. This may be the case with computer operated systems where the information prints out at a different location. However, the log must be compared to the printout (recorded information) and the printout signed by a supervisor prior to the product being release.

D.4.5.9. Issue: The holding tube is designed so that no sections of pipe can be left out resulting in a shortened holding time. The holding tube does not have a device in any portion of it that permits a shortened holding time. For dairies that process several types of products on the same pasteurizer, changing the holding tube length may be necessary.

Deviation: If the holding tube is designed so that the length or diameter can be changed, the system must be tested using all holding tube options. Plant management must demonstrate a method of controlling the type of holding tube used for every process/product. For holding tubes with devices in them that can alter the holding time, a method such as hardwiring the device to the controller program must be in place and tested.

D.4.6 Checklist. Guidelines for auditing fluid dairy facilities are contained in the following checklist.

# APPENDIX D

| FLUID DAIRY CHECKLIST<br><br>USPHS Publication 229 (PMO) and CFR Title 21, Part 173 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1 | Milk originates from accredited tuberculosis-free and brucellosis-free herds, and from countries/regions determined to be acceptable. (Sec. 8). |
| B7, H6 | A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days. (Sec. 7, Item 12p). |
| E1 | Upon arrival, raw milk and/or raw products for pasteurization comply with bacteriological, chemical and temperature standards of Sec. 7, Table 1. |
| E4 | Raw milk and milk products are screened for drug residue. (Sec. 6). |
| E2 | Raw milk and milk products are held at 45° F (7° C) until processed. (Sec. 7, Item 17p). |
| C3 | Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (Sec. 7, Item 10p). |
| C2 | All milk contact surfaces of multi-use containers and equipment are constructed of American Iron and Steel Institute (AISI) 300 series stainless steel or other non-corrosive material as described in the Pasteurized Milk Ordinance (PMO). (Sec. 7, Item 11p). |
| C5 | Equipment is designed to protect against surface and overhead contamination. (Sec. 7). |
| B7 | Storage tanks are cleaned when emptied and are emptied at least every 72 hours. (Sec. 7, Item 12p). |
| C7 | Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7-day temperature recording device. (Sec. 7, Item 12p). |
| C5 | Equipment complies with the sanitary design and construction standards of the PMO. (Sec. 7). |
| E2 | The overflow of the top rim of the constant level raw milk tank is lower than the lowest milk level in the regenerator. (See High Heat Short Time (HHST) exception) (Sec. 7, Item 16p(D)). |
| E2 | Raw milk in the regenerator drains back to the constant-level tank. (Sec. 7, Item 16p(D)). |
| E2 | The pasteurized side of the regenerator is always under higher pressure than the raw side. (Sec. 7, Item 16p(D)). |
| E2 | An atmosphere break exists at least 30.48 centimeters above the raw milk. (See HHST exception) (Sec. 7, Item 16p(D)). |
| E2 | There is no flow promoting device between the regenerator and the air-break. (Sec. 7, Item 16p(D)). |
| E2 | There is no pump between the raw milk inlet to regenerator and the raw milk supply tank. (See HHST exception) (Sec. 7, Item 16p(D)). |
| E2 | The holding tube is designed so that no deviations can be made to the flow rate or holding time. (Sec. 7, Item 16p(B)). |
| E2 | The flow control sensor (Recording Thermometer) is not more than 46 centimeters (18 inches) up stream from the control device. (Sec. 7, Item 16p(B)). |

FLUID DAIRY CHECKLIST - Continued.

| | |
|---|---|
| E2 | The indicating and recorder thermometers are properly located. Sec. 7, Item 16p(B)). |
| E2 | The flow diversion devices are properly installed and functioning. (Sec. 7, Items 16p(B)(C)). |
| E2 | The flow promoting devices are properly located and of the proper speed, displacement, and capacity. (Sec. 7, Item 16p(F)). |
| E2 | Pasteurized milk is not strained or filtered except through a perforated metal strainer. (Sec. 7, Item 15p(A)). |
| E2 | Manual valves meet PMO standards (stop/leak grove/close coupled). (Sec. 7, Item 16p(A)). |
| E2 | Pasteurization equipment and controls testing is performed in accordance with the PMO. (Appendix I). |
| H8 | Pasteurization recording charts are maintained on file at the processing plant. (Sec. 7, Item 16p(E)). |
| C7 | Thermometers meet requirements. (Sec. 7, Item 16p(A) & 16p(B), Appendix H). |
| E2 | Air space heating is accomplished when required for Batch Pasteurization. (Sec. 7, Item 16p(A)). |
| E2, H8 | Recording charts are complete and maintained. (Sec. 7). |
| C8 | Culinary steam is in accordance with PMO. (Sec. 7, Item 16p(B)). |
| B8 | Boiler water additives comply with 21 CFR 173.310. |
| C8 | Air under pressure is in accordance with 3-A Accepted Practices. (Appendix H). |
| E2 | There is no cross-connection or direct contamination of pasteurized milk or milk product. (USPHS Publication 229). |
| B6, C5 | All openings, including valves, pipes, milk tanker trucks, etc. are capped or otherwise protected. (Sec. 7, Item 15p(A)). |
| E5 | Filling lines are equipped with a device capable of detecting, in each container before filling, volatile organic contaminants. The device is interconnected so that the system will not operate unless the detection device is operational. (Sec. 7, Item 12p). |
| E2, E5 | Recirculated cooling water is protected from contamination. (Appendix G). |
| E4 | Recirculated cooling water is tested once per six-month period. (Appendix G). |
| C7 | Clean-In-Place (CIP) systems are in compliance with PMO. CIP systems have a recording device installed in the return solution line or other appropriate area to record the temperature and time at which the line or equipment is exposed to cleaning and sanitizing solution (retained for 3 months) (Sec. 7, Item 12p). |
| H6, H7, H8, H9 | Record of CIP cleaning process is maintained for recirculated cleaning systems. (Sec. 7, Item 12p). |
| C7 | During processing, pipelines and equipment used to conduct milk are effectively separated from cleaning and sanitizing solutions (see the PMO for methods). (Sec. 7, Item 15p(B)). |
| B3 | Plants where containers are manually cleaned have a two-compartment sink and a steam cabinet to sanitize containers, or a three-compartment sink if a chemical sanitizer is used. (Sec. 7, Item 12p). |
| E4, H8 | Pasteurized milk and/or milk products comply with bacteriological, chemical and temperature standards of Sec. 7. Results are recorded and records maintained. (Sec. 7, and Table 1.) |

FLUID DAIRY CHECKLIST - Continued.

| | |
|---|---|
| E2 | Pasteurized milk and milk products are cooled to 45° F (7° C) and maintained at that temperature. (Sec. 7, Item 17p) |
| E4, H8 | Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. Results are recorded and records maintained. (Sec. 7, Item 12p). |
| E1 | Packaged milk and milk products which have physically left the premises or processing plant are not repasteurized for Grade A use (see the exception) (Sec. 7, Item 15p(A)). |
| B5 | Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (Sec. 7, Item 15p(A)). |
| B5 | Only approved rodenticides and insecticides are used. (Sec. 7, Item 15p(A)). |

NOTE: Cited reference documents for the above are U.S. Public Health Service Publication 229 and 21 CFR 173.

# APPENDIX E - Shell Eggs

## E.1 SCOPE

E.1.1 Scope. This appendix contains guidelines for auditing egg processing facilities. The information contained herein is intended for guidance.

## E.2 APPLICABLE DOCUMENTS

E.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

E.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Title 7, Parts 56 and 59

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/cfr-table-search.html - page1)

## E.3 DEFINITIONS

E.3.1 Definitions. Definitions are contained in the basic handbook.

## E.4 GUIDELINES

E.4.1 General. Unnecessary handling at the farm, during transportation or processing, and poor packaging procedures can reduce the natural protection of the shell and provide entry sites for bacteria. Packaging plants must provide effective methods of screening eggs so that damaged eggs are removed.

Ideally, eggs should be held at ambient temperatures between 40º-50º F (4º-10º C) at 70-80% humidity. Lowering the temperature of the egg should begin at the farm. The distance from the farm to the packaging plant will influence the extent of cooling necessary at the farm before subsequent transportation.

To ensure that eggs are cleaned effectively, the following components of the egg washing process must be considered: wash water temperature, water quality characteristics (e.g., hardness and pH), detergent type and concentration, and de-foamer. Wash water must be potable and should be added continuously to maintain a constant overflow rate. Chlorine or quaternary

ammonium sanitizing compounds may be added to the replacement water provided they are compatible with the detergent. The iron content of the water may influence the growth of bacteria when the egg membrane is penetrated. Consequently, wash water may contain no more than 2 ppm iron. The wash water should be maintained at a pH of 10 to 11. USDA regulations require that wash water temperature be at 90ºF (32ºC) or higher, or at least 20ºF (-7ºC) warmer than the highest egg temperature (which ever is greater). Cooler water temperatures may create conditions that would draw water through the porous eggshell, contaminating the egg contents. Wash water must be changed every four hours, or more often if needed to maintain sanitary conditions. According to USDA regulations, the eggs cannot be immersed at any time.

After washing, eggs are rinsed with hot water and then dried utilizing ambient air. The eggs may then be oiled using clean edible oil. The process should be continuous in order to limit exposure to ambient temperatures outside the preferred temperature zones. Rapid placement back into storage coolers is vital to maintaining a high quality product.

Packaging equipment should be designed in such a way as to minimize damage to the egg.

E.4.2 Checklist. Guidelines for auditing egg processing facilities are contained in the following checklist.

# APPENDIX E

| SHELL EGGS CHECKLIST<br><br>CFR Title 7, Part 56 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E3 | Grading and packing rooms are kept reasonably clean during grading and packaging operations, and are thoroughly cleaned at the end of each day. (56.76(a) (2)). |
| B4 | The egg grading or candling area is adequately darkened to make possible the accurate quality determination of the candled appearance of eggs. There are no other light sources or reflections of light that interfere with or prohibit accurate quality determination of eggs in the grading or candling area. Other light sources and equipment or facilities are provided to permit the detection and removal of stained or dirty eggs, or other under grade eggs. (56.76(b)(1) & (2)). |
| E3 | The cooler room has refrigeration facilities capable of reducing within 24 hours and holding the maximum volume of eggs handled to 45° F (7° C) or below. Accurate thermometers are provided. (56.76(c) (1)). |
| E3 | Eggs with excess moisture on the shell are not shell protected (oil processed). (56.76(d) (1)). |
| E3 | Oil having any off odor, or that is obviously contaminated, is not used in shell egg protection. (56.76(d) (2)). |
| E1 | Processing oil that has been previously used and which has become contaminated is filtered and heated at 180° F (82° C) for 3 minutes prior to use. (56.76(d) (3)). |
| C4, E2 | Shell egg processing equipment is washed, rinsed and treated with a bactericidal agent each time the oil is removed. It is preferable to filter and heat treat processing oil and clean processing equipment daily when in use. (56.76(d) (4)). |
| E2 | The temperature of the wash water is maintained at 90° F (32° C) or higher, and is at least 20° F (-6° C) warmer than the temperature of the eggs to be washed. These temperatures are maintained throughout the cleaning cycle. (56.76(e) (2)). |
| E2 | Replacement water is added continuously to the wash water of washers to maintain a continuous overflow. Iodine sanitizing rinse is not used as part of the replacement water. (56.76(e) (5)). |
| E4, H6 | An analysis of the iron content of the water supply, stated in parts per million, is performed. When the iron content exceeds 2 parts per million (ppm), equipment is provided to correct the excess iron content. If the water source is changed, new tests are performed. (56.76(e) (6)). |
| E2, E4, H6 | The washing and drying operation is continuous and is completed as rapidly as possible. Eggs are not allowed to stand or soak in water. Immersion washers are not used. (56.76(e) (8)). |

SHELL EGGS CHECKLIST – (Continued)

| | |
|---|---|
| E2, E4 | Washed eggs are spray-rinsed with water having a temperature equal to, or warmer than, the temperature of the wash water, and containing an approved sanitizer of not less than 50 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternate procedures, in lieu of a sanitizer rinse, are approved by the FDA or MACOM. (56.76(e) (10)). |
| E2 | During any rest period, eggs are removed from the washing and rinsing area of the egg washer and from the scanning area whenever there is a buildup of heat. (56.76(e) (12)). |

NOTE: Reference to the controlling CFR Title 7, Part 56 sections are identified in parentheses.

# APPENDIX F - Frozen Desserts

## F.1 SCOPE

F.1.1 Scope. This appendix contains guidelines for auditing frozen dessert production facilities. The information contained herein is intended for guidance.

## F.2 APPLICABLE DOCUMENTS

F.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

F.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

Most current Frozen Dessert Processing Guidelines, U. S. Department of Health and Human Services, Food and Drug Administration.

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 135

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html)

## F.3 DEFINITIONS

F.3.1 Definitions. Definitions are contained in the basic handbook.

## F.4 GUIDELINES

F.4.1 General. Of utmost importance in a frozen dessert plant is where the mix is made. Some facilities purchase mix from another establishment and it is trucked over the road to their establishment. If the mix goes over the road, it should be re-pasteurized prior to it being used. If

the facility is not re-pasteurizing the product, this may be a finding of significant public health importance.

For the purpose of this audit, break down the plant tour as raw (prior to pasteurization), pasteurized, and finished product.

Everything prior to the divert valve is considered raw. Milk (ice cream is not considered Grade A) is trucked into the establishment. Raw milk should be unloaded in a protected bay. Tankers must be vented to prevent them from collapsing; ensure there is a filter or screen on top of the tanker when it is off-loading (to protect the product). Some tests that may be performed in the raw off-loading area are: Standard Plate Count (SPC), Direct Microscopic Clump Counts (DMCC), Freezing Point, Antibiotics, and Somatic Cell Count. The acceptable levels for Non-Grade A are higher. Raw milk should be pumped into raw silos and be kept at a temperature around 40° F (4° C) for not more than 72 hours. Verify the time and temperature by reviewing the recorder controller charts. Also, verify silo Clean In-Place (CIP) cleaning by these charts. Determine how the silos are vented; whether the vent is on top of the silo or at eye level. There can also be a port at the top of the silo. Ask if there are any other openings. Also, establish if they are separating the fat out of the milk and storing that in a separate silo. They will reintroduce the fat into the mix to satisfy recipes. All additional ingredients should be added prior to pasteurization. The only ingredients which may be added after pasteurization are those flavoring and coloring ingredients that are:

- subjected to prior heat treatment sufficient to destroy pathogenic microorganisms
- of 0.85% water activity or less
- of pH less than 4.7
- roasted nuts (added at the freezer)
- contain high alcohol content
- bacterial cultures
- fruits and vegetables added at the freezer
- subjected to any other process that will assure that the ingredient is free of pathogenic microorganisms

Ingredients added after pasteurization should be tested to ensure that the final product is not contaminated during post-pasteurization processing.

After pasteurization comes the filling process. Some establishments might store pasteurized product in a silo, prior to filling. The silo holding pasteurized product must be in a separate area of the plant, away from the raw silos. Product will be chilled to the consistency of a soft serve product prior to filling. Different fillers are used for the different size containers. The product could be used in the creation of novelty items (e.g., ice cream sandwiches, ice cream bars, etc.). Ensure that the product is shielded against contamination during the entire filling process. After the filling process, the product should be sent immediately to a blast freezer.

Perform a tour around the plant to look for the presence of rodent/insect harborages and entryways into the establishment. Go onto the establishment's roof, looking for low-lying areas where water can pool. Pooling water can cause leaks into the establishment. While on the roof, look up at the silos to see if there are any ports on the top.

Points of interest: Find out how much rework is incorporated back into the product. In addition, where the rework is stored and at what temperature it is stored. Review recorder controller charts to see if there were any interruptions during the pasteurization process (if product went through diverted flow). If product went through diverted flow, see if there is an explanation on the recorder controller. Check recorder controller charts also for the CIP process. Make sure divert valves pulsed during CIP process. A proper CIP process should take between 90 to 120 minutes (there is no mandated time). Higher coliform counts in the product could be tied back to poor sanitation, or improper CIP of the pasteurizer.

F.4.2 Checklist. Guidelines for auditing frozen dessert production facilities are contained in the following checklist.

# APPENDIX F

| FROZEN DESSERTS CHECKLIST<br>TABLE I - GENERAL CONSIDERATIONS<br>Frozen Dessert Processing Guidelines | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E2, H6 | Raw milk, low fat milk, skim or cream which was heated above 45º F (7° C), but below 160º F (71° C) for separation, is used in frozen dessert if: 1) It was heated only once for pasteurization, 2) After separation, it was immediately cooled to below 45º F (7° C), 3) No more than 3 days have elapsed between separation and shipment to the frozen dessert plant, or 4) If it is heated above 125º F (51° C), it meets 30,000 Standard Plate Count and 10 coliforms at plant of shipment, 100 coliforms at plant of receipt. (Page 4). |
| C5 | Adequate physical breaks to the atmosphere (at least as large as the piping diameter) are provided in order to eliminate cross-connections, and are verifiable by walk-through with installation drawings. (Page 9). |
| E2 | All openings into product or onto sanitized product-contact surfaces are capped, closed, or adequately protected. (Page 9). |
| C4 | Fill line connections are made to tank fittings, and tank lids are not propped open during filling. (Page 9). |
| E3 | Absorbent items such as rags and sponges are not used in the plant environment, and separate brushes are used for product and non-product surfaces. (Page 10). |
| B8 | All containers, utensils, and equipment are cleaned and sanitized at least once during each day they are used; storage tanks are emptied and cleaned at least every 72 hours. (Page 11). |
| E2 | Piping equipment and containers used to process or package aseptically processed frozen dessert mix beyond the final heat-treatment process are sterilized before any aseptically processed product is packaged. (Page 11). |
| E2 | Pasteurized mix is frozen, dried, packaged, or shipped within 72 hours of being pasteurized. (Page 12). |
| C1 | All openings in covers of tanks, vats, separators, etc. are protected by raised edges or other means to prevent the entrance of surface drainage. (Page 13). |
| C1 | There are no threads used in contact with milk, milk products, frozen desserts, or frozen dessert mixes except where needed for functional and safety reasons, such as clarifiers, pumps, and separators. (Page 14). |
| B2 | The following areas are separate from one another: 1) the tank truck receiving area, 2) the processing area, 3) the can or case wash areas, 4) the dry storage areas, 5) the packaging area. (Page 16). |
| E2 | All milk, milk products, frozen dessert mix, liquid eggs, and dairy ingredients are maintained at 45º F (7° C) or below. Products in coolers are stored at temperatures under 45º F (7° C). (Page 17). |

| FROZEN DESSERTS CHECKLIST<br>TABLE II - PLANT SYSTEMS<br>Frozen Dessert Processing Guidelines | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E2 | Pressurizing air processing systems which incorporate air directly into the product, such as freezers, air blows, and air agitating systems, are properly designed to reduce potential contamination. They are equipped with filters and sanitary check valves. (Page 25). |
| B8, H6 | Where steam is used to provide heat for vat or HHST processes, the water source for the boiler is identified as potable and is in compliance with CFR, Title 21. (Page 27). |
| E4, H6 | The re-circulating cooling water (sweetwater) and re-circulating glycol and water mixtures are tested at least every six months and are free of coliforms and listeria. (Page 28). |
| B4 | Outside air entering the facility is filtered and free of condensates. (Page 29). |
| E2 | Dusty, raw ingredient blending operations which create powdery conditions are located away from pasteurized product areas. (Page 32). |
| E2 | Products are pasteurized in accordance with the time/temperature tables listed in the Frozen Dessert Processing Guide. (Page 33). |
| E2 | Pasteurization is in accordance with the methods explained in the Frozen Dessert Processing Guide. (Pages 32 through 67). |
| E1 | Mix shipped in bulk tank trucks to another location is re-pasteurized at that plant prior to freezing and packaging. (Page 68). |
| E2 | All dairy products, eggs, egg products, cocoa products, emulsifiers, stabilizers, liquid sweeteners and dry sugar are added prior to pasteurization. (Page 69). |
| E2 | All reconstitution or recombination of dry, powdered, or condensed ingredients with water is done prior to pasteurization. (Page 69). |
| E2, H6 | Ingredients which may be added after pasteurization are limited to those flavoring and coloring ingredients which are: 1) subjected to prior heat treatment sufficient to destroy pathogenic microorganisms, 2) of 0.85% water activity or less, 3) of pH less than 4.7, 4) roasted nuts added at the freezer, 5) contain high alcohol content, 6) bacterial cultures, 7) fruits and vegetables added at the freezer, and 8) subjected to any process which will assure that the ingredient is free of pathogenic microorganisms. (Page 69). |
| E4 | A plant quality assurance program is in place to assure that the fresh fruit and vegetable products are of high quality and do not contaminate the dairy product. (Page 69). |
| C1 | To prevent contamination, lids of tub and canister-type containers for frozen desserts are designed to overlap the tub or container to be overwrapped. (Page 70). |
| E2 | If de-foamers are used, they do not return product or foam to the filler bowl. (Page 70). |

| FROZEN DESSERTS CHECKLIST<br>TABLE III - SPECIFIC PLANT OPERATIONS<br>Frozen Dessert Processing Guidelines<br>21 CFR 135 | |
|---|---|
| B7 | Pails used for rework or adding flavors are cleaned after each use and sanitized prior to reusing. (Page 71). |
| C8 | The air supply in the freezer is properly filtered. (Page 71). |
| E2 | A bright distinctive food color is added to the brine used on novelty sticks if the brine is calcium carbonate, in order to detect leakage onto the finished product. (Page 72). |
| B3 | When a stainless steel chute is used to convey product (novelty) to the wrapper after extraction, the chute is cleaned at least every four hours during the production run. (Page 72). |
| E2 | Water used to glaze product to help prevent sticking to the paper wrapper is pasteurized or treated to lower the pH. Water dips have a continuous over-flow to minimize product accumulation throughout the product run. (Page 73). |
| C1 | There is a physical break between pasteurized product for re-pasteurization when the product is loaded in a raw product receiving area. Particular attention should be paid to product and CIP connections, so that raw product in lines and tanks is never directly connected to any line that extends back to the pasteurized product lines or tanks. A physical break is required.<br>(Page 68). |
| C1 | Adequate drip deflectors are provided at each filler valve. (Page 70). |
| C1 | Tanks used for holding cooling media are adequately protected and are coliform and pathogen free. (Page 70). |
| E1 | For reclaiming operations, only product that has not left the plant premises is reclaimed. (Page 74). |
| C1 | Woven wire strainers are not used to remove bulky ingredients. (Page 74). |
| E1 | Reworked product, such as ice cream, which is retained in buckets during startup while overrun is stabilized, is kept to a minimum. If this product is to be recycled back into product, it is properly protected and re-pasteurized.<br>(Page 75). |
| E4, H6 | Microbiological criteria for end items are not more than 50,000 cfu/g Standard Plate Count; not more than 10 coliforms/g; and not more than 20 coliforms/g for fruits, nuts, or other bulky flavors. (21 CFR 135). |
| E2 | Hardening is performed immediately after mix is containerized. Rapid freezing is recommended from 0º F (-18° C) to -15º F (-26º C). (21 CFR 135). |

NOTE: Page numbers cited in parentheses apply to the controlling Frozen Dessert Processing Guidelines or 21 CFR 135.

# APPENDIX G - Ice

## G.1 SCOPE

G.1.1 Scope. This appendix contains guidelines for auditing ice production facilities. The information contained herein is intended for guidance.

## G.2 APPLICABLE DOCUMENTS

G.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

G.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

40 CFR Part 141 NATIONAL PRIMARY DRINKING WATER REGULATIONS

(Copies of this document are available for free download at http://www.access.gpo.gov/nara/cfr/waisidx_01/40cfr141_01.html)

G.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

INTERNATIONAL PACKAGED ICE ASSOCIATION

Sanitary Standard for Packaged Ice, 6/26/89

(Application for copies should be addressed to the International Packaged Ice Association, P.O. Box 1199, Tampa, FL 33601.)

## G.3 DEFINITIONS

G.3.1 Definitions. Definitions are contained in the basic handbook.

## G.4 GUIDELINES

G.4.1 General.
Consider the following guidelines when performing an audit on an Ice Establishment:

Only potable water is to be used for ice production. The frequencies of laboratory tests and maximum contaminant levels are listed in 40 CFR, Part 141 Subparts B, C, and G. Review laboratory sampling and ensure that tests and examinations are performed at frequencies prescribed by the CFR.

Once a potable water system is contaminated by the inadvertent action of a user, the foreign or toxic material can be distributed throughout the facility's potable plumbing system and adjacent premises connected to the same supply. Find out where the water comes from and how it is treated.

Watch for cross-connections. They are actual or potential links between the potable water supply and source of contamination (sewage, chemicals, gas, etc.). A cross-connection can be any temporary or permanent direct connection, by-pass arrangement, jumper connection, removable section, swivel or change-over device that connects potable and non-potable systems together.

Watch for back-siphonage. This is a backflow that occurs when the pressure in the water supply drops below zero (less than atmospheric pressure or negative head pressure) and the adjacent nonpotable source is “sucked” or siphoned into the potable supply. Be familiar with different backflow devices that are used by industry. Air gaps (or physical air gap, “air break”) are the most desirable method of backflow prevention. An air gap is an unobstructed, vertical air space that separates potable from nonpotable water systems.

Physical adulterants are a large concern. Check overhead areas for peeling paint, rusty pipes, and lubricant from processing chains. Make sure the overhead lights have protective shields or shatter proof bulbs. Watch for any toxic lubricants, chemicals, fuels, metal fragments, sanitizers, etc. that might contaminate the ice.

Air and water filters need to be changed in accordance with the manufacturer’s guidance. Galvanized surfaces, solder, and corrosion-resistant surfaces are a concern. If the water pH is less than 6.5, and the establishment has galvanized surfaces, then potable water, core water, and ice samples should be tested for heavy metals.

Filters, setting tanks and contact surfaces should be sanitized as often as necessary to assure a bacteria free product.

When dipping wells are used, ice should not come in direct contact with water in the dipping wells. When canvas covers are used, there has to be a single-service lining. Watch for dirty core in block ice.

A separate room should be a used for processing and packaging of ice intended for human consumption. Finished product should not be handled with bare hands.

Finished product should be protected against cross contamination during storage and shipping.

G.4.2 Checklist. Guidelines for auditing ice production facilities are contained in the following checklist.

# APPENDIX G

| ICE PLANT CHECKLIST<br>INTERNATIONAL PACKAGED ICE ASSOCIATION<br><br>Sanitary Standard for Packaged Ice | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E4, H6 | Bacteriological tests of the finished ice are conducted monthly, chemical and physical tests annually, and radiological tests every four (4) years (Section 7, para 5). |
| E4, H6 | Random samples of ice produced in the plant are tested by an approved laboratory at least monthly for fecal and/or total coliform organisms and Heterotrophic Plate Count (HPC). Total coliform is not greater than 2.2 organisms/100 ml. using the Most Probable Number (MPN) method and not greater than 1 organism/100 ml. using the Membrane Filtration (MF) method. The HPC does not exceed 500 colonies/ml. Records of these tests are maintained for two (2) years. (Section 7, para 6). |
| E4, H6 | A testing program has been implemented to obtain background information on the chemical and microbiological content of the brine solution as it relates to leaking cans and the subsequent contamination of the product. Such data reflects the presence of any refrigeration defrosting chemicals, such as ethylene or propylene glycol (if used in the plant), lead (Pb), cadmium (Cd), zinc (Zn), chromium (Cr), and nitrate ($NO_2$). The finished products (varying product types and packages) are randomly sampled and analyzed on a quarterly basis for ethylene or propylene glycol (if applicable) and chlorides (Cl). Reports of analyses are maintained for two years. (Section 7, para 7 & 8). |
| E3 | Packaged ice products are tightly sealed and clearly labeled to show the name, manufacturer, location of processing plant, date code, and net weight. (Section 8, para 3). |
| E2 | Filtering equipment is designed to protect ice from contamination and is subject to periodic treatment and cleaning. (Section 6, para 1) |
| E2 | Freezing tank covers of acceptable materials are designed and constructed to protect ice containers from splash, drip, and other contamination; are easily cleanable and are kept clean and in good repair. Such covers are equipped with rings or similar devices when hooks are used for pulling. Can or tank covers, and the ledges of sides of the tank upon which the cover rests, are cleaned as often as necessary to keep them in sanitary condition. (Section 6, para 4). |
| C8 | Air used for water agitation is filtered or otherwise treated to remove dust, dirt, insects, and extraneous material. Filters are placed upstream of the compressor and are easily removable for cleaning or replacement. The compressor used to supply air for water agitation is designed to deliver oil-free air. (Section 6, para 8 & 9). |

ICE PLANT CHECKLIST - Continued.

| ICE PLANT CHECKLIST<br>INTERNATIONAL PACKAGED ICE ASSOCIATION<br><br>Sanitary Standard for Packaged Ice | |
|---|---|
| C2 | Air lines and core or sucking (vacuum) devices are used as needed to produce ice free of rust or other foreign materials. (Section 6, para 11). |
| A6 | Hands do not come into direct contact with the ice at any time during manufacturing, processing, packaging, and storage. (Section 7, para 1). |
| E3 | All frozen unpackaged ice blocks intended for sale for human consumption or for refrigeration of food products are washed thoroughly with potable water. Ice manufactured for industrial purposes is handled and stored separately from ice intended for human consumption. (Section 7, para 2). |
| B10 | Water used for washing or rinsing is not reused and is disposed of as liquid waste. (Section 7, para 3). |
| B7 | All equipment used to store or deliver water, or in contact with ice in the freezing process, is regularly sanitized. (Section 7, para 4). |

NOTE: Cited reference document for the above is Sanitary Standard for Packaged Ice.

# APPENDIX H - Seafood

## H.1 SCOPE

H.1.1 Scope. This appendix contains guidelines for auditing cured, salted and smoked fish production facilities. The information contained herein is intended for guidance.

## H.2 APPLICABLE DOCUMENTS

H.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

H.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Title 21, Part 123, 161, and 172.

Title 50, Part 260

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

FDA FISH AND FISHERY PRODUCTS HAZARDS & CONTROLS GUIDE (JAN 98).

(Available on-line at: http://vm.cfsan.fda.gov/~dms/haccp-2a.html. Single copies of this Guide may be obtained as long as supplies last from the FDA district offices and from: U.S. Food and Drug Administration, Office of Seafood, 200 C St., SW, Washington, D.C. 20204, (202) 418-3133. Multiple copies may be obtained from: National Technical Information Service, U.S. Department of Commerce, (703) 487-4650. This guide is also available electronically at: http://www.fda.gov/. Select "foods;" then select "seafood;" then select "HACCP.")

CURED, SALTED AND SMOKED FISH ESTABLISHMENTS GOOD MANUFACTURING PRACTICES (Revision June 1997)

(Available from Association of Food and Drug Officials, 2550 Kingston Road, Suite 311 York, PA 17402, Email: afdo@afdo.org)

H.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices. An Association of Food and Drug Officials Model Code.

(Application for copies should be addressed to Association of Food and Drug Officials, 2250 Kingston, Suite 311, York, PA 17402, (717) 757-2888, http://www.healthfinder.gov/text/orgs/hr0316.htm/.)

H.3 DEFINITIONS

H.3.1 Definitions. Definitions are contained in the basic handbook.

H.4 GUIDELINES

Additional guidance for the hazards associated with fish and fish products, to include risk assessment and HACCP plans, are found in the FDA's Fish and Fishery Products Hazards & Controls Guide. Fresh seafood production establishments are inspected using Appendix A, in general, and Table VI (HACCP), specifically.

H.4.1 General.

ACIDIFIED, FERMENTED, AND SALTED FISH AND FISHERY PRODUCTS

Process establishment. Except where finished product water phase salt, pH, or water activity analysis is the monitoring procedure, the adequacy of the pickling/brining/formulation process should be established by a scientific study. It should be designed to ensure: a water phase salt level in the loin muscle of at least 5%; a pH in the loin muscle of 5.0 or below; a water activity in the loin muscle of 0.97 or below; or a combination of salt, pH, and/or water activity in the loin muscle that, when combined, prevent the growth of *C. botulinum* type E and nonproteolytic types B and F (established by scientific study). Expert knowledge of pickling/brining/ formulation processes is required to establish such a process. Education or experience or both can provide such knowledge. Establishment of pickling/brining/formulation processes requires access to adequate facilities and the application of recognized methods. In some instances, pickling/brining/formulation studies will be required to establish minimum processes. In other instances, literature establishing minimum processes is available. Characteristics of the process and/or product that affect the ability of the established minimum pickling/brining/formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained.

Critical aspects of processes. Critical aspects of pickling, brining, or formulation processes may include:

- Brine/acid strength;
- Brine/acid to fish ratio;

- Brining/pickling time;
- Brine/acid temperature;
- Thickness, texture, fat content, quality, and species of fish;
- Water phase salt, pH, and/or water activity of the finished product;
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

BATTERED FISH AND FISHERY PRODUCTS

Potential food safety hazard. *S. aureus* toxin formation in hydrated batter mixes can cause consumer illness. This toxin, in particular, is a concern because heating steps that may be performed by the processor or the consumer cannot destroy the toxin. Pathogens other than *S. aureus,* are, in many cases, less likely to grow in hydrated batter mixes, and are likely to be killed by the heating steps that follow.

Control measures. *S. aureus* can enter the process on raw materials. It can also be introduced into foods during processing from unclean hands and unsanitary utensils and equipment. The hazard develops when a batter mix is exposed to temperatures favorable for *S. aureus* growth for sufficient time to permit toxin development. *S. aureus* will grow at temperatures as low as 44.6º F (7º C) and at a water activity as low as 0.83. However, toxin formation is not likely at temperatures lower than 50º F (10º C). For this reason, toxin formation can be controlled by minimizing exposure of hydrated batter mixes to temperatures above 50º F (10º C). Exposure times greater than 12 h for temperatures between 50º F (10º C) and 70º F (21.1º C) could result in toxin formation. Exposure times greater than 3 h for temperatures above 70º F (21.1º C) could also result in toxin formation.

FDA guidelines.

- Hydrated batter mix temperatures should not exceed 50º F (10º C) for more than 12 h, cumulatively; and
- Hydrated batter mix temperatures should not exceed 70º F (21.1º C) for more than 3 h, cumulatively.

Critical aspects of processes. Critical aspects of battered fish and fishery product processes may include:

- Temperature of the hydrated batter;
- Length of time the hydrated batter has been held at temperatures above 50º F (10º C);
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

COOKED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Pathogen survival through a cook step can cause consumer illness. Cooking is a relatively severe heat treatment, usually performed before the product is placed in the finished product container. Cooking procedures are often established to develop the desirable sensory attributes characteristic of cooked fish and fishery products, not specifically to

eliminate pathogens. An important consequence of thorough cooking is the destruction, or reduction to an acceptable level, of vegetative cells of pathogens that may have been introduced in the process by the raw materials or by processing that occurs before the cook step. Cooking processes are not usually designed to eliminate spores of pathogens.

Undercooking may allow the survival of pathogens leading to several unintentional but potentially hazardous conditions: 1) direct contamination of a ready-to-eat product with pathogens, 2) elimination of other less heat resistant microorganisms that, if present, may suppress pathogen growth or cause spoilage prior to significant pathogen growth, and 3) thermal conditioning of pathogens and increasing their heat resistance to any subsequent cooking or reheating step. It is also possible for a sub-lethal heating step to trigger bacterial spores to germinate, producing vegetative cells that are more hazardous than spores, but also far more vulnerable to subsequent reheating.

Control measures. Generally, after cooking, fishery products are referred to as cooked, ready-to-eat. Examples of cooked, ready-to-eat products are: crabmeat, lobster meat, crayfish meat, cooked shrimp, surimi-based analog products, seafood salads, and hot-smoked fish. Controlling pathogen survival through the cook step is accomplished by:

- Scientifically establishing a cooking process that will eliminate pathogens or reduce their numbers to acceptable levels; and
- Designing and operating the cooking equipment so that every unit of product receives at least the established minimum process.

A thorough hazard analysis is important when evaluating a thermal process. In some cases, a cooking or heating step will not present a potential health hazard even if it is sub-lethal to pathogens. Examples include a blanching step to inactivate enzymes and a pan-fry operation to set the breading on products to be fully cooked by the consumer.

FDA guidelines. FDA's recommendations for cooking fish and fishery products to destroy organisms of public health concern in food service, retail food stores, and food vending operations include:

- Raw fish and foods containing raw fish are cooked to heat all parts of the food to 145º F (63º C) or above for 15 s.
- Comminuted fish and foods containing comminuted fish are cooked to heat all parts of the food to 155º F (68º C) for 15 s.
- Stuffed fish or stuffing containing fish are cooked to heat all parts of the food to 165º F (74º C) for 15 s.

FDA guidelines for cooling cooked fish and fishery products:

- Cooked products should generally be cooled from 140º F (60º C) to 70º F (21.1º C) or below within 2 h and to 40º F (4º C) or below within another 4 h.

DRIED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Pathogen growth in the finished product as a result of inadequate drying of fishery products can cause consumer illness. Examples of dried fish products include

salmon jerky, octopus chips, dried shrimp, and stockfish. The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below.

Control measures. Dried foods are usually considered shelf stable and are, therefore, often stored and distributed at ambient temperatures. The characteristic of dried foods that makes them shelf stable is their low water activity ($a_w$). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogens. A water activity of 0.85 or below will prevent the growth of pathogens such as *C. botulinum*, and toxin production from *S. aureus*. *S. aureus* grows at a lower water activity than other pathogens (growth above $a_w$ of 0.83, toxin production above $a_w$ of 0.85), and should, therefore, be considered the target pathogen for drying.

Pathogen growth is not a concern in dried products that are stored, distributed, displayed, and sold frozen, and are so labeled. These products need not meet the control measures outlined in this chapter since in this case drying is not critical to product safety. Similarly, drying may not be critical to the safety of dried products that are stored refrigerated, since refrigeration may be sufficient to prevent pathogen growth.

FDA guidelines.

- Finished product has a water activity of 0.85 or less.
- Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved using salt, drying, pickling, or fermentation must be eviscerated prior to processing. Without evisceration, toxin formation is possible during the process. Small fish, less than 5 inches (12.7 cm) in length, that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10%, a water activity of below 0.85, or a pH of 4.6 or less are exempt from the evisceration requirement.

Process establishment. Except where finished product water activity analysis is the monitoring procedure, the adequacy of the drying/dehydration unit operation should be established by a scientific study. It should be designed to ensure the production of a shelf stable product with a water activity of <0.85. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment is required to establish such a drying process. Education or experience or both can provide such knowledge. Establishment of drying processes requires access to adequate facilities and the application of recognized methods. The drying equipment must be designed, operated, and maintained to deliver the established drying process to every unit of product. In some instances, drying studies will be required to establish the minimum process. In other instances, existing literature or federal, state or local regulations establish minimum processes or adequacy of equipment. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum drying process should be taken into consideration in the process establishment. A record of the process established should be maintained by the processor.

Critical aspects of processes. Critical aspects of drying processes may include:

- Drying time;
- Input/output air temperature, humidity, and velocity;

- Dry and wet bulb temperatures at dryer inlet and outlet;
- Flesh thickness;
- Accuracy of thermometers, recorder thermometer charts, high temperature alarms, maximum indicating thermometers, and/or digital data loggers; and
- Accuracy of other monitoring and timing instruments.

SMOKED FISH AND FISHERY PRODUCTS

Potential food safety hazard. *C. botulinum* toxin formation can result in consumer illness and death. *C. botulinum* produces a potent toxin when it grows which can cause death by preventing breathing. It is one of the most poisonous naturally-occurring substances known. The toxin can be destroyed by heat (e.g., boiling for 10 min). There are 2 major groups of *C. botulinum*, the proteolytic group (i.e., those that break down proteins) and the nonproteolytic group (i.e., those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The nonproteolytic group includes *C. botulinum* type E and some of types B and F. *C. botulinum* is able to produce spores. In this state the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the nonproteolytic group. The vegetative cells of all types are easily killed by heat. Temperature abuse occurs when product is exposed to temperatures favorable for *C. botulinum* growth for sufficient time to result in toxin formation.

Packaging conditions that exclude oxygen (e.g., vacuum packaging) favor the growth of *C. botulinum*, because oxygen is toxic to the pathogen. Vacuum packaging inhibits the growth of many spoilage bacteria, which increases the shelf life of the product. The safety concern with these products is the increased potential for the formation of *C. botulinum* toxin, before spoilage makes the product unacceptable to consumers. Both smoked and raw products in vacuum packaging and other reduced oxygen packaging require strict refrigeration (or frozen storage conditions) throughout distribution.

*C. botulinum* forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth of *C. botulinum* type E and nonproteolytic types B and F is 38º F (3º C). For type A and proteolytic types B and F, the minimum temperature for growth is 50º F (10º C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50º F (7-10º C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50º F (10º C).

Sources of C. botulinum. *C. botulinum* can enter the process on raw materials. The spores of *C. botulinum* are very common in nature. They have been found in the gills and viscera of finfish, crabs, and shellfish. *C. botulinum* type E is the most common form found in freshwater and marine environments. Types A and B are generally found on land, but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

Control measures. There are at least 3 steps to control *C. botulinum* in smoked and smoke-flavored fishery products:

- Controlling the amount of salt or preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as heat damage and competitive bacteria, sufficient to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F;
- Managing the amount of time that food is exposed to temperatures that are favorable for *C. botulinum* growth and toxin formation during processing and storage; and
- Controlling the growth of *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage.

Achieving the proper concentration of salt and/or nitrite in the flesh of salted, smoked, and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and nonproteolytic types B and F during storage and distribution. In salted fish, the salt concentration alone is responsible for this inhibition. In smoked and smoke-flavored fish, salt works along with smoke and any nitrites that are added to prevent toxin formation by *C. botulinum* type E and nonproteolytic B and F. (Note: nitrites may only be used in salmon, sable, shad, chubs, and tuna - 21 CFR 172.175 and 21 CFR 172.177.) In hot-smoked products, heat damage to the spores of *C. botulinum* type E and nonproteolytic types B and F also helps prevent toxin formation. In these products control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

In cold-smoked fish, it is important that the product does not receive so much heat that the number of spoilage organisms is significantly reduced. This is true because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and nonproteolytic types B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process is, therefore, critical to the safety of the finished product.

The interplay of these inhibitory effects (salt, temperature, smoke, and nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing *C. botulinum* type E (and nonproteolytic types B and F) toxin production is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying is also critical in order to achieve the finished product water phase salt level (the concentration of salt in the water portion of the fish flesh) needed to inhibit the growth and toxin formation of *C. botulinum*. Processors should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish of approximately uniform size. This minimizes the complexity of controlling the operation.

Salt levels alone in some salted products may be adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. However, even the combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent the growth of type A and proteolytic types B and F. Strict refrigeration control must be maintained

to prevent the growth of *C. botulinum* type A and proteolytic types B and F in these products (FDA, 1998).

FDA guidelines.
Smoker temperature (cold smoking):

- For cold-smoked fish and fishery products, the smoker temperature must not exceed 90º F (32º C) (FDA, 1998).

Internal fish temperature (hot smoking):

- For hot-smoked fish and fishery products, the internal temperature of the fish must be maintained at or above 145º F (63º C) throughout the fish for at least 30 min.

Water phase salt:

- For air packaged smoked fish or smoked-flavored fish, not less than 2.5% water phase salt in the loin muscle; and
- For vacuum or modified atmosphere packaged smoked fish or smoke-flavored fish, not less than 3.5% water phase salt in the loin muscle, or, where permitted, the combination of 3.0% water phase salt in the loin muscle and 100-200 ppm nitrite (21 CFR 172.175; 21 CFR 172.177).

Temperature control during processing:

- The product must not be exposed to temperatures above 50º F (10º C) for more than 12 h nor to temperatures above 70º F (21º C) for more than 4 h, excluding time above 140º F (60º C).

Temperature control during in-process and finished product storage:

- The product must not be exposed to temperatures above 50º F (10º C), which may be assured by:
- A maximum cooler temperature of 50º F (10º C); and/or
- The presence of sufficient cooling media (e.g., adequate ice to completely surround the product).

Temperature control at receipt of smoked and smoke-flavored fishery products for storage or further processing:

- The product must not be exposed during transportation to temperatures above 50º F (10º C), which may be assured by:
- A maximum refrigerated container temperature of 50º F (10º C) throughout transit; or
- The presence of sufficient cooling media (e.g., adequate ice to completely surround the product) upon receipt.

## VACUUM AND MODIFIED ATMOSPHERE PACKAGED FISH AND FISHERY PRODUCTS

Potential food safety hazard. Packaging conditions that exclude oxygen (e.g., vacuum packaging and other reduced oxygen packaging) favor the growth of *C. botulinum*, because oxygen is toxic to the pathogen. Vacuum packaging inhibits the growth of many spoilage bacteria, which increases the shelf life of the product. The safety concern with these products is the increased

potential for the formation of *C. botulinum* toxin, before spoilage makes the product unacceptable to consumers.

*C. botulinum* forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth of *C. botulinum* type E and nonproteolytic types B and F is 38ºF (3ºC). For type A and proteolytic types B and F, the minimum temperature for growth is 50ºF (10ºC). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. Processors should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained (especially for the nonproteolytic group). Surveys of retail display cases indicate that temperatures of 45-50º F (7-10º C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50º F (10º C).

Control measures. Both smoked and raw products in vacuum packaging and other reduced oxygen packaging require strict refrigeration (or frozen storage conditions) throughout distribution.

FDA guidelines.
Vacuum packaged raw and cooked fish and fishery products:

- A maximum temperature of 40º F (4º C) for finished product coolers and for trucks or other carriers throughout transportation; or
- Sufficient ice or other cooling media to fully cover containers at all times during storage and distribution.

Vacuum packaged smoked fish and fishery products:

- A maximum temperature of 50º F (10º C) for finished product coolers and for trucks or other carriers throughout transportation; or
- Sufficient ice or other cooling media to fully cover containers at all times during storage and distribution.

H.4.2 Checklist. Guidelines for auditing seafood production facilities are contained in the following checklist.

# APPENDIX H

| SEAFOOD CHECKLIST<br>Cured, Salted and Smoked Fish Establishments<br>Good Manufacturing Practices CFR,<br>Title 21, Parts 123 and 172 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENTS |
| B2 | Processing rooms are separated/segregated to eliminate contamination. (Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP), 2.1 (a)). |
| E2 | Equipment and utensils used in the handling of raw or frozen fish portions are not used in the handling, transport, or packaging of product after it has entered the smoking chamber or used in the handling of finished product. (FGMP, 2.2 (b)). |
| E2 | Sanitary zones are established around areas in which processed fish is handled/stored. (FGMP, 2.2 (c)). |
| E1 | Containers used to convey, brine, or store fish are not nested (stacked) while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents. (FGMP, 3.1 (b)). |
| C6 | Each smoking chamber is equipped with a temperature monitoring device so installed as to indicate accurately at all times the internal temperature of the fish within the smoking chamber. (FGMP, 3.1 (g)). |
| E2 | Equipment and utensils are marked in some way to ensure that equipment and utensils used to handle raw fish are not used to handle product that has entered the smoking chamber, or used in the handling of finished product. (FGMP, 3.1 (I)). |
| E1 | Imported fish or fishery products are obtained from approved sources. (Section 56.76, para (d) (4)) (21 CFR 123.12). |
| E1 | Fresh and frozen fish received are inspected and adequately washed before processing. (FGMP, Sec. 4.1 (a)). |
| E3 | Fresh fish, except those immediately processed, are iced or otherwise refrigerated to an internal temperature of 38° F (3° C) or below upon receipt and are maintained at that temperature until fish are to be processed. (FGMP, 4.1 (c)). |
| E3 | All fish received in a frozen state are thawed promptly and processed, or stored at a temperature which will maintain it in a frozen state. (FGMP, 4.1 (d)). |
| E2 | After thawing, fish are washed thoroughly with a vigorous potable water spray or a continuous water flow system. When thawing and brining occur concurrently, the fish are washed in this same fashion following the thawing and brining. (FGMP, 4.1 (f)). |
| E2 | All fish are free of viscera prior to processing (see reference document for exceptions). (FGMP, 4.1 (g)). |
| E2 | The evisceration of fish is conducted in a segregated or separate processing room. The evisceration is performed with minimal disturbance of the intestinal tract contents, and the fish, including the body cavity, is washed thoroughly with a vigorous spray or a continuous water flow system following evisceration. (FGMP, 4.1 (h)). |

SEAFOOD CHECKLIST - Continued.

| | |
|---|---|
| E4, H6 | All processed fish are produced pursuant to the process as established by a competent processing authority. (FGMP, 4.2 (b)). |
| E3 | All processed fish are distributed and sold in a manner that ensures that the internal temperature is maintained at 38° F (3° C) or below (see reference for exceptions). (FGMP, 4.2 (d)). |
| E2 | The vacuum packaging or modified atmosphere packaging of processed fish is conducted only within the facilities of the manufacturer. (FGMP, 4.2 (e)). |
| E4 | Processed fish to be vacuum packaged or modified atmosphere packaged are chemically analyzed for water phase, salt, and for nitrate and other additives when used, with sufficient frequency to ensure conformance with finished product specification requirements. (FGMP, 4.2 (f)). |
| A10 | The finished product is handled only with clean, sanitized hands, gloves or utensils. Manual manipulation of the product is kept to a minimum. (FGMP, 4.4 (a)). |
| E3 | Shipping containers, retail packages and shipping records relating to processed fish are appropriately labeled in accordance with the perishable nature of the product. (FGMP, 4.4 (c)). |
| E3 | Each container of processed fish is legibly marked or labeled with an identifying code and required identification. (FGMP, 4.4 (d)). |
| E2, H6 | Brining operations are performed IAW the appropriate time and temperature parameters. (FGMP, 5.1 (a)). |
| E2 | For dry salting, the fish are returned to a refrigerated area of 38° F (3° C) or lower immediately after the application of the salt. (FGMP, 5.1 (b)). |
| E2 | Different species of fish are not mixed in the same brine tank. (FGMP, 5.1 (c)). |
| E2, E4, H6 | Brines are not reused without an adequate process available to return the brine to an acceptable microbiological level. (FGMP, 5.1 (d)). |
| E2 | Fish are rinsed with fresh potable water after brining, except for fish which have been injected with brine. (FGMP, 5.1 (e)). |
| E2 | Drying of a product to be cold smoked is carried out in a refrigerated area of 38° F (3° C) or below. (FGMP, 5.1 (f)). |
| E3, H6 | The use of sodium nitrite is permitted with those species of fish allowed by regulation. (FGMP, 5.1 (g)). (21 CFR 172.175 and 172.177). |
| E3 | Fish are of relatively uniform size and weight and arranged without overcrowding or touching each other within the smokehouse oven. (FGMP, 5.2 (a)). |
| E2 | Liquid smoke, generated smoke, or a combination of liquid smoke and generated smoke are applied to all surfaces of the product at the appropriate times. (FGMP, 5.2 (b)). |
| C7 | Hot processed smoked fish is produced by a controlled process that utilizes a temperature monitoring system to assure that all products reach the required temperature. (FGMP, 5.3 (a)). |
| E2, H6 | For hot processed smoked fish to be air packaged, a controlled process is used to heat the fish. (FGMP, 5.3 (b)). |
| E2, H6 | For hot processed smoked fish to be vacuum or modified atmosphere packaged, a controlled process is used to heat the fish. (FGMP, 5.3 (c)). |

SEAFOOD CHECKLIST - Continued.

| | |
|---|---|
| C7, H6 | Cold processed smoked fish are produced by a controlled process that utilizes a temperature monitoring system assuring all products do not exceed process temperatures in accordance with authorized methods. (FGMP, 5.4 (a)). |
| E2, E4, H6 | For cold processed smoked fish to be air packaged, fish that have brine contain not less than 2.5 percent water phase salt in the loin muscle of the finished product. (FGMP, 5.4 (b)). |
| E2, E4, H6 | For cold processed smoked fish to be vacuum or modified atmosphere packaged, fish that have been brined contain not less than 3.5 percent water phase salt in the loin muscle of the finished product, or a combination of 3.0 percent water phase salt in the loin muscle of the finished product and not less than 100 nor more than 200 parts per million of sodium nitrite. (FGMP, 5.4 (c)). |
| E3 | The finished products are properly cooled to 70º F (21° C) within 2 hours and further cooled to 38º F (3° C) within an additional 4 hours. Finished products are then maintained at 38º F (3° C). (FGMP, 5.5). |
| H8 | Records are kept of every transaction involving the sale and distribution of processed fish. (FGMP, 4.3 (a)). |
| H6 | Fish processing records are legibly written in English and identify the processing procedures, the product processed, process time, temperature, and the results of the chemical examination, together with the identifying lot code, the number of containers per coding interval, the size of the containers coded, and the year, day, and period when each lot was packed. (FGMP, 4.3 (b)). |
| H8 | Records are maintained for the chemical examination of the finished product for the purpose of validating the water phased salt and sodium nitrite requirements. (FGMP, 4.3 (c)). |
| H8 | All records relative to the scheduled process used to produce processed fish or smoked fish are readily available to government inspection personnel. (FGMP, 4.3 (d)). |
| H8 | Records of refrigerated and/or frozen products, the general adequacy of equipment, process used, or results of scientific studies and evaluations, are retained for the amount of time specified in 21 CFR 123.9. |
| E1 | Seafood is derived from shellstock received from harvesters certified by a shellfish control authority CFR 123.28 |
| E1, H6 | Identification tags, containing all required information are affixed to each container. CFR 123.28 |
| E3 | Chilled or iced shucked shellstock is maintained at 45°F during storage and transport. CFR 123.11 |
| E1 | Shucked shellfish from different lots are not commingled. CFR 123.11 |
| E1 | Potable ice used to store shellstock. CFR 123.11 |

NOTE: Reference to the controlling sections of the FGMP and of 21 CFR 123 and 172 are identified in parentheses.

# APPENDIX J - Pasteurized, Refrigerated Juices

## J.1 SCOPE

J.1.1 Scope. This appendix contains guidelines for pasteurized, refrigerated juice processing facilities. The information contained herein is intended for guidance.

## J.2 APPLICABLE DOCUMENTS

J.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

J.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

21 CFR Part 110, CGMPs

21 CFR Part 120, HACCP

Federal Register Volume 66, Number 13

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

## J.3 DEFINITIONS

J.3.1 Definitions. Definitions are contained in the basic handbook.

## J.4 GUIDELINES

J.4.1 General. All juice produced for DoD is pasteurized (heat treated) by a system that is validated to achieve a 5-log reduction in microbiological load. Time/temperature controls cited in this appendix are for reference only and are not mandatory.

Dairy juice producers. Pasteurizing equipment is used for both milk and juice. It should meet all FDA PMO requirements including equipment testing. Major concern is usually the implementation and documentation of HACCP.

Juice-only producers

- The juice-only industry is largely self-policing as far as food safety is concerned. FDA inspections are infrequent. FDA does not perform pasteurizer testing.

- When present, USDA in-plant inspector performs sporadic sanitary inspections. In-plant USDA inspector's main job is quality grading to meet USDA grading requirements and applicable state marketing requirement ("Florida Orange Juice" trademark).

- Many juices are blends of products imported from foreign countries. FDA makes U.S. processors responsible for verifying that the foreign juices meet the part 120 HACCP requirements.

- IAW 21 CFR part 120, producers may obtain a copy of water test results from the community sources. However, an on-site water potability testing is required by Appendix A, Table II. Water and ice from on-site wells require separate testing.

- Heat-pasteurization of juices does not eliminate chemical and physical contamination hazards. For example, "pasteurized" apple juice can still contain excessive levels of the mycotoxin, patulin. FDA lists a number of instances and recalls for juices with excessive detinning, lead, and cleaning solution contamination. The agency intends the HACCP system to address these shortcomings.

- Each producer is allowed to evaluate its own process.

Common juice processing equipment.

Decanter
Clarifier
Cross flavor fill tanks
Extraction Machines
Tubular heat exchanger
Plate heat exchanger
Coil sterilizer
Steam (hot water) lines/injection
Jacket tubular heater

Juice reference information.

- Most juice productions involve re-pasteurization before filling at a temperature high enough to destroy most microorganisms present. This involves heating to a temperature of 150-170°F, filling, closing, and processing with or without agitation. Consequently, juice is cooled to room temperature and filled under aseptic conditions into pre-sterilized containers.

- Pasteurization. Destruction of microorganisms by heating juice (before packaging) at temperatures ranging from 150-190°F. In sugar and similar non-toxic substances, a higher temperature or a longer exposure time is required to affect sterilization of a fruit juice.

Chemical preservatives such as benzoates increase the death rate of microorganisms. The death rate of microorganisms and required pasteurization temperature is dependent upon the microorganism of concern (based on juice type/fruit) and the composition of the juice (e.g., pH, concentration of soluble solids, and presence of added or natural inhibitors).

- HTST pasteurization means rapidly heating the juice to temperatures just below the boiling point of water. The usual temperatures range from 180-190°F for periods of 25-30 seconds. Under usual conditions, juice is not exposed to high temperatures for over 3 minutes, including heating, holding and filling. Basic operations heat the juice very rapidly by passing it in a thin film between plates or through small diameter tubes that are heated by steam or hot water. The water used for steam/heating operations is subject to microbiological examination. The high flow rates serve to create the turbulence required to prevent scorching of the product and ensure each particle of juice achieves the desired temperature. The hot juice is filled into containers, sealed and immediately cooled.

- Carrot juice is a non-acid juice and therefore more difficult to pasteurize/sterilize.

- Yeasts, with few exceptions, may be destroyed at temperatures of 145°F (or above) for 1-2 minutes. Non-sporeforming, acid tolerant microorganisms are destroyed at 150F. Spore forming, acid tolerant organisms require temperatures ranging from 190–200°F for several minutes to affect destruction.

- Thermophilic organisms require temperatures of 248°F for 10 – 35 minutes for complete destruction. Mold is normally destroyed at a temperature of 175°F for 5 minutes.

Commercial sterilization. The destruction by heat of microorganisms that will develop under storage conditions. This does not completely destroy all microorganisms.

- High – Short Sterilization**.** Rapid heating of liquid foods to temperatures above 212°F for periods of a few seconds and then cooling to a filling temperature below 212°F, thereby filling hot and allowing sterilization of the inner surface of the container simultaneously. Example: Rapid and continuous heating of tomato juice to 250-280°F in a heat exchanger, hold at 250°F for 0.7 minutes, cool to 190-200°F, and fill hot, seal and hold for 3 minutes at 190°F (or 1 minute at 200°F).

- Tubular Heat Exchangers**.** Based on velocity and agitation, material and thickness of the tube, circulation of steam and removal of condensates, specific heat of the juice and steam, temperature differences from initial, final, and the average temperatures. Check heating per area volume, this plus velocity and agitation has greatest effect on rate of heat transfer (flow rate of heating medium).

- Flatten or Coiled Tubes. May increase the heat transfer rate and allow for faster contact times.

- Vertical Tube Banks . If constructed with short sections also reduce heat transfer rate time considerably.

- "Mallory" Small Tube Heat Exchanger**.** This system forces liquid at high velocity through coils of small stainless steel tubes (usually less than ½ inch in diameter) enclosed in a heating chamber. Rate of flow is normally 20-30 gallons per minute. This is best adapted for holding times of 10 seconds. A good system for higher temperature requirements ( 250-280°F). This is an old system not often found in CONUS.

- Hot Fill. Hot filled non-processed acid products may be "sterilized" by hot filling upright cans, then holding and rolling after closure. Automatic rolling devices have been dubbed "air sterilizers". This is not truly sterilization or pasteurization and is only a hot fill, not to be confused with retorting operations.

Juices.

Apple Juice**.** In apple juice, ascorbic acid is used to control browning, added during or immediately after crushing but before pressing to delay oxidation long enough to permit oxygen removal by de-aeration and enzyme deactivation by pasteurization. It is also used as an antioxidant additive in other bottled juices, but not normally used in canned juices.

Fresh Berry Juices (Black, Boysen, Goose, Logan, Rasp, Strawberry). These juices are normally exposed to a pre-cook operation at temperatures ranging from 140-180°F through a hot press; or alternatively cold pressed through filters, then flash pasteurized at approximately 207°F for 15 seconds and filled at approximately 180°F.

Canned and Bottled Berry Juices (Black, Young, Logan, Boysen, Raspberry). Flash pasteurize at 190°F for 1 minute, fill at the same temperature into pre-heated bottles or cans. The cans are sealed and cooled immediately by water troughs. Blueberry juice is normally processed at 180°F, lower than the other juices listed above.

Cherry Juice. This juice is processed through a heat wash at 150°F and hot pressed. Chill the pressed juice to 50°F and allow to settle overnight. Siphon off the clear juice, add a filter aide if necessary or desired and filter juice. Juice may be cold pressed by soaking the washed fruit in chilled water overnight. Press and quickly heat the juice to 190-200°F, cool to 120°F, add pectic enzyme and hold for 3 hours. Heat the juice to 170-180°F, cool and filter. Pasteurize this juice at 140-145°F for 30 minutes or flash pasteurize at 207°F for 15 seconds.

Cranberry Juice Cocktail. Flash pasteurize at 180°F, hot fill. Fill cans to ¼ inch of the top, seal and invert cans before cooling.

Black Currant Juice. Steam heat to 176°F, dilute, filter and flash to 170F. Fill this juice hot.

Grape Juice. Wash, crush, and heat to 140°F and press. Heat the juice to higher temperatures for longer periods based on desired color extraction. Flash heat in tubular or plate heat exchanger at 175-185°F. Cool juice to 32°F and hold for 1-6 months for settling.

This is done to allow potassium bitrate, tannins and other agents to settle. Siphon off juice after settling, flash pasteurize and hot fill.

Chilled Orange Juice and Frozen Concentrate: Heat to 180°F to inactivate pectinesterase and reduce microbiological load. Heating time may range from 30 seconds to one minute. Chill rapidly to 30°F and fill. Hold at 30°F for 2 weeks for settling. Concentrate is heated at 180°F in evaporator for 30 seconds to one minute then hold at –10°F.

Pineapple Juice: Blending temperature is used at approximately 140°F and then juice goes directly to packaging. Fill at 140°F and spiral cook in cans to 190/195°F.

Prune Juice: Extract juice at 185°F. Evaporate liquor and set desired Brix. Filter the juice and disintegrate at boiling temperatures of 60-80°F. Siphon juice, set Brix and clarify. Heat to 180°F and fill containers. Pasteurization may be achieved by heating at 190°F for 35 minutes. Processes for prune juice may vary widely.

J.4.2 Checklist. Guidelines for auditing pasteurized, refrigerated juice processing facilities are contained in the following checklist.

# APPENDIX J

| PASTEURIZED, REFRIGERATED JUICES CHECKLIST<br><br>21 CFR part 110, 120 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| H7 | HACCP plan is validated and signed every 12 months by trained individuals. |
| E1 | Imported juice originates from processors in a country with an active MOU with the FDA, a validated and documented HACCP plan, and each delivery is accompanied by Certificates of Conformance (COC) from government officials. |
| E2 | Process controls exist to achieve a 5-log reduction in microbiological load and records of routine examination are available for review. |
| H8, H10 | Pasteurization equipment is validated for achieving 5-log reduction. |
| H1 | Juice processors with no HACCP plan, based on validated hazard analysis, will reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food 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; or the intended use or intended consumers of the finished product be re-validated as required. |
| E4 | Each production batch tested for E.coli presence/absence and yeast & mold. |
| H6 | Records of equipment validation available. |
| H8 | Procedures, steps, practices documented. |
| H3 | Customer complaint process are in place to determine whether complaints relate to the performance of the HACCP plan or reveal unidentified CCPs. |

# APPENDIX K - Bottled Water/Soft Drink

## K.1 SCOPE

K.1.1 Scope. This appendix contains guidelines for bottled water/soft drink processing facilities. The information contained herein is intended for guidance.

## K.2 APPLICABLE DOCUMENTS

K.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

K.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

21 CFR, Parts 129 and 165

40 CFR, Part 141 National Primary Drinking Water Regulations

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

## K.3 DEFINITIONS

K.3.1 Definitions. Definitions are contained in the basic handbook.

## K.4 GUIDELINES

K.4.1 General. Bottled water is water that is intended for human consumption and is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable anti-microbial agents. Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). Although products labeled as “carbonated water,” “filtered water,” “seltzer water,” “soda water,” “sparkling water”, and “tonic water” do not comply with the description of bottled water under 21 CFR 165.110, they are audited under the requirements of Appendix K, MIL-STD-3006A.

When auditing a bottled water/soft drink facility, key points to verify are:

- Water is from an approved source (e.g., artesian well, natural spring, community water source, etc.).
- Type of treatment utilized to process water prior to the bottling operation. This may include processes such as: distillation, ion-exchange, filtration (sand filters or other filtration devices) ultraviolet treatment, ozone treatment, reverse osmosis, carbonation, mineral addition.
- Filling, capping, or sealing operations.
- Cleaning and sanitizing processes.
- Process controls, to include microbiologic, physical, and chemical evaluation methods.
- Frequencies and results of laboratory tests.

K.4.2 Checklist. Guidelines for auditing bottled water/soft drink processing facilities are contained in the following checklist.

# APPENDIX K

| BOTTLED WATER/SOFT DRINK CHECKLIST<br><br>CFR Title 21, Parts 129 and 165 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| B2 | The bottling room is separated from the other plant operations or storage areas by tight walls, ceilings, self-closing doors, and size of conveyor opening. Bottle washing and sanitizing are in an enclosed room and are positioned to minimize post-sanitization contamination. (129.20 (a), 129.20 (d)). |
| B5 | Adequate ventilation is provided to minimize odors, noxious fumes, or vapors; and condensation in processing, bottling, container washing and sanitizing rooms. Ventilation equipment is clean. (129.20 (c)). |
| E2 | Product in process in other than sealed piping systems under pressure is protected from back-siphonage and other sources of contamination. (129.20 (b)). |
| B2 | Processing, washing, and storage rooms are not directly connected to room(s) used for domestic household purposes. (129.20(e)). |
| E1, H6 | Product water used for bottling is from an approved source that has been inspected and the water sampled, and found to be of a safe and sanitary quality according to applicable laws and regulations of the government agencies having jurisdiction. (129.35 (a)). |
| E4, H6 | Representative bacteriological samples tested weekly for each type of finished product water produced during a day's production. (129.80 (g)) (165.110). |
| E4, H6 | Representative chemical, physical, and radiological samples analyzed annually for each type of finished product water. (129.80 (g)) (165.110). |
| E4, H6 | Source water analyzed annually for chemical and physical parameters and once every four years for radiological parameters. Source waters, other than municipal sources, are analyzed weekly for microbiological quality. (129.35 (a)). |
| E4 | Source and finished product test results meet requirements of 21 CFR Part 165.110(b) for maximum contaminants level. Product water from a public water system or water that has been treated with a chlorine-based disinfectant or ozone are tested for the residual disinfectants and disinfect ion by-products (DBP's) listed in §165.110(b)(4)(iii)(H). (129.35(a)(4), 129.80(g)) |
| B8 | Product water contact surfaces (utensils, pipes, equipment, etc.) are clean and are adequately sanitized daily. (129.37 (a)). |
| B8 | Product water contact surfaces (utensils, pipes, equipment, etc.) are maintained free of scale, oxidation, and other residue. The presence of any unsanitary condition is corrected immediately. (129.37 (a)). |
| E3 | Containers, caps, or seals are purchased and stored in sanitary closures (original containers) in a clean, dry place. They are examined before use and are handled, dispensed and used in a sanitary manner. They are washed, rinsed, and sanitized as needed. (129.37 (c)). Filling, capping, closing, sealing, and packaging are done in a sanitary manner.(129.37 (d)). |

BOTTLED WATER/SOFT DRINK CHECKLIST - Continued.

| | |
|---|---|
| E2 | Treatment equipment processes and substances are used which preclude contamination or adulteration of the product. (129.80 (a)). |
| E3 | Storage tanks closed to exclude all foreign matter. Filtered vents provided. Filters are readily cleanable or have replaceable elements. (129.40 (a)) |
| E2, H6, H8 | Treatment methods accomplish their intended purpose. Records are maintained to show type and date of treatments and physical inspections of equipment. Conditions found, performance and effectiveness are noted. (129.80 (a)). |
| E4, H6 | Product water samples are taken after processing, prior to bottling, to assure uniformity and effectiveness of the treatment process. Methods of analysis are approved by the government agency having jurisdiction. (129.80 (a)). |
| E2 | All unsanitary or defective containers are reprocessed or rendered unusable and discarded. Multi-service primary containers are cleaned, sanitized, and inspected immediately prior to being filled, capped, and sealed. (129.80 (b)). |
| C5, H6 | Mechanical washers are inspected. Records of physical maintenance, inspections, conditions found, and performance of the mechanical washer, are maintained by the plant. (129.80 (b)). |
| E3 | Multi-service shipping cases are maintained to assure that they will not contaminate primary containers or the product. (129.80 (b)). |
| H11 | Records of the intensity of the sanitizing agent and the contact time duration are maintained by the plant. (129.80 (c) and (d)). |
| E2 | Sanitizing operations meet requirements contained in 129.80 (d) |
| E2 | Each unit package is identified by a production code. The code identifies the particular batch or segment of a continuous run, and the production date. (129.80 (e)). |
| H6, H8 | Records are maintained of product type, volume produced, date produced, lot code used, and distribution to wholesale and retail outlets. (129.80 (e)). |
| E1 | Containers and closures are nontoxic and comply with FDA standards. (129.80 (f)). |
| E2 | Filling, capping, and sealing are monitored. Filled containers are visually or electronically inspected. (129.80 (f)). |
| E4, H6 | Quarterly swab and/or rinse bacterial counts on not less than 4 containers and closures (prior to filling) is performed. (129.80 (f)). |
| E4, H6 | Records are maintained of sampling date, type of product, production code, and results of each analysis. (129.80 (h)). |
| H8 | All records are retained for two years. Current certificates or notifications of approval authority for source and supply of product and operations water are on file. (129.80 (h)). |

NOTE: References to the controlling 21 CFR 129 and 21 CFR 165 sections are identified in parentheses.

# APPENDIX L - Off-Post Caterers And Civilian Restaurants

## L.1 SCOPE

L.1.1 Scope. This appendix contains guidelines for auditing off-post caterers and civilian restaurant facilities. The information contained herein is intended for guidance.

## L.2 APPLICABLE DOCUMENTS

L.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

L.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

FDA Food Code, 1999

(Application for copies should be addressed to U.S. Department of Health and Human Services, Food and Drug Administration, Food Service Sanitation Branch, Washington, DC 20204. Document No. PB99-115925 available printed, on CD ROM, or on diskette from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; 1-800-553-6847); or download from web site: http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

## L.3 DEFINITIONS.

L.3.1 Definitions. Definitions are contained in the basic handbook.

## L.4 GUIDELINES

L.4.1 General. This standard is written for CONUS and OCONUS. The reference for the checklist is the "Food Code" U.S. Public Health Service, Food and Drug Administration. The definitions found in Part 1-2 of the "Food Code" apply. Disregard the automatic critical defects identified in the "Food Code." Consider the entire public health risk when evaluating defects in catering and restaurant facilities. Do not use the forms provided in the "Food Code." For auditing the normal Good Manufacturing Practices, use Appendix A.

You must perform temperature evaluations during these audits. Use two calibrated thermometers when performing an inspection at a catering or restaurant facility. Your appearance is important. Be sure to take a clean over-garment to wear over your street cloths.

Always wear a head cover when walking through the facility. Before beginning the audit, wash your hands and continue to wash your hands each time after you touch equipment or foods during the audit. The primary areas to check are the dining area (if applicable), salad bar, cooking area, preparation area, coolers/freezers, dry storage, and waste area. These facilities may vary from a single room to multi-complex food preparation areas with many rooms.

The primary purpose of the audit is to ensure the customer is receiving a safe, unadulterated, and honestly presented product. Place special consideration on Potentially Hazardous Foods (PHF). PHFs include any food of animal origin that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified in the "Food Code."

L.4.2 Checklist. Guidelines for auditing off-post caterers and civilian restaurant facilities are contained in the following checklist.

# APPENDIX L

| OFF-POST CATERERS AND CIVILIAN RESTAURANTS CHECKLIST<br><br>FDA Food Code | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1 | Food prepared in a private home is not used or offered for human consumption in a food establishment. (3-201.11). |
| E1, E2 | If game animals are used they have been commercially raised for food, are processed under a regulatory inspection program, and in accordance with applicable meat and poultry laws. (3-201.17). |
| E2 | A food employee does not use a utensil more than once to taste food that is to be sold or served. (3-301.12). |
| A10 | Food is protected from cross contamination by separation, packaging, cleaning, or other means. (3-302.11). |
| E3 | Food items are stored in their original containers or are identified with their common name on working containers. (3-302.12). |
| E1 | Pasteurized eggs or egg products are substituted for raw shell eggs in applicable foods, with exceptions as noted in the reference. (3-302.13). |
| E1 | Prepared foods do not contain unapproved additives. (3-302.14). |
| E2 | Raw fruits and vegetables are thoroughly washed/disinfected prior to processing, with exceptions as noted in the reference. (3-302.15). |
| E1 | Ice used as an external cooler is not used as food. (3-303.11). |
| E2 | During pauses in food preparation or dispensing, food preparation and dispensing utensils are stored in a manner to inhibit/reduce contamination. (3-304.12). |
| A6 | If used, single-use gloves are used for only one task. Slash-resistant gloves and cloth gloves are used in an appropriate manner. (3-304.15). |
| E3 | During preparation, unpackaged food is protected from environmental sources of contamination. (3-305.14). |
| E2 | Raw animal foods comply with cooking requirements listed in the Food Code. (3-401.11/12). |
| E2 | Fruits and vegetables that are cooked for hot holding are cooked to a temperature of 140° F (60° C). (3-401.13). |
| E2 | Raw, raw-marinated, partially cooked, or marinated-partially cooked fish other than molluscan shellfish are frozen throughout to a temperature of either -4° F (-20° C) or below for 168 hours (7 days) in a freezer, or -31° F (-35° C) or below for 15 hours in a blast freezer, with exceptions as noted in the reference. Records are created and retained as specified, with exceptions as noted in the reference. (3-402.11/12). |
| E2 | Potentially hazardous food (PHF) that is cooked, cooled, and reheated for hot holding is reheated so that all parts of the food reach a temperature of at least 165° F (74° C) for 15 seconds, with exceptions as noted in the reference. (3-403.11). |

OFF-POST CATERERS AND CIVILIAN RESTAURANTS CHECKLIST - Continued.

| | |
|---|---|
| E2 | Reheating for hot holding is done to ensure the food is not between 41° F (5° C) and 165° F (74° C) for more than 2 hours. (3-404.11) |
| E2 | Frozen PHF is slacked under refrigeration below 41° F (5° C) with exceptions as noted in the reference. (3-501.12). |
| E2 | Frozen PHF is thawed under proper refrigeration; proper running water technique; proper cooking techniques; and for proper time periods. (3-305.13). |
| E2 | Cooked PHF is cooled utilizing proper time temperature requirements, and proper cooling methods, with exceptions as noted in the reference. (3-501.14/15). |
| E2 | PHF is maintained in accordance with proper hot and cold holding procedures. (3-501.16). |
| E3 | Ready-to-Eat PHF prepared and held refrigerated for more than 24 hours is clearly marked at the time of preparation with appropriate date marking, with exceptions as noted in the reference. (3-501.17). |
| E2 | A food establishment obtains a variance from the regulatory authority when specialized processing methods are employed. (3-502.11). |
| C7 | Food temperature measuring devices with glass stems or sensors are encased in shatterproof coatings. (4-201.12) . |
| C6, C7 | Temperature measuring devices are properly designed, located and easily readable. (4-203.12). |
| C7 | Warewashing machines are equipped with proper temperature and pressure indicating devices. (4-203.13 & 4-204.115). |

NOTE: Cited reference document for the above is the Food Code.

# APPENDIX M - Slaughter And Fabrication Of Fresh Meat Products In OCONUS Areas

## M.1 SCOPE

M.1.1 Scope. This appendix contains guidelines for auditing of slaughter and fresh meat products fabrication facilities in overseas areas. The information contained herein is intended for guidance.

## M.2 APPLICABLE DOCUMENTS

M.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

M.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

9 CFR, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

## M.3 DEFINITIONS.

M.3.1 Definitions. Definitions are contained in the basic handbook.

## M.4 GUIDELINES

M.4.1 General. This guideline has been written for military procurement overseas. Therefore, it is extremely important that an auditor know about the herd health in the region the livestock are coming from. It is not unusual in today's meat production business to ship livestock from one major region to another. Livestock destined for food production must be tested and/or certified as Tuberculoses and Brucellosis free. Animals must also be free of the following diseases: BSE, Foot-and-Mouth, equine piroplasmosis, bovine piroplasmosis, splenetic fever, swine erysipelas, bluetongue, anthrax, chlamydiosis, Newcastles disease or poultry diseases caused by *Salmonella* enteritidis, African swine fever, hog cholera, Teschen disease, European fowl pest, contagious equine metritis, vesicular exanthema, screwworms, Pleuropneumonia, Rinderpest, Scrapie and Infectious Anemia. No animals infested with ticks or exposed to severe tick infestation should be rendered for food or human consumption. Auditors must be knowledgeable of the signs and symptoms of the medical conditions listed above in order to ensure wholesome meat products are consumed. Regional Public Health Officials should be able to provide a herd health status report

for their region; therefore, good communications should be maintained between overseas health authorities and the Army Veterinary Service.

NOTE: Tuberculosis status may be determined by intradermal tuberculin test or other applicable diagnostic procedure. Facilities found to contain tuberculosis-infected animals must be disinfected immediately. Disinfection may be performed with sodium orthophenylphenate at one pound per 12 gallons of water; applied at 60° F (16° C) or higher. If the ambient temperature is less than 60° F (16° C), the solution must be heated to 120° F (49° C).

Ante-mortem inspections are performed on each animal prior to slaughter for the purpose of eliminating those unfit for food. Competent ante-mortem inspection gives the only assurance that unfit animals will not enter the slaughter facility (abattoir). It should be assumed that some livestock providers intentionally send sick animals to the abattoir. Many conditions develop during transit, in the holding pens, or at the stunning area that may render an animal less than fit for entry into the abattoir. These conditions are covered in 9 CFR Part 313, "Humane Slaughter of Livestock." Auditors should be familiar with these requirements. Auditors must also keep in mind that the standards written in 9 CFR Part 313 were intended for practices in the United States and that many countries overseas may not have similar standards. If an auditor identifies a normal practice taking place in an overseas plant that does not comply with the CFR requirements; it must be brought to the attention of the plant management. If there is clear resistance to change based on cultural differences, the auditor should not get involved in an argument. The auditor should carefully review the host country's methods and make a decision for deviation based on the wholesomeness of the end item.

Many diseases and otherwise unfit conditions affecting animals are not detectable on ante-mortem examination. Therefore, a post-mortem examination of the carcass and viscera of each animal passed for slaughter is performed to eliminate it or any part of it if diseased or otherwise unfit. Some overseas areas may have alternative methods for performing post-mortem examinations. In these cases, a Veterinary Corp Officer must determine if the alternative methods are adequate (equivalent). In any case, the auditor must be familiar with the basic required post-mortem examinations to include: examination of the lymph glands, viscera (lungs, heart, liver and paunch), and carcass.

The slaughter line is a dangerous area to work around. Auditors should have their own clean knee-high rubber boots, adequate outer clothing, and a good-fitting hard hat. Never enter the slaughter area directly from the holding pens without first washing your boots. Inspect yourself before entering the slaughtering area to ensure you are clean. Take special care around mechanical hide pullers. It is not unusual for chains to come loose during the pulling motion and create a dangerous situation. Check disinfecting units during slow-downs or breaks so that you do not interfere with the workers. Stay clear of electrical stimulation devices; you are working in a wet area and the possibility of an electrical problem does exist. Under no conditions should the auditor enter the stunning box.

Most modern facilities will have an overhead rail system but many developing countries may still use the cradle method. The cradle method is slow and often results in excessive contamination from the hide if care is not taken while de-hiding the carcass. If the cradle method

is used, ensure that the gut buggy does not cross-contaminate the carcass. Also, pay special attention to the water being used to wash the floor. In an effort to make the facility look cleaner, workers will often continuously wash the floor with high pressure hoses while the carcass is still in the cradle. The washing often results in an increased amount of splash contamination. Also, pay special attention during the hoisting of the carcass. Ensure that the anterior of the carcass does not drag on the floor during the hoisting process.

The overhead rail is the most common system used today for beef slaughter. The normal steps are as follows: (this information may be used for describing the methodology) Stunning, Shackling, Sticking, Bleeding, Head Skinning, Foot Skinning, Leg Breaking, Ripping, Rimming Over, Rumping, Hide Pulling, Breast Sawing, Eviscerating, Tail Sawing, Scribing/Splitting, Trimming, Inspection, Washing, and Chilling. Recommended maximum times from the stunning-box to the bleeding is twenty minutes, and from stunning to the cooler is sixty minutes. The deepest part of the carcass should reach 40° F (4° C) within 48 hours. The above time recommendations include saved parts (hearts, tongues, livers, etc.). As a general rule, all equipment, tools, and surfaces contacted by animal tissue should be rinsed and disinfected prior to coming in contact with the next animal. Examples include brisket splitting, tools, knives, gut buggies, tables, hooks, rodding tools, splitting saws, and chains.

The principle objectives for slaughtering animals are that they are humanely slaughtered and processed in such a manner as to minimize potential contamination.

Meat fabrication only includes meats that have been cut (even to individual cuts) and chilled. Comminuted meats, hearts, livers and kidneys will be included in the category of fabrication, even though some textbooks may not include them. Meat fabrication does not include meats that have additives (e.g., smoke, cure) added to them or have been made into a sausage. This standard does not include meat processing. All fabrication rooms must be equipped with an adequate number of disinfection units (sometimes referred to as sanitizers). The temperature of the product should never exceed 40° F (4° C). Meat that is not boned must be fabricated in an adequately chilled room and must immediately be chilled. Prior to each day's production, a pre-operational sanitary inspection must be performed (by either an auditor or acceptable company representative).

This portion was written to acquaint you with livestock (meat) slaughtering and fabrication. It was not intended for use with poultry. You will find numerous variations of slaughtering and dressing procedures throughout the world. One major change over the last ten years has been the final rinse. Many areas use an organic acid while others may use steam. Anytime you identify a variation or deviation from the normal procedures, contact your Veterinary Officer for advice. The final determination should be based on the wholesomeness of the finished product and not solely on the fact that it is not mentioned or allowed in the Code of Federal Regulations. The Code of Federal Regulations should be viewed as the basic requirement, but exceptions may be made after professional consideration by proper medical authorities.

M.4.2 Checklist. Guidelines for auditing of slaughter and fresh meat product fabrication facilities in overseas areas are contained in the following checklist.

# APPENDIX M

| CHECKLIST<br>SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OCONUS AREAS<br>SUBPART A - ANTE-MORTEM (UNLOADING RAMPS TO STUNNING AREA)<br>CFR Title 9, Parts 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| A1, E1 | Livestock originate from an approved region. Food production animals are free of communicable disease. Animals from a quarantine region are processed in that region. (9 CFR 71/72/75/53/54). |
| E1 | Handling of livestock from the unloading ramps to the stunning area is done in a humane manner. (9 CFR 313). |
| B2 | Pens, chutes and alleys are paved, drained and supplied with adequate hose connections for cleanup purposes. (9 CFR 307.2). |
| E2 | Livestock entering the facility receive an adequate ante-mortem inspection on the day of and before slaughter and are properly segregated when required. (9 CFR 309.1/2). |
| B2 | Satisfactory pens, equipment, lighting, and assistants are available for conducting ante-mortem inspection and for separating, marking and holding apart passed livestock from livestock which have been identified as suspect or condemned. (9 CFR 307.2). |
| B2 | When holding pens of an establishment are located in a public stockyard, such pens are regarded as part of the premises of that establishment. (9 CFR 309.1). |
| B2 | Holding and shackling pens are located outside of, or effectively separated from, the slaughtering department. (9 CFR 307). |
| E1 | Animals have access to water in all holding pens, and if held longer than 24 hours, feed is provided. (9 CFR 313.2). |
| E1 | Seriously crippled animals, "downers," are identified as suspects and properly disposed of. (9 CFR 309.2). |
| E1 | Livestock found to be dead or in a dying condition on the premises of an establishment are identified as condemned and disposed of. (9 CFR 309.3). |
| E1 | Any swine having a temperature of 106° F (41° C) or higher, and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105° F (40° C) or higher are identified as condemned. (9 CFR 309.3) |
| B2 | Floors of livestock pens, ramps, and driveways are constructed and maintained as to provide good footing for livestock. (9 CFR 313.1). |
| E1 | Humane methods of slaughter are applied within an appropriate stunning area. (9 CFR 313). |
| E1 | Animals are adequately stunned prior to being shackled, hoisted, thrown, cast, or cut (bleeding). (9 CFR 313.2). |
| E2 | A careful post-mortem examination and inspection is made of carcasses and parts of all livestock slaughtered. (9 CFR 310.1). |
| E2 | The head, tail, tongue, thymus gland, and all viscera of each slaughtered animal are handled in such a manner as to identify them with the rest of the carcass and as being derived from the particular animal involved, until the post-mortem examination of the carcass and parts thereof has been completed. (9 CFR 310.2). |

SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OCONUS AREAS
CHECKLIST – Continued.

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| E2 | Identification devices (e.g., ear tags) are removed from the animal's hide or ear by an establishment's employee and are placed in a clear plastic bag and affixed to the corresponding carcass. Supervising veterinarian may allow alternate methods of tracing carcasses back to live animal records. (9 CFR 310.2). |
| E2 | Each carcass, including all detached organs and other parts, in which any lesion or condition is found that might render the meat or any part unfit for food purposes, or otherwise adulterated, and which, for that reason, would require a subsequent inspection, is retained. All parts are retained until an approved, authorized veterinary final inspection has been completed. Retained carcasses are not washed or trimmed unless authorized by a veterinary official. (9 CFR 310.3). |
| E2 | Each carcass or part which is found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated is conspicuously marked. (9 CFR 310.5). |
| E2 | Spermatic cords and pizzles are removed from all carcasses. Preputial diverticuli are removed from hog carcasses. (9 CFR 310.7). |
| E2 | When a carcass is to be dressed with the skin left on, the skin is thoroughly washed and cleaned before any incision is made for the purpose of removing any part thereof or evisceration. (9 CFR 310.10). |
| E2 | All hair, scurf, dirt, hoofs and claws are removed from hog carcasses, and the carcasses are thoroughly washed and cleaned before any incision is made for inspection or evisceration. (9 CFR 310.11). |
| E2 | The sternum of each carcass is split, and abdominal and thoracic viscera removed at the time of slaughter in order to allow proper inspection. (9 CFR 310.12). |
| E2 | Carcasses found before evisceration to be affected with anthrax are not eviscerated but are retained, condemned, and immediately tanked and the complete working area is cleaned immediately and disinfected. (9 CFR 310.9). |
| E2 | The kidney capsule is opened to expose the kidneys for the purpose of inspection. (9 CFR 310.19). |
| E2 | Partially skinned carcasses are not stimulated. (9 CFR 308.16). |
| B7 | For hide-off stimulation, the carcass contact surfaces of equipment are disinfected between carcasses. (9 CFR 308.16). |
| E2 | Carcass contamination of edible tissue by stomach contents, feces and/or urine is unacceptable. To prevent this contamination, any of the following are used prior to electrical stimulation: (9 CFR 308.16).<br>a. Leave the sphincter muscles intact.<br>b. Cut the rectum (scalp the bung) and the urethra free from surrounding tissue and securely tie each off.<br>c. Partially open the mid-line and/or slay the brisket to reduce pressure on the visceral organs.<br>d. Any other pressure-relieving or discharge-restricting alternative acceptable to the chief veterinary inspector.<br>e. Rod (separate the esophagus from the surrounding tissue) and tie it off. |

SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OCONUS AREAS
CHECKLIST – Continued.

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| E2 | When only a portion of a carcass is to be condemned on account of slight bruises, either the bruised portion is removed immediately and disposed of, or the carcass is promptly placed in a retaining room and kept until chilled, and the bruised portion is then removed and disposed of.<br>(9 CFR 310.14). |
| C1 | Tables, benches, and other equipment on which post-mortem inspection is to be performed are of such design, material, and construction as to enable inspectors to conduct their inspection in a ready, efficient and clean manner. (9 CFR 307.2). |
| E2 | Cases, Carcasses, organs, and other parts are handled in a sanitary manner to prevent contamination (adulteration) with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it is promptly removed in a manner satisfactory to the inspector. (9 CFR 310.18). Specific preventive measures include:<br>a. Knives are immediately disinfected after contamination (e.g., after sticking, head removal, following the initial cut through the hide/skin, after removal of an abscess, bruise or contamination).<br>b. No water is placed onto a carcass until the entire hide has been removed and the carcass inspection has been performed.<br>c. Manual hide removal begins at the hind leg and proceeds downward, allowing the hide to be laid back away from the flesh.<br>d. The final wash is begun at the highest point of the carcass and works downward.<br>e. No portion of the forequarters comes in contact with eviscerating/inspection tables.<br>f. Overhead rails are free of flaking rust or grease.<br>g. Carcasses do not come in contact with walls, pillars, dividers or other features that will result in cross-contamination.<br>h. Adequate separation is provided between offal rooms and product areas.<br>i. Pressurized water used to wash down equipment and facilities is only used when carcasses are not in the location (to avoid splash contamination).<br>j. Ventilation is provided at the location of a mechanical hide puller.<br>k. Condensation does not drip onto carcasses.<br>l. Carcasses are washed immediately after the final inspection and prior to being placed into a cooler.<br>m. The floor area (dry landing) within the stunning box is maintained in a reasonably dry condition. |
| B8 | Nonpotable water is permitted only in those parts of the establishment where no edible product is handled or prepared, and then only for limited purposes, such as on ammonia condensers not connected with potable water supply.<br>(9 CFR 308.3). |
| B8 | Nonpotable water is not permitted for washing floors, areas, or equipment involved in trucking materials to and from edible product departments, nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. (9 CFR 308.3). |

SLAUGHTER AND FABRICATION OF FRESH MEAT PRODUCTS IN OCONUS AREAS
CHECKLIST – Continued.

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| B9 | In all cases, nonpotable water lines are clearly identified. (9 CFR 308.3). |
| B8 | If hot water is used for cleaning, it is not at a temperature of less than 180° F (82° C). (9 CFR 308.3). |
| B2 | Rails are located so as to prevent product from coming in contact with posts, walls, and other fixed parts of the building, barrels, boxes, etc. (9 CFR 308.3). |
| A4 | Butchers and others who dress or handle diseased carcasses or parts cleanse their hands with liquid soap and hot water, and rinse them in clear water, before handling or dressing other parts. (9 CFR 308.8). |
| B7 | Implements used in dressing diseased carcasses are thoroughly cleansed with hot water having a minimum temperature of 180° F (82° C) or approved disinfectant. (9 CFR 308.8). |
| B3 | The rooms and compartments in which any product is prepared or handled are free from dust and from odors from dressing and toilet rooms, catch basins, hide cellars, casing rooms, inedible tank and fertilizer rooms, and livestock pens. (9 CFR 308.3). |
| A10 | Such practices as spitting on whetstones; spitting on the floor; placing skewers, tags, or knives in the mouth; inflating lungs or casings with air from the mouth are prohibited. (9 CFR 308.8). |
| C7, B5 | Disinfecting units are maintained above 180° F (82° C) and are adequately located. Chemical disinfectants may be used during production when approved by the MACOM Veterinarian. (9 CFR 308.3). |
| C1 | Cutting boards and tables are solid, clean and sanitary. (9 CFR 308.7). |
| A1 | Employees showing evidence of a communicable disease or affected with boils, sores, or infected wounds do not handle or prepare any product. (9 CFR 308.14). |
| A2 | Aprons, frocks, and other outer clothing worn by persons who handle product are clean and are changed each day. (9 CFR 308.8). |
| C1 | Scabbards are constructed of a smooth impervious material. (9 CFR 308.6). |
| E2 | Fabrication rooms are maintained at 50° F (10° C) |
| E2 | Fresh meat does not exceed 45° F (7° C) during storage or fabrication. If hot boning is in place, the production takes place in a room that is maintained at 50° F (10° C) and the finished product is immediately chilled. (21 CFR 110.80). |
| E4 | Livestock must be tested for Escherichia coli Biotype 1 (E. coli) at a minimum of one sample during each week of operation. (9 CFR part 310.25(a)(2)) |

NOTE: Cited reference documents for the above are 9 CFR 53, 54, 71, 72, 75, 110, 307, 308, 309, 310, and 313.

# APPENDIX N - Dry Dairy Products

## N.1 SCOPE

N.1.1 Scope. This appendix contains guidelines for auditing dry dairy products facilities. The information contained herein is intended for guidance.

## N.2 APPLICABLE DOCUMENTS

N.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

N.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

U.S. Public Health Service Publication 229 Grade “A” Pasteurized Milk Ordinance 1997,

Supplement 1 to the PMO, Condensed and Dry Milk Ordinance, 1995 Revision

(Application for copies should be addressed to U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch, 200 C Street SW, Washington, DC 20204.)

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

National Institute of Standards and Technology, Handbook 44

(Application for copies should be addressed to National Institute of Standards and Technology, 110 Bureau Drive, Gaithersburg, MD 20899-0001, http://www.nist.gov/.)

CODE OF FEDERAL REGULATIONS (CFR)

21 CFR, Parts 131 and 173.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

N.2.3 Non-government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/ASHRAE 52.1-1992 - Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter

(Application for copies should be addressed to American National Standards Institute, 11 West 42nd Street, New York, NY 10036, http://www.ansi.org/.)

N.3 DEFINITIONS.

N.3.1 Definitions. Definitions are contained in the basic handbook.

N.4 GUIDELINES

N.4.1 General. Pasteurization Systems. The facility and pasteurization requirements detailed in the fluid dairy Appendix of this handbook apply to condensed and dry milk production. These standards must be met prior to the plant being evaluated for condensed and dry milk production. In most cases, the process will be a continuous one.

Dry Milk Processing. Some primary factors to be evaluated when auditing the drying portion of milk processing are identified below. These factors should not be considered all inclusive.

- Evaluate the source and nature of the water supply and any subsequent treatment.
- Ensure pasteurization of raw milk/milk products, raw whey/whey products is accomplished before products enter the evaporation, condensing, reverse osmosis, or ultra-filtration process.
- Be alert for careless handling of powdered ingredients (vitamins, flavors, etc.), which may contribute to product contamination.
- Obtain sources of Vitamins A & D and other optional ingredients.
- Condensed milk should be held at 45° F (7° C) or less.
- All whey for condensing is maintained at a temperature of 45° F (7° C) or less; or 145° F (63° C) or greater until processed.
- Condensed whey is cooled during the crystallization process to 45° F (7° C) or less within 18 hours of condensing.
- All pasteurized milk and milk products, pasteurized whey and condensed milk products, except those to be immediately dried, are cooled immediately in approved equipment to a temperature of 45° F (7° C) or less.
- If surge tanks or balance tanks are used between the evaporator and the drier, such tanks hold the product at a temperature of 150° F (66° C) or more, or are completely cleaned at a minimum of once every 4 hours of operation or less. Exception: acid type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.

- Evaluate equipment construction characteristics for assurance that static accumulations are controlled, particularly in fluid milk drying and conveying equipment, sifters, rollers, drum, and sanitizers.
- Determine if equipment is constructed and maintained to protect the product from dust and environmental contamination.
- Condensed milk from one facility and transported to a drying plant will be re-pasteurized at the drying plant.
- Equipment used for the manufacture of dried dairy products should not be used in drying other products unless effectively cleaned and sanitized prior to the drying of the dairy products.
- Pre-heaters and hotwells should be fitted with tight covers when in use.
- Spray dryers should be a continuous discharge type, easily cleanable and should be cleaned and inspected at least daily.
- Rollers and collectors should be located in a room separated from other operations to
- prevent airborne contamination.
- Conveying equipment, such as augur ends, bucket elevators, etc., should be cleaned at least daily to prevent accumulation of static material.
- Sifter screens should be easily removable and maintained in a clean condition.
- Evaluate air filtration system and determine the air-flow throughout the plant. Consider the following:
  - Quality and source of intake air.
  - Is the air recycled, filtered? How? Are the filters reusable or disposable?
  - Air for cooling powder may pass over refrigerated coils and pick up dust or powder contaminants.
  - Proximity of air exhaust to air intake.
  - Air temperature at critical points, e.g., entering and leaving drying chamber.
  - Potential for plumbing back-flow. For example, can water used to produce vacuum be back siphoned into the plant's water supply?
- Plant air supply systems should provide clean, adequately filtered air for all post-pasteurization processing rooms in which the finished product is exposed to the air, e.g., instantizing and packaging rooms.
- Clean, adequately filtered air should be supplied to product dryers, product coolers, dry product handling equipment and instantizing equipment. The air supply system should be maintained in a clean, sanitary, and efficient operating condition including changing or cleaning of filters as often as necessary. Filters should be tightly fitted or sealed in frames to avoid air by-pass.
- Plant forced air intakes should be properly located to prevent the entrance of airborne contaminants.
- Air exhausts from buildings or equipment should be so constructed as to prevent back-flow of air or material when not operating.
- If the air for cooling powder is mechanically cooled, refrigeration units should be maintained in a clean condition.
- Be alert for condensate formation throughout the plant and for optimum moisture and temperature conditions conducive to *Salmonella* growth in static material.

- Evaluate the handling and treatment of the condenser cooling water. Small amounts may be drawn into the systems during operation. If cooling water is circulated over a cooling tower, evaluate the potential for *Salmonella* and other bacterial contamination.
- Cooling water utilizing a cooling tower may not be used directly for cooling of product in a plate heat exchanger or other mechanical system where product may be contaminated.
- Condensing water for evaporator must be from a safe source unless the evaporator is constructed and operated to preclude contamination of such equipment or its contents by condensing water; or by water used to produce vacuum.
- Examine the inspection, sampling and cleanout ports on the evaporator for buildup of static material and avenues for airborne contaminants.
- Evaluate product flow through the plant and determine whether there is unnecessary product movement between areas which may increase the likelihood of cross-contamination.
- Observe procedure for incorporating Vitamin A & D and other optional ingredients into the product. Review the volume control records on the use of vitamins. Compare the usage with products produced. Review the records of vitamin testing if products produced are vitamin fortified.
- Observe and evaluate the packaging operation to determine:
  - The suitability of finished product containers.
  - Storage of unused containers.
  - Container cleaning, if applicable.
- Evaluate the safeguards and precautions in the filling and packaging areas to avoid product contamination, i.e., the method of final weight adjustment and the sanitary handling of packaging containers at this point.
- Topping off to obtain proper net weight should be conducted in a sanitary manner using clean utensils and equipment and using fresh dry milk which is protected from airborne contamination.
- The contents of damaged containers of dry milk should be reconstituted, re-pasteurized, and processed if intended for food use and if no visible extraneous material was introduced into the product.
- Determine quality control specifications for raw materials, e.g., bacterial load, antibiotics, pesticides, butterfat, sediment, etc.
- Evaluate sampling, test procedures and results of incoming raw milk, pasteurized milk, base powder, and other ingredients.
- Ascertain scope of *Salmonella* testing of water supply, and the air supply, at critical processing points, in the plant environment, and in finished products.
- Determine the qualifications of laboratory personnel, adequacy of laboratory equipment, and record keeping procedures.
- Determine if production lots are quarantined until completion of finished product analysis.
- Observe employee habits and dress, particularly use of special clothing while handling or contacting in-process materials and equipment surfaces that contact the product.
- Evaluate cleaning methods (CIP, vacuum, compressed air, etc.) for all raw ingredient, in-process, and dried milk contact equipment, e.g., pumps, valves, tanks, lines, belts, conveyors, air filtering bags, packaging machines, etc.

- Observe scheduled plant and equipment cleanup including plant start-up and shut down procedures. The evaluation should consider the following:
  - Separate cleaning equipment should be used exclusively for the drying system and should be stored properly.
  - Frequency of cleaning.
  - Equipment suitability, including smooth impervious construction, easily accessible for cleaning, etc.
  - Degree of employee supervision.
- Determine the identity, strength, and use of sanitizing agents. Proper use requires flushing these agents from the system.
- Verify that box dryer(s) are being sanitized as described in Supplement 1 of the PMO.
- Determine the disposition of powder and dust collected during plant cleanup.
- Milk powder recovered from bag collectors and other places in the instantizing process (other than "fines" which are recirculated) may be fed back into the system, but, unless rehydrated and pasteurized prior to recycling, this may be a source of bacterial build-up and recontamination.
- Sifter tailings should not be used for food purposes and should be disposed of in a manner that would preclude contamination of plant facilities or finished products.

N.4.2. Nonfat Dry Milk (NFDM) powder used as an ingredient for further processing. NFDM powder from any source is acceptable for use as an ingredient for frozen desserts and recombined dairy products if:

a. It is produced in a state of the United States, or
b. The source is listed in the Directory, or
c. It has met the NFDM export requirements of a country included in the list maintained by the MACOM veterinarian, with official certifying paperwork accompanying each lot, or
d. It has been imported into a state of the 50 United States, and
   (1) Each lot is accompanied by an official Government report from the country of origin stating that the lot has been tested and found free of *Salmonella*, or
   (2) A certified laboratory has tested each lot and found each lot free of *Salmonella*. When using this alternative, collect and submit samples of NFDM for testing as follows: Despite the lot size, aseptically select eight 100-gram samples. The testing laboratory will prepare two 400-gram composites from each set of eight samples received. The inspector should consider the presence of *Salmonella* in either sample of the lot represented as sufficient reason to reject that lot. Discontinue use of NFDM from that source unless subsequent lots are determined *Salmonella*-free before use.

N.4.3 Checklist. Guidelines for auditing dry dairy products facilities are contained in the following checklist.

# APPENDIX N

| DRY DAIRY PRODUCTS<br>CHECKLIST<br>USPHS Publication 229 and CFR Title 21, Part 173 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1 | Milk originates from herds accredited tuberculosis-free, and brucellosis-free, and is from countries/regions determined to be acceptable. (PMO, Sec. 8). |
| E1 | The sources of water (to include reclaimed water), vitamins, flavorings, etc. meet standards. (Sec. 7, Item 7p and Appendix G of Suppl 1). |
| B7 & H6 | A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days (Sec. 7, Item 12p). |
| E1 | Upon arrival, raw milk and/or raw products for pasteurization comply with bacteriological, chemical and temperature standards of Sec. 7, Table 1. |
| E4 | Raw milk and milk products are screened for drug and pesticide residue. (Sec. 6 and Table 1). |
| E2 | Raw milk and milk products are held at 45° F (7° C) until processed. (Sec. 7, Item 17p). |
| E2 | Condensed milk is held at 45º F (7° C) or less. (Suppl 1, Sec. 7, Item 17p) |
| E2 | Whey for condensing is maintained at 45º F (7° C) or less, or 145º F (63º C) or greater, until processed. (Suppl 1, Sec. 7, Item 17p and Table 1). |
| E2 | Condensed whey is cooled during the crystallization process to 45º F (7° C) or less within 18 hours of condensing. (Suppl 1, Sec. 7, Item 17p and Table 1). |
| E2 | If the surge tanks or balance tanks are used between the evaporator and the drier, such tanks hold the product at 150º F (66º C) or above, or are cleaned at least once every 4 hours of operation (see exception for acid type whey or pH factor). (Suppl 1, Sec. 7, Item 17p). |
| C3 | Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (Sec. 7, Item 10p). |
| C2 | All milk contact surfaces of multi-use containers and equipment are constructed of American Iron and Steel Institute (AISI) 300 series stainless steel or other non-corrosive material as described in the PMO. (Sec. 7, Item 11p). |
| C5 | Equipment is designed to protect against surface and overhead contamination. (Sec. 7, Item 11p). |
| B7 | Raw milk storage tanks are cleaned when emptied and should be emptied at least every 72 hours. (Sec. 7, Item 12p). |
| C7 | Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7-day temperature recording device. (Sec. 7, Item 12p). |
| C5 | Pasteurizing equipment complies with the sanitary design and construction standards of the PMO. (Sec. 7, Item 11p). |
| E2 | Pasteurization equipment and controls testing is performed in accordance with the PMO. (Appendix F). |

DRY DAIRY PRODUCTS CHECKLIST - Continued.

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| H8 | Pasteurization recording charts are maintained on file at the processing plant. (Sec. 7, Item 16p(E)). |
| C7 | Thermometers meet requirements. (Sec.7, Item 16p(A.e) Appendix E). |
| E2, H8 | Temperature and pH recording charts are complete and maintained. (Sec. 7, Item 16p(C), Appendix H of Suppl 1). |
| C4 | Equipment is constructed to ensure static accumulations are limited. (Sec. 7, Item 11p). |
| B2 | Rollers and collectors are located in a room separate from other operations, to prevent airborne contamination. (Sec. 7, Item 5p). |
| C1 | Conveying equipment is cleaned at least daily. (Sec. 7, Item 12p). |
| C1 | Sifter screens are easily removed and kept clean. (Sec. 7, Item 12p). |
| C5 | The plant air filtration system meets requirements. (Sec. 7, Item 4p, 15p, and Appendix C of Suppl 1). |
| E2 | Cooling water used in a cooling tower is not used where it will come in direct contact with products (cooling products). (Sec. 7, Item 7p). |
| E2 | Safeguards are in place to preclude the contamination of finished products during filling. (Sec. 7, Item 18p). |
| E2 | The topping off of containers to obtain the proper weight is done in a sanitary manner. (Sec. 7, Items 15p and 18p). |
| E1 | Ingredients from damaged containers are reprocessed prior to being repackaged. (Sec. 7, Item 15p). |
| C8 | Culinary steam is in accordance with PMO. (Sec. 7, Item 16p(B) and Suppl 1, Sec. 7, item 15p(A) and Appendix D). |
| B8 | Boiler water additives comply with 21 CFR 173.310. |
| C8 | Air under pressure is in accordance with 3-A Accepted Practices. (Appendix C). |
| E2 | There are no cross-connections or direct contamination of pasteurized milk or milk products. (Sec. 7, Item 15p, and potable and non-potable waters (Sec. 7, item 7p to Suppl 1). |
| B6, C5 | All openings, including valves, pipes, milk tanker trucks, etc. are capped or otherwise protected. (Sec. 7, Item 15p(A)). |
| E2, E5 | Re-circulated cooling water is protected from contamination. (Sec. 7, Item 7p). |
| E4 | Re-circulated cooling water is tested once per six-month period. (Appendix D and Appendix G). |
| C7 | Clean-in-place (CIP) systems are in compliance with PMO. CIP systems have a recording device installed in the return solution line or other appropriate area to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing solution (retained for 3 months). (Sec. 7, Item 12p). |
| H6, H7, H8, H9 | Record of CIP cleaning process is maintained for recirculated cleaning systems. (Sec. 7, Item 12p). |
| B3 | Plants where containers are manually cleaned have a two-compartment vat and a steam cabinet to sanitize containers, or a three-compartment vat if a chemical sanitizer is used. (Sec. 7, Item 12p). |

DRY DAIRY PRODUCTS CHECKLIST - Continued.

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| E4, H8 | Pasteurized milk and/or milk products and water comply with bacteriological, chemical and temperature standards of Sec. 7, Table 1 and Appendix K of Suppl 1 and vitamin volume control of Sec 6 of Suppl 1. These are recorded and records maintained. (Sec. 7). |
| E4, H8 | Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. This is recorded and records maintained. (Sec. 7, Item 12p). |
| B5 | Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (Sec. 7, Item 15p(A)). |
| B5 | Only approved rodenticides and insecticides are used. (Sec. 7, Item 15p(A)). |
| A10 | Employee habits and dress, particularly the use of special clothing while handling or in contact with products or product contact surfaces, is appropriate. (Sec. 7, Item 20p). |

NOTE: Cited reference documents for the above are USPHS Publication 229 with Supplement 1 and 21 CFR, Parts 131 & 173.

# APPENDIX O - Slaughter and Fabrication of Poultry Products in OCONUS Areas

## O.1 SCOPE

O.1.1 Scope. This appendix contains guidelines for auditing of slaughter and fresh poultry products fabrication facilities in overseas areas. The information contained herein is intended for guidance.

## O.2 APPLICABLE DOCUMENTS

O.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

O.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

9 CFR, Part 381.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, http://www.access.gpo.gov/nara/cfr/index.html/.)

## O.3 DEFINITIONS.

O.3.1 Definitions. Definitions are contained in the basic handbook.

## O.4 GUIDELINES

O.4.1 General. This guideline has been written for military procurement overseas. Therefore, it is extremely important that an auditor know about the prevalence of diseases affecting poultry in the region the flocks are kept in. In general, flocks are kept within a short drive of the plant where they will be slaughtered. At the slaughterhouse, they are normally kept in cages until slaughter. However, after slaughter they can be shipped across national boundaries for further processing. Flocks destined for food production must be free of tuberculosis, diseases of the leukosis complex, septicemia or toxemia, airsacculitis, inflammatory processes, tumors, and parasites.

Auditors must be knowledgeable of the signs and symptoms of the medical conditions listed above in order to ensure that wholesome meat products are consumed. Regional Public Health Officials should be able to provide an auditor with their region's status concerning the health of the flock; therefore, good communications should be maintained between overseas health

authorities and the Army Veterinary Service. If you are examining a flock, make sure you take all necessary precautions to ensure that you do not introduce any diseases to the flock.

Poultry production is often performed at high speeds. Many plants process thousands of birds each day. However, this does not preclude the need for ante-mortem and post-mortem inspection. Ante-mortem inspections are performed on each bird prior to slaughter for the purpose of eliminating those unfit for food. Competent ante-mortem inspection gives the only assurance that unfit animals will not enter the slaughter facility. Many conditions develop during transit, in the holding pens, or at the stunning area that may render an animal unfit for further processing. If an auditor identifies a normal practice taking place in an overseas plant that does not comply with the CFR requirements, it must be brought to the attention of the plant management. If there is clear resistance to change based on cultural differences, the auditor should not get involved in an argument. The auditor should carefully review the host country's methods and make a decision for deviation based on the wholesomeness of the end item.

Many diseases and otherwise unfit conditions affecting animals are not detectable on ante-mortem examination. Therefore, a post-mortem examination of the carcass and viscera of each bird is performed. Each bird slaughtered is examined to eliminate it or any part of it if diseased or otherwise unfit. Normally, the body cavity is opened and the organs are exposed but not removed prior to post-mortem inspection. If any part of the viscera is removed, its identity with the carcass must be maintained. Some overseas areas may have alternative methods for performing post-mortem examinations. In these cases, a Veterinary Officer must determine if the alternative methods are adequate (equivalent). In any case, the auditor must be familiar with the basic required post-mortem examinations, to include examination of the viscera and carcass.

The slaughter line is a dangerous working area. Auditors should have their own clean knee-high rubber boots, adequate outer clothing, and a good fitting hardhat. Never enter the slaughter area directly from the live bird holding area without first washing your boots. Inspect yourself before entering the slaughtering area to ensure that you are clean. Stay clear of electrical stimulation devices if you are working in a wet area and the possibility of an electrical problem exists.

Although there may be variations, the basic steps in poultry production are as follows:

1. STUNNING AND SLAUGHTERING: Birds are usually stunned electrically prior to slaughter.

2. BLEEDING: Birds are bled immediately after slaughter. Kosher/Halal birds are killed and bled simultaneously by severing the trachea.

3. SCALDING AND DE-FEATHERING: Scalding is necessary to loosen the feathers prior to de-feathering. Tanks of circulating hot water are most often used. The temperature of water is usually between 60°C (for frozen poultry) to 50°C (for fresh chilled poultry). Excessively high temperatures can damage the cuticle and result in a cooked appearance which would result in condemnation of the carcass IAW the CFR. Too long in the scald tank can result in peeling of the skin. Water in the scald tank must be circulated to preclude the accumulation of pathogens in the scald tank water, which would contaminate the birds passing through it. De-feathering is usually accomplished mechanically with a series of rubber flails. There is considerable spread of

aerial contamination at this stage, so it should be separated from cleaner areas. The flails themselves may transfer micro-organisms from one carcass to another and mechanical damage to the carcass may also occur. Scald tank temperatures that are too low, or poorly adjusted/maintained flails, may result in incomplete de-feathering.

4. HOCK CUTTING AND SHANK REMOVAL: May be accomplished manually or mechanically.

5. EVISCERATION: Evisceration may be accomplished manually or mechanically. Post-mortem examination is normally accomplished prior to evisceration. Cross-contamination readily occurs at this stage. In some cases, the carcass may be injected to enhance weight or other qualities. Any form of injection into poultry raises the possibility of introducing contamination into the deep muscle tissue, but there has been little evidence that this practice has caused foodborne disease outbreaks.

6. WASHING: Spray washing is normally carried out as soon as possible after evisceration, to prevent attachment of bacterial contaminants to the skin. Normally efficient washing results in a 1-log reduction of the microbial load. In the U.S., spray washing is a mandatory requirement to ensure the carcass is wholesome and ready to cook, prior to chilling.

7. CHILLING: Chilling is carried out promptly after washing; normally this is accomplished by chilled water and/or ice. The CFR has strict guidelines on how quickly water must be chilled, based on bird weight. Water and/or ice comes in direct contact with carcasses, which makes this medium a potential source of contamination. Salmonella and other microorganisms may buildup in improperly operated water chillers

8. PACKAGING: Packaging includes wrapping, trussing and, in the case of whole turkeys, the adding of giblets and neck. Giblets (hearts, livers, gizzards) usually carry a high microbial load and must be handled with as much care as the whole bird. If giblets are allowed to spoil they will accelerate the spoilage of the bird. Giblets are normally inserted into the body cavity of the bird during the first stage of packaging.

Once the bird is slaughtered and chilled, it may be further processed/fabricated by boning, and grinding, as would any other meat or potentially hazardous food product. The Current Good Manufacturing Practices apply.

O.4.2 Checklist. Guidelines for auditing of poultry product fabrication facilities in OCONUS areas are contained in the following checklist.

# APPENDIX O

| CHECKLIST<br>SLAUGHTER AND FABRICATION OF POULTRY PRODUCTS IN OVERSEAS AREAS | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1 | Birds originate from a healthy flock. Birds are free of communicable disease. Birds from a quarantine region are processed in that region. (9 CFR 381.36). |
| B1, B7 | Buildings must be in good repair and constructed and maintained in such a way as to preclude the entry of pests and vermin. (9 CFR 381.46). |
| B2 | Rooms used for processing edible poultry are separate from areas used for inedible products. Rooms will be of sufficient size and construction to permit the processing of poultry in a sanitary manner. (9 CFR 381.47) |
| E2 | Birds will receive ante mortem inspection and will be properly segregated when required. (9 CFR 381.36). |
| B2 | Batteries, coops or other facilities in which live poultry are presented for ante mortem inspection are arranged, constructed and lighted so that the inspector can carry out the inspection. (9 CFR 381.36). |
| E2 | Post-mortem inspection is made on a bird-by-bird basis. (9 CFR 381.76). |
| E2 | Body cavity is opened to permit post-mortem inspection. No viscera is removed prior to post-mortem inspection, unless identity with the rest of the carcass is maintained. (9 CFR 381.76). |
| E2 | The presence of the following conditions result in condemnation of the carcass: (9 CFR 381.80 thru 381.93)<br>tuberculosis<br>leukosis complex<br>airsacculitis<br>tumors<br>parasites<br>bruises affecting the whole carcass<br>overscald (flesh has a cooked appearance)<br>cadavers (died prior to slaughter)<br>decomposition |
| C6 | Receptacles for condemned carcasses must be watertight and readily cleanable. (9 CFR 381.53). |
| E2 | Blood from the killing operation is confined to a relatively small area. (9 CFR 381.65) |
| E2 | Birds have been thoroughly bled and have stopped bleeding prior to scalding. (9 CFR 381.65) |
| B10 | The overflow outlets in scalding equipment is of sufficient size to permit feathers and water to be carried off. (9 CFR 381.53) |
| E2 | Scalding tanks and chilling tanks are cleaned as often as is necessary, but not less frequently than once a day when in use. (9 CFR 381.65) |
| B9 | Only potable water or potable ice may be used in chill tanks (9 CFR 381.66) |
| E2,E5 | Poultry carcasses contaminated with visible fecal material are prevented from entering the chilling tank. (9 CFR 381.65) |

SLAUGHTER AND FABRICATION OF POULTRY PRODUCTS IN OVERSEAS AREAS
CHECKLIST – Continued

| | |
|---|---|
| E2 | The chilling medium in the warmest part of the system may not exceed 65°F. (9 CFR 381.66) |
| E2 | Poultry carcasses are chilled to not more than 40°F within the following times: (9 CFR 381.66)<br>• under 4 pounds – 4 hours,• 4 to 8 pounds – 6 hours, • over 8 pounds – 8 hours |
| E2 | Giblets are chilled to 40°F or lower within 2 hours after separation from the inedible viscera, unless they remain attached to the carcass. (9 CFR 381.66) |
| E2 | Continuous chillers use a fresh water intake of not less than ½ gallon per chicken and 1 gallon per turkey. (9 CFR 381.66) |
| E2 | In continuous chillers, whenever the elevators or conveyors removing poultry from the chilling unit are stopped, the agitation must also be stopped and the carcasses must be removed within 15 minutes, unless the chilling medium is maintained at 40°F or below. (9 CFR 381.66) |
| C2 | Ice shovels are smooth surfaced and made of impervious material. (9 CFR 381.53) |
| C6 | Immersion or spray freezing equipment is constructed of noncorrosive metal or other acceptable material. Compounds used in immersion or spray freezing are acceptable for contact with food. (9 CFR 381.66) |
| E2 | Chicken which is further processed after slaughter may have a temperature no higher than 55°F. (9 CFR 381.66) |
| E2 | Final product is practically free of: (9 CFR 381.1)<br>- protruding pin feathers<br>- vestigial feathers<br>- head<br>- feet<br>- crop<br>- oil glands<br>- trachea<br>- esophagus<br>- entrails<br>- mature reproductive organs<br>- lungs |
| B9 | Nonpotable water is permitted only in those parts of the establishment where no edible product is handled and then only for limited purposes such as vapor lines serving inedible product rendering tanks or in sewer lines for moving solids in the sewage. (9 CFR 381.50). |
| B9 | Nonpotable water is not permitted for washing floors or areas; nor is it permitted in boilers, scalders, chill vats or ice making machines. (9 CFR 381.50). |
| B9 | In all cases, nonpotable water lines are clearly identified. (9 CFR 381.50). |
| B6 | If hot water is used for cleaning, it is not at a temperature of less than 180° F. Chemical disinfectants may be used during production when approved by the MACOM Veterinarian. (9 CFR 381.10). |
| E4 | Birds must be tested for Escherichia coli Biotype 1 (E. coli) at a minimum of one sample during each week of operation. (9 CFR part 310.25(a)(2)) |

NOTE: Cited reference documents are 9 CFR 381 10, 36, 45, 46, 50, 51, 61, 65, 66, and 76-93.

# APPENDIX P - Fresh-Cut Produce

## P.1 SCOPE

P.1.1 Scope. This appendix contains guidelines for auditing fresh-cut produce facilities. The information contained herein is intended for guidance.

## P.2 APPLICABLE DOCUMENTS

P.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

P.2.2 Government documents. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations (CFR), Title 21, Part 110.

(Available on-line at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1)

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Guidance for Industry, Oct. 98, U. S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN).

(Application for copies should be addressed to Food Safety Initiative Staff, HFS-32, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street S.W., Washington, DC 20204, http://www.foodsafety.gov/~dms/prodguide.html/.)

P.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

Food Safety Guidelines for the Fresh-Cut Produce Industry, 2001, Fourth Edition, International Fresh-Cut Produce Association

Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce, 1993, A Report Prepared by the International Fresh-Cut Produce Association
(Available at International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314, or http://www.fresh-cuts.org/publications.)

Fresh Cut Produce Handling Guidelines, 1997, International Fresh-Cut Produce Association and Produce Marketing Association

(Application for copies of this document should be addressed to International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314 http://www.fresh-cuts.org/publications1329/publications.htm/, or Produce Marketing Association, P.O. Box 6036, Newark, DE 19714.)

Voluntary Food Safety Guidelines for Fresh Produce, Voluntary Guidelines for Minimizing Microbial Contamination in Fresh Produce, 1997, International Fresh-Cut Produce Association (IFPA) and Western Growers Association (WGA).

(Application for copies of this document should be addressed to International Fresh-cut Produce Association, 1600 Duke Street, Suite 440, Alexandria, VA 22314 http://www.fresh-cuts.org/publications1329/publications.htm, or Western Growers Association, 17620 Fitch Street, Irvine, CA 92614.)

Postharvest Chlorination - Basic Properties and Key Points for Effective Distribution, 1997

(Application for copies should be addressed to University of California, Davis, Dept. of Vegetable Crops, Div. Of Agriculture and Natural Resources, Attn: Trevor Suslow, Extension Specialist, One Shields Avenue, Davis, CA 95616 http://www.vric.ucdavis.edu/selectnewtopic.minproc.htm)

## P.3 DEFINITIONS

P.3.1 Definitions. Definitions are contained in the basic handbook.

## P.4 GUIDELINES

P.4.1 General. Minimal Processed Fruits and Vegetables include the following items:

- Peeled and sliced potatoes
- Shredded lettuce and cabbage
- Washed and trimmed spinach
- Chilled peach, mango, melon and other fruit slices
- Vegetable snacks (celery/carrot sticks, broccoli/cauliflower florets
- Packaged mixed salads
- Cleaned and diced onions
- Peeled citrus fruits

Receiving. Incoming produce can be the source of microbiological, physical and chemical hazards. Processors should have a supplier certification program that requires growers to demonstrate conformance to Good Agricultural Practices (GAPs). Periodic microbiological testing of raw produce, the requirement to provide a Letter of Food Guarantee, or the

requirement to pass an independent third-party audit are all examples of practices used to ensure the safety and quality of incoming ingredients.

Processing. Measures must be taken to prevent cross contamination and other hazards throughout the different points of production. Some of the most important critical control points in processing are

- Trim/Core Operation. Employee hygiene to prevent microbiological contamination and foreign object control to prevent staples, wood slivers, etc. This area should be separate from other areas of processing to prevent cross contamination between raw and finished products.
- Water treatment. Potable water must be used for all postharvest operations including grading, flume transports, cooling, washing, and final rinse and equipment sanitization. The quality of water may vary from one point in the process to another (e.g., cooling water versus final rinse water). All water must meet the microbial standards for drinking water consistent with EPA standards. Reused water in a series of processes must flow counter to the movement of produce. Practices that ensure water quality are:
  - Periodic water sampling and microbial testing
  - Changing water as necessary to maintain sanitary conditions and to remove organic matter that will affect antimicrobial agents
  - Cleaning and sanitizing water contact surfaces
  - Installation of backflow devices and legal air gaps
  - Maintenance of equipment designed to maintain water quality (e.g., chlorine injectors)
- Antimicrobial Chemicals. The effectiveness of any antimicrobial agent depends upon its chemical and physical state, treatment conditions (such as water temperature, pH, and contact time), resistance of pathogens, and the nature of the fruits or vegetable surface. All chemical substances that disinfect wash water and contact food must be used in accordance with FDA and EPA regulations. Chemicals should be prepared according to manufacturers' instructions and must not exceed allowable levels in wash water. Chemical levels should be routinely monitored and recorded. Other parameters that affect the effectiveness of the anti-microbial used, should also be monitored and recorded.
- Wash Methods. Wash method used (e.g., brush washing, dump tank, sprayer over continuous belt) reduces the overall potential for microbial food safety hazards. Maintaining the efficacy of wash treatments greatly reduces the microbial load. For some operations, a series of washes may be used, or certain products (e.g., cabbage) may be washed separately from others. Certain types of produce (e.g., apples, celery, tomatoes) may need to be air cooled prior to washing in order to avoid a pressure differential between the product and the wash water that can cause pathogens to be pulled into produce.
- Drying Methods. Free moisture must be completely removed after washing for many minimally processed products. This step in the process is associated mainly with pre-packaged salads or other salad items. Centrifugation is used most often. Food contact surfaces must be cleaned and sanitized.
- Sliced/Diced Melons. Due to the high incidence of *Salmonella* spp. contamination in cantaloupes and other melons, processors of these products must use proper cleaning and sanitizing of knives during cuts from the rind inward following an outer wash. Sanitizer dip stations should be accessible for cutting utensils and for employees' hands. Product internal temperatures should be maintained at 4.4º C (40º F).

Packaging. The packaging material for produce is usually a multi-layered high ethylene/vinyl acetate copolymer (EVA) and low-density polyethylene film (LDPE). These films are characterized by a high gas but low water vapor permeability. Whatever packaging material is selected, processors must demonstrate that the oxygen transmission rate of the material is commensurate with the respiratory needs of the fresh-cut produce. Vacuum packaging and gas flushing establishes a modified atmosphere quickly and increases shelf life and quality. The key parameters for any Modified Atmosphere Packaging (MAP) are to allow for high surface-to-volume ratios, and transparency over at least 50% of the surface area.

Labeling. Temperature control of minimal processed products is important for controlling the growth of *Clostridium botulinum.* All product packages must display a "KEEP REFRIGERATED" label. Packages for foodservice or retail should have a clear code dating system. A "USE BY" date is recommended. Product labeling should not interfere with transparency, in order to detect signs of spoilage.

Storage. Temperature, product rotation, GMP of the storage area, and pest control are critical factors to look at in the storage facilities of fresh-cut produce.

Distribution. Temperature and sanitation of delivery vehicles.

P.4.2 Checklist. Guidelines for auditing fresh-cut produce facilities are contained in the following checklist.

# APPENDIX P

| FRESH-CUT PRODUCE CHECKLIST<br><br>Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables<br><br>Food Safety Guidelines for<br>the Fresh-Cut Produce Industry<br><br>Postharvest Chlorination -<br>Basic Properties and Key Points for Effective Distribution<br><br>Fresh Cut Produce Handling Guidelines<br><br>IFPA/WGA Voluntary Food Safety Guidelines<br>for Fresh Produce<br><br>Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E2 | Trimming, coring, cutting and culling operations are performed in a sanitary manner. (21 CFR 110.35, 110.37, 110.40). |
| E2, E4, H6 | Wash water disinfectant level established and pH (if applicable) monitored<br>- Chlorine level parameter is established and monitored at 50-200 ppm total chlorine; pH 6.0-7.5, final rinse required. NOTE: Oxidation-Reduction Potential (ORP) monitoring recommended at values of 650 to 700 mV when used.<br>- Hydrogen peroxide level not to exceed 59 ppm in wash water; final rinse required.<br>- Peroxyacetic acid level not to exceed 80 ppm in wash water; pH range 1.0 – 8.0.<br>- Ozone concentrations recommended at 1 ppm for 6 min. contact time or 2 ppm for 3 min. contact time; pH range 6.0-8.0.<br>- Chlorine dioxide level not to exceed 3 ppm residual followed by a final rinse; pH range 6.0-10.0.<br>- Ultraviolet (UV) light effective at 240-260 nanometer wavelength range. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry). |
| E2, H6 | Product contact time is established and monitored (dump tank, submersion, sprayer, flume, hydrocooler method). (Food Safety Guidelines for Fresh-Cut Produce Industry; Postharvest Chlorination - Basic Properties and Key Points for Effective Distribution.) |
| E2, H6 | Water recirculation method is established and monitored (filtration, displacement, replacement). (Food Safety Guidelines for the Fresh-Cut Produce Industry; Postharvest Chlorination - Basic Properties and Key Points for Effective Disinfection). |

FRESH-CUT PRODUCE CHECKLIST - Continued.

| | |
|---|---|
| E2 | Only approved treatment process water additive(s) or water additive(s) such as surfactants to increase chlorine performance are used. (Food Safety Guidelines for the Fresh-Cut Produce Industry). |
| E2, H6 | Dewatering, centrifugation, or drying methods established (when applicable) to ensure removal of free surface moisture after washing. (Minimal Processed Fresh Fruits and Vegetables, UC Davis) |
| E5, H6 | Method(s) to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves). (Food Safety Guidelines for the Fresh-Cut Produce Industry). |
| E2 | Holding time throughout the entire process, especially post-wash and prior to packaging (weighing, transporting, collecting), is minimized. (Handling Guidelines for Fresh Cut Produce; IFPA/WGA Voluntary Food Safety Guidelines for Fresh Produce). |
| E2, H6 | Packaging materials are made of approved material, gas-permeable, and preclude packaging migration, the entrance of foreign materials, spoilage prior to toxin production and avoid anaerobic respiration. Gas permeable packaging material must be transparent over an area of at least 50% of the surface to permit the visual detection of spoiled product (IFPA Guidelines, pg 20) (Food Safety Guidelines for the Fresh-Cut Produce Industry; IFPA/WGA Voluntary Food Safety Guidelines for Fresh Produce). |
| E2, H6 | Parameters for modified atmosphere(s) packaging are established and monitored (e.g., 2 - 8% oxygen/5 - 15% carbon dioxide). (Food Safety Guidelines for the Fresh-Cut Produce Industry; Assessment of the Risk of Botulism Contributed by Modified Atmosphere Packaging of Fresh-Cut Produce). |
| E2 | Each retail and food service package has a “USE BY DATE” or distinguishable coding and a “KEEP REFRIGERATED” label. (IFPA, pg 20) |
| E3 | Product temperatures maintained at 4.4ºC (40ºF) during storage and distribution. (IFPA Guidelines, pg 20) |
| E4 | All product contact water has established and monitored disinfectant parameters to include filtration and recirculation methods.<br>Note: Recycled water should run counter flow to produce (e.g., final rinse water may be used as cooling water). (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Food Safety Guidelines for the Fresh-Cut Produce Industry). |

NOTE: Reference to the controlling documents are identified in parentheses.

# APPENDIX R - Mushrooms

## R.1 SCOPE

R.1.1 Scope. This appendix contains guidelines for auditing mushroom growing and processing facilities. The information contained herein is intended for guidance.

## R.2 APPLICABLE DOCUMENTS

R.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

R.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

40 CFR, PART 141, NATIONAL PRIMARY DRINKING WATER STANDARDS

(Available at http://www.access.gpo.gov/nara/cfr/waisidx_01/40cfr141_01.html)

R.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents, which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

GOOD MANAGEMENT PRACTICES FOR SAFE GROWING, HARVESTING, AND PACKING OF FRESH MUSHROOMS

(This document is available at http://www.americanmushroom.org/gmp.htm)

## R.3 DEFINITIONS

R.3.1 Definitions. Definitions are contained in the basic handbook.

## R.4 GUIDELINES

R.4.1 General.

These guidelines are based on the following basic principles for maintaining the safety of fresh mushroom products:

- Water has the potential to be a source of contamination during mushroom growing and subsequent handling.

- The use of animal manures in substrate preparation should be managed carefully to minimize the potential for microbial contamination of mushrooms.
- Worker hygiene and sanitation practices during growing, harvesting, and handling play a critical role in minimizing the potential for microbial contamination of mushrooms.
- Growers and packers should consider themselves suppliers of a fresh food that may not be cooked and, therefore, should follow all applicable laws and regulations designed to ensure safe food products.

Mushrooms are grown from microscopic spores. A mature mushroom will drop as many as 16 billion spores. The root structure of the mushroom is a network of lacy white filaments called mycelium. When the mycelium is formed, a thin layer of sterile peat moss is spread over the surface of the mycelium. Tiny white protrusions called fruiting bodies form on the mycelium and push up through the sterile peat moss. It takes 17 to 25 days to produce mature mushrooms from the time sterile peat moss is placed over the white protrusions.

Harvesting takes place over a period of several weeks. After harvesting, each growing house (room) is emptied and steam-sterilized before the process begins again. The total process from start to finish takes about four months. There are six major steps in mushroom farming:

- Phase 1. Phase I usually takes place outdoors. A concrete slab, often referred to as a wharf, is required for composting. Composting is initiated by mixing and wetting the ingredients as they are stacked in rectangular piles with tight sides and loose centers. Nitrogen and gypsum supplements are added to the tip of the bulk ingredients and are thoroughly mixed by a turner. Adequate moisture, oxygen, nitrogen, and carbohydrates result in the activity of microorganisms producing heat and some heat-releasing chemical reactions.

- Phase II. Phase II is the finishing of the compost. Phase II composting can be viewed as a controlled, temperature-dependent, ecological process using air to maintain the compost in a temperature range best suited for the de-ammonifying organisms to grow and reproduce. The growth of thermophilic (heat-loving) organisms depends on the availability of usable carbohydrates and nitrogen. The high temperature Phase II system involves an initial pasteurization period of at least 145$^{o}$ F for six hours. The temperature of the compost is then lowered 2-3 degrees per day until the ammonia is dissipated. This Phase II system takes 10 - 14 days to complete. The low temperature Phase II system allows the compost to obtain a temperature of 126$^{o}$F (range 125$^{o}$F - 130$^{o}$F) for four or five days and then is allowed to decrease in temperature at two degrees per day until the ammonia is dissipated.

- Spawning. Spawning is the process of inoculating the compost with mushroom spawn. Spawn is commercially produced mycelium.

- Casing. Casing is the top-dressing applied to the spawn-run compost on which mushrooms form. Casing is usually clay-loam field soil and a mixture of peat moss, ground limestone, or reclaimed spent compost. Casing acts as a water reservoir and a place where rhizomorphs form. Casing is pasteurized to eliminate insects and pathogens it may be carrying.

- Pinning. Pinning is the management of temperature and humidity during the maturing of the pins. This step is also referred to as airing-out. Cropping follows pinning; the harvesting of

mushrooms at various growth stages. Cropping is done in a method of thinning out the crop. Mushrooms are usually harvested in a 7 - 10 day cycle, but this may be longer or shorter depending on the temperature, humidity, cultivars and stage when they are picked.

Additional information can be obtained from the National Mushroom Growers' Association - http://www.mushroomcouncil.com. A complete list of references is available at: http://www.attra.org/attra-pub/mushroom.html.

R.4.2 Checklist. Guidelines for auditing mushroom facilities in OCONUS areas are contained in the following checklist.

# APPENDIX R

| MUSHROOMS CHECKLIST<br><br>Good Management Practices For Safe Growing, Harvesting, And Packing Of Fresh Mushrooms | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E-2 | Pre-operational inspections, audits, or microbial sampling of the environment or of food contact surfaces are conducted to ensure cleaning and sanitizing procedures are effective. Pg. 11, 3. |
| B2 | Areas where: raw animal manure; unpasteurized substrate which contains raw manure; or other potentially hazardous materials are processed, stored, or transported -- are clearly separated from those areas where mushrooms are grown, harvested, and packed. (Pg. 4, 1) |
| B2 | Separate areas are provided for the receipt of raw materials and mushroom loading and shipping areas. Pg. 4, 1 |
| A10 | Traffic patterns for employees and equipment are established to avoid contamination of pasteurized substrate, casing materials, and mushrooms with raw manure and unpasteurized substrate. Pg. 4, 1 |
| B2 | In rooms that are not steam pasteurized, floors are constructed of washable, nonporous materials and adequately sloped to allow drainage. Pg. 5, 3 |
| B2, B3 | Walls and ceilings where mushrooms are handled are made of light-colored, washable, and nonporous materials, or are steam cleaned. Pg. 5, 3. |
| B2 | Ventilation systems are designed so that air does not flow from potentially contaminated areas to clean areas, and are adequately cleaned and maintained. Pg. 5, 3. |
| E2 | Equipment for moving, mixing, or otherwise handling unpasteurized substrate is not used for handling pasteurized substrate, casing materials, or mushrooms and is cleaned as needed to protect against contamination of the premises. Pg. 6, 1. |
| C7 | Temperature recording devices, timers, alarms, data loggers, and any other equipment used to monitor and record process data are regularly maintained and calibrated. Pg. 6, 3. |
| E1 | Controls for potential microbiological, chemical, and physical hazards in all materials received should be established by implementing a vendor approval and certification program. Pg. 7, 1 |
| E1, H8 | Appropriate records are kept to monitor the performance of suppliers and if necessary for traceback of sources of contamination. Pg. 7, 1. |
| E3 | Raw materials and unpasteurized substrate are stored as far away as possible from areas where mushrooms are grown, harvested, packed, and stored. Pg. 8, 2. |
| B9 | Water that directly contacts mushrooms or surfaces that come into contact with mushrooms meets federal drinking water standards. Pg. 9, 1 |
| B9. E4 | Surface water, and ground water that is influenced by surface water, are treated to eliminate chemical or microbiological contamination. Water supply is tested on-site for fecal contamination. Pg. 9, 1 |
| B6, B9, E4 | The concentrations of anti-microbial chemicals in treated water are routinely monitored and recorded to ensure they are maintained at appropriate levels. Pg. 10, 3. |

MUSHROOM CHECKLIST- Continued

| | |
|---|---|
| B6, B7 | Application of approved pesticides is undertaken by or under the supervision of a licensed pest control applicator. The glue boards or mechanical traps with non-toxic bait are used in areas where mushrooms are grown unless the bait is of sufficient size to be prevented from mixing with the product. Pest control logs are maintained that include dates of inspection, inspection reports, and steps taken to eliminate any problems. Pg. 11, 6.1. |
| E3, H8 | The label on all packages for wholesale or retail sale includes all items required by federal, state, and local regulations, including: name, street address, city, state, zip code, and product code that enables traceback to the point at which the mushrooms were grown and date they were processed. Pg. 16, 1. |
| H4, H5 | Written procedures are developed in the event that a mushroom grower or processor wishes to remove a product from the marketplace. Pg. 16, 2. |
| E2 | Temperatures are achieved during production of Phase I substrate and Phase II pasteurization that are adequate to kill mesophilic human pathogens. Pg. 18, 2. |
| E5 | Where slicing blades are used, continuous monitoring of metal in packaged mushrooms is performed using an online detector. Pg. 18, 3. |
| E3 | The presence of at least two 1/8 inch film ventilation holes per package is maintained and monitored. Alternative packaging methods which do not create an air tight environment are acceptable. Pg. 18, 4. |
| C7 | Refrigerators holding harvested mushrooms are maintained at or below 40 degrees Fahrenheit. Pg. 18, 5. |
| E3 | Storage areas are either protected from rainfall by covering the materials or the runoff is collected using barriers or physical containment measures such as concrete blocks, soil berms, pits, or lagoons. Pg. 8, 2. |
| H6 | The scheduled master cleaning program specifies what areas or equipment are cleaned and/or sanitized, the person responsible, the method and frequency of cleaning, and verification procedures. Pg. 10, 5.1. |
| E2 | A regularly scheduled and “as needed” program is implemented that ensures all parts of the operation are appropriately clean and sanitary. Pg. 10, 5.1. |

# APPENDIX S - Vegetable Sprouts

## S.1 SCOPE

S.1.1 Scope. This appendix contains guidelines for auditing sprouts growing and processing facilities. The information contained herein is intended for guidance.

## S.2 APPLICABLE DOCUMENTS

S.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

S.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

FDA Guidance for Industry, "Reducing Microbial Food Safety Hazards For Sprouted Seeds", Oct 1999

This document is available at http://www.cfsan.fda.gov/~mow/sprouts2.html

40 CFR, PART 141, NATIONAL PRIMARY DRINKING WATER STANDARDS

(Available at http://www.access.gpo.gov/nara/cfr/waisidx_01/40cfr141_01.html)

## S.3 DEFINITIONS

S.3.1 Definitions. Definitions are contained in the basic handbook.

## S.4 GUIDELINES

S.4.1 General.

Seed Production. Seeds for sprout production should be grown under good agricultural practices (GAPs) in order to minimize the likelihood that they will contain pathogenic bacteria.

Seed Conditioning, Storage, and Transportation. Seeds that may be used for sprouting should be conditioned, stored and transported in a manner that minimizes the likelihood that the seeds will be contaminated with pathogens. For example, seeds should be stored in closed or covered containers in a clean, dry area dedicated to seed storage. Containers should be positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests and to facilitate regular monitoring for pest problems.

Sprout Production**.** Facilities and equipment should be maintained in a condition that will protect against contamination. Good sanitation practices must be maintained throughout all stages of sprout production.

Seed Treatment. Seeds for sprouting should be treated with one or more treatments (such as 20,000 ppm calcium hypochlorite) that have been approved for reduction of pathogens in seeds or sprouts. Some treatments can be applied at the sprouting facility while others will have to be applied earlier in the seed production process. However, at least one approved antimicrobial treatment should be applied immediately before sprouting.

Testing for Pathogens. Sprout producers should conduct microbiological testing on spent irrigation water from each production lot to ensure that contaminated product is not distributed. This can be accomplished as early as 48 hours into the 3 to 10 day growing period.

Traceback. Sprout producers, seed producers, conditioners and distributors should develop and implement systems to facilitate traceback and recalls in the event of a problem.

S.4.2 Checklist. Guidelines for auditing of vegetable sprouts are contained in the following checklist.

# APPENDIX S

| VEGETABLE SPROUTS CHECKLIST<br><br>FDA Guidance For Industry, "Reducing Microbial Food Safety Hazards For Sprouted Seeds", Oct 1999 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1, H8 | Appropriate records are kept to monitor the performance of suppliers and when necessary for traceback of sources of contamination. (ISGA) |
| E3 | Adequate measures and monitoring are used to control in-storage humidity and moisture of dry beans. (ISGA) |
| E2 | Seeds are pre-washed and soaked to provide adequate protection against microbiological growth. (ISGA) |
| B8 | Recycled germination and growth containers are cleaned and disinfected prior to use. (ISGA) |
| B9 | Water, to include irrigation water, that directly contacts sprouts or surfaces that come in contact with sprouts meets requirements of 40 CFR, Part 141. |
| E2 | Adequate measures are taken to protect against any contamination during harvesting and packaging. (ISGA) |
| E2, E4 | Wash water is adequately chilled and chlorinated. (ISGA) |
| B8 | Wash tank and collection bins are cleaned and disinfected as needed. (ISGA) |
| E5 | Methods to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves, or other means). (Sec 110.80). |
| E3 | Chill storage and distribution temperature is less than 40°F +/- 4°F. |
| E3 | Products are dated and stock rotation controlled. |
| E4 | Testing of irrigation water for pathogens is conducted after the initial 48 hours for each batch within the growing cycle. |

# APPENDIX T - Low-Acid Canned Food (LACF)

## T.1 SCOPE

T.1.1 Scope. This appendix contains guidelines for auditing low-acid canned food (seafood, coconut milk) processing facilities. The information contained herein is intended for guidance.

## T.2 APPLICABLE DOCUMENTS

T.2.1 General. The documents listed in this section are specified in this appendix. This section does not include documents cited in other sections of this handbook or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that all specified documents cited in this appendix apply, whether or not they are listed.

T.2.2 Government documents. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

CODE OF FEDERAL REGULATIONS (CFR)

21 CFR, Parts, 108, 110, 113

(Available on-line at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1)

T.2.3 Non-government publications. The following documents form a part of this appendix to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted, are those listed in the issue of DoDISS cited in the solicitation; and the issues of documents not listed in the DoDISS are the issues most current in publication.

LOW-ACID CANNED FOOD MANUFACTURER'S GUIDES

Part 1: Administrative Procedures / Scheduled Processes

Part 2: Processes-Procedures

(Publications are on-line at:
http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt101.html or contact FDA, 1-888-INFO-FDA (1-888-463-6332) for publication information.)

## T.3 DEFINITIONS

T.3.1 Definitions. Definitions are contained in the basic handbook.

## T.4 GUIDELINES

T.4.1 General.

When food product is acidified to a pH of 4.6 or less, according to FDA's good manufacturing practices, inhibition of the growth of C. botulinum is assured.

The auditor must be prepared to audit the firm's compliance with the LACF regulations 21CFR Part 113.40. The equipment used in the retort process must be the same as that upon which the temperature distribution studies were performed. Thermal processing equipment must be operated in the manner prescribed by the regulations and the firm's processing authority.

Low-acid foods are foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity ($a_w$) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

Improper sterilization creates a condition for C. botulinum to grow in foods and produce spores and powerful toxins which affect the nervous system. C. botulinum will only grow in foods which: are packaged in the absence of oxygen; have a "favorable" pH and temperature; and contain water and nutrients necessary for its growth. Low-acid canned foods provide this favorable environment.

The thermal retort process is the primary means used to achieve commercial sterility. It is imperative that equipment heat distribution, and penetration of sealed container, be applied for a period of time and at a temperature scientifically determined to be adequate to ensure lethal destruction of microorganisms of public health significance.

T.4.1.1 Summary guidelines for inspection of LACF processors using retort systems

The following list extracted from LACF guidelines Part II, has been compiled in an effort to obtain the minimum information necessary to make a valid assessment of a processor operation. Auditors should include, but are not limited to, all applicable items.

Product Preparation, Filling and Closing Operations

Product Formulation and Specifications

- Products packed, ingredients, styles of pack, packing medium (covering liquid).
- Product specifications (e.g., formulation, consistency, particle size, pH, etc.).

Product preparation.

- Blanching equipment and conditions (e.g., time and temperature) and control thereof.
- Preparation and holding kettles and tanks; times, temperatures, and controls.
- Preparation of packing medium.

Containers - source, type, and size(s) used.

Filling

- Method (e.g., hand fill, mechanical with vibrating or shaking actions, etc.) and equipment, including manufacturer.
- Controls and records of fill weight, net weight, drained weight.
- Packing medium; filling method and equipment, temperature and control of.
- Headspace control (e.g., mechanical, volume, weight, etc.).

Development of vacuum

- Exhausting of container (e.g., steam exhaust box, hot fill, steam injection, mechanical vacuum chamber, etc.).
- Mechanical vacuum readings if critical to the thermal process.

Closing operations

- Closing machine model and make.
- Closure examinations; specifications, frequency and recording of visual and tear-down examinations.
- Qualifications and training of persons performing container examinations. Operating under the supervision of an individual who has attended a school of instruction as per 21 CFR 113.10.
- Coding method and information.

Thermal Processing Schedules, Operations and Equipment**.**

Scheduled Processes

- Scheduled processes including critical factors of each product in each container size covered during the inspection.
- Source and date of processes.
- Scheduled venting procedures for steam retorts.
- Scheduled come-up procedures for water immersion cascading water and steam-air retorts.
- Procedures for handling process deviations.

Operations

- Scheduled processes/operating procedures (e.g., venting, come-up) posted or on file.
- Use of heat sensitive indicators and retort traffic control.
- Initial temperature, method and frequency of measurement.
- Type and accuracy of process timing devices.
- Operating under the supervision of a person who has attended a school of instruction as per 21 CFR 113.10.
- Actual venting or come-up procedures used.
- Actual retort operations, time(s), and temperature(s).
- Actual cooling practices.

Equipment and procedures

- Type, size and number of retorts.
- Mercury-in-glass (MIG) thermometer specifications, date of accuracy checks, accuracy at time of check, standard used, method used to check accuracy.
- Temperature recording device(s); specifications of chart, installation, accuracy of timing mechanism, agreement with MIG thermometer.
- Retort temperature and pressure controllers; type (e.g., mechanical, air operated, computer controlled, etc.) description of operation.
- Pressure gauges and pressure relief valve; specifications, installation and location, if applicable.
- Steam entry, description of steam spreaders, steam injectors, heat exchangers, etc.
- Retort crates, divider plates, container orientation, etc. comply with regulations and filed scheduled process requirements.
- Steam supply, boiler size and type, steam pressure at boiler, steam pressure at header, size of supply headers and pipes, length of pipes and headers.

Still steam retorts

- Crate supports, vertical retorts.
- Bleeders; specifications, location, installation and use.
- Vents on steam retorts; type, location, installation and operation. If vents differ from specification in the regulations or if divider plates are used, evidence of adequacy is required.

Still water immersion retorts

- Crate supports and guides in vertical retorts.
- Drain valve, type, screened.
- Water level indicators, type, use.
- Air supply and control.
- Method of water circulation, regulation compliance, temperature distribution studies.
- Cooling water supply.
- Location of control temperature sensing probe.

Continuous agitating steam retorts

- Capacity and number of steps in reel.
- Vents and bleeders specifications and locations.
- Method of removing condensate, condensate bleeder.
- Retort speed timing method and frequency, tamper proof.
- Procedures for handling emergency stops and temperature drops.

Discontinuous agitating steam retorts

- Capacity and number of steps in reel.
- Retort speed timing method and frequency.
- Procedures for removing condensate.
- Vents and bleeder specifications, locations.
- Procedures for handling emergency stops and temperature drops.

Discontinuous agitating water retorts

- RPMs timing and control.
- Over-pressure supply and control.
- Method of heating water.
- Come-up steps to heat to processing temp.

Hydrostatic retorts

- Type, number of chains and number of flights in steam, timing of container carrier.
- Where the scheduled process specifies maintenance of particular temperatures in the feed and exit water legs, location of MIG thermometers and recording devices in the water legs.
- Vents and bleeders, specifications and location
- Disposition of stray containers.

Cascading/spray water retorts

- Method of heating water (e.g., heat exchanger, direct injection of steam into water, steam distribution pipes).
- Come-up steps in process.
- Water flow, measurement, (e.g., flow meter, pressure, none) is flow the same as that during temperature distribution studies.
- Method used to insure water distribution system is not clogged (e.g., examination of water distribution manifold and sprays, physical cleaning, chemical cleaning).
- Water pump size, inlet diameter, and horsepower.
- Location of water inlet into shell.
- Timing of RPMs on rotational models.

Steam-air

- % steam/air mixture; is it the same as that used during temperature distribution studies?
- Fan operation, method of checking.
- Timing of RPMs on rotational models

Processing and Production Records

Production Records

- Frequency of measurement and recording of critical factors.
- Evidence of critical factors not within established limits.

Processing Records

- Thermal processing records maintained as per 21 CFR 113.100.
- Thermal processing charts and records can be correlated.
- Computer generated records, if used, document that all information required by 21 CFR 113 is being captured. Document manufacturer of hardware and software; report procedures for validation/maintenance of equipment.

Finished Product

Warehouse
- Evidence and extent of spoilage and/or abnormal containers
- Incubation practices

Complaint Files - Evidence of under-processing and/or spoilage

Product Recalls
- Nature of recall, date of recall
- Disposition of product

Process Deviations
- Procedures for handling
- Disposition is documented.

T.4.2. Checklist. Guidelines for auditing low-acid canned food production facilities are contained in the following checklist.

# APPENDIX T

| LOW-ACID CANNED FOOD CHECKLIST<br><br>21 CFR PARTS, 108, 110, 113 | |
|---|---|
| APPENDIX A PARAGRAPH | REQUIREMENT |
| E1, E2 | Raw materials are handled in a manner that does not allow the growth of microorganisms, challenge the lethality of the thermal process, or cause food product to spoil under normal conditions of canning and storage. 21 CFR, Part 110.80(a) |
| E1 | Materials and ingredients are suitable for use in processing low-acid food. 21 CFR, Part 113.81 (a) |
| A11 | Trained personnel supervise the operators of processing systems, retorts, systems and container and closure inspections. 21 CFR, Part 113.10 |
| E2, H1, H2 | Scheduled process includes: company name, date, product, production code, retort number, container size, # of containers, initial temp, time steam on, time vent closed, vent temp, time temp up, time steam off, actual processing time, MIG and recorder chart temperatures and other critical factors, specified in the scheduled process. 21 CFR, Part 113.83, Part 108.35 (a) |
| H8 | Raw material and factors that are critical to the thermal process are identified by the processing authority and filed with the FDA as part of the scheduled process. 21 CFR, Part 108.35(a) |
| H3 | Critical factors specified in the scheduled process are measured and recorded on the processing record at intervals not exceeding 15 min. 21 CFR, Part 113.100(a) |
| H4, H6 | Process deviations from the scheduled process are recorded and substantiated by qualified scientific authority prior to using the change. 21 CFR, Part 108.35(c)(2) |
| E2 | Can size and type are the same as those identified on the scheduled process for each item being produced. 21 CFR, Part 108.35(c)(3) |
| E2, C8 | Water activity and the thermal process are controlled when the firm's filed scheduled process lists an $a_w$ greater than 0.85 but less than the $a_w$ that would allow the growth of spores of public health significance. 21 CFR, Part 113.81 (f) |
| E2, C8 | pH is controlled and monitored when acids are added to reduce the pH of the product. 21 CFR, Part 113.81 (e) |
| C2, C4 | Cans must meet container specifications and be free of serious defects. 21 CFR, Part 113.60 (a) |
| C2, E4 | Visual seam inspections are conducted as often as necessary but not less than every 30 minutes, and after each startup, prolonged break, and each seamer jam. Can Seam Teardowns are conducted at least every 4 hours. 21 CFR, Part 113.6, 113.60(a)(1) |
| C2, C3 | Can seam measurements are performed using Micrometer Method-Cover hook, body hook, width, tightness, thickness measured in 3 places about 120° apart. Seam Scope/Seam Projector Method- Body hook, overlap, tightness, thickness by micrometer measured in 2 places. 21 CFR, Part 113.60, (a) (b) (c) |
| C7 | Retort is properly fitted with temperature recorders, pressure gauges, steam controls, spreaders and bleeders. 21 CFR, Part 113.40(a) |

LOW-ACID CANNED FOOD CHECKLIST - Continued

| | |
|---|---|
| C7 | Each retort is equipped with an accurate mercury-in-glass thermometer tested for accuracy against a known accurate standard. Calibration records are annotated and thermometers are identified. 21 CFR, Part 113.40 C(a)(1) |
| C7 | MIG thermometer divisions are readable to 1° F, and temperature range does not exceed 17° F per inch of graduated scale. 21 CFR, Part 113.40 C(a) |
| C7 | Retort has an accurate temperature-recording device. A means of preventing unauthorized changes in adjustment is provided. 21 CFR, Part 113.40 C(a)(2) |
| E2 | Crates, trays, gondolas, etc., for holding containers are made of strap iron, adequately perforated sheet metal, or other suitable material. 21 CFR, Part 113.40 (a) (9) |
| E2 | Dividers between the layers of containers should be perforated approximately the equivalent of 1-inch holes on 2-inch centers. CFR, part 113.40 C (a) (9) |
| A11 | Retort operating and venting procedures for each product and container size being packed are posted near the processing equipment, or are readily available to the retort operator. 21 CFR, Part 113.87(a) |
| E2 | Traffic in the retort room and processing area is controlled to prevent unprocessed LACF from circumventing the thermal process, as well as mixing of processed and unprocessed containers. 21 CFR, Part 113.87(b) |
| C7 | Trucks, crates, etc. of retorted food product are plainly and conspicuously marked with a heat sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, the units that have been retorted. 21 CFR, Part 113.87(b) |
| E2, H1 | Initial temperature of the contents of the containers to be processed is determined and recorded. Product temperature is not lower than the minimum initial temperature specified in the scheduled process. 21 CFR, Part 113.87(b) |
| E2 | Pocket or wristwatch is not used to record processing and venting time. 21 CFR, Part 113.87(d) & (e) |
| B9 | Water used for cooling must be potable. Container cooling water is chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler. |
| B9 | When the steam comes into contact with the LACF, through direct injection of the steam into the food; during the exhausting of containers in a steam exhaust box; through injection of steam into the headspace of containers to form a vacuum, or through any other means, the boiler additives must be approved for use as a food additive and labeled for that use as per 21 CFR Part 173.310 |

# CONCLUDING MATERIAL

Custodians:

Army - MD2
Navy - SA
Air Force - 03

Review Activities:

Navy - MS, MC
DLA - SS

Preparing Activity:

Army - MD2
Project No. 89GP-0006

# STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

## INSTRUCTIONS

1. The preparing activity must complete blocks 1, 2, 3, and 8. In block 1, both the document number and revision letter should be given.

2. The submitter of this form must complete blocks 4, 5, 6, and 7, and send them to preparing activity.

3. The preparing activity must provide a reply within 30 days from receipt of the form.

NOTE: This form may not be used to request copies of documents, nor to request waivers, or clarification of requirements on current contracts. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements.

| I RECOMMEND A CHANGE | 1. DOCUMENT NUMBER<br>MIL-HDBK-3006A | 2. DOCUMENT DATE *(YYYYMMDD)*<br>20020607 |
|---|---|---|

3. DOCUMENT TITLE
GUIDELINES FOR AUDITING FOOD ESTABLISHMENTS

4. NATURE OF CHANGE *(Identify paragraph number and include proposed rewrite, if possible. Attach extra sheets as needed)*

5. REASON FOR RECOMMENDATION

6. SUBMITTER

| a. NAME *(Last, First, MI)* | b. ORGANIZATION | |
|---|---|---|
| c. ADDRESS *(Include ZIP Code)* | d. TELEPHONE *(Include Area Code)*<br>(1) Commercial<br>(2) DSN<br>*If applicable* | 7. DATE SUBMITTED<br>*(YYYYMMDD)* |

8. PREPARING ACTIVITY

| a. NAME<br>COL S. Severin | b. TELEPHONE *(Include Area Code)*<br>(1) Commercial<br>(703) 681-3056<br>(2) DSN<br>761-3056 |
|---|---|
| c. ADDRESS *(Include ZIP Code)*<br>Director, DoD Veterinary Service Activity<br>Office of the Surgeon General/HQDA<br>5109 Leesburg Pike<br>Falls Church, VA 22041-3258 | IF YOU DO NOT RECEIVE A REPLY WITHIN 45 DAYS, CONTACT:<br>Defense Standardization Program Office (DLSC-LM)<br>8725 John J. Kingman Road, Suite 2533,<br>Fort Belvoir, VA 22060-6221<br>Telephone (703) 767-6888 DSN 427-6888 |