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DEPARTMENT OF DEFENSE
MILITARY HANDBOOK

GUIDELINES FOR AUDITING FOOD ESTABLISHMENTS

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AMSC N/A FSG 89GP

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FOREWORD

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

2. This handbook is used in conjunction with the requirements delineated in MIL-STD-3006C, its appendices and supporting Government or non-Government publications. Other requirements that are not prescribed in the referenced documents do not apply.

3. This handbook contains guidelines for auditing commercial food establishments, including manufacturing, packaging, and storage facilities.

4. Each appendix is based on regulatory, industry and DOD requirements.

5. Comments, suggestions, or questions on this document should be addressed to the Director, DOD Veterinary Service Activity, Office of the Surgeon General/HQDA, 5109 Leesburg Pike, Falls Church, VA 22041-3258. Since contact information can change, you may want to verify the currency of this address information using the ASSIT Online database at http://assist.daps.dla.mil.

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1. SCOPE

1.1 Scope. This handbook provides guidance related to conducting audits of commercial food establishments. The requirements for these audits and related DOD policy are contained in MIL-STD-3006C and AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G and AFI 48-116, 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 the basic sanitation standards for food establishments. The CGMP requirements are based upon the Federal Food, Drug and Cosmetic Act of 1938, as amended. The handbook also provides specific product guidance within individual appendices for use in the 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. Compliance with MIL-STD-3006C is mandatory for listing of establishments in the *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement* (*Worldwide 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 regulatory, industry and DOD requirements, reducing the risk of intentional or unintentional adulteration of food.

1.4 Limitations. In OCONUS locations, the Major Command (MACOM) Veterinarian may supplement this document. In cases where CGMPs are provided for specific subsistence items (e.g., Low-acid canned foods), the specific requirements for that item will be applied in addition to those found in 21 CFR Part 110. Additional Government and non-Government documents are listed in the individual appendices.

2. APPLICABLE DOCUMENTS

2.1 General. The documents listed below are not necessarily all the documents referenced herein, but are those needed to understand the information provided by this handbook.

2.2 Government Documents.

2.2.1 Standard. The following standard forms a part of this document to the extent specified herein.

DEPARTMENT OF DEFENSE STANDARD

MIL-STD-3006C, Sanitation Requirements for Food Establishments.

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(Copies of this document is available online at http://assist.daps.dla.mil/quicksearch/ or http://assist.daps.dla.mil or from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094.)

2.2.2 Other Government publications. The following other Government documents and publications form a part of this document to the extent specified herein.

MILITARY PUBLICATIONS

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

AR 40-5, Preventive Medicine.

AR 40-657/NAVSUPINST 4355.4 /MCO P10110.31, 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 Acceptable Sanitation Audit Rating. No Critical findings or no more than three Major findings. 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 Finding, due to increased public health significance.

3.3 Adulterated. A food is deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health IAW the Federal Food, Drug and Cosmetic Act, Section 402.

3.4 Allergens. Ingredients that are “known” allergens include eggs, milk, fish, soybeans, peanuts, tree nuts, crustacea and wheat or any food that contains proteins derived from these foods.

3.5 Bioterrorism. Bioterrorism is the use of biological agents, such as pathogenic organisms or agricultural pests, for terrorist purposes against a civilian or military population by a Government, organization, or individual.

3.6 Corrective Action Request (CAR). A written request from the auditor to management addressing specific findings that require a response from management as to the root cause of the finding as well as the action(s) taken to correct and prevent recurrence of the finding(s).

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3.7 Controlled Atmosphere Packaging (CAP). The packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

3.8 Critical Finding. An imminent health hazard caused by a condition which presents a biological, chemical or physical food safety or food defense hazard that if not prevented, eliminated or reduced by a subsequent process, practice, step or procedure (hurdles); or that may cause food to be unsafe for consumption or otherwise adulterated.

3.9 Directed Routine Sanitation Audit. Conducted at the direction of the applicable MACOM Veterinarian within establishments listed in the *Worldwide Directory* when laboratory results indicate a need for further sanitation cognizance or other reasons. The focus of this audit is normally limited to the areas of concern.

3.10 Dual-Listed Establishments. Dual-Listed establishments are establishments listed in the *Worldwide Directory* and another recognized Federal or State approved listing.

3.11 Food Defense Finding. Any condition, practice, step or procedure noted relating to the risk of intentional food tampering or increased food vulnerability. Food Defense Findings can occur at any stage during receipt, storage, in-processing, packaging, packing, warehousing or distribution. Severity of findings will be classified as Critical, Major or Observation as defined within this handbook.

3.12 Food Defense Plan. A written document or approach that uses established risk management procedures for preventing intentional food tampering and responding to threats or actual incidents of intentional tampering.

3.13 Food Defense Program. A program developed by an establishment to assess and mitigate the vulnerabilities within the food system or infrastructure to an attack from deliberate or intentional acts of food destruction, contamination or tampering. By conducting a vulnerability assessment and determining the most vulnerable points in the system, the establishment can then determine which vulnerabilities can be addressed and improved to increase the overall food defense level of their establishment and products.

3.14 Food Operational Risk Management (FORM). A simplified food safety and defense risk assessment process based on severity and frequency to prioritize risks, target resources and focus efforts on short-term accomplishments. The approach is similar to a Hazard Analysis Critical Control Point (HACCP) plan and used to minimize food safety and defense risks. Components of FORM include: (1) Identify the hazards; 2) Assess the risk; 3) Analyze risk control measures; 4) Make control decisions; 5) Implement risk controls; and 6) Supervise and review. FORM provides for a more effective use of resources and can be used to improve food safety and defense. Note: A HACCP plan supports, but does not substitute a FORM assessment.

3.15 Food Safety and Defense. A food is deemed safe when it has been received, prepared, packed, stored and distributed under sanitary conditions whereby it has not been rendered injurious to health. Food Defense is the implementation of programs or barriers that

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prevent or reduce the susceptibility and/or vulnerability of food systems to deliberate or intentional acts of destruction, contamination or tampering.

3.16 Food Safety Program (FSP). A written or practiced non-regulatory plan (similar to HACCP) that is implemented and practiced by establishment personnel and is designed to ensure the safe production of food. To differentiate mandatory (regulatory) HACCP from a voluntary program, this document makes reference to the Food Safety Program.

3.17 Functional Area. Areas (commonly referred to as Unit Operations) within a food processing establishment where food is received, stored, staged, prepared, processed, packaged, packed, and distributed (shipped).

3.18 Imminent Health Hazard. A significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on: (1) the number of potential injuries, and (2) the nature, severity, and duration of the anticipated injury.

3.19 Initial Sanitation Audit. A comprehensive evaluation of a commercial food establishment that determines the sanitary status for the first time. The Initial sanitation audit is triggered by a request to list a commercial establishment in the *Worldwide Directory*. This audit is used to approve or disapprove the establishment as a source for Armed Forces procurement. Initial sanitation audits are a complete assessment of the facilities production procedures, and food safety and food defense control systems.

3.20 Major Finding. Condition, practice, step or procedure which in itself does not present a food defense or imminent health hazard yet has the potential to affect food safety or the product's intended use due to loss or lack of verifiable control.

3.21 Modified Atmosphere Packaging (MAP). The packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide. MAP is achieved by two distinct processes, active or passive.

3.22 Objective Evidence. Data confirming the status (presence or absence) of a condition, practice, step or procedure. Objective evidence may be obtained through observation, interviews, measurement, tests, record reviews, or other means.

3.23 Observation. Condition, practice, step or procedure that is not in accordance with food safety and defense requirements, and does not meet the criteria of a Critical or Major finding.

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

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3.25 Qualified Auditor (QA). An individual certified by education, experience, technical ability, and temperament in accordance with governing regulations.

3.26 Reduced Oxygen Packaging (ROP). Provides an environment that contains little or no oxygen.

3.27 Root Cause. A true cause of a finding based on an in-depth investigation.

3.28 Routine Sanitation Audit. An evaluation to determine the current sanitary status and overall status of the sanitation and food defense programs of an establishment providing subsistence to the Armed Forces. These audits result in the continued approval of the establishment or a notice to its management of the possibility of disapproval if the sanitary findings observed are not corrected in a reasonable amount of time, as determined by the MACOM Veterinarian. Routine sanitation audits will be thorough enough, and at a frequency that allows the auditor to evaluate the current conditions of the establishment and associated operations. The in-plant assessment during Routine Sanitation Audits are normally performed in the same depth and complexity as Initial Sanitation Audits.

3.29 Sanitation Audit. An in-depth examination of an establishment’s policy and procedures to determine effectiveness and compliance as it applies to the protection of food. Sanitation audits examine and evaluate the adequacy of an establishment's food safety, food defense, and other applicable control systems. Sanitation audits include Initial, Routine, Directed Routine, and Special audits.

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

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

3.32 Special Sanitation Audit. An evaluation to determine whether the establishment will remain an approved source for the procurement of subsistence for the Armed Forces. This audit is performed after an establishment has been rated "Unacceptable" after a Routine or Directed Routine sanitation audit, or the MACOM Veterinarian has reason to suspect products may be a threat to public health. The focus of this audit is normally limited to the findings found during a previous audit that was rated “Unacceptable”.

3.33 Unacceptable Sanitation Audit Rating. The rating given to an establishment that does not comply with the requirements of the sanitation audit. One Critical finding or more than three Major findings constitute an unacceptable audit rating. Observations alone will not result in an “Unacceptable" rating. The cumulative effect of multiple Observations indicating an out-of-control process may require an upgrade to a Major finding due to increased public health significance.

3.34 Vacuum Packaging. Reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside.

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3.35 Validation. That element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP or Food Safety plan, when properly implemented, will effectively control the identified food hazards.

3.36 Verification. Those activities, other than monitoring, that establish the validity of the HACCP or Food Safety plan and that the system is operating according to the plan.

3.37 Veterinary Corps Officer (VCO). Army Veterinary Corps Officers (Doctor of Veterinary Medicine (DVM)/Veterinary Medicine Doctor (VMD)) and Warrant Officers (Veterinary Corps Food Safety Officer, military occupational specialty (MOS) 640A).

3.38 Vulnerability. A weakness in the design, implementation or operation of an asset or system that can be exploited by an adversary or disrupted by a natural hazard.

3.39 Water Potability Certificate. When an establishment uses water in food processing, or cleaning and sanitizing of food equipment, the establishment will provide a water potability certificate indicating the absence of coliforms. Water samples will be drawn from within the establishment on an annual basis and tested by an EPA certified or equivalent laboratory. If an establishment does not produce or handle unpackaged food, then a copy of the annual water certificate from the city water authority indicating compliance with the EPA Primary Drinking Water Standards will be available for review during the audit. Testing of chemical contaminants should be in full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations (40 CFR parts 141 and 143).

3.40 Working Papers. The auditors or audit working papers may include written notes and instructions, checklists, questionnaires, matrixes, draft reports, etc.

4. GENERAL GUIDANCE

4.1 Auditing Personnel.

4.1.1 Sanitation Audits. A qualified VCO (64 series or 640A) or qualified Civilian personnel, which include Veterinary Medical Officers (GS 0701) and Quality Assurance Specialists (Subsistence, GS 1910), may perform Initial, Special, Routine, and Directed Routine Sanitation Audits at the discretion of the District Veterinary Commander or equivalent. A qualified Noncommissioned Officer (NCO) (MOS 68R, SSG or above) (Food Inspection Specialist) may perform routine sanitation audits of those food establishments that manipulate/handle packaged foods. Under exceptional circumstances the MACOM Veterinarian may authorize qualified NCOs to perform sanitation audits on food establishments that process or manipulate/handle unpackaged foods.

4.1.2 Joint Audits. May be performed: to facilitate training; to investigate concerns normally under the regulatory purview of another agency; in order to obtain a necessary expertise; and/or at the discretion of the District Veterinary Commander or equivalent.

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4.1.3 Certification Program. A formal education and training program designed and implemented by MACOM Veterinarians for auditors, to standardize audit techniques and ensure highly qualified auditors are performing sanitation audits.

4.2 Audit Performance. Establishments requiring *Worldwide Directory* listing will be audited in accordance with MIL-STD 3006C. Refer to AR 40-657 /NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116 for guidance, exemptions and definitions.

4.2.1 Sanitation Approval Requirements for Procurement. Refer to AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116 for guidance to include the following: Commercial food establishments; off-post caterers and civilian restaurants; home delivery service; dinner theaters; unit parties; on-post retail grocery store, restaurant, and fast food outlets; mobile canteens and/or snack trucks servicing military installations; privately prepared foods; installation events; and Commercial Food Storage Warehouses.

4.2.2 Establishments that may not have to be *Worldwide Directory* Listed. Refer to AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G for a list of establishments that may not have to be *Worldwide Directory* listed (exemptions).

4.3 Thermally Processed Food in Hermetically Sealed Containers. Establishments furnishing thermally processed foods in hermetically sealed containers are normally exempt from *Worldwide Directory* or local listing when the products are known to possess little or no potential health hazard. In OCONUS areas however, the MACOM Veterinarian may require audit approval and *Worldwide Directory* listing of these commercial establishments. This exemption does not apply to aseptically processed and packaged milk/milk products (as defined in the PMO), canned meat, poultry, fish items, sous vide or cook/chill operations unless the appropriate recognized federal agency inspects and lists the establishment. Refer to applicable appendices within this handbook for specific guidance.

4.4 Irradiated Foods. The following foods are approved by the FDA for irradiation:

Food	Approved Use	Dose
Spices and dry vegetable seasoning	decontaminates and controls insects and microorganisms	30 kGy
Dry or dehydrated enzyme preparations	controls insects and microorganisms	10 kGy
All foods	controls insects	1 kGy
Fresh foods	delays maturation	1 kGy
Poultry	controls disease-causing microorganisms	3 kGy
Red meat (such as beef, lamb and pork)	controls spoilage and disease-causing microorganisms	4.5 kGy (fresh), 7 kGy (frozen)

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Food Product	Agency / Approval Date	Purpose for Irradiation / Maximum permitted dosage (kiloGray)
Wheat and wheat powder	FDA – August 21,1963	Insect Deinfestation 0.20 to 0.50
White potatoes	FDA – July 8, 1964	Inhibit sprout development 0.05 to 0.15 (Maximum dose increased from 0.10 to 0.15 on November 9, 1965.)
Spices and dry vegetables	FDA – July 5, 1983 (Insect deinfestation approved June 1984.)	Microbial disinfection and insect deinfestation 10.0
Dry or dehydrated enzyme preparations (Refers to substances used as ingredients for flavoring or aroma (e.g., culinary herbs, seeds, spices, and vegetable seasonings). Includes turmeric and paprika when used as color.)	FDA – June 10, 1985	Microbial disinfection 10.0
Pork carcasses or fresh nonheated processed cuts	FDA – July 22, 1985	Control Trichinella spiralis 0.30 to 1.00
Fresh foods	FDA – April 18, 1986	Delay maturation 1.0
Dry or dehydrated aromatic vegetable substances	FDA – April 18, 1986	Microbial disinfection 30.0
Fresh, frozen uncooked poultry	FDA – May 2, 1990 USDA – October 21, 1992	Control foodborne pathogens 3.0
Refrigerated and frozen uncooked beef, lamb, goat, and pork	FDA – December 3, 1997 USDA – February 22, 2000	Control foodborne pathogens and extend shelf life 4.5 (refrigerated) 7.0 (frozen)
Fresh shell eggs	FDA – July 21, 2000	Control salmonella 3.0

Source: 21 C.F.R. 179.26 (Apr. 1, 1999, ed.) and FDA and USDA/FSIS officials.

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4.5 Food Handler's Certificates. In the United States, assign a finding 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's certificates.

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

4.7 Change in Establishment Location (Relocation). Advise the management to follow procedures for requesting an Initial sanitation audit. The new establishment will not be *Worldwide Directory* listed until approved by the MACOM Veterinarian or local list approval authority.

4.8 Sanitation Audit Frequency. Frequencies will be in accordance with AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116 and command policy memorandums. Quarterly is defined as every ninety days. Semi-Annual is defined as every 180 days. Annual is defined as every 365 days. The MACOM Veterinarian will dictate the time frame for the completion of all commercial sanitation audits within their respective area of responsibility (AOR). Frequencies of audits may be reduced IAW AR 40-657 and current MACOM policy.

4.9 Use of Documents. Appendix A, General Provisions, is the base document for use when conducting a sanitation audit for all establishments. Use the General Provisions in conjunction with the appropriate appendix located in this handbook. When a product does not have a specific supporting appendix, use Appendix A. Additional documents incorporated by reference are authorized for use. The possibility exists that more than two appendices are required as references for the conduct of an audit; for example, canned seafood requires the use of Appendix A, General Requirements; Appendix H, Fish & Fishery Products and Appendix T, Low-acid Canned Foods. See paragraph 5.1.2.

4.9.1 Appendix A Subparts. Subparts are utilized in conjunction with all other appendices to assign finding codes. When a finding is identified in a specific appendix, the finding codes correspond back to the Subpart(s) in Appendix A. For example, the E5 finding identified in Appendix B "Sifter screens will be minimum mesh to allow passage of product" corresponds back to Appendix A, Subpart E (Raw Materials and Operations) "Methods to exclude physical contaminants are established and monitored (21 CFR 110.80(b))". In this example the governing reference for 21 CFR 110.80(b) is the Code of Federal Regulations, Title 21 Part 110. The parenthetical reference in the specific appendix is tied back to the governing reference and cross-referenced to the Finding codes in Appendix A. The ability to cross reference back to Appendix A allows for automated data search and trending.

4.9.2 Sanitation Audit Report – Scoring Findings. Findings are scored as: Critical (C), Major (M), or Observation (O). It is possible to have multiple 'unrelated' findings with the same reference code listed (scored) separately. For example, an auditor is auditing using Appendix F

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and notes the following findings: (1) All openings into product or onto sanitized product-contact surfaces are not capped and (2) Products are not pasteurized in accordance with time/temperature tables. These findings may be recorded on the SAR as two separate E2 findings. It is also possible to have multiple 'related' findings listed under the same score (i.e., Observation, Major, or Critical).

If an establishment has implemented a HACCP or Food Safety plan, whether it is mandated or voluntary, findings will be assigned under Appendix A, Subpart H.

5. AUDIT PROCEDURES FOR SANITATION AUDITS

5.1 Planning, Scheduling, and Conducting the Sanitation Audit. It is essential to perform a thorough sanitation audit of establishments that provide subsistence to U.S Forces. The key to a successful audit is preparation and planning. Auditors must ensure that they are familiar with the product being processed or produced, the conditions that it is being processed or stored under in the establishment, and the basic requirements followed in the industry to safely produce and/or store the final product.

It is the auditor's responsibility to determine and evaluate the establishment's Approach, Deployment & Results (ADR), as it relates to food safety. One way to do that is using the "Tell me, Show me, Verify" concept of auditing. The auditor observes the operations and practices in the establishment, reports findings and makes a recommendation to the commander. The commander will then, in turn, take action appropriate action based on the audit to 1) list, 2) de-list, or 3) allow the establishment continued listing in the *Worldwide Directory*, as appropriate.

- Tell me – Determine the establishments' approach to food safety through interviews and food safety program document review (HACCP plan or similar).

- Show me – Observe the actual production of the item(s) being manufactured, processed or stored and the proper implementation and deployment of food safety controls/factors; e.g., CGMPs, CCPs, public health controls, etc.

- Verify – Review production records and results: CCP monitoring, corrective action reports, quality control checks, food safety records, lab-sampling results, etc.

5.1.1 Scheduling the Sanitation Audit. Sanitation audits are normally announced and scheduled. Refer to AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116 for exceptions. For Initial sanitation audits, the completed Pre-audit Questionnaire (PAQ) is required from the establishment prior to scheduling the audit. Review the PAQ for completeness, problem areas and determine if the products produced are required to be Directory listed. The auditor will schedule the audit by mail, e-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, ensure the establishment is operational and producing requested products on the day of the audit, and finally, re-confirm audit date.

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5.1.2 Assemble and Review all Reference Materials. References will include as a minimum: MIL-STD-3006C, MIL-HDBK-3006C, procedures, applicable appendices, reference documents, current MACOM Microbiological and Chemical Guidance/Tolerance Levels for products, previous audits, CAR(s), laboratory results, etc. An "Audit Appendix - Food Item Cross-Reference Chart" (Figure 1) has been provided as a guide concerning which appendices could be used to audit commercial food establishments for various food items when listing is required in the *"Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement"*, VETCOM Circular 40-1. Listing requirements vary based on worldwide location, at the discretion of the responsible MACOM Veterinarian.

The chart lists the "Potential Appendices to be Used" for a particular food item, however not all of the potential appendices may be required for a particular food item audit. Additionally, auditors may not be able to determine which one of several potential appendices will be used (e.g., D versus F, or both) until the manufacturing process is fully understood. If questions still exist as to which appendix is to be used for a particular item (to include new food items) or clarification concerning unique manufacturing processes, contact the MACOM Veterinarian for guidance.

Note: Reference materials are available in Lotus Notes.

5.1.3 Pre-audit Preparation. Review the audit folder and have a basic understanding of the establishment's food safety program before arrival at the establishment. For Initial and as required, Routine sanitation audits, the auditor may need to obtain specific information (to include pictures) regarding items produced, equipment or other information by searching the internet (e.g., Google, Yahoo, etc.). This helps gain a better understanding about the establishment and the process prior to arrival at the establishment.

Develop an audit plan (outline or checklist) that includes the things that must be reviewed during the audit (e.g., water potability, most recent reports from other agencies, pest control records, etc.). Make notes on a "working" copy of the previous sanitation audit report, especially in the methodology and administrative areas and highlight information that should be verified or further clarified during the audit. Draft an outline that can be followed as a basic script during the pre-audit meeting. Being well prepared for the audit is a professional approach and sets the right tone from the very beginning.

- Print out the establishment's actual listing as it currently appears in the *Worldwide Directory.*
- Develop a checklist of documents for review.
- Print a copy of the last audit report (Final) for the audit POC and a "working" copy to keep notes on. Identify areas for further questioning/investigation.
- Prepare pre-printed or Draft SAR (database or Word version) to capture the "Findings" on before leaving the establishment.

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5.2 Performance of the Sanitation Audit.

5.2.1 Arrival at Establishment. Upon arrival at the establishment, auditors may be asked to show identification and to sign in on a visitor's log or roster. The establishment may also require auditors to wear a badge, a different color smock or hat, or some other means to distinguish visitors from employees. Many establishments will require all visitors to sign a statement acknowledging a basic understanding of GMPs. Ensure that auditors remove all loose items in pockets above the waist (especially smock pockets) and all jewelry including watches, rings with stones (plain wedding bands are generally acceptable) and ladies should remove their earrings. Auditors should properly wear hair restraints, step in footbaths (as required) and immediately wash their hands upon entering the processing area.

5.2.2 Refusal of Entry. Auditors may encounter situations where an establishment's representatives refuse to allow access to the establishment, refuse open access to operational areas of the production area or refuse access to documents. This is a delicate situation that must be handled carefully and diplomatically by the auditor as the end result may be removal of the establishment from the *Worldwide Directory* and an immediate suspension of product deliveries.

In this situation, an auditor should explain to the audit escort or management the requirements for open access and the possible implications associated with delisting. This may include loss of current and future DOD business and the requirement for the establishment to submit a new initial sanitation audit request. Often, a thorough description of the implications is enough to encourage the establishment to cooperate and allow open access to the establishment and the review of documents.

In some cases, corporate policy may require requests in writing to review documents (e.g., establishment's production and laboratory records, HACCP plans etc.). Management must follow specific corporate rules, since in many cases; establishment representatives do not have the authority to release records without approval from corporate headquarters or corporate legal counsel. If the auditor is aware of such policy, the auditor should submit the request before arriving at the manufacturing establishment to ensure records are accessible during the audit.

If establishment representatives continue to refuse access or otherwise fails to cooperate, it is appropriate for the auditor to contact their chain of command to explain the circumstances and get the commander's guidance on how to proceed.

5.2.3 Confidentiality. Auditors are required to maintain the confidentiality of specific procedures, processes, ingredients, formulations, trade secrets, food defense plans and other proprietary information that they become aware of as a result of the audit. Auditors may be asked to sign a confidentiality agreement indicating that they will not divulge trade secrets or other proprietary information. It is appropriate to sign the confidentiality agreement. Assure the audit escort that auditors will not disclose their proprietary information. During the audit, auditors must also resist any inquiries by the establishment representatives to discover "how other establishments do it."

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After the audit, auditors should limit their discussion of proprietary information to parties that have a need to know as part of their official duties (audit review chain). Failure to protect proprietary information may be a violation of the U.S. Code and may be punishable under the Uniform Code of Military Justice or applicable service regulations.

5.2.4 Harassment or Abuse. Under no circumstances should an auditor be forced to endure harassment or abuse from establishment representatives. Auditors that feel they are being verbally abused, harassed or otherwise treated improperly have the option of terminating the audit at their discretion. This may include, but is not limited to, discrimination based on race, color, religion, national origin, and gender (including sexual harassment).

Under these circumstances, the auditor should excuse himself or herself from the establishment and consult telephonically with the chain of command.

5.2.5 Pre-audit Meeting. The auditor will notify management immediately upon arrival and conduct the pre-audit meeting. It is important to be prepared for the pre-audit (or opening) meeting. It is common for company executives to attend the pre-audit meeting – especially during an initial sanitation audit. Be confident and courteous; project a professional image and demonstrate that you are well versed in both the audit process and the production of the item. Be prepared to exchange business cards and to discuss the audit steps, scope and possible results. Carefully describe your role as an auditor (fact finder) and the roles you play in the process (observe, report & recommend). During this meeting discuss and review:

- Scope of the audit.
- Contents of the Pre-audit Questionnaire.
- Applicable standards.
- Process methodology.
- The plan for conducting the audit.
- Areas to be audited.
- Sequence of areas to be audited.
- Previous sanitation audits if applicable.
- Results of other agencies' audits/inspections.
- Food safety/defense program:
    - Sanitation Standing Operating Procedures (SSOP's).
    - Pest management program.
    - HACCP program if available.
    - Food safety program.
    - Food defense program.
- Requirements for laboratory analyses.
- Interviews with various establishment personnel to obtain objective evidence.
- Establishment representative's cognizance of all establishment production operations.
- Pertinent rules of audit results:
    - Scoring methods (severity of findings, effect on rating of establishment and *Worldwide Directory* listing).
- Corrective actions (on the spot vs. post-audit):

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- Establish a time and location for the post-audit meeting and, if necessary, the requirement for the CAR(s).

Additionally, you might follow this basic script, especially when the formal meeting has concluded and you are working with the audit escort or POC:

- Review the establishment's listing in the *Worldwide Directory* to ensure all information is correct and that all necessary changes from the last audit were correctly made. Have them verify the company name, address, phone number and email address. Ensure that plant establishment is listed for the products being produced. Capture changes for submission with the final audit report in the Remarks section of the sanitation audit report. During the audit, it may be necessary to explain the requirements for *Worldwide Directory* listing. Establishments who produce multiple items should understand that not all products require listing and this should be explained clearly to the establishment so as not to imply that certain non-PHF items or products which are under another federal agency's jurisdiction are not approved or eligible for sale to U.S. Forces.

- Present a printed copy (stamped: FINAL) of the last audit report. Review the administrative information and the Methodology to determine if there are any misrepresentations in the previous audit and to determine if there have been any changes to the process, the food safety plan (HACCP), chemical or raw material supplier(s), pest control operator, etc.

- Discuss an approach to the audit. You may find that you want to perform the document review first and then do the tour of the establishment, or you may prefer to do the walk-through to get the "macro-view" of the operation if this is your first visit.

- Present a pre-printed list of documents that you would like to review during the audit. By doing this, you give the audit POC an idea of the scope and depth of your audit and you avoid sending the audit POC all over the establishment to collect documents one at a time. Together, you and the audit escort can decide where, when and how it is easiest to accomplish the document review. You may find that you need to review the lab documentation in the laboratory when you get there during the tour, or the audit POC may already have all of the documents you need staged in his or her office or in a conference room. Additionally, by giving the audit POC a copy of the list early in the audit, they can dispatch an assistant to collect any documents that were not previously pulled or prepared for the audit. These documents may include, but are not limited to the HACCP or food safety plan, training records (human resources), back-flow certification inspections or filter changing schedules (maintenance), brand names (sales), laboratory records (QA office or lab), pest control records, etc.

- Discuss areas to be visited, the flow of the walk-through (raw to finished, or finished to raw), special considerations (safety), etc. Confirm hours of operations and make necessary changes to the audit schedule to ensure areas to be audited are in operation.

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- Confirm housekeeping needs. Discuss and decide on office space for the auditor and audit team as well as provisions for phones, clerical assistance, copiers, etc. Determine meal times and locations. Discuss other special needs that may contribute to a smooth audit.

5.2.6 Conducting the Audit - Document Review. Many establishments have numerous documents that you may want to review during the audit. Auditors must exercise caution during document review. You should review enough documents to develop confidence in the establishments approach to food safety. However, a good set of documents does not always guarantee that the product is safely manufactured on the production floor. Do not spend four hours of a five or six-hour audit reviewing documents and then only spend 30 minutes walking through the establishment. A thorough physical inspection of the establishment is important and auditors should budget enough time during the audit to spend some time observing operations (production, cleaning and sanitizing, etc.). Documents reviewed during the audit may include, but are not limited to:

- Water Potability & Safety
  - "Absent for Coliforms", IAW paragraph 3.3.1 of this handbook
  - Statement of Compliance with Title 40, Part 141 (from Municipal water purveyor, or for a sample drawn from well-water)
  - Back-flow Prevention Device Inspection Reports

- Inspection Reports from Other Agencies
  - FDA, USDA, State Department of Agriculture, Ministry of Health (OCONUS)
  - Third-party audit results or other customer audits

- Laboratory Sampling Results (internal and external)
  - Incoming or Raw Materials and Finished Product
  - Food Contact Surfaces (Sanitation Monitoring)
  - Environmental Sampling (Drains and floors for Listeria spp., Coliforms, Aerobic Plate Count (APC), etc.)

- Sanitation Monitoring Records
  - Pre-operational inspection
  - Rapid methods (ATP Bioluminescence)

- HACCP or Food Safety Plan Documents
  - Hazard Analysis & Master Plan
  - Critical Control Point Monitoring Records
  - Current Good Manufacturing Practices (CGMPs)
  - Sanitation Standard Operation Procedures (Instructions)
  - Master Cleaning and Sanitation Schedule and Records
  - Equipment Maintenance Schedule and Records
  - Recall Procedures and Mock Recall Results
  - Allergen Control Program

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- Verification and Validation Activities/Meetings

- Pest Control Operator's Book
  - Applicator's License for Contractor
  - Layout of Bait Stations/Traps/Insect Lights
  - Monitoring Records/Inspection Reports (Activity, Chemical Application, etc.)

- Employee Handbook
  - Good Manufacturing Practices (GMPs)
  - Training Materials and Records (Credentials)

5.2.6.1 Water & Sanitary Plumbing. The source and safety of the water used in the establishment is of paramount concern. Water is used in many facets of production (as an ingredient, in cleaning & sanitizing, as a cooling agent, etc.), and can have a significant impact on the safety of the final product.

The basic premise of sanitary plumbing is to ensure that potable water is not contaminated by non-potable water. By isolating hazards, an establishment can ensure that there are no cross-connections between potable and non-potable water. Typically, this is accomplished by ensuring there are adequate air gaps (physical gap of NLT ½ the diameter of the pipe, or NLT 1 inch (2.54 cm)) or that there are appropriate back-flow prevention devices in place.

The FDA and the EPA have manuals available that describe the basics of sanitary plumbing, the different types of devices and their specific uses, and guidance that you can use to determine if the establishment is following good sanitary plumbing practices. Additionally, the FDA State Training Branch offers course material in sanitary plumbing and cross-connections in conjunction with dairy and shellfish training. This type of training may also be available locally through the health department or water purveyors.

Carefully weigh the severity of findings related to water, especially if water is the main ingredient in the final product (e.g., ice, bottled water, juice, rehydrated milk products, etc.). For example, water that is only used for cleaning and sanitizing must still be "safe" (absent for coliforms).

5.2.6.2 Inspection Results from other agencies. Auditors should perform a document review of reports from other agencies that also audit the establishment. This may include reports from the FDA, USDA, the state Department of Agriculture, the local health department (especially caterers & restaurants), the Ministry of Health or similar agencies (OCONUS), and customer audits or third-party auditors. During the review, note trends or areas that may merit additional attention during your audit. Record the agency, date of audit and results (score or summary) and include this information on the final sanitation audit report.

5.2.6.3 In-house Laboratory. In CONUS, a full audit of the laboratory is probably not practical during most routine sanitation audits. However, a review of the laboratory programs,

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basic procedures, laboratory results and corrective actions taken due to nonconforming results is appropriate. Laboratory audits OCONUS will be IAW MACOM Veterinarian guidance.

Scoring findings in this area requires significant consideration of the public health risks associated with the problem area. For example, a high APC count in a fresh-cut FF&V product may not trigger a significant response from the laboratory. However, a positive laboratory result for a pathogen should always result in appropriate corrective action by the establishment to mitigate the risk associated with that product. The reaction may include, but is not limited to: reworking the product (rewashing), diverting the suspect product to another line (where it is cooked or baked) or to another establishment, confirmatory testing by an outside laboratory, product hold pending further action/review or a recall of product that was already shipped.

5.2.6.4 Sanitation Monitoring Records. Many establishments may perform in-house sanitation monitoring. Sanitation monitoring may include food contact surfaces, non-food contact surfaces and environmental sampling or drains for *Listeria* spp., *E. coli.*, APC or coliforms (as indicators). Sanitation monitoring may be accomplished on-site in a fully equipped laboratory, using rapid testing equipment (e.g., bioluminometers for ATP) or by submitting samples to a third-party laboratory. Although it is not standard practice, there may be occasions when you may want to conduct side-by-side sanitation monitoring with the establishment using your own rapid testing equipment. Request permission to use your equipment and carefully explain the results so that the establishment can take any information obtained from your testing to improve the overall sanitation of the facility.

Review procedures, operating or critical limits and records of results. Use records to identify trends and areas of the establishment that have proven, historically, more difficult to clean. Review the establishment's immediate response procedures (reclean, resanitize, retest) and long-term corrective actions. Summarize the sanitation-monitoring program in the methodology and assign findings as appropriate (failure to respond to nonconforming results IAW company policy) or an inappropriate response to finding a pathogen of public health concern (no records of recleaning, appropriate remedial action or product recall).

5.2.6.5 Hazard Analysis Critical Control Points (HACCP). HACCP exists primarily in two forms in audited food establishments – mandated and voluntary. While the seven principles of HACCP are universally accepted, especially under the Codex Alimentarius Commission (Food and Agricultural Organization [FAO], and the World Health Organization [WHO]), there is wide variation within the industry in the development and implementation of HACCP programs, including the development and deployment of prerequisite programs, critical control points, monitoring and records.

HACCP is mandated by law in the Code of Federal Regulations and required by Military Standard 3006 in three types of establishments (below). All other establishments using HACCP have a voluntary HACCP program.

1. Meat & Poultry – Title 9, Part 417
2. Seafood (Fish & Fishery Products) – Title 21, Part 123
3. Juice – Title 21, Part 120

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Note: All commercial processors of low-acid canned foods and acidified foods are required to register their establishments and file processing information for all products with the Food and Drug Administration, using appropriate forms. Registration and process filing are required for both U.S. establishments and those in other countries that export such foods to the United States (Title 21, Part 108).

HACCP is covered at length in numerous other references and courses. Auditors should receive HACCP training (formal or on the job) in preparation for performing independent audits of establishments with HACCP programs. This training is extremely important when auditing establishments without a HACCP program because it prepares the auditor to look for and verify critical aspects within the establishment. It is important for auditors to be able to identify the different requirements in each type of establishment and to be able to make decisions regarding the public health and food safety controls that impact the safety of the final food product.

5.2.6.6 Pest Control. Integrated Pest Prevention (IPP) is a program combining the principles of proper sanitation (housekeeping, personnel practices, & storage of subsistence), proper physical design of facilities (physical barriers), employment of non-chemical and mechanical barriers, and chemical pesticides (including insecticides and rodenticides).

Many establishments will contract IPP to a licensed Pest Control Operator (PCO). Often, you will find bait stations on the exterior and perimeter of the establishment; and a combination of mechanical traps (tin cats, Ketch-alls, etc.), insect light traps (ILTs), and pheromone traps (dry storage areas) on the interior. Auditors should review documents mentioned in the list above and should review monitoring records to identify trends. For example, if interior mechanical traps 23, 24 and 25 have frequent activity, the auditor should find these traps during the physical inspection of the establishment and try to determine what conditions contribute to the activity (e.g., open doors, improper seals around pipes, plumbing or electrical outlets, poor sanitation, etc.). Then the auditor should properly assign the finding to the root cause (B2-Building structure and design, B3-Inadequate sanitation practices, B6-Missing screens, etc.).

Pesticides should be approved by the Environmental Protection Agency (http://epa.gov/oppad001/chemregindex.htm) or local regulatory authority in OCONUS locations for use in and around food processing establishments. The means to verify compliance is by reading the labels on the pesticides or other instructions provided by the manufacturer and should be available for review at the time of the audit.

5.2.6.7 Employee Handbook and Training. All employees involved in the production of food must be familiar with the basic principles of safe food handling. This includes, but is not limited to: employee health and personal hygiene, wearing clean outer garments, proper handwashing, and protection of food products, ingredients, single-service articles and equipment from contamination by employees. Employees may receive formal training in a classroom setting or may be trained on the job. Local jurisdictions may have a requirement for food handler training (verified by cards or certificates) or an employee health certificate as a result of a medical examination (usually overseas for Hepatitis screening, etc.).

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Auditors can determine compliance by observing employee habits and practices, by interviewing employees during the audit or by a review of employee records (personnel or training). Both permanent and temporary employees should receive training in GMPs. Some establishments may have employees sign a statement indicating they have received or reviewed a copy of the employee handbook and that they understand the GMPs. Ensure that training materials, handbooks or procedures are available for employees that speak different languages. This may be accomplished by the use of bi-lingual supervisors or trainers or through the use of signage that uses pictures in lieu of words.

5.2.7 Conducting the Audit – Walk-through Audit. Conduct the sanitation audit in the presence of management or a designated representative. Ask the audit escort if there are any special considerations (e.g., safety, path from raw to finished or finished to raw, etc.) for the walk-through of the establishment. Auditors should ensure that a representative from the establishment stays with them throughout the audit so that the escort can alert the auditor to hazards, field questions and witness any potential problems that may be scored on the final report as a finding. Ensure that audit team members follow the GMPs and set a good example. Always ask before touching any equipment or product - you don't want to flip a light switch and end up shutting down the entire production line.

During the walk-through of the establishment, be alert and observant and attempt to identify areas where the food could become inadvertently contaminated or adulterated by employees, the physical facilities (including the environment), production practices or equipment. This is especially important between the final processing step (assembly, cooking, etc.) and packaging of the product.

Spend some time watching the employees; some auditors do not dedicate enough time to simply watching employees during sanitation audits. Observe the employees as they return from the restroom or break, as they work at their station on the line or as they move between tasks. Observe that employees wash their hands anytime they may have become contaminated or when they move from handling raw product to finished product. Ensure that employees have their hair restrained, are properly dressed in clean outer garments and are not wearing loose jewelry.

Inspect objects and equipment for condition and cleanliness during the audit. Carefully inspect cleaned food contact surfaces for food debris and the product contact surfaces of cleaned equipment for inadequate cleaning or build-up of food residue. Attempt to identify where ingredients, work in process (WIP) or finished product may become contaminated by splash, drip or condensation. Troubleshoot the operation and ask open-ended, scenario-based questions that elicit a thoughtful, descriptive response from the audit escort.

Evaluate the following phases of the system, as necessary to ensure compliance to food safety/defense:

- In the pre-operational phase, focus on the effectiveness of the cleaning and sanitizing program, e.g., Rapid Method analysis, Swabbing, etc.

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- 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.
- Recall program. Most establishments will have a written plan for conducting recalls and many will test or challenge their recall program using scenario-driven mock recall events. Review the recall procedures, which normally identify the recall team members and their roles, immediate corrective action, long-term corrective actions and other agencies that may require notification (usually a roster with agency names and phone numbers). The plan may also include a protocol for notifying the media and the public. Additionally, ensure that you review the results and efficacy of the recall (e.g., "3271 cases, 100% recalled within two hours" or similar) and record the results in the appropriate section of the sanitation audit report.
- Conduct a thorough review of the laboratory program.
  - All establishments are subject to laboratory testing IAW AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116.
  - Evaluating Laboratory/Quality Control Programs. Utilize a laboratory checklist for those establishments that have laboratories within their establishment. Laboratory checklists will be developed for use by the MACOM Veterinarian. Review the laboratory reports for those establishments that utilize independent laboratories. Products identified as nonconforming based on laboratory analyses should have procedures established for corrective action and records of the action taken.
- Laboratory samples.
  - All establishments are subject to laboratory testing IAW AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116.
  - Selection of samples for laboratory analyses is normally performed during an Initial, Directed Routine or Special sanitation audit. Auditors may pull samples at their discretion during an audit when they feel there may be a need for further analysis to determine compliance or to add new items to the establishment's *Worldwide Directory* listing. Auditors should ensure that samples are properly handled during selection, transport, packing and shipping to prevent possible contamination, adulteration or temperature abuse of the samples.
  - Additionally, auditors should encourage the audit escort to pull stand-by or duplicate samples for submission to their own laboratory. Samples are prepared and shipped IAW the Department of Defense Food Analysis & Diagnostics Laboratory (DOD FADL) Lab Sample Submission Guide (available via the DOD FADL web page) or guidance provided by the appropriate supporting laboratory (OCONUS). The auditor may provide results of laboratory sampling to the audited establishment electronically (electronic mail or FAX) or in conjunction with the next routine sanitation audit.
- Additional auditor guidance.

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- Once initiated, complete the sanitation audit regardless of the severity and number of findings noted when conducting the audit.
- Keep the management representative fully aware of what is being observed and recorded.
- Discuss positive as well as deficient conditions noted throughout the audit.
- Document observations (potential audit findings) and obtain objective evidence to determine compliance or noncompliance. Collect objective evidence through interviews, physical observations, measurements, and examination of documents.
- If appropriate, a finding that is corrected on-the-spot may be scored as an Observation when it no longer presents a food safety/defense hazard and is not systemic.

5.2.8 Scoring Findings. Auditors must rely on their education, training and professional judgment when scoring findings. Careful consideration must be given to the severity of the finding and the public health implications that the finding has on the overall safety of the product.

The Sanitation Audit rating is based upon both food sanitation and food defense. The sanitation audit will be rated either "Acceptable" or "Unacceptable". A Critical finding in either system will result in an Unacceptable rating. More than three Major findings will result in an Unacceptable rating. Observations will not result in an Unacceptable rating; however, the cumulative effect of multiple observations indicating an out-of-control process may require an upgrade to one Major finding, due to the increased public health or food defense significance.

It is possible to have multiple ‘unrelated’ findings with the same reference code listed (scored) separately. For example, an auditor is auditing using Appendix F and notes the following findings: (1) All openings into product or onto sanitized product-contact surfaces are capped, closed, or adequately protected, and (2) Fill line connections are made to tank fittings to ensure that and tank lids are not propped open during filling. These findings may be recorded on the SAR as two separate C6 findings.

It is also possible to have multiple ‘related’ findings listed under the same score (i.e., Observation, Major, or Critical). It is recognized that not all items (bullets) listed in the checklist may apply to a certain establishment. These items are therefore considered "NA" (Non-applicable) by the auditor.

It is important to consult with the Unit Commander, warrant officer or designated representative before assigning a Critical finding or an Unacceptable rating (more than three Majors). If neither of these resources are available, it is appropriate to call another auditor or to ask for guidance from higher up the chain of command (within the audit review chain) IAW unit policy.

5.2.9 Draft Audit Report Preparation. It is appropriate (and common practice) to ask your audit escort for a place to prepare your draft report and to confer with your co-auditor(s). This gives you the opportunity to: organize your notes and thoughts, identify and consider

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findings, discuss your findings with your co-auditor, plan the post-audit meeting or, if necessary, consult telephonically with your commander or warrant officer.

5.2.10 Post-audit Meeting. During the post-audit meeting, company executives or even the owner of the establishment may be present. Be prepared to describe the results of the audit and answer any questions for the personnel present. Auditors must be firm and confident when describing findings during the post-audit meeting. In some circumstances, establishment representatives may present new objective evidence during the closing meeting (e.g., a copy of a document that could not be immediately located earlier during the audit) and the auditor may find that it is appropriate to remove the finding from the draft sanitation audit report. Some personnel from the establishment might be defensive and try to talk you out of scoring findings. Be firm, but fair and consider all counter-points and evidence being offered.

Auditors should prepare, review and leave, at a minimum, a copy (hand-written if necessary) of a draft Sanitation Audit Report (Figure 2) listing the key administrative information (date, results, recommendations), findings, and as required, any CARs (Figure 3) for all Initial, Routine, Special, and Directed Routine audits, prior to departing the establishment. Some auditors prefer to leave a handwritten copy of the SAR, while others prefer to draft the report on their laptop and print out a draft using a portable printer. Ensure that your electronic equipment is in proper working order before attempting this (power cords, ink, paper etc.). It may be a good idea to carry a paper copy of a blank SAR and CAR in case you experience technical difficulties when preparing the report. Unit procedures will describe exactly what the minimum requirements are, as established by your commander or the MACOM Veterinarian.

Present a copy of the draft report and review the findings. Explain the scoring and classification of each finding and carefully explain the severity; place special emphasis on any failure of public health controls. Do not make specific recommendations for corrective actions; however, guidelines for the steps necessary to meet the standards may be discussed. Describe the recommended result of the audit (Acceptable or Unacceptable) and all follow-up actions. Explain your recommendation as to whether the establishment will or will not be listed (initial and special sanitation audits), or if the establishment will remain listed in the *Worldwide Directory*. Advise management that a sanitation audit report will be sent, and projected time line. Conclude the post-audit meeting politely, formally and professionally and discuss positive comments (if possible) to ensure good relations are maintained between representatives of the Government and industry.

Additional points to address when CAR's are assigned:

- Prepare CAR(s) for Critical and Major Findings on all Initial, Routine, Special, and Directed Routine audits resulting in an "Unacceptable" rating.
- Prepare CAR(s) for all Findings (Critical, Major, and Observations) on Initial audits resulting in an "Unacceptable" rating. On Initial audits resulting in an "Acceptable" rating, the requirement for the issuance of CAR(s) for Observations will be per MACOM Veterinarian guidance.
- Prepare CAR(s) for Major Findings on all "Acceptable" audit ratings.

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- Prepare and sign Part I of the CAR(s) (to include management signature) and leave the original with the establishment. If management will not sign the CAR(s), leave an unsigned original.

Additional points to address when Unacceptable ratings are assigned:

- If the establishment is rated "Unacceptable" during an Initial or Special audit, advise management of procedures for re-applying for *Worldwide Directory* listing and potential time lines. Refer to AR 40-657/NAVSUPINST 4355.4F/MCO P1010.31G or AFI 48-116 for instructions to reapply for Initial re-audit.
- If the establishment is rated "Unacceptable" during a Routine or Directed Routine audit, advise management of the requirement for a Special audit, potential for removal from *Worldwide Directory* listing and projected time lines. Additionally, discuss the potential for delivery suspension.

Additional points to address when laboratory sampling is conducted:

- When samples are selected as a part of an audit, notify management that any significant laboratory results will be considered when determining the establishment's final rating. Nonconforming results determined by laboratory analysis, customer complaints, destination sampling, etc., may result in suspension or removal from *Worldwide Directory* listing. Auditors should advise the establishment to pull their own stand-by samples for establishment testing in conjunction with DOD Veterinary Laboratory analyses.

5.2.11 Courtesies and Gifts. Auditors may find situations where establishment representatives offer them drinks, meals, or product samples. Auditors are authorized to accept items that are offered to the general public, within limits set by Department of Defense and Army regulations and unit or command policy. This is normally limited to water, coffee or similar refreshments to be consumed during the audit. Auditors should be cognizant of local customs, courtesies and social niceties (especially OCONUS) and carefully exercise good judgment. As a basic rule of thumb, auditors should politely refuse anything offered to them during an audit due to the perception that gifts may influence the auditor's report or that an auditor may be able to influence current or future business with the Government.

Auditors are NOT authorized to accept gifts of significant monetary value, vouchers, tickets, money, "extra" product samples or any other item of value that may be perceived as a bribe. Auditors should consult with their chain of command, unit policy letters or their ethics counselor for additional information or guidance.

6. REPORTING PROCEDURES

6.1 Initial, Routine, Special, and Directed Routine Sanitation Audit Reports. Sanitation Audit Reports are distributed as follows:

- Sanitation Audit Report. Distributed per MACOM Veterinarian guidance.

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- Corrective Action Request(s) (if required). When returned (Part 2 completed) from the establishment, the auditor will complete Part 3, and return a copy to the establishment.

7. NOTIFICATION GUIDANCE FOR UNACCEPTABLE SANITATION AUDITS

7.1 Immediate Notification. Prior to the post-audit meeting the auditor will immediately notify their Unit Commander, warrant officer or designated representative when an establishment receives an "Unacceptable" rating. The auditor will provide information describing all audit findings, current contracts (e.g., purchasing agencies, contract or purchase order numbers, expiration dates of the contracts, items being delivered, and destinations), and make recommendations concerning delivery suspension. The Unit Commander or his designated representative will immediately notify the MACOM or local list approval authority with a recommendation to suspend or not suspend deliveries. The MACOM or local list approval authority makes the final decision on delivery suspensions. If the approving authority concurs with the delivery suspension recommendation, the Unit Commander or designated representative will take the applicable actions described below. See paragraph 5.2.10 for additional points to address.

7.1.1 Unacceptable Routine or Directed Routine with Delivery Suspension.

7.1.1.1 Agencies Notification. Notify all major purchasing and contracting commands (e.g., DeCA, NEX, AAFES, DSCP, etc.) and local purchasing and contracting offices (e.g., base MWR contracting, G-4 contracting officials, Navy contracting, etc.) if the establishment is a subcontractor on a contract or an active bidder on current solicitations. Advise the purchasing agencies in writing (electronically, mail, or fax) of the impending Special sanitation audit and a possible supply failure if the establishment does not pass the audit (receive an Acceptable rating).

7.1.1.2 State and Local Notification. Before conducting the Special sanitation audit notify the appropriate regulatory, military, and other agencies of delivery suspension. Invite regulatory agencies to participate in the Special sanitation audit.

7.1.1.3 Delivery Suspensions. Delivery suspensions will remain in effect until completion of a Special sanitation audit. Special sanitation audits will determine approval or disapproval for continued listing in the *Worldwide Directory* or local list.

7.1.1.4 Interstate Milk Shippers (IMS) List Deletions. The Food and Drug Administration (FDA) notifies the DOD Approved Source Division whenever an IMS listed dairy receives a revised rating that is less than 90. The Federal or State agency will not re-audit for a minimum of fifteen (15) days. The dairy establishment will remain in a non-approved status until a rating of 90 or higher is received. Deliveries are suspended.

8. STANDARDIZED FORMATS AND INSTRUCTIONS

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8.1 Notification Letter to the Establishment of an Upcoming Sanitation Audit. Figure 4 provides a standardized format for an Audit Notification Letter to the establishment informing them of the upcoming Initial audit. Figure 5 provides a standardized format for an Audit Notification Letter to the establishment informing them of the upcoming Routine, Special or Directed Routine audit.

8.2 Pre-audit Questionnaire (PAQ). Figure 13 lists the information necessary to request/process Initial sanitation audit requests and to update records (if required) prior to Special or Directed Routine sanitation audits. In OCONUS locations, the MACOM Veterinarian may authorize modifications to the PAQ to meet specific needs.

8.3 Letter to the Establishment. Figure 6 provides a standardized format for an Audit Results Letter informing an establishment of the results on an Acceptable or Unacceptable Initial sanitation audit. Figure 7 provides a standardized format for an Audit Results Letter informing an establishment of the results on all Acceptable Routine, Special, and Directed Routine sanitation audits. Figure 8 provides a standardized format for an Audit Results Letter informing an establishment of the results on Unacceptable Routine and Directed Routine sanitation audits. Figure 9 provides a standardized format for an Audit Results Letter informing an establishment of the results on all Acceptable sanitation audits with an optional Corrective Action Request Statement. Forward the Audit Results Letter along with the sanitation audit report to the establishment per MACOM Veterinarian guidance. This letter becomes a part of the audit packet.

8.4 Request for Removal from the *Worldwide Directory*. An establishment may be recommended for deletion or removal from *Worldwide Directory* or Local listing due to other than unsanitary conditions. For establishment's that have been inactive less than two years, request for removal will be per MACOM Veterinarian guidance. Establishment's that request voluntary removal from *Worldwide Directory* listing must fill out a deletion request that has been signed by a member of management (Figure 10). The auditor may omit the signed request if the establishment has attained exempt status or has gone out of business and the auditor cannot contact management (Refer to AR 40-657). Use the format outlined in Figure 10 and instructions provided in Figure 11.

8.5 Sanitation Audit Report (SAR). Figure 2 shows the mandatory form to list establishment information, report findings and document methodology.

8.5.1 Methodology Format for Sanitation Audit Report. The corresponding sections contained in the Pre-audit Questionnaire (Figure 13) should be used to develop the written methodology on page 3 of the Sanitation Audit Report (Figure 2). The written methodology should contain summary information obtained from the Pre-audit Questionnaire. The "PROCESS" section will contain a detailed narrative description of the manufacturing process, including identified Critical Control Points (CCP) or key food processing safety parameters (specific time, temperature, pressure, kill steps, pH, Aw, ppm, etc.) A product/process flow chart and detailed narrative that documents the processing steps from receipt of raw materials to the finished product will be included in the sanitation audit report. List major processing equipment, test controls (thermometers, testing strips, etc.), and quality control program (i.e., Statistical

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Process Control (SPC), In-line Inspection Points, etc.). A methodology will be completed or updated during each audit.

8.6 Corrective Action Request (CAR). Figure 3. See paragraph 5.2.10 for requirements.

8.7 Recommendation for Deletion. Figures 10 and 11 provide a standardized format and instructions for a letter recommending removal of an establishment from the *Worldwide Directory*.

8.8 General Laboratory Checklist. Use IAW MACOM Veterinarian guidance.

8.9 Dairy Laboratory Checklist. Use IAW MACOM Veterinarian guidance.

8.10 Food Defense Questionnaire. Figure 14 may be used to evaluate the establishments' food defense program.

8.11 Recommended use of Forms in the Audit Management Database. If a computer is unavailable, Figures 2, 3, 4, 5, 6, 7, 8, 9, and 10 provide examples for use as a template.

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 may be used to identify this handbook during retrieval searches:

Sanitation Audit Report
Corrective Action Request
Auditing Personnel
Initial Audit
Routine Audit
Special Audit
Directed Routine Sanitation Audit
Methodology
Laboratory Audit
Recommendation for Deletion
Request for Removal
Food Safety
Food Defense
Worldwide Directory

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.

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Audit Appendix - Food Item
Cross-Reference Chart

Federal Supply Class (FSC)	****Food Item***	***Potential Appendices To Be Used***
8905	Buffalo meat; Rabbits.	A, M, & Y
8905	Crabs, live; Crawfish, live; Fish, fresh or frozen, whole and/or eviscerated, head on or off, unscaled, unpackaged; Lobster, live; Shrimp, fresh or frozen, processed (including breaded, peeled, deveined); Shrimp, fresh or frozen, whole or head off; Squid and octopus, processed and unprocessed; Salmon, smoked.	A, H & Y
8905	Fish, fresh or fresh smoked, modified atmospheric packaged.	A, H, T & Y
8910	Cream, sterilized; Dairy products, canned and retorted; Eggnog, canned.	A, D, T & Y
8910	Creamer, coffee, dairy; Dairy mixes, powdered.	A, D, N & Y
8910	Dairy mixes, liquid.	A, D, F & Y
8910	Desserts/puddings, frozen (not canned).	A & Y
8910	Egg substitutes.	A, Q & Y
8910	Italian ices and frozen novelties, non-dairy, non-fruit filled.	A, F & Y
8910	Topping, real cream; Yogurt, fresh or frozen.	A, D & Y
8915	Fruits and vegetables, pre-cut pre-packaged, minimum processed, ready-to-eat; Fruits and vegetables, frozen; Kimchee; Salads, non-meat, with or without dressing, not USDA listed.	A, P & Y
8915	Fruits and vegetables, unprocessed, fresh.	A, W & Y
8915	Fruits and vegetables, hermetically sealed.	A, P, T & Y
8915	Juices and nectars, pasteurized, including frozen concentrates and shelf stable.	A, J & Y
8915	Mushrooms, whole; Mushrooms, sliced.	A, R & Y
8915	Sprouts.	A, S & Y
8915	Tofu and soy-based products.	A & Y

FIGURE 1. Audit appendix food item cross-reference chart.

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Federal Supply Class (FSC)	****Food Item***	***Potential Appendices To Be Used***
8920	Bakery and cereal products, baked and unbaked, frozen and fresh; Bakery items filled with meat or dairy cream fillings; Bakery items filled with fillings other than meat and dairy cream fillings; Cake mix, dry; Cheesecakes; Cookie dough, chilled; Cookie mix, dry; Cookies and crackers, unfilled; Dough, frozen or chilled; Dumplings, frozen; Flour; Melba toast; Pancake batter, frozen; Pancake and waffle mix; Pancakes, frozen; Pasta, wet (noodles); Pasta, dry (noodles); Pie crusts, unfilled; Pizza crust, unfilled; Quiche; Taco shells; Tortillas, corn and flour.	A, B & Y
8920	Batter mix, dry; Biscuits, canned.	A & Y
8925	All confectionary, nuts, sugars, and honey.	A & Y
8930	All jams, jellies, and preserves.	A & Y
8935	Soups, frozen or chilled.	A & Y
8935	Bouillon and soups, shelf stable or dehydrated.	A, Y & T
8940	Dietary foods and specialty preparations, specifically: Fish, meat, poultry, dairy, egg, and shellfish products with >3% ingredients of animal origin; Chocolate drink mix, non-dairy; Creamer, coffee, imitation (non-dairy); Dips, non-dairy; Gelatin; Popcorn; Sandwiches, meat and non-meat; Soy drinks; Toppings, non-dairy; All other dietary foods and specialty preparations.	A & Y
8940	Baby formula, canned.	A, T & Y
8940	Cheese, nacho, canned.	A, T & Y
8940	Chips, nacho or potato.	A, B & Y
8940	Cook-chill products.	A & U
8940	Dips, dairy.	A & Y
8940	Eggs, pickled.	A, E & Y
8940	Frozen dinners with meat/poultry; Frozen dinners, without meat/poultry.	A, L & Y
8940	Pizzas.	A, B & Y
8940	Pudding novelties, frozen or chilled.	A, D, F & Y
8940	Pudding novelties, shelf-stable.	A, D & Y

FIGURE 1. Audit appendix food item cross-reference chart – Continued.

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Federal Supply Class (FSC)	****Food Item***	***Potential Appendices To Be Used***
8945	Fats and food oils, including margarine.	A & Y
8950	Condiments and related items, specifically: Salad dressings; All other condiments and related items.	A & Y
8950	Salsa, fresh; Salsa, shelf-stable.	A, P & Y
8950	Olives.	A, T & Y
8955	Cocoa, coffee, and tea, dry.	A & Y
8955	Cocoa, coffee, and tea, ready-to-drink, dairy, canned and retorted.	A, D, T & Y
8955	Cocoa, coffee, and tea, ready-to-drink, non-dairy.	A & Y
8960	Beverages, non-alcoholic, specifically: Beverages, carbonated; Beverages, non-carbonated, to include energy drinks; Water, bottled, carbonated and non-carbonated.	A, K & Y
8960	Fruit drink mix containing no fruit juice.	A, J & Y
8960	Ice	A, K, G & Y
8970	MRE composite food packages.	A & Y
N/A – No FSC	Distributors of products from approved sources, specifically: Storage, Government-owned products; Storage, non-Government-owned products.	A & Y
N/A – No FSC	Caterers	A, L, P & Y

*Note: Food Items listed are based off the VETCOM Circular 40-1, Appendix A. Food items may vary based on worldwide location, per discretion of the responsible MACOM Veterinarian.

FIGURE 1. Audit appendix food item cross-reference chart – Continued.

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SANITATION AUDIT REPORT	
1. VC#/NAME/ADDRESS/PHONE:	**2. UNIT/IRC/ADDRESS/PHONE/AUDITOR/EMAIL:**
3. NAME & TITLE OF THE ESTABLISHMENT'S POC:	**4. ESTABLISHMENT'S OWNER:**
5. DATE OF AUDIT:	**6. TYPE OF AUDIT:** **☐ Routine ☐ Initial ☐ Special ☐ Directed Routine**
7. PRODUCT(S) FOR DIRECTORY LISTING:	**8. OTHER PRODUCT(S) PRODUCED OR STORED:**
9. SAMPLING IS REQUIRED IN CONJUNCTION WITH THIS AUDIT. **☐ Yes ☐ No Are results attached? ☐ Yes ☐ No ☐ Pending**	
10. AUDIT RATING: **☐ Acceptable ☐ Unacceptable**	**11. DELIVERY STATUS:** **☐ Suspended ☐ Not Suspended ☐ N/A**
12. APPENDICES USED AND ENCLOSURES:	
13. OTHER INSPECTION AGENCIES/AUDIT ORGANIZATIONS:	
14. REMARKS:	
15. BRAND NAMES AND POINT OF ORIGIN CODE(S)*: BRAND: CODE: LANDMARK/LOCATION: **EU PLANT CODE*:** *** If code is not applicable or not available, enter None.**	
16. COMPANY ALIAS:	
17. REQUEST FOR REDUCTION:	

FIGURE 2. Sanitation audit report.

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FINDINGS	
ESTABLISHMENT:	**AUDIT DATE:**
SCORE: **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
SCORE: **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
SCORE: **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
SCORE: **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
SCORE: **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
AUDITOR'S TYPED NAME & SIGNATURE	**DISTRICT COMMANDER'S TYPED NAME AND SIGNATURE**

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

FIGURE 2. Sanitation audit report - Continued.

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METHODOLOGY	
ESTABLISHMENT:	**AUDIT DATE:**
PERSONNEL/ADMINISTRATION:	
GENERAL:	
FACILITIES:	
FOOD PROTECTION AND SANITATION:	
PROCESS:	
STORAGE:	
DISTRIBUTION:	
SECURITY:	

FIGURE 2. Sanitation audit report - Continued.

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CORRECTIVE ACTION REQUEST	
1. ESTABLISHMENT & VC#:	**2. ESTABLISHMENT POC:**
PART 1	
DEFICIENCY FOUND	
3. RESPOND TO THE FOLLOWING DEFICIENCY BY: **SCORE:** **SUBPART PARA:** **REQUIREMENT:** **DESCRIPTION:**	
AUDITOR'S NAME, SIGNATURE AND DATE	**MANAGEMENT'S NAME, SIGNATURE AND DATE**
PART 2	
ROOT CAUSE OF DEFICIENCY	
ACTION TAKEN TO CORRECT AND PREVENT RECURRENCE OF DEFICIENCY	
4. PERSON RESPONSIBLE FOR IMPLEMENTING CORRECTIVE ACTION:	**5. SIGNATURE:**
PART 3	
AUDITOR'S EVALUATION OF CORRECTIVE ACTION(S)	
6. DISPOSITION OF CORRECTIVE ACTION:	**7. FOLLOW-UP AUDIT REQUIRED:** ☐ **Yes** ☐ **No**
8. REMARKS:	
AUDITOR'S NAME, SIGNATURE AND DATE:	

FIGURE 3. Corrective action request.

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DEPARTMENT OF THE ARMY
HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

For initial listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*, a member of the Veterinary Command must conduct a sanitation audit of your establishment in accordance with Military Standard 3006C.

I will perform the sanitation audit of your establishment on «Date_of_Audit». To receive an acceptable rating, your establishment may not score any **critical** findings or no more than three (3) **major** findings during the audit. The audit requires the presence of a person knowledgeable in all aspects of the establishment operations and that the facility is in production of said product the day of the audit. I will also be submitting samples of your product to our Laboratory (if applicable).

« Enclosed you will find the MIL-STD 3006C Appendix A based on the Code of Federal Regulations, Title 21, Part 110. I will use this reference document along with the pre-audit questionnaire that was provided by your establishment at the time of initial sanitation audit request to evaluate your establishment and to prepare the processing methodology. »

« Enclosed you will find the MIL-STD 3006C Appendix A based on the Code of Federal Regulations, Title 21, Part 110, and a pre-audit questionnaire. I will use these references to evaluate your establishment and to prepare the processing methodology. Complete the enclosed pre-audit questionnaire and fax or email to the fax number or email address below within seven (7) days prior to the scheduled audit date. »

FIGURE 4. Audit notification letter for initial sanitation audits.

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Please, contact me if you have any questions regarding this audit. I can be reached by telephone «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,

«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 4. Audit notification letter for initial sanitation audits - Continued.

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HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

For continuous listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*, a member of the Veterinary Command must conduct a sanitation audit of your establishment in accordance with Military Standard 3006C.

I will perform the sanitation audit of your establishment on «Date_of_Audit». To receive an acceptable rating, your establishment may not score any **critical** findings or no more than three (3) **major** findings during the audit. The audit requires the presence of a person knowledgeable in all aspects of the establishment operations and that the facility is in production of said product the day of the audit. I will also be submitting samples of your product to our Laboratory (if applicable).

Please, contact me if you have any questions regarding this audit. I can be reached by telephone «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,

«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 5. Audit notification letter for routine, special, and directed routine sanitation audits.

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HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

On «Date_of_Audit», I conducted an initial sanitation audit of your establishment in accordance with MIL-STD 3006C. Your establishment has received an «Acceptable_Unacceptable» rating and «has_has not» been recommended for approval and listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement* for delivery of «List_Products». A copy of the Sanitation Audit Report is enclosed.

You may contact us at the address indicated at the top of this letter, by telephone at «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,

«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 6. Audit results letter for acceptable and unacceptable initial sanitation audits.

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HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

On «Date_of_Audit», I conducted a «routine_special_directed routine» sanitation audit of your establishment in accordance with MIL-STD 3006C. Your establishment has received an acceptable rating and is recommended for continued listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*. A copy of the Sanitation Audit Report is enclosed. Any discrepancies noted during this audit require your corrective action to comply with the requirements contained in MIL-STD 3006C.

You may contact us at the address indicated at the top of this letter, by telephone at «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,

«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 7. Audit results letter for acceptable routine, special, and directed routine audits.

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HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

On «Date_of_Audit», I conducted a «routine_directed routine» sanitation audit of your establishment in accordance with MIL-STD 3006C. Your establishment received an unacceptable rating. Your delivery status «has_has not» been suspended. A copy of the Sanitation Audit Report is enclosed. Any discrepancies noted during this audit require your corrective action to comply with the requirements contained in MIL-STD 3006C.

An auditor is scheduled to conduct a special sanitation audit on or around «Date_of_Audit». In order for our auditor to conduct the special sanitation audit, you must submit to us the Corrective Action Request form(s) or other documentation describing your actions taken to correct the Major and Critical findings found during the «routine_directed routine» sanitation audit. If the documentation is not received by «Suspense_Date», the special sanitation audit will not be conducted and a recommendation will be submitted to remove your establishment from listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement* (the Directory). In addition, failure to obtain an acceptable rating during the special sanitation audit will result in a recommendation to remove your establishment from listing in the Directory.

You may contact us at the address indicated at the top of this letter, by telephone at «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,
(Note: leave 5 spaces here)
«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 8. Audit results letter for unacceptable routine and directed routine sanitation audits.

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HEADQUARTERS, NATIONAL CAPITAL DISTRICT VETERINARY COMMAND
FORT BELVOIR, VIRGINIA 22060-5400

«Civilian_Date_of_Writing»

REPLY TO
ATTENTION OF

Veterinary Services

«Establishment_VC#»
«Establishment_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

Dear «List_Establishment_POC»:

On «Date_of_Audit», I conducted a «routine_special_directed routine» sanitation audit of your establishment in accordance with MIL-STD 3006C. Your establishment has received an acceptable rating and is recommended for continued listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement.* A copy of the Sanitation Audit Report is enclosed.

« We request that you submit to us the enclosed Corrective Action Request(s) containing specific root cause analysis and actions taken by your establishment to correct and prevent reoccurrence of the finding(s). Failure to return the documentation by«Suspense_Date», may result in the recommendation to remove your establishment from listing in the *Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement.* »

You may contact us at the address indicated at the top of this letter, by telephone at «Telephone_Number», FAX: «Fax_Number» or email «Email_Address».

Sincerely,

«Auditor_Name»
«Auditor_Rank»
«Auditor_Title»

«Enclosures»

FIGURE 9. Audit results letter for acceptable sanitation audits with optional CAR statement.

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DATE: «Date»

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

TO: Commander,
«Unit_Name»
«Unit_Address»
«Unit_City_State_Zip»

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: _«Establishment_VC#»
«Establishments_Name»
«Establishment_Address»
«Establishment_City_State_Zip»

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

_____
(Signature)

_____
(Typed/Printed Name)

_____
(Title)

FIGURE 10. Vendor request for removal.

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EXAMPLE OF A DIRECTORY OR LOCAL LIST DELETION RECOMMENDATION

(Letterhead)

(Office Symbol) (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)

(6) SIGNATURE BLOCK

(Identify Enclosures, if any)

Use with "Instructions for Preparing a *Worldwide Directory* or Local List Deletion Recommendation" (FIGURE 11).

FIGURE 11. Recommendation for deletion.

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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.)

(1) 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 MACOM Veterinarian: or FOR the Commander with approval authority for the local list.

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

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

(4) 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 list the subject establishment as establishment number 1322. Therefore, the establishment is exempt from *Worldwide Directory* listing in accordance with AR 40-657.

- On 2 OCT 06, 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, establishment manager, stated that ice cream production ceased on 2 OCT 06. Therefore, the establishment is exempt from *Worldwide Directory* listing in accordance with AR 40-657.

- During a routine sanitation audit on 2 OCT 06, 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.

(5) Enter the name and telephone number of the point of contact.

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

FIGURE 12. Recommendation for deletion instructions.

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PRE-AUDIT QUESTIONNAIRE

ESTABLISHMENT NAME/ADDRESS

- Please provide the establishment name?
- Please provide the establishments' physical address (production facility)?
- Please provide the establishments' phone/fax number(s)?
- Please provide the Federal, Foreign (EU), and/or State plant number(s) for your establishment?
- Please provide any product codes that are listed under your plant number (e.g., USDA plant# 43-1123)?
- Please list all products produced at this establishment.
- Please provide a copy of your company's letterhead.
- Please provide the business card of your establishment's audit representative.
- Please provide directions to your establishment.

PERSONNEL/ADMINISTRATION

- What are the names of the key personnel along with their position (title) and email addresses?

GENERAL

- Indicate the hours of operation for both production and administrative offices (M-F, shifts, etc.)?
- Indicate the number of employees (full, part-time or seasonal) that work in the establishment. Do you use a temporary agency for hiring employees? Who provides Food Safety and Security training to the temporary employees?
- If known and applicable, describe the specifics of the Department of Defense contract you have, or have had (contract number, type of product you supply, where you shipped to, volume, etc.).
- Please list other inspection audit agencies (Government and civilian) and frequency of visits.
- Indicate the output of product produced in your establishment. Is this year round, or seasonal?

Code Dates:

- What production code information is placed on your product?
- If closed coded, what is the interpretation?
- Which character(s) within the production code designate your establishment?
- If no code is used, how is your product identified as being manufactured at your establishment?

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FIGURE 13. Pre-audit questionnaire.

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Brand:

- What are the brand name(s) of product(s) produced in your establishment?

Labeling:

- Is there a special label for product sold to U.S. Forces?
- Please describe and attach samples of the actual film/label.

Shelf-life:

- What is the recommended shelf-life of your product(s)?
- Under what conditions (e.g., temperature) should your product(s) be stored in order to maximize the shelf-life?
- Describe the shelf-life studies performed on your product?

Traceability:

- Describe your traceability/recall program.
- Is there a recall team? Who are the members? Do you conduct mock recalls? How often, and list the date of last mock recall?

FACILITIES

- Describe the location and the area surrounding your establishment.
- What year was your establishment constructed?
- What is the date of the most recent renovation? What was done? Are there any projected renovations?
- Describe the building as well as the material(s) used in the construction of your establishment.
- What is the square footage of your establishment?
- What are the various areas that make up the production area?
- What are the major pieces of equipment utilized in the production area?

FOOD PROTECTION AND SANITATION

HACCP and/or Food Safety Control Program:

- What is your approach to controlling food safety?
- Do you have a written Hazard Analysis Critical Control Point Program (HACCP) plan?
- If yes, when was it developed and what was the date it was last reviewed?
- If you have a HACCP plan, what are the Critical Control Points (CCPs)?
- How is each CCP monitored?
- What are the critical limits for each CCP?
- What is the protocol when critical limits are exceeded?
- If you do not have a HACCP plan, describe the Food Safety controls you have in place?

FIGURE 13. Pre-audit questionnaire – Continued.

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Raw Materials:

- What is the source of water utilized in your establishment? What type of microbiological/chemical testing is performed on the water? Are samples pulled from within your establishment, and how often?
- What are the major raw ingredients in your product(s)?
- Who are the suppliers? Who transports the materials?
- What procedures/documentation is in place to ensure raw materials are safe, wholesome, and meet specifications?

Laboratory Testing:

- What laboratory analyses are performed on raw materials and finished product(s)?
- What are the critical limits for each element/analytes tested?
- What is the protocol when critical limits are exceeded?
- Is product held pending laboratory results?
- Describe the microbiological and environmental testing program within the establishment?
- What is the name of the laboratory that performs the tests? Is it an internal or external lab?

Employee Hygiene and Sanitation:

- Do employees receive a medical examination prior to employment?
- What are the employees tested for and what is the frequency of the exam?
- Are employees trained in sanitation and hygiene (CGMPs)? How often, by whom, and is it documented?
- Are training, signage, and other pertinent instructions available in all applicable languages? If not, does your establishment have a translator?

Plant Sanitation:

- What is the make-up of the personnel that perform sanitation functions (production employees, sanitation team, contractor, etc.)?
- Is there a written and documented master sanitation schedule and/or program?
- What is the name of the sanitation team leader? Is there an alternate? Who provides sanitation training? Are records of training available for review?
- Who is your chemical supplier? What type of support do they provide at your establishment? How often do they provide that support? Do you retain documentation locally to demonstrate this support and is it available for review?
- When are the master sanitation tasks conducted?
- Is there a system in place to keep sanitation employees/equipment on the raw material side separate from sanitation employees/equipment on the finished product side?
- What chemicals are utilized and how are they stored in the establishment?

FIGURE 13. Pre-audit questionnaire – Continued.

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- How are chemical sanitizer concentrations verified? How often? Are results documented and available for review?
- Are there pre operation and post operation checklists/procedures in place? Are they documented and available for review?
- Are environmental and rapid method detection procedures in place to monitor sanitation?
- If so, are environmental and rapid method detection results reviewed by sanitation personnel?
- How are chemicals dispensed into other containers labeled?
- What other chemicals, other than those required for production, sanitation, and maintenance functions are stored at your establishment?

Pest Control:

- Who performs the pest control functions at your establishment?
- Is the pest control technician licensed?
- What services are provided? Are records of the services retained locally for review?
- How often are the pest control services provided?
- Describe the key components of your pest control system (bait stations, traps etc.)
- Is there a pest control diagram of all the pest control devices utilized at your establishment?
- Does the pest control provider store extra equipment or pest control chemicals at your location? If so, how and where are they stored?

Waste Management:

- Who provides waste management services for your establishment?
- How often is waste picked-up?
- Are the waste collection area(s) (interior and exterior) included in your sanitation program and under surveillance of the pest control provider?

PROCESS

- Describe the processing steps from receipt of raw materials to the finished product. Specify time, temperature, pressure, kill steps, etc. List major processing equipment at each step, test control(s) (thermometers, testing strips, etc.), and quality control program(s) (e.g., Statistical Process Control (SPC), In-line Inspection Points, etc.). If there is a HACCP in place, indicate the CCP's in the narrative. Please provide a copy of the process flow diagram with all CCP's clearly annotated.

FIGURE 13. Pre-audit questionnaire – Continued.

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STORAGE

- Describe the raw and finished product storage areas (purpose, location, quantity, temperature requirement, and humidity)?
- How often are these areas cleaned and sanitized? Are they on the master sanitation schedule or included in the sanitation program?

DISTRIBUTION

- Describe the product distribution and transportation system.
- Indicate how finished product gets from the production establishment to U.S. Forces.
- Indicate how often the transportation assets are cleaned and sanitized.

FOOD DEFENSE

- See the Food Defense Questionnaire.

FIGURE 13. Pre-audit questionnaire – Continued.

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FOOD DEFENSE QUESTIONNAIRE

1. Does your establishment have an implemented *Food Defense Policy* that adequately reduces food defense vulnerabilities?

2. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from *Outside Grounds and Roof* areas?

3. Does your establishment have an *Employee and Visitor* program in place and implemented to adequately reduce food defense vulnerabilities?

4. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Material Receiving* area(s)?

5. Does your establishment have processes within *Facility Operations* that adequately reduce food defense vulnerabilities?

6. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Finished Goods Storage/Shipping* area(s)?

FIGURE 14. Food defense questionnaire.

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GENERAL PROVISIONS

A.1 SCOPE

A.1.1 Scope. This appendix contains guidelines for auditing food processing and food warehousing establishments. The information contained herein is intended for guidance.

A.2 APPLICABLE DOCUMENTS

A.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

A.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODEX ALIMENTARIUS

Recommended International Code of Practice, General Principles of Food Hygiene. CAC/RCP 1-1969, (Current Revision).

(Available online at: http://www.codexalimentarius.net/web/index_en.jsp.)

CODE OF FEDERAL REGULATIONS (CFR)

Title 21, Part 110 (Updated annually in April).

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

U.S. DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), “Requisite Scientific parameters for Establishing the Equivalence of Alternative Methods of Pasteurization”, Aug 2004.

(Available on-line at: http://www.fsis.usda.gov/ophs/nacmcf/2004/nacmcf_pasteurization_082704.pdf.)

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Food, Drug and Cosmetic Act, 1938, as amended Public Law (PL) 107-188.

(Application for copies should be addressed to Superintendent of Public Documents, U. S. Government Printing Office, Washington, DC 20402-0001, or online at http://www.fda.gov or http://www.gpoaccess.gov/.)

Public Law No: 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act of 2002).

(Available online at: (http://tis.eh.doe.gov/biosafety/library/PL107-188.pdf or: http://www.fda.gov/oc/bioterrorism/bioact.html.)

A.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

AIB INTERNATIONAL (AIB)

The AIB Guide to Food Security.

(Application for copies should be addressed to the AIB International, 1213 Bakers Way, P.O. Box 3999, Manhattan, KS 66505-3999: Available on-line at: http://www.aibonline.org/.)

A.3 DEFINITIONS

A.3.1 Definitions. General definitions are contained in this handbook.

A.4 GUIDELINES

A.4.1 General. The main purpose of an audit under Appendix A, General Provisions is to ensure the safety of the food for the military community and to determine compliance with the current Good Manufacturing Practices (CGMPs), as specified in Title 21, Part 110 (quoted below) and Section 402(a)(3) of the Federal Food and Drug Cosmetic Act (1938, as amended):

Sec. 110.5 Current good manufacturing practice. (as quoted)

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining

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whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

A.4.2 Films, Packages, Containers & Lids. These items must be approved for contact with food IAW Title 21, Part 177, Indirect Food Additives - Polymers. Most establishments will have a letter of guaranty or certificate of compliance from their film or package supplier indicating compliance with FDA regulations.

Additionally, the oxygen transmission rate (OTR), or permeability of packaging films must be considered when *Clostridium botulinum* is reasonably likely to occur (fresh fruits & vegetables, seafood, etc.). If the films are not oxygen (O2) permeable, a vacuum packaged or gas flushed (Carbon Dioxide or Nitrogen) environment can create the anaerobic conditions conducive to the growth and subsequent toxin production associated with *C. botulinum*. The food safety plan should address these hazards and implement appropriate controls to mitigate the risks. Additionally, the establishment should have film studies or Certificates of Analysis or Compliance from their film suppliers containing technical data (OTRs) and indicating compliance with FDA rules.

A.4.3 Ingredients. A list of substances approved as ingredients, anti-caking agents, preservatives and antioxidants, etc., can be found in Title 21, Part 172, Food Additives Permitted for Direct Addition to Food for Human Consumption.

A.4.4 Sanitizers. Chemicals and sanitizers must be approved for use in contact with food IAW Title 21, Part 173 Secondary Direct Food Additives Permitted in Food for Human Consumption. Auditors should verify that chemicals are being used IAW the label, manufacturer's instructions and federal law. Verify that chemical sanitizers are properly mixed to the correct concentration (observe mixing, use test strips, review logs) and are properly applied during cleaning and sanitizing.

A.4.5 Allergens. Proper control of allergens is essential to an establishment's food safety program. There are eight primary allergens of concern, as identified by the FDA: milk, eggs, wheat, soy, peanuts, tree nuts, fish, and crustacean shellfish.

Auditors should be aware that approximately 3-5% of the U.S. population suffers from allergic reactions or chemical sensitivities (colors and dyes) related to food products. The Food Allergen Labeling Consumer Protection Act (FALCPA) requires food manufacturers to clearly label allergens that are contained in food products or to place warning statements on the packaging (e.g., "May contain" or "Processed in a facility that also processes..."). Additional information related to food allergens can be found at the FDA website (www.fda.gov).

Food processors should have adequate controls in place to prevent cross-contamination of allergens during storage of ingredients, mixing and scaling operations, processing or production,

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and storage of finished product. Special attention should be paid to the cleaning and sanitizing between processing of non-allergen and allergen containing products. Auditors should also review ingredient lists of raw materials (ingredients) to ensure that food manufacturers have identified all possible allergen hazards in the final food products.

A.4.6 Water & Sanitary Plumbing. Proper design, placement and use of back-flow prevention devices are very important. An approved device is usually marked with the symbol or acronym of an accrediting agency (similar to Underwriter's Laboratory for electrical devices). Common markings include the Uniform Plumbing Code (UPC) shield, or acronyms representing American Society for Sanitary Engineers (ASSE), American Society for Mechanical Engineers (ASME), American National Standards Institute (ANSI) or the Canadian Standards Agency (CSA). Two common brand names found on back flow prevention devices are Watts and FEBCO.

Some examples of devices and their most common uses are described below:

Device or Control	Use
Air gap	Faucets (sinks), drains, fill lines
Atmospheric Vacuum Breaker (AVB)	Used on faucets and hose bibbs
Pressure-type Vacuum Breaker (PVB)	Hoses under continuous pressure (nozzles)
Dual Check Valve Assembly (DCVA)	Fire Suppression Mains, food plants or residential
Reduced Pressure Zone Device (RPZ)	Water main, boiler, chemical mixing station

All establishments in CONUS that are connected to a municipal water supply will have a device (usually a Reduced Pressure Zone Device or RPZ) between the establishment and the city water main. This device is usually located inside the establishment and above ground (to prevent it from cross-contamination due to flooding; to protect it from freezing and to make it accessible for maintenance, testing and inspection.). If the establishment is in a shopping center (strip mall), and all of the collocated facilities are connected to one water main, ensure that there are separate backflow prevention devices that isolate the separate establishments from each other.

Many establishments have a second or dedicated water system for fire suppression (sprinklers). This system is generally plumbed separately from the main water supply line and is protected by an RPZ. Boiler make-up tanks and boiler chemicals (water softeners and injection of descaling chemicals) must also be isolated from the potable water supply; this is normally accomplished using an air-gap, RPZ or DCVA, or a combination of these devices.

Chemical mixing stations will usually be isolated by a dual check valve with an intermediate atmospheric vent, or by a check valve assembly that is built-in by the chemical company.

A.4.7 FDA Registration requirements. (Where applicable in CONUS) In accordance with section 305 of the Bioterrorism Act of 2002, the owner, operator, or agent in charge of a domestic or foreign establishment that manufactures/processes, packs or holds food for human or animal consumption in the U.S., or an individual authorized by one of them must be registered

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with the FDA. A domestic establishment must register whether or not food from the establishment enters interstate commerce. Foreign establishments must designate a U.S. agent, and the agent must live or maintain a place of business in the U.S.

The following establishment's are exempt from such registration: private residences, non-bottled water collection and distribution establishments and structures, transport vehicles, farms, restaurants, groceries, delis, roadside stands, non-profit food establishments, fishing vessels (non-processing) and USDA federally listed and regulated meat, poultry and egg plants.

If the submitted registration information changes, the establishment must submit an update to the establishment's registration within 60 days of the change.

A.4.8 Checklists. Guidelines for auditing food production establishments are contained in the following Tables A-I through A-VII, Subparts A, B, C, E, G, H, and J checklists.

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TABLE A-I.

GENERAL PROVISIONS Subpart A – Personnel checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
A1	Adequate disease control measures are practiced. Employees that are ill or otherwise suspected of carrying a communicable disease are excluded from processing or reassigned to other duties where they are not in contact with food, equipment or utensils. (21 CFR 110.10(a))			
A2	Employees are wearing suitable clothing. (21 CFR 110.10(b))			
A3	Employees are maintaining adequate cleanliness. (21 CFR 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. (21 CFR 110.10(b))			
A5	Employees working in the processing area are free from unsecured jewelry or other objects. (21 CFR 110.10(b))			
A6	Employees are using proper gloves and maintaining them in an intact, clean, and sanitary condition. (21 CFR 110.10(b))			
A7	Employees are wearing effective hair or beard restraints. (21 CFR 110.10(b))			
A8	Employees' personal belongings are being properly stored. (21 CFR 110.10(b))			
A9	Employees are not eating food, chewing gum, drinking beverages or using tobacco where food or single-service articles are exposed or where equipment and utensils are washed or could become contaminated. (21 CFR 110.10(b))			
A10	Precautions are taken to protect food, equipment and packaging materials from being contaminated by employees. (21 CFR 110.10(b))			
A11	Employees are trained in food safety and handling and have clearly assigned responsibilities, and are supervised. Supervisors will be trained to a level of competency that will ensure the production of clean and safe food. (21 CFR 110.10(9)(c) and (d))			

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

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TABLE A-II.

GENERAL PROVISIONS Subpart B - Buildings and facilities checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
B1	Grounds are maintained in a condition that will protect against product or establishment contamination or foster the harborage of pests. (21 CFR 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. (21 CFR 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. (21 CFR 110.20(b)) and (21 CFR 110.35(a))			
B4	Adequate protection against glass breakage over exposed foods, processing equipment and containers is provided. (21 CFR 110.20(b)(5), (6) and (7))			
B5	Adequate lighting, ventilation, and screening will be provided. (21 CFR 110.20)			
B6	Substances used for cleaning, sanitizing and pest control are safe, adequate, used IAW instructions; and are properly marked and stored. (21 CFR 110.35(b)) and (21 CFR 110.35 (d)(5))			
B7	Adequate measures are taken to exclude pests from processing and storage areas and to protect against contamination of foods by pests, and/or pesticides. (21 CFR 110.35(c))			
B8	Food contact surfaces and non-food contact surfaces are adequately cleaned and sanitized as frequently as necessary. Food contact surfaces, non-food contact surfaces of equipment and single service articles are properly protected against contamination. (21 CFR 110.35(d) and (e))			
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. (110.37(a)) (Not applicable for warehouses that do not process food.)			
B10	The plumbing is adequate in size and is adequately installed and maintained. (21 CFR 110.37 (b))			

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

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TABLE A-II – Continued.

GENERAL PROVISIONS Subpart B - Buildings and facilities checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
B11	Sewage is adequately disposed. (21 CFR 110.37(c))			
B12	Adequate toilet facilities are provided for employees and are sanitarily maintained in good repair, and do not open directly into food processing areas. (21 CFR 110.37(d))			
B13	Adequate hand-washing facilities are provided at convenient locations. (21 CFR 110.37(e))			
B14	Rubbish and offal will be conveyed, stored and disposed of so as to minimize the development of odor or presence of a food safety hazard and minimizes the potential for becoming an attractant or harborage for pests. (21 CFR 110.37(f))			

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

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TABLE A-III.

GENERAL PROVISIONS Subpart C - Equipment and utensils checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
C1	All pieces of equipment and utensils are adequately designed so as to be cleanable and are properly maintained and cleaned as often as necessary. (21 CFR 110.40(a))			
C2	Food contact surfaces are corrosion resistant, made of nontoxic materials and will be maintained to prevent contamination of food from any source. (21 CFR 110.40(a))			
C3	Equipment lubrication does not contaminate the product; only food grade lubricants are used in the food zone. (21 CFR 110.40(a))			
C4	Seams on food-contact surfaces are smoothly bonded or maintained so as to minimize the growth of microorganisms. (21 CFR 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. (21 CFR 110.40(c))			
C6	Holding, conveying and manufacturing systems are designed and constructed so that they can be maintained in an appropriate sanitary condition. (21 CFR 110.40(d))			
C7	Adequate indicating thermometers, temperature-measuring devices, temperature-recording devices, and temperature controls are in place. (21 CFR 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 (e.g., condensate, oil or unfiltered air). (21 CFR 110.40(g))			
C9	Installed thermometers or temperature recording devices are required for freezers and cold storage areas that hold food capable of supporting microbial growth. (21 CFR 110.40(e))			
C10	Instruments and controls for recording temperature(s), pH, acidity, water activity or other processing controls will be accurate (calibrated) and properly maintained. (21 CFR 110.40(f))			

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

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TABLE A-IV.

GENERAL PROVISIONS Subpart E - Raw materials and operations checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110 Federal Food, Drug and Cosmetic Act, 1938 (the Act)		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
E1	Raw materials and other ingredients are inspected at receipt, are purchased from an approved supplier, and are clean, and suitable for processing. Compliance verified by any effective means including supplier guarantee or certification. Raw materials are properly handled at all times to protect from contamination and adulteration. (21 CFR 110.80(a))			
E2	Manufacturing operations are conducted under conditions and controls necessary to minimize the potential growth of microorganisms or contamination of foods. (21 CFR 110.80(b))			
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. (21 CFR 110.93) and (21 CFR 110.80(b))			
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. (21 CFR 110.80(b))			
E5	Methods to exclude physical contaminants are established and monitored (e.g., metal detection, visual screening, sieves, or other suitable effective means IAW best industry practices). (21 CFR 110.80(b))			
E6	Process controls are adequate to ensure that known public health risk(s) associated with the food being processed have been addressed in accordance with current good manufacturing practices to prevent contamination and to prevent the food from being considered adulterated within the meaning of the act. (21 CFR 110.80(b)) and (the Act)			
E7	When ice is used in contact with food, it will be made from water that is of adequate sanitary quality and will only be used if it has been manufactured in accordance with good manufacturing practices as outlined in this part. (21 CFR 110.80(b)(16))			
E8	Food manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products. (21 CFR 110.80(b)](17))			

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

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TABLE A-IV – Continued.

GENERAL PROVISIONS Subpart E - Raw materials and operations checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
E9	Ingredients that are known allergens (e.g., eggs, milk, fish, soy, peanuts, tree nuts, crustacea and wheat) are stored, segregated, handled and processed to prevent the inadvertent contamination of non-allergen food products, shared food contact surfaces storage areas and packaging. (21 CFR 110.80) and (21 CFR 110.5)			
E10	Packaging materials are safe and suitable for use in contact with food. (21 CFR 110.80(b)(13)(iii))			
E11	Food will not be prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. (21 CFR 110.5 (a))			

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

TABLE A-V.

GENERAL PROVISIONS Subpart G - Defect actions levels checklist REQUIREMENTS as specified in: Good Manufacturing Practices, CFR Title 21, Part 110 Federal Food, Drug and Cosmetic Act, 1938 (the Act)		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
G1	Ingredients purchased and foods produced are in compliance with applicable defect action levels. (21 CFR 110.110(a))			
G2	Compliance with defect action levels does not excuse violation of the requirements of the act that food not be prepared, packed or held under unsanitary conditions or meet current good manufacturing practices. (21 CFR 110.110(c)) and (the Act)			
G3	Mixing of food exceeding maximum defect action levels with a lot of complying food (dilution of defect) is prohibited. (21 CFR 110.110(d))			

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

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TABLE A-VI.

GENERAL PROVISIONS Subpart H - Hazard analysis (HACCP)/Food safety program (FSP) checklist REQUIREMENTS as specified in: CODEX Alimentarius National Advisory Committee of the Microbiological Criteria of Foods (NACMCF) Good Manufacturing Practices, CFR Title 21, Part 110		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
H1	Hazard analysis is performed for ingredients, formulated product, and all production steps. (CODEX Alimentarius and NACMCF)			
H2	A HACCP or Food Safety Plan (FSP) is developed and a plan is written, implemented and validated for each product produced with identified hazards. (CODEX Alimentarius and NACMCF)			
H3	HACCP or FSP plan includes prerequisite programs, flow diagram, hazard analysis, critical control point summary, critical limits, monitoring procedures, corrective action plans, verification procedures and record keeping system. (CODEX Alimentarius and NACMCF)			
H4	Corrective action plan is followed and deviant product segregated. (CODEX Alimentarius and NACMCF)			
H5	Corrective actions and product disposition results are fully documented. (CODEX Alimentarius and NACMCF)			
H6	Records include all required information. (CODEX Alimentarius and NACMCF)			
H7	Records are reviewed, signed and dated as required. (CODEX Alimentarius and NACMCF)			
H8	Records are retained as required (per reference standard) and are available and subject to public disclosure limitations. (CODEX Alimentarius and NACMCF)			
H9	Internal reviews are performed as required. (CODEX Alimentarius and NACMCF)			
H10	A trained individual performs verification activities when a process change is made or when the HACCP or FSP is modified. (CODEX Alimentarius and NACMCF)			
H11	Prerequisite programs are performed and documented with sufficient frequency to ensure compliance with CGMPs. (21 CFR 110)			

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

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TABLE A-VII.

GENERAL PROVISIONS Subpart J – Food defense program checklist REQUIREMENTS as specified in: The AIB Guide to Food Safety (AIB)		**C** *	**M** **	**O** ***
ITEM	REQUIREMENT			
J1	A Food Defense program exists and is fully implemented. (AIB, Section 1.0)			
J2	The outside grounds and roof are adequately safeguarded. (AIB, Section 2.0)			
J3	Employee and visitor programs adequately address food defense policies. (AIB, Section 3.0)			
J4	Material receiving system provides appropriate food defense measures. (AIB, Section 4.0)			
J5	Establishment operations provide appropriate food defense measures. (AIB, Section 5.0)			
J6	Finished goods storage/shipping system provides appropriate food defense measures. (AIB, Section 6.0)			

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

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BAKERY

B.1 SCOPE

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

B.2 APPLICABLE DOCUMENTS

B.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

B.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

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, or online at: http://www.gpoaccess.gov/cfr/index.html.)

B.2.3 Non-Government publications. The following documents form a part of document to the extent specified herein.

BAKING INDUSTRY SANITATION STANDARDS COMMITTEE (BISSC)

Sanitation Standards for the Design and Construction of Bakery Equipment and Machinery.

(Application for copies should be addressed to the AIB International P.O. Box 3999, Manhattan, KS 66502-3999, http://www.bissc.org/.)

B.3 DEFINITIONS

B.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

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Mesh size – related to the screen on the sifter (30-mesh equals 30 strands of wire per square inch). This is often a CCP in the process.

B.4 GUIDELINES

B.4.1 General. The establishment will have an allergen control program where allergen containing materials are identified, tagged, and segregated to prevent cross contamination. Pay special attention to allergen control throughout all facets of the operation.

It is always beneficial to follow the flow of the product; however, some establishments might not want you to go from the raw side portion of their establishment into the finished product side to prevent microbiological cross contamination. Be sure to work out all details of the audit with management in the pre-audit meeting. Bulk deliveries can be received by rail car or tractor-trailer. 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, locked, and labeled upon completion of the off-loading process. The bulk flour may passes through a screening method to remove foreign objects. Common industry practices include: magnets, socks, 30-mesh screen for finely milled material; 16-mesh screen or a mesh determined by the granulation size of the product will be used for materials that are not finely milled such as graham or semolina flour prior to being pumped into a silo. Sifters for flour may also be provided after the silo. Sifter screens should be checked for screen integrity on a scheduled basis and a daily review and documentation of sifter tailings should be conducted. Ask if the establishment is testing any of their raw ingredients (e.g., composite analysis for quality factors). Most establishments do not typically conduct testing. Ask management if they review their ingredients and if they verify Certificates of Analysis (COA)’s for the raw materials they receive on site to meet their ingredient specifications.

In OCONUS locations, listing of bakery items may be required due to the potential risk of aflatoxins in the flour. When this is the case, verification of testing for aflatoxins can be accomplished either at the production facility, or by documented evidence provided by the accompanying COA from the raw material supplier. There may be random testing completed on a periodic basis to verify COA’s. 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. For materials such as liquid eggs, for which the pathogen Salmonella can be a hazard, receiving documents should include testing documentation for the lot number received that indicates Salmonella negative. For all bulk liquid ingredients received at the establishment, a strainer should be in place, checked after delivery, and documented as a foreign material control measure. Establishments using bagged flour should be using pre-sifted flour. If they are not, be alert to the possibility of an insect problem.

Materials will typically be stored in a dry warehouse, cooler or freezer after receipt. In addition, thermometers should be provided in coolers and freezers and be checked on a routine frequency. Temperatures in these storage areas, should be maintained IAW industry standards. Exceptions to these storage requirements may be made in the case that coolers are being used to temper product for quality and not for food safety reasons.

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The scaling and mixing (ingredient preparation) area should be next in the product flow. It can be completely automated or ingredients metered out and added to the mixer. If there is a batching room, be sure the product is protected until it is added to the mixer. Ingredients should be protected when not in use. After mixing, the dough may sit in troughs to rest. Dough may then go into a proofer where it can rise. Proofers provide a hot, humid environment that is conducive to mold growth. Auditors should be especially observant for evidence of mold growth in these areas.

The dough is then formed and baked. Time and temperatures are product (recipe) specific. 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. If mold is a problem in the establishment, it can be a problem in the finished product. The biggest mold problem is machinery mold and can be difficult to remove from the process.

The product is usually cooled at this time by sitting on racks, or traveling along a conveyor with fans, spiral or other forced air coolers blowing on the product. Fans should be clean, (the air is not required to be filtered) and there should be protection against condensation and other over-head 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 establishments are contained in the following Table B-I checklist.

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TABLE B-I.

APPENDIX A PARAGRAPH	Bakery checklist REQUIREMENTS as specified in: Baking Industry Sanitation Standards Committee (BISSC) CFR Title 21, Part 110
E9	Ingredients that are known allergens (eggs, milk, soybeans, peanuts, tree nuts, and wheat) are stored, segregated, handled and processed to prevent the inadvertent contamination of non-allergen food products, shared food contact surfaces storage areas and packaging. (21 CFR 110.80 and 110.5)
C8	Air or other gases mechanically introduced into the product or product zone will be filtered or washed to remove particles 5 microns or larger, and will not contain oil, water and other liquids, unless such materials are specifically required as an operational procedure. (BISSC 3.1.19)
C1	Equipment other than that on solid bases attached to the floor will provide a floor clearance of at least 6 inches (150mm) or will be accessible for cleaning. (BISSC 3.2.6)
C3	Where lubrication is required, the design and construction will be such that the lubricant cannot leak, drip or be forced into the product zone. (BISSC 3.2.9)
C1	Conveyors which are an integral part of the equipment and which carry the product through a filling, icing or glazing application will be readily removable or appropriately fitted for in-place cleaning. (BISSC 4.5.1.8)
E2	Potable water inlet lines will terminate not less than 1 inch (25mm) or twice the inlet pipe diameter, whichever is greater, above the overflow level of the bowl. (BISSC 4.6.1.14)
C6	Drip and/or catch pans used to collect spillage or drips are readily accessible or readily removable. (BISSC 4.7.2.1, 4.7.2.1.7, 4.7.2.1.12, 4.7.2.1.22, and 4.7.2.1.23)
C6	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. (BISSC 4.6.1.13)
C1, E5	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. (BISSC 4.1.1.3)
C5, C6	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. (BISSC 4.1.1.10)
C4, C6	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. (BISSC 4.1.3.1)

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TABLE B-I – Continued.

C8	The air supply for blowers or compressors is filtered to exclude particles of 5 microns or larger. (BISSC 4.1.3.4)
E5	Sifter screens will be minimum mesh size to allow passage of product. (BISSC 4.1.4.5)
C6, C8	Separate conveying air systems are provided before and after an atmospheric sifter in the system. (BISSC 4.1.4.1)
C1, C6	A removable flexible connection is provided between the inlet to the hopper and the product delivery equipment. (BISSC 4.1.5.1)
C1, C3, E2	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. (BISSC 3.1.13)
C1	Flexible tubing is transparent or translucent. Nozzles are readily removable. (BISSC 4.5.1.3)
C1, C6	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. (BISSC 4.18.2.3)
C1, C2	Stationary mixer bowls drain completely. Close-coupled sanitary drain valves which are accessible or removable are provided. (BISSC 4.6.2.11)
C2, 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. (BISSC 4.16.1.1)
C1, C6	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. (BISSC 4.16.1.16)
C1, C6	The icing and/or glazing reservoir return is readily accessible and self-draining. (BISSC 4.31.1.2)

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MANUFACTURED CHEESE PRODUCTS

C.1 SCOPE

C.1.1 Scope. This appendix contains guidelines for auditing manufactured cheese establishments. The information contained herein is intended for guidance.

C.2 APPLICABLE DOCUMENTS

C.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

C.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

ARMY REGULATION

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

(Available on Line at: http://www.army.mil/usapa/epubs/pdf/r40_657.pdf.)

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 7, Part 58.

CFR Title 21, Parts 133, and 173.

(Application for copies should be addressed to Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402-0001, or online at: http://www.gpoaccess.gov/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/.)

U.S. DEPARTMENT OF AGRICULTURE

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USDA Dairy Plants Surveyed and Approved for USDA Grading Service Publication.

(Available on-line at: http://www.ams.usda.gov/dairy/dypubs.htm.)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) 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, 5100 Paint Branch Parkway, College Park, MD 20740-3835.)

C.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

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. General definitions are contained in this handbook. Appendix specific definitions are listed below.

In manufacturing non-grade “A” dairy products, milk is used. In terms of animal health, milk must be obtained from healthy animals and is defined as follows:

The term milk will include the following:

(1) Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. The cows will meet the animal health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian in overseas areas.

(2) Goat milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy goats. The goats will meet the animal health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian in overseas areas. Goat milk will only be used to

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manufacture dairy products that are legally provided for in 21 CFR or recognized as non-standardized traditional products normally manufactured from goat's milk.

(3) Milk from any other hoofed mammal will meet the animal health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian in overseas areas.

C.4 GUIDELINES

C.4.1 General. Not all establishments listed in the "Dairy Plants Surveyed and Approved for USDA Grading Service" are exempt from *Worldwide Directory* listing. The following establishments will be listed in the *Worldwide Directory*:

(1) Those establishments denoted with "P" codes (packaging and processing) must be listed in the *Worldwide Directory*. Audit emphasis will be on determining the source of raw materials being processed and packaged.

(2) Those establishments denoted with "C" codes are only approved for those codes. All other products require an audit and *Worldwide Directory* listing, unless specifically exempt by the Directory approval authority.

(3) "C-coded plants" may serve as sources of manufactured or processed dairy products by product code.

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 often times, 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 may be coated with a wax or wrapped and then aged for a specific period of time, depending on the flavor and consistency desired. Cheese is then classified into four primary varieties: Very Hard, Hard, Semi-soft or Soft.

The following cheese varieties must be manufactured from pasteurized milk in accordance with 21 CFR Part 133; cottage, cream, Monterey, and Monterey jack, high-moisture

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jack, mozzarella, scamorza, low-moisture mozzarella, low-moisture scamorza, part-skim mozzarella, low-moisture part-skim mozzarella and scamorza, muenster, and Neufchatel.

Other cheese varieties may be manufactured from pasteurized or un-pasteurized dairy products. If the manufactured from un-pasteurized dairy products, the cheese must be aged for NLT 60 days at a temperature of NLT 35^{o}F in accordance with 7 CFR, Part 58.439. The auditor must determine whether the cheese is manufactured by this aging process.

Cheeses manufactured from pasteurized dairy products and not meeting the aging requirement above will be audited in accordance with this appendix and Appendix D. One exception is cheese used for manufacturing, pasteurizing of ingredients and aging are not required if the further processing involves sufficient heating to eliminate pathogens of concern.

Basic terms used in cheese making:

Cured. Flavor and texture characteristics are partially determined by the time enzymes and/or microorganisms are allowed to develop in the product.

Natural cheese. This cheese is the natural solids or casein portion of milk curd separated from whey, treated with organisms 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.

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(c) Camembert - a semi-soft, made with whole milk; has and 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 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 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 may be found packaged in small wheels or blocks, 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 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

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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 process 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 low, but may have grave results for those affected. Most often noted are contaminated raw ingredients and errors in manufacturing that contribute to the contamination of the product. Improper pasteurization of dairy products and post processing contamination of the cheese are areas of great concern in cheese manufacturing operations.

Variety cross comparison of soft cheeses (not all inclusive).

(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.

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(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 (not all inclusive).

(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, Muenster.
(cc) Reblochon: Beaumont, Esrom, Beaufort, Tomme, Raclette, Port Salut or Fontina.
(aa) Ricotta, solid: buffalo-milk Mozzarella.
(ee) Roquefort: Gorgonzola, Stilton.
(ff) Saint Paulin: Port Salut, Esrom or Havarti.

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(gg) Samsoe: Gouda or Bel Paese.
(hh) Sarmorza: Mozzarella, Cacciocavallo, or Provolone.
(ii) String cheese: Mozzarella.
(jj) Syrian cheese: Jack or Muenster.
(hh) Tilsit: havarti, Esrom or Port Salut.
(ll) Tomme: Reblochon, Beaufort or Gruyere.

Variety cross comparison of semi-firm (hard) cheeses (not all inclusive).

(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 cheese products establishments are contained in the following Table C-I checklist.

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TABLE C-I.

APPENDIX A PARAGRAPH	Manufactured cheese products checklist REQUIREMENTS as specified in: CFR Title 7, Part 58 CFR Title 21, Parts 133 and 173 USPHS/FDA Pasteurized Milk Ordinance (PMO) AR 40-657, Veterinary/Medical Food Inspection and Laboratory Service
E1	Milk originates from farms that meet the requirements or intent of the PMO and herds that meet the animal health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian in overseas areas. (PMO, Sec. 8)
E1, E4	Cheese not aged for NLT 60 days at NLT 35° F is made from milk in which every particle has been pasteurized. (7 CFR 58.439)
B2, B3	Building and facilities are maintained for laboratory, starter rooms, grading rooms, etc. (7 CFR 58.126)
C1,C5, C6	All CIP systems, weighing and receiving tanks comply with 3-A accepted practices. (7 CFR 58.128)
C7, C8, C10	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). (7 CFR 58.128 (c))
E1, E4, H6, H8	Raw milk conforms to basic quality and classification specifications of 58.132 - 133 and is tested at the frequencies required, and records are maintained. (7 CFR 58.134 – 139)
E2, E6, C5, C6	Receiving, holding, and processing of milk and cream and the manufacturing, handling, packaging, storing, and delivery of dairy products is in accordance with 7 CFR Part 58.
H6, H8	Records are maintained for all required tests and analyses. (7 CFR 58.148)
C1, C5	Sanitary seal assemblies are removable on all agitators, pumps, and vats, and are inspected at regular intervals and kept clean. (7 CFR 58.146 (a))
B3, C1, E4, H6	Packaging room atmosphere is practically free from mold and verified in accordance with 7 CFR Part 58.151.
E1	Salt is free flowing, white, refined sodium chloride, and meets the requirements of 7 CFR Part 58.
E1	Color additives will be approved by U.S. FDA. (7 CFR 58.329, and 58.719)
B2, B5, H6	A separate starter room or properly designed starter tanks with satisfactory air movement is provided. The air supply is filtered to 90% efficiency in accordance with ASHRAE Synthetic Dust Arrestance Test. (7 CFR 58.406)

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TABLE C-I – Continued.

E4, H6	Mold counts for make rooms are not more than 15 colonies per plate/15 minutes. (7 CFR 58.407)
B2, B3	Brine room is separately constructed and maintained with minimum corrosion. (7 CFR 58.408)
B2, E3	Adequate shelving, air circulation, temperature and humidity control is provided and maintained in drying rooms. (7 CFR 58.409)
B2, E2	Separate rooms are provided for packaging and boxing; maintained at proper temperature to prevent sweating prior to paraffining. (7 CFR 58.410)
E1	Bulk cheese for cutting, shredding, slicing or re-packaging must be manufactured in an approved establishment. (AR 40-657, Chapter 2-15)
B2	Separate rooms are provided for preparation of bulk cheese to be cut and wrapped into smaller packages. Air movement is outward moving. (7 CFR 58.413)
C6, C7	Bulk starter vats are equipped with tight fitting lids and have adequate temperature controls and indicating/recording devices. (7 CFR 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. (7 CFR 58.416)
C1	Mechanical agitators, shields, shafts, hubs, blades, forks, and stirrers are in accordance with 3-A Accepted Standards. (7 CFR 58.417)
C1, C8	Automatic salters meet the specific requirements (salting method, design, and steam quality) of 7 CFR 58.418.
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. (7 CFR 58.419)
C1, C2	Reuse of single service press cloths is prohibited. (7 CFR 58.421)
E2	Brine tanks, vacuumizers, and monorail systems do not contribute to the contamination of the product. (7 CFR 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. (7 CFR 58.427)
E1, H6	Hydrogen peroxide, catalase, cheese cultures, calcium chloride, and other authorized ingredients comply with requirements. (21 CFR 133, 7 CFR 58.431, 58.432, and 58.433)
E1	Rennet, pepsin, and other milk clotting/flavor enzymes meet the requirements of 7 CFR 58.436
E2	Based on the variety of products produced, the stated quality, identity, and analytical requirements of 7 CFR 58 are met.

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TABLE C-I – Continued

E1	Nonfat dry milk and whey will be of USDA Extra grade (or equivalent) except for moisture (Processed cheese). (7 CFR 58.716, 58.717)
B8	Conveyors, grinders/shredders, and cookers maintained clean to prevent contamination. (7 CFR 58.707, 58.708, and 58.709)
E2	Fats/oils used on the surface of the cheese will be of food grade. (21 CFR 133)

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PASTEURIZED MILK PRODUCTS

D.1 SCOPE

D.1.1 Scope. This appendix contains guidelines for auditing pasteurized milk establishments. The information contained herein is intended for guidance.

D.2 APPLICABLE DOCUMENTS

D.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

D.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

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, or online at: http://www.gpoaccess.gov/cfr/index.html.)

U.S. DEPARTMENT OF AGRICULTURE (USDA)

USDA Dairy Plants Surveyed and Approved for USDA Grading Service Publication.

(Available on-line at: http://www.ams.usda.gov/AMSv1.0/.)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) 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, 5100 Paint Branch Parkway, College Park, MD 20740-3835.)

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U.S. FOOD AND DRUG ADMINISTRATION (FDA)

IMS List, Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers

(Available on-line at: http://www.cfsan.fda.gov/~ear/ims-toc.html.)

Hazards and Controls Guide for Dairy Foods HACCP.

(Available on-line at: http://www.cfsan.fda.gov/~ear/daihaz.html.)

FDA Milk Pasteurization Controls and Tests Handbook.
FDA Dairy Farm Sanitation & Inspection Handbook.
FDA Milk Plant Sanitation & Inspection Handbook.

(Publications are available from FDA State Training Branch.)

U.S. ENVIRONMENTAL PROTECTION AGENCY

EPA's Registered Sterilizers, Tuberculocides, and Antimicrobial Products Against Certain Human Public Health Bacteria and Viruses

(Available on-line at: http://epa.gov/oppad001/chemregindex.htm.)

D.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

3-A SANITARY STANDARDS INC

3-A Sanitary Standards Inc.

(Available on-line: at http://www.3-a.org/.)

D.3 DEFINITIONS

D.3.1 Definitions. General definitions are contained in this handbook.

D.4 GUIDELINES

D.4.1 General.

Pressure conversions:

1 PSI = 6.89 kilopascal (kPa); 1 kPa = 0.1450 PSI

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1 PSI = 0.0689 Bar; 1 Bar = 14.5038 PSI

1 Bar = 100 kPa; 1 kPa = 0.01 Bar

Personnel who are required to perform audits on pasteurized milk products will attend specialized training as determined by the MACOM Veterinarian. Pasteurization systems will be audited based on the overall food safety program in place (from raw materials to the finished product). In general, the safety of all fluid milk processing revolves around the ability to verify adequate system design and operation. Essential public health controls include, but are not limited to:

a. Product pasteurization temperature.
b. Product holding time and flow rate.
c. Pasteurizer pressure differential between raw and pasteurized product (product-to-product and water-to-product) in the regenerator.

Vat Pasteurization Systems. The following areas need to be evaluated when determining if the vat pasteurization systems meet requirements:

- 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 provide continuous mechanical agitation.
  - Must be constructed/designed to be easily cleanable or removable.
  - Shafts must be fitted with effective drip deflection shields.
  - Annular space around agitator is fitted with an umbrella or drip shield.
  - Must ensure temperature variance does not exceed 1°F (0.5° C) between any two product locations in the vat.
- Indicating and Recording Thermometer
  - Should be compared to each other at the start of each holding period and results recorded on the recording chart.
  - Recording thermometer does not read higher than the indicating thermometer.
  - Both the indicating and the recording thermometers do not read less than the pasteurization temperature throughout the holding time.
- Airspace Heater and Thermometer

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  - Air space thermometer bulb must be located 1 inch/25 millimeters or more above product during processing.
  - Air space temperature must be recorded on the recording thermometer chart at the beginning and end of each holding period.
  - Air space temperature must be not less than 3°C (5°F) higher than the minimum required temperature of pasteurization.
  -
- Recording Chart includes the following information and is retained for three months:
  - Date.
  - Number and location of recorder when more than one is used.
  - A continuous record of the product temperature.
  - Extent of holding time, including filling and emptying times, when required.
  - Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart.
  - Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart.
  - Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to the Regulatory Agency.
  - Amount and name of product represented by the 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 pasteurizing. Ingredients must be added prior to pasteurization except for those listed in the PMO and Milk Plant Sanitation inspection guidelines.
  - 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 contaminating substance.

High Temperature Short Time (HTST) Pasteurization Systems. The following are areas that need to be evaluated when determining if HTST pasteurization systems meet requirements:

- 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 diameter 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/12 inches higher than any raw milk downstream from the balance tank.

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- 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.
  - Gauges installed at the highest raw milk/medium inlet and lowest 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.
- 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 in 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 daily by the plant operator and recorded.
  - 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.

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  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording Chart includes (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.
- General
  - No ingredients are added after pasteurizing (e.g., flavoring, coloring). Ingredients must be added prior to pasteurization except for those listed in the PMO.

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

- Constant Level Supply Tank (Balance Tank)
  - All re-circulation lines, divert lines, and leak detect lines must have an air gap NLT twice the diameter 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/12 inches above the highest raw milk downstream from the balance tank may be eliminated if a differential pressure controller is used and 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.

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- 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.
  - Have 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 (aseptic systems) 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 daily by the plant operator and recorded (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 is required.

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  - Leak detect line is self-draining.
  - Inter-wired with the booster pump.
- Recording chart includes (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.
- Other pasteurization systems: Other systems such as triple tube, spiraflow, steam injection, etc. are utilized and may be found in fluid milk processing establishments. Prior to performing an audit on these systems, auditors should thoroughly research the process to appropriately understand required public health controls.

Note: * Indicates areas related only to HHST systems.

D.4.2 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. All establishments and codes/products must achieve a sanitary compliance rating of 90% or higher to be eligible for listing in the IMSL. The actual score for Transfer Stations, Receiving Stations, and Dairy Plants will not be printed in the IMSL, but must be 90% or higher. If an IMSL plant is de-listed for a code/product, that plant must be *Worldwide Directory* listed in order to supply that item code to U.S. Forces.

D.4.3 Commercial dairies located outside the United States (OCONUS).

- 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 countries such as Australia and New Zealand that are free of Bovine Brucellosis and Tuberculosis and have independent farm inspection programs.

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- Farm evaluations should be performed if local Government agencies do not perform regulatory functions equivalent to those required by the PMO.

D.4.4 Deviations from the PMO: Deviations will be approved by the MACOM Veterinarian. Deviations submitted for review must be in keeping with the intent of the PMO. 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 risk to public health may result elsewhere in the system. The following issues and authorized deviations have been observed in the past.

D.4.4.1 Issue: As part of the dairy plant audit, the raw milk source must be evaluated.

Deviation: 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. They are usually cheaper and more effective. Currently, the Charm II and other systems are capable for the screening 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 commonly used in much of the developing world. Farm visits are 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.4.4.2 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). Note: Not applicable to pasteurization systems with the flow diversion device located downstream from the pasteurized regenerator and/or cooler section.

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). Alternatively, normally open valves installed in free draining pipes below the lowest point of raw milk in the regenerator, together with drilled plates, may be installed to completely drain the raw regenerator into the floor during shutdown.

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D.4.4.3 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 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 line (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.4.4.4 Issue: The flow diversion valve should not be more than 46 centimeter (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 divert 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.4.4.5 Issue: The PMO does not authorize the use of computers as a sole means of operating public health controls on pasteurization system.

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.4.4.6 Issue: The majority of the tests required by the PMO are to be 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 affect 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.

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D.4.4.7 Issue: Anytime 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 made, and the testing results (to include the name of the person performing the test) will be fully documented. This information will be made available to the auditor during the next audit.

D.4.4.8 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 to be written on the recording thermometer chart along with the initial of the plant operator that performed the checks. For systems without a recording thermometer that can be written on, this may not be possible.

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.4.4.9 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.4.5 Checklist. Guidelines for auditing pasteurized milk establishments are contained in the following Table D-I checklist.

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TABLE D-I.

APPENDIX A PARAGRAPH	Pasteurized milk products checklist REQUIREMENTS as specified in: USPHS/FDA Pasteurized Milk Ordinance (PMO)
E1	Milk originates from farms that meet the requirements or intent of the PMO and herds that meet the animal health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian in overseas areas. (PMO, Sec. 8)
C1, E6, H6, H8	A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days. (PMO, Sec. 7)
E1, E4	Upon arrival, raw milk and/or raw products for pasteurization complies with bacteriological, chemical and temperature standards. (PMO, Sec. 7)
E4	Raw milk and milk products are screened for drug residue. (PMO, Sec. 6)
E3	Raw milk and milk products (except acid type whey) are held at 45° F (7º C) or less until processed. (PMO, Sec. 7)
C4	Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (PMO, Sec. 7)
C1	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). (PMO, Sec. 7)
C1, C6	Equipment is designed to protect against surface and overhead contamination. (PMO, Sec. 7)
B8, C1, E2	Storage tanks are cleaned when emptied and are emptied at least every 72 hours. (PMO, Sec. 7)
C9	Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7-day temperature recording device. (PMO, Sec. 7)
C1, C5, C6	Equipment complies with the sanitary design and construction standards. (PMO, Sec. 7)
C1, E6	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) (PMO, Sec. 7)
C1, E6	Raw milk in the regenerator drains back to the constant-level tank. ((PMO, Sec. 7)
C1, C10, E6	The pasteurized side of the regenerator is always under higher pressure than the raw side. (PMO, Sec. 7)
C1, C6, E2	An atmosphere break exists at least 30.48 centimeters or 12 inches above the highest point of raw milk. (PMO, Sec. 7)
C1, C6, E2, E6	There is no flow-promoting device between the regenerator and the air-break. (PMO, Sec. 7)

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TABLE D-I – Continued.

C1, C6, E2, E6	There is no pump between the raw milk inlet to regenerator and the raw milk supply tank, unless it meets the design and operation requirements in the PMO for regenerative heating systems. (PMO, Sec. 7, Para. 16p.(D).5)
C1, C6, E2, E6	The holding tube is designed so that no deviations can be made to the flow rate or holding time. (PMO, Sec. 7)
C6, E2, E6	The flow control sensor (Recording Thermometer) is not more than 46 centimeters (18 inches) up stream from the flow control device. (PMO, Sec. 7)
C7, E2	The indicating and recording thermometers are properly located. (PMO, Sec 7)
C6, E6	The flow diversion devices are properly installed and functioning. (PMO, Sec. 7)
C6, E6	The flow-promoting devices are properly located and of the proper speed, displacement, and capacity. (PMO, Sec. 7)
C6, E2, E5	Pasteurized milk is not strained or filtered except through a perforated metal strainer. (PMO, Sec. 7)
C6, E2	Valves meet PMO standards (stop/leak groove/close coupled). (PMO, Sec. 7)
C10, E2, E6	Pasteurization equipment and controls testing is performed. (PMO, Appendix I)
E2, H6, H8	Pasteurization recording charts are maintained on file at the processing plant for 3 months (3 years for aseptic milk and milk products). (PMO, Sec. 7)
C1, C7, C9, C10	Thermometers meet requirements. (PMO, Appendix H)
C6, C10, E6	Air space heating is accomplished when required for Batch Pasteurization. (PMO, Sec. 7)
C8, E2	Culinary steam is in accordance with PMO. (PMO, Sec. 7)
B6	Boiler water additives comply with PMO requirements. (PMO, Appendix H)
C8	Air under pressure is in accordance with 3-A Accepted Practices. (PMO, Appendix H)
B10, C6, E2	There is no cross-connection between raw and finished product or direct contamination of pasteurized milk or milk product. (PMO, Sec 7)
B2, C6	All openings, including valves, pipes, milk tanker trucks, etc., are capped or otherwise protected. (PMO, Sec. 7)
C1, E6	Filling lines are equipped with a device capable of detecting volatile organic contaminants in each container before filling. The device is interconnected so that the system will not operate unless the detection device is operational. (PMO, Sec. 7)
B10, E2, E5	Recirculated cooling water is protected from contamination. (PMO, Sec. 7)
E4	Recirculated cooling water is tested once per six-month period. (PMO, Sec. 7)

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TABLE D-I – Continued.

C6, E6	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). (PMO, Sec. 7)
H6, H8	Record of CIP cleaning process is maintained for recirculating cleaning systems for 3 months. (PMO, Sec. 7)
C6, E6	During processing, pipelines and equipment used to conduct milk are effectively separated from cleaning and sanitizing solutions (see the PMO for methods). (PMO, Sec. 7)
B2, C1	Establishments 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. (PMO, Sec. 7)
E4, H6, H8	Pasteurized milk and/or milk products comply with bacteriological, chemical and temperature standards. Results are recorded and records maintained. (PMO, Sec. 7, and Table 1)
E2, E3, E6	Pasteurized milk and milk products are cooled to 45° F (7° C) or less and maintained at or below that temperature. (PMO, Sec. 7)
E4, H6, H8	Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. Results are recorded and records maintained. (PMO, Sec. 7)
E1	Packaged milk and milk products which have physically left the premises or processing plant are not repasteurized for Grade A use. (PMO, Sec. 7)
B6	Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (PMO, Sec. 7)
B6	Only approved pesticides are used. (PMO, Sec. 7)

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SHELL EGGS

E.1 SCOPE

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

E.2. APPLICABLE DOCUMENTS

E.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

E.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 110.

CFR Title 7, Parts 56 and 59.

CFR Title 9, Part 590.

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

E.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

U. S. DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE

Shell Egg Inspections Handbook.

(Available through USDA, AMS, Standardizations Branch, Washington, DC.)

E.3 DEFINITIONS

E.3.1 Definitions. General definitions are contained in this handbook.

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E.4 GUIDELINES

E.4.1 General. These guidelines have been written for military procurement of shell eggs.

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

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 90º F (32º C) or higher, or at least 20º F (-7º C) 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.

In OCONUS locations washing of shell eggs are seldom allowed. The public health controls of not washing shell eggs must be carefully evaluated to include strict adherence to the refrigeration requirements.

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.

E.4.2 Checklist. Guidelines for the auditing of shell egg establishments are contained in the following Table E-I checklist.

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TABLE E-I.

APPENDIX A PARAGRAPH	Shell eggs checklist REQUIREMENTS as specified in: CFR Title 7, Part 56 CFR Title 9, Part 590
B3, E3	Grading and packing rooms are kept reasonably clean during grading and packaging operations, and are thoroughly cleaned at the end of each day. (7 CFR 56.76(b)(4))
B2, 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. (7 CFR 56.76(c)(1))
C7, C9, C10, E3	Storage facilities have adequate refrigeration facilities capable of reducing the temperature of the maximum volume of eggs to 45° F (7.2° C) or below within 24 hours and maintaining that temperature during the entire storage process. Storage facility should be equipped with humidifying equipment capable of maintaining a relative humidity which will minimize shrinkage. Accurate thermometers hygrometers are provided. (7 CFR 56.76(d)(1) and (2))
E3	After packaging and packing, shell eggs must be held, stored and distributed under continuous refrigeration at a temperature not to exceed 45° F (7.2° C). (9 CFR 590.50(a))
E2	Eggs with excess moisture on the shell are not shell protected (oil processed). (7 CFR 56.76(e)(3))
E2	Oil having any off odor, or that is obviously contaminated, is not used in shell egg protection. (7 CFR 56.76(e)(4))
E2, E5, E6	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. (7 CFR 56.76(d)(3))
C1, E2	Shell egg processing equipment is washed, rinsed and treated with a bactericidal agent each time the oil is removed. Processing oil should be filtered and heat treated daily. Processing equipment should be cleaned daily when in use. (7 CFR 56.76(e)(5))
C7, E6	If eggs are washed, the temperature of the wash water must be 90° F (32.2° C) or higher, and will be at least 20° F (-6.7° C) warmer than the temperature of the eggs to be washed. Temperatures will be maintained throughout cleaning. (9 CFR 56.76(f)(3))
E2	If eggs are washed, wash water must be added continuously to the wash water to maintain a continuous overflow. Rinse water and chlorine sanitizing rinse may be used as part of the replacement water. Iodine may not be used. (9 CFR 56.76(f)(6))
E4, E2, 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. (7 CFR 56.76(f)(7))

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TABLE E-I – Continued.

C6, E2	If eggs are washed the washing operation will be continuous. Eggs will not be allowed to stand or soak in water. Immersion type washers will not be used. (9 CFR 56.76(f)(9))
E2, E4, H3	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 100 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 the MACOM Veterinarian. (7 CFR 56.76(f)(11))
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. (7 CFR 56.76(f)(13))

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FROZEN DESSERTS

F.1 SCOPE

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

F.2 APPLICABLE DOCUMENTS

F.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

F.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 110 and 135.

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) 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, 5100 Paint Branch Parkway, College Park, MD 20740-3835.)

F.3 DEFINITIONS

F.3.1 Definitions. General definitions are contained in this handbook.

F.4 GUIDELINES

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F.4.1 General. Of utmost importance in a frozen dessert plant is where the mix is made. Some establishment's purchase mix from another establishment and it is trucked over the road to their establishment. Problems may occur when frozen dessert mix and other dairy ingredients are pasteurized at one establishment and transported to another establishment for further processing without being re-pasteurized. In order to reduce the potential for contamination, frozen dessert mix should ideally be packaged in the plant where it is pasteurized. When mixes are transported to another location they should be re-pasteurized prior to being used. If the establishment is not re-pasteurizing the product, this may be a finding of significant public health importance. When re-pasteurization does not occur, the following requirements must be met.

The establishment must demonstrate excellent sanitation and the audit frequency will not be reduced. Furthermore, finished products will not be distributed pending acceptable microbial laboratory results from the in-plant laboratory or from an independent laboratory. During the audit, finished product samples will be selected and submitted to the regional laboratory for microbial testing. The finished product microbiological parameters will be IAW AR 40-657/NAVSUPINST 4355.4F/ MCO P1010.31G or AFI 48-116.

F.4.2 Wash and Sanitization Records for Bulk Tankers Transporting Pasteurized Mix over the Road.

The bulk milk hauler/sampler will be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, or milk tank truck cleaning establishment. A milk tank truck without proper cleaning and sanitizing documentation will not be loaded or unloaded until the proper cleaning and sanitization is verified.

A cleaning and sanitizing tag will be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. Normally the following information is on the cleaning and sanitization tag:

(1) Identification of the milk tank truck
(2) Date and time of day the milk tank truck was cleaned and sanitized
(3) Location where the milk tank truck was cleaned and sanitized
(4) Signature or initials of the person who cleaned and sanitized the milk tank truck.

The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk mix hauler/sampler. A bulk tank truck transporting pasteurized ice cream mix products to a frozen dessert plant from a milk plant to a freezing or finished products plant is required to be marked with name and address of the origin plant and the mix tank truck will be under a proper seal. All shipping documents must contain the following information:

(1) Shipper's name, address and permit number. Each milk tank truckload of pasteurized mix will include the Bulk Tank Unit (BTU) identification number(s) or the origin plant name and

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address or corresponding establishment number on the manifest.

(2) Permit identification of the hauler, if not an employee of the shipper.
(3) Point of origin of shipment.
(4) Milk tank truck identification number.
(5) Name of product.
(6) Weight of product.
(7) Temperature of product when loaded.
(8) Date of shipment.
(9) Name of supervising Regulatory Agency at the point of origin of shipment.
(10) Seal number on inlet, outlet, wash connections and vents.

F.4.3 Audit Procedures. For the purpose of the audit, break down the establishment audit into raw (prior to pasteurization), pasteurized, and finished product areas.

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 have to 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 unloading area are Standard Plate Count (SPC) or Direct Microscopic Clump Counts (DMCC), Freezing Point, Antibiotics screening, and Somatic Cell Count. The acceptable microbiological levels for Non-Grade A milk are higher than those for Grade A product. Raw milk should be pumped into designated raw silos and be kept at a temperature around 40° F (4° C) and not stored for more than 72 hours. Verify the time and temperature and silo Clean In-Place (CIP) cleaning by reviewing the recorder controller charts. Ask 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, just 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 added 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 (e.g., Liqueurs);
- bacterial cultures;
- fruits and vegetables added at the freezer;
- subjected to any other process, which will assure that the ingredient is free of pathogenic microorganisms.

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

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After pasteurization comes the filling process. Some establishments might store pasteurized product in a silo, prior to filling. This silo holding pasteurized product has to be in a separate area of the plant away from the raw silos holding raw product. 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 (ice cream sandwiches, ice cream bars, etc.). Ensure 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 determine 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 top look at the top of the silos to see if there are any ports exposed or unsecured.

Points of interest: Find out how much re-work 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 a 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 procedures associated with the pasteurizer.

F.4.4 Checklist. Guidelines for auditing frozen dessert establishments are contained in the following Table F-I checklist.

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TABLE F-I.

APPENDIX A PARAGRAPH	Frozen desserts checklist REQUIREMENTS as specified in: Frozen Dessert Processing Guidelines (FDPG) USPHS/FDA Pasteurized Milk Ordinance (PMO) CFR Title 21, Part 110 CFR Title 21, Part 135
E4, E6, H6	Raw milk, reduced fat or low fat milk, nonfat milk or skim milk, 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 (or less) cfu/mL Standard Plate Count and 10 (or less) cfu/mL coliform at the plant of shipment, 100 (or less) cfu/mL coliform at plant of receipt. (FDPG, Page 4)
B10, C6	Adequate physical breaks to the atmosphere (at least as large as the piping diameter) are provided in order to eliminate cross-connections, and are verified by walk-through with installation drawings. (FDPG, Page 9)
C1, C6	All openings into product or onto sanitized product-contact surfaces are capped, closed, or adequately protected. (FDPG, Page 9)
C6, E2	Fill line connections are made to tank fittings to ensure that tank lids are not propped open during filling. (FDPG, Page 9)
B8	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. (FDPG, Page 10)
B8, C1	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. (FDPG, Page 11)
B8	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. (FDPG, Page 11)
E2	Dairy products which will sustain bacterial growth are not held in storage longer than 72 hours prior to pasteurization. Pasteurized mix is frozen, dried, packaged, or shipped within 72 hours of being pasteurized. (FDPG, Page 12)
C1, E2	All openings in covers of tanks, vats, separators, etc., are protected by raised edges or other means to prevent the entrance of surface drainage. (FDPG, Page 13)
C1, C6	There are no pipe 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. (FDPG, 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. (FDPG Page 16)

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TABLE F-I – Continued.

E3	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). (FDPG, Page 17)
E9	Ingredients that are known allergens (e.g., eggs, milk, nuts, etc) are stored, segregated, handled and processed to prevent inadvertent contamination of non-allergen food products, shared food contact surfaces, storage areas and packaging. Products that contain or may contain known allergens are properly labeled. (21 CFR 110.80 and 110.5)
C8	Pressurized air processing systems which incorporate air directly into the product, (e.g., freezers, air blowsers, air agitating systems, etc.) are properly designed to reduce potential contamination. They are equipped with filters, sanitary check valves, oil and vapor removal systems or other systems as necessary to prevent contamination or adulteration of food. (FDPG, Page 25)
B9	Culinary steam used to provide heat for vat or HTST processes, the water source for the boiler is identified as potable. (21 CFR 135) (FDPG, Page 27)
E4	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 pathogens. (FDPG, Page 28)
B5	Outside air entering the establishment is filtered and free of condensates. (FDPG, Page 29).
B2	Dusty, raw ingredient blending operations which create powdery conditions are located away from pasteurized product areas. (FDPG, Page 32)
E6	Products are pasteurized in accordance with the time/temperature tables listed in the Frozen Dessert Processing Guide. (FDPG, Page 33)
E6	Pasteurization is in accordance with the methods explained in the Frozen Dessert Processing Guide or the Pasteurized Milk Ordinance. (FDPG, Pages 32 through 67) (PMO, Appendix H)
E2, E6	All dairy products, eggs, egg products, cocoa products, emulsifiers, stabilizers, liquid sweeteners and dry sugar are added prior to pasteurization. (FDPG, Page 69)
E6	All reconstitution or recombination of dry, powdered, or condensed ingredients with water is done prior to pasteurization. (FDPG, Page 69)
E1, 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. Establishment will have a record that ingredients added after pasteurization meet this requirement. (FDPG, Page 69)
E1, 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. (FDPG, Page 69)

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TABLE F-I – Continued.

E2, E10	To prevent contamination, lids of tub and canister-type containers for frozen desserts are designed to overlap the tub or container to be over wrapped. (FDPG, Page 70)
E2	If de-foamers are used, they do not return product or foam to the filler bowl. (FDPG, Page 70)
B8, E2	Pails used for rework or adding flavors are cleaned after each use and sanitized prior to reuse. (FDPG, Page 71)
B5	The air supply in the freezer is properly filtered. (FDPG, 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. (FDPG, Page 72)
B3, B8	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. Cleaning and sanitizing is documented. (FDPG, Page 72)
B9, C1, C6, 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. (FDPG, Page 73)
B10, C6, E2	There is a physical break between pasteurized product for re-pasteurization when the product is loaded in a raw product receiving area, with particular attention being paid to product and CIP connections, so that raw product in lines and tanks is never directly connected to any line which extends back to the pasteurized product lines or tanks. A physical break is required. (FDPG, Page 68)
C1, E2	Adequate drip deflectors are provided at each filler valve as required. (FDPG, Page 70)
B8, C6, E4	Tanks used for holding cooling media are adequately protected and are coliform and pathogen free. (FDPG, Page 70)
E6	For reclaiming operations, only product which has not left the plant premises may be reclaimed. (FDPG, Page 74)
C1	Woven wire strainers are not used to remove bulky ingredients. (FDPG, Page 74)
E3, E6	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. (FDPG, Page 75)
E4, H6	Microbiological criteria for end items are not more than 50,000 cfu/g Standard Plate Count; not more than 10 cfu/g coliforms; and not more than 20 cfu/g coliforms with added fruits, nuts, or other bulky flavors. (21 CFR 135)
B8, E6, H6	Mix shipped in bulk tankers to another location must be re-pasteurized at the new location plant prior to freezing and packaging. When frozen desserts plants receive pasteurized ice cream mix from other plants, and do not re-pasteurize the mix before freezing and packaging, the mix will have been transported in a washed, sanitized, and sealed container (tanker). (FDPG Page 12, 17 & 68).

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TABLE F-I – Continued.

E6	Mix transferred between plants in a tanker that was not properly sanitized in accordance with applicable standards (conveyances not cleaned/sanitized properly) is re-pasteurized at that new location plant prior to freezing and packaging. (FDPG, Page 12)
H6, H8	All tankers transporting pasteurized mix have detailed records. (FDPG, Page 12)
E4	Finished product has no detectable residues from cleaners, sanitizers or other adulterants. (FDPG, Page 76)

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ICE

G.1 SCOPE

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

G.2 APPLICABLE DOCUMENTS

G.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

G.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 40, Part 141 National Primary Drinking Water Regulations.

(Available on-line 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 document to the extent specified herein.

INTERNATIONAL PACKAGED ICE ASSOCIATION (IPIA)

The PIQCS (Packed Ice Quality Control Standards) Manual.

(Application for copies should be addressed to the International Packaged Ice Association, P.O. Box 1199, Tampa, FL 33601, or on-line at: http://www.packagedice.org/downloads/PIQCSManualFINAL.pdf.)

G.3 DEFINITIONS

G.3.1 Definitions. General definitions are contained in this handbook.

G.4. GUIDELINES

G.4.1 General. Consider the following guidelines when performing an audit on an ice establishment:

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Only potable water will be used for ice production. All source water must adhere to the criteria specified by the FDA and EPA for drinking water or equivalent. Water samples must be drawn from within the establishment. If the ice plant uses a municipal water source, the FDA and EPA criteria should have been met. It is the ice plant's responsibility to show records indicating that source water is compliant. 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. These 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 connections, removable sections, swivel or change-over devices that connect 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. 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.

Some establishments still utilize brine baths for ice production. Note: Brine baths can increase the risk for contamination.

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.

Verify that finished product testing is in compliance with the Packaged Ice Quality Control Standards. Auditors will review test results for Total Fecal Coliforms, and Total Hydrophilic Count (THC) or Heterotrophic Plate Count (HPC).

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Finished product will be labeled in accordance with the applicable cited references, and protected against cross contamination during storage and shipping.

G.4.2 Checklist. Guidelines for auditing ice production establishments are contained in the following Table G-I checklist.

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TABLE G-I.

APPENDIX A PARAGRAPH	Ice checklist REQUIREMENTS as specified in: Packaged Ice and Quality Control Standards (PIQCS) CFR Title 40, Part 141
A1, A10	Personnel in direct contact with ice or ice contact surfaces will not put their hands or fingers in their mouth, nose, hair, eyes, or any other part of the body that could potentially contaminate the product. (PIQCS, Sec 1)
B2, B3	Ice manufacturing, processing, packaging, and storage operations will be conducted in an enclosed building maintained in a sanitary condition and in a state of good repair. (PIQCS, Sec 2)
B2, B3, E2	Ice for human consumption will be processed and packaged only in rooms used solely for those operations. The floors, walls, and ceilings of all rooms in which ice is manufactured, processed, packaged, and stored will be of impervious material, and so constructed that they can be maintained in a clean and sanitary condition. (PIQCS, Sec 2)
B2, E2	Ice for human consumption will not be processed or packaged on open platforms or on trucks or delivery vehicles, or in a manner that would permit contamination from overhead drip, condensation, dirt or other contaminant. (PIQCS, Sec 2)
B4	Light bulbs, fixtures, skylights, or other glass suspended over product areas will be of the safety type or shielded to prevent the scattering of broken glass onto ice, contact surfaces, or equipment. (PIQCS, Sec 2)
B5	Adequate ventilation will be provided to minimize odors, noxious fumes or vapors, and condensation in manufacturing, processing, and storage rooms. (PIQCS, Sec 2)
B2, C6	Fixtures, ducts, and pipes are installed properly to preclude drips or debris from contaminating product. (PIQCS, Sec 2)
B10, C6	The piping of any non-potable water system approved by the health authority will be adequately installed and identifiable so that it is readily distinguishable from piping that carries potable water. (PIQCS, Sec 2)
B10	Plumbing will be of adequate size and design, and installed and maintained in accordance with applicable state and local plumbing laws, ordinances, and regulations. (In OCONUS areas, plumbing adequacy is subject to review by the MACOM Veterinarian.) (PIQCS, Sec 2)
B2, B11, E2	Soil, waste, or drainpipes will be located, installed, and maintained to prevent a source of contamination of ice, equipment, and utensils. (PIQCS, Sec 2)
B2, B10, B11	Floor drains will be functional and properly trapped. Floor drainage will be provided in all areas where floors are subject to flood-type cleaning, normal operations discharge, or release water of other liquid waste onto the floor. (PIQCS, Sec 2)
B10, B11	All sewage and waste water will be disposed of by means of a public sewer system or an approved swage disposal system which is constructed, operated, and maintained in conformance with applicable state and local laws, ordinances, and regulations. PIQCS, Sec 2)

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TABLE G-I – Continued.

B6	The only toxic materials used or stored in a plant will be those that are necessary for cleaning and sanitizing or for the plant's operation. Cleaning and sanitizing substances will be free from undesirable microorganisms, and be safe for the conditions of use (where applicable food grade approved). All toxic materials will be clearly identified, held and stored as labeled. (PIQCS, Sec 3)
B6, B7	The use of insecticides and rodenticides will be in accordance with appropriate regulations. All chemicals should be clearly labeled. Inspections for infestations will be routine and carried out by either plant personnel or a pest control service provider. (PIQCS, Sec 3)
B7	No live animals including dogs, cats, or birds will be allowed in any area of the plant. (PIQCS, Sec 3)
B8	Single service supplies will be stored, dispensed, and handled in a sanitary manner and will be used only once. (PIQCS, Sec 3)
B8, C1, C5	All portable equipment and utensils will be stored in a suitable means that provides protection from contamination when not in use. When equipment and utensils become soiled they will be thoroughly cleaned and sanitized prior to re-use. (PIQCS, Sec 4)
C1, C6, E2	Filter equipment and filter beds must be designed to protect ice from contamination and allow for periodic treatment and cleaning. (PIQCS, Sec 4)
C4, C6	Holding, conveying, manufacturing and storage systems will be of impervious material and will protect ice from contaminants that may result from shredding, flaking, peeling, or fragmentation of the surface. (PIQCS, Sec 4)
B9, E1, E4, H6	Water source for manufacturing ice will originate from: (a) a municipal or other source which has met all of the requirements of the EPA National Primary Drinking Water Regulation, or (b) a source which meets the standards stipulated by the EPA Safe Drinking Water Act, 42 USC, for untreated water sources (e.g., wells). (40 CFR 141)
E4, H6, H8	Bacteriological tests of the finished product will be conducted at least monthly. Ice will be tested by an approved laboratory for Total Hydrophilic Count (THC) or Heterotrophic Plate Count (HPC) with results not to exceed 500 cfu/ml or gram and total Fecal Coliform bacteria (negative). Records will be maintained for two years. (PIQCS, Sec 5 and 7)
A6, E2	Adequate provisions (such as sanitary gloves) will be made so that hands will not come in direct contact with the ice at any time during manufacturing, processing, packaging, and storage. (PIQCS, Sec 5)
E1, E10	Packaging will be accomplished with non-toxic materials and in a sanitary manner. The bags will be of sound strength and quality to prevent fracture or tearing during handling. They will be stored in a dry, rodent, and dust proof environment. (PIQCS, Sec 5)
E6	Packaged ice products must be tightly sealed and clearly labeled to show the name, manufacturer, and location of processing plant, (date code), and approximate or minimum net weight. (PIQCS, Sec 6)

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TABLE G-I – Continued.

B2, E3	All product storage and holding areas are to be refrigerated and kept in a clean and sanitary manner. (PIQCS, Sec 6)
E3	While being transported or delivered, ice will be protected from contamination. Vehicles used to transport ice will be of cleanable construction, and kept clean and in good repair. (PIQCS Sec 6)
C8	Air used for water agitation will be filtered or otherwise treated to remove dust, dirt, insects, and extraneous material. The compressor or blower system used to supply the air will be designed to deliver oil-free air. Filters will be placed upstream from the compressor and will be easily removable for cleaning or replacement. (PIQCS, Sec 8)
E5	Air lines or vacuum type devices used to remove contaminates from the product's core will be used as needed to produce ice free of rust or other foreign materials. (PIQCS, Sec 8)
B9, E2	Only potable water will be used in sprays and in the thaw tanks for the removal of ice from cans. Ice will not come in direct contact with water in dipping wells. (PIQCS, Sec 8)
C1, C2	Ice cans will be leak proof and the inner surfaces of such containers will be free of corrosion. (PIQCS, Sec 8)
B3, C1, C5	Freezing tank covers of acceptable materials will be designed and constructed to protect ice containers from splash, drip, and other contamination. Can or tank covers, and the ledges or sides of the tank upon which the cover rests, will be cleaned as often as necessary to keep them in a sanitary condition. (PIQCS, Sec 8)

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FISH AND FISHERY PRODUCTS

H.1 SCOPE

H.1.1 Scope. This appendix contains food safety and related guidelines for auditing fresh or frozen processed fish, retorted seafood and specialty fishery product establishments. The information contained herein is intended for guidance.

H.2 APPLICABLE DOCUMENTS

H.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

H.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 114, 123, 161, and 172.

CFR Title 50, Part 260.

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

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

FDA Fish and Fisheries Products Hazards & Control Guide.

(Available on-line at: http://www.cfsan.fda.gov/~comm/haccp4.html.)

Hazard Analysis and Critical Control Point Principles and Application Guidelines.

(Available on-line at: http://vm.cfsan.fda.gov/~comm/nacmcfp.html.)

National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish (2005 version).

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(Available on-line at: http://www.cfsan.fda.gov/~ear/nss3-toc.html. Note: This updated version only includes the full text for those sections of the table of contents revised as a result of actions taken at the 2005 Interstate Shellfish Sanitation Conference. All remaining sections, for which no changes were made, can be accessed via the 2003 Guide at: http://www.cfsan.fda.gov/~ear/nss2-toc.html.)

Regulatory Fish Encyclopedia (RFE).

(Available on-line at: http://www.cfsan.fda.gov/~frf/rfe0.html.)

H.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

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, E-mail: afdo@afdo.org.)

NATIONAL SEAFOOD HACCP ALLIANCE FOR TRAINING AND EDUCATION

Compendium of Fish and Fishery Product Processes, Hazards, and Controls.

(Available on-line at: http://seafood.ucdavis.edu/haccp/compendium/compend.htm.)

Seafood HACCP Alliance Sanitation Control Procedures Training Information.

(Available on-line at: http://seafood.ucdavis.edu/haccp/scp.htm.)

The Fish & Fisheries Products Hazards and Controls Guidance (FDA Guide) SGR 121.

(Available on-line at: http://seafoodhaccp.cornell.edu/manuals_pdf.html.)

H.3 DEFINITIONS

H.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

Fish – also referred to as waterfoods or seafood; includes fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

Fishery product – any human food product in which fish is a characterizing ingredient.

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Molluscan shellfish – any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

Seafood – commonly referred to as waterfoods or fish and includes all fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life. *Excerpted from the January 28, 1994 FDA Federal Register Proposed Rule, “To establish procedures for safe processing and importing of fish and fishery products”.

Shellstock – raw, in-shell molluscan shellfish.

Shucked shellfish – molluscan shellfish that have one or both shells removed.

Smoked or smoke-flavored fishery products – finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

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 Fisheries Products Hazards & Controls Guide. A validated HACCP plan is compulsory for all seafood operations.

H.4.1 General. The Center for Food Safety and Applied Nutrition (CFSAN) located in the Office of the Food and Drug Administration (FDA) in the Department of Health and Human Services is the primary Federal office with the responsibility for the assurance of seafood safety. The Center houses a wide range of programs devoted to the research and management of seafood, including aquaculture products. The FDA derives its authority for such programs primarily through two statutes: 1) the Federal Food, Drug, and Cosmetics Act (FFDCA: 21 U.S.C. 301 et. seq.), and 2) the Public Health Service Act (PHSA: 42 U.S.C. 262, 294 et seq.). Under the FFDCA, the FDA is assigned responsibility to ensure that seafood shipped or received in interstate commerce is "safe, wholesome, and not misbranded or deceptively packaged." Under PHSA, FDA is empowered to control the spread of communicable diseases from one State, territory, or possession to another.

When dealing with seafood the number of species, related hazards, and processes is staggering. You will need to refer to the references listed above often while preparing for an audit of a seafood establishment. *The Regulatory Fish Encyclopedia (RFE)* is a valuable reference tool that provides a compilation of data in several formats that assists with the accurate identification of fish species. It is highly recommended that the auditor be certified in seafood HACCP. The Seafood NIC website, (http://seafood.ucdavis.edu/) run by UC Davis is a valuable resource. Also found on the Seafood NIC is a schedule of seafood training events held in the United States and abroad.

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The Fish & Fisheries Products Hazards and Controls Guidance (FDA Guide) SGR 121 (the purple book) should be the first reference you use. Once you have identified the species of seafood you will be auditing, Chapter 3 will tell you what hazards are identified with that species.

As a general rule we will not audit shellfish plants in CONUS. In OCONUS areas however, the MACOM Veterinarian may require audit, approval, and *Worldwide Directory* listing of these commercial suppliers. By doing business in CONUS, a Shellfish Shipper or Packer (SS/SP) is engaging in interstate commerce and therefore by law must be listed in the Interstate Certified Shellfish Shippers List (ICSSL). Because so much of the program relies on monitoring the water that shellfish is harvested from, it is not practical to approve shellfish SS/SP establishments overseas. If you are tasked to audit a SS/SP establishment, contact your State or FDA office in your area and coordinate training. A list of POCs in your area is in the ICSSL.

The 2005 NSSP Model Ordinance (MO) dictates the severity of all defects. The defects are listed as Critical, Key, Observation, and Swing. A Key is equivalent to our Major. The Military will only inspect Shellstock Shippers (SS), Shucker Packers (SP), Repackers (RP), and Reshippers (RS). Depuration Processors will not be inspected without coordination with the FDA.

FISH AND FISHERIES SPECIFIC INFORMATION

Information presented on the following fish and fisheries products has been obtained from the National Seafood HACCP Alliance for Training and Education, *Compendium of Fish and Fishery Product Processes, Hazards, and Controls.*

Because spores of *Clostridium botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation must be eviscerated prior to processing. Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration must be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Small fish, less than 5 inches in length, that are processed in a manner that prevents toxin formation, and that reach a water phase salt content of 10 percent in refrigerated products, or a water activity of below 0.85 (Note: this value is based on the minimum water activity for growth of *Staphylococcus aureus*) or a pH of 4.6 or less in shelf-stable products, are exempt from the evisceration requirement.

BIOLOGICAL HAZARDS AND CONTROLS

Scombrotoxin (Histamine) Formation – Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with free histidine, a naturally occurring chemical that is present in larger quantities in some fish than in others. The result is the formation of histamine. Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth is more rapid, however, at high-abuse

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temperatures [e.g., 70° F (21.1° C]) than at moderate-abuse temperatures (e.g., 45° F [7.2° C]). Growth is particularly rapid at temperatures near 90° F (32.2° C). Histamine is more commonly the result of high temperature spoilage than of long term, relatively low temperature spoilage. Nonetheless, there are a number of opportunities for histamine to form under more moderate abuse temperature conditions. Freezing may inactivate the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is formed, it cannot be eliminated by heat (including retorting) or freezing. After cooking, recontamination of the fish with the enzyme-forming bacteria is necessary for additional histamine to form. For these reasons, histamine development is more likely in raw, unfrozen fish. Rapid chilling of fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin, especially for fish that are exposed to warmer waters or air, and for large tuna that generate heat in the tissues of the fish following death. It is recommended that:

- Generally, fish should be placed in ice or in refrigerated seawater or brine at 40° F (4.4° C) or less within 12 hours of death, or placed in refrigerated seawater or brine at 50° F (10° C) or less within 9 hours of death;
- Fish exposed to air or water temperatures above 83° F (28.3° C), or large tuna (i.e.,, above 20 lbs.) that are eviscerated before on-board chilling, should be placed in ice (including packing the belly cavity of large tuna with ice) or in refrigerated seawater or brine at 40° F (4.4° C) or less within 6 hours of death;
- Large tuna (i.e., above 20 lbs.) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 50° F (10°C) or less within 6 hours of death.

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, the validity of such testing is dependent upon the design of the sampling plan. The amount of sampling required to accommodate such variability is necessarily quite large. For this reason, chemical testing alone will not normally provide adequate assurance that the hazard has been controlled. Because histamine is generally not uniformly distributed in a decomposed fish, a guidance level of 50 ppm has been set. If 50 ppm is found in one section, there is the possibility that other sections may exceed 500 ppm. Observations for the presence of honeycombing in precooked tuna loins intended for canning is also a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any fish that demonstrate the trait should be destroyed.

Vibrio *cholerae* – was first described as the cause of cholera by Pacini in 1854. Pathogenic *V. cholerae* produces a heat-sensitive enterotoxin that causes the characteristic cholera symptoms, including "rice water stool." The species comprises several somatic (O) antigen groups, including O-group-1, which is associated with classical and El Tor biotypes. *V. cholerae* Ol may have several serotypes, including Inaba, Ogawa, and Hikojima. *V. cholerae* non-O1 (referred to in older literature as nonagglutinable or NAG vibrios) also can cause gastrointestinal disease, though typically less severe than that caused by *V. cholerae* O1 (Yamamoto et al., 1983). Serotype O139 is an exception, and produces classic cholera symptoms. This serotype was first identified in 1992 (CWG, 1933) as the cause of a new epidemic of cholera in India and Bangladesh. Non-O1 *V. cholerae* is found more readily in estuarine waters and seafood in the United States than is the Ol serogroup; however, the 0139

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serogroup has not yet been found here. Because this species can grow in media lacking sodium chloride, it is not considered a halophilic Vibrio, although traces of sodium ion are required for growth. The standard FDA method for recovery of *V. cholerae* is qualitative (presence/absence). Testing *V. cholerae* O1 and non-O1 isolates for production of cholera toxin is recommended. There is a zero tolerance of toxigenic 01 or non-01 *V. cholerae in r*eady-to-eat fishery products (minimal cooking by consumer).

CHEMICAL HAZARDS AND CONTROLS

Chloramphenical – a potent antibiotic that can cause severe toxic effects in humans, including hypo-aplastic anemia, which is usually irreversible and fatal. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man. Because of these human health impacts, chloramphenical, nitrofurans and similar veterinary drugs are not approved for use in food-producing animals in the United State. Other countries have been found to use these drugs in the aquaculture of shrimp and other seafood, including Thailand, Vietnam and China.

Methyl Mercury – the draft Fish and Fishery Products Hazards and Controls Guide (February 16, 1994) listed methyl mercury as a potential safety hazard for bonito, halibut, Spanish mackerel, king mackerel, marlin, shark, swordfish, and bluefin tuna. The selection of these species was based on historical data on levels of methyl mercury found in fish consumed in the U.S. The selection was also based on an FDA action level of 1.0 ppm in the edible portion of fish.

ACIDIFIED FISHERY PRODUCTS

Acidified fishery products must meet the requirements outlined in 21 CFR, Part 114.

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 if the product is refrigerated. If the product is shelf stable the water phase salt level should be 20%, water activity should be 0.85 or below, and a pH of 4.6 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 non-proteolytic types B and F. 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.

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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.
- Maintenance of appropriate temperature if kept refrigerated (40º F (4º C).

BATTERED FISH AND FISHERY PRODUCTS

Potential food safety hazard. *Staphylococcus 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 insanitary 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 hours (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. FDA guidelines for batter mix temperatures of fish and fishery products:

- 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:

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- 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 of vegetative cells of pathogens (or reduction to an acceptable level) 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, and 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 prevent a potential health hazard. 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 processing operations include:

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- 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 seconds (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. Controlling pathogen growth and toxin formation by drying is best accomplished by:

- Scientifically establishing a drying process that reduces the water activity to 0.85 or below, if the product will be stored and distributed unrefrigerated (shelf-stable);
- Scientifically establishing a drying process that reduces the water activity to below 0.97, if the product will be stored refrigerated (not frozen) in reduced oxygen packaging.

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

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scientific study. For shelf-stable products, it should be designed to ensure the production of a shelf stable product with a water activity of 0.85 or less. For refrigerated (not frozen), reduced oxygen packaged products, it should be designed to ensure a finished water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment is required to establish such a drying process. 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 established process 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. 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 non-proteolytic 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.

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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).

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.

Reduced oxygen packaging. There are a number of conditions that can result in the creation of a reduced oxygen packaging environment. They include:

- Vacuum packaging or modified or controlled atmosphere packaging. These packaging methods directly reduce the amount of oxygen in the package;
- Packaging in hermetically sealed containers (e.g., double seamed cans, glass jars with sealed lids, heat sealed plastic containers), or packing in deep containers from which the air is expressed (e.g., caviar in large containers), or packing in oil. These and similar processing/packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

Packaging that provides an oxygen transmission rate of 10,000 cc/m^2/24hrs (e.g., 1.5 mil polyethylene) can be regarded as an oxygen-permeable packaging material for fishery products. This can be compared to an oxygen-impermeable package which might have an oxygen transmission rate as low as or lower than 100 cc/m^2/24hr (e.g., 2 mil polyester). An oxygen permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures. However, use of an oxygen permeable package will not compensate for the restriction to oxygen exchange created by practices such as packing in oil or in deep containers from which the air is expressed (FDA, 2001).

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;

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- 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 numbers of spoilage organisms are 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,).

<u>FDA guidelines</u>. Cold-smoked fish (Reduced Oxygen Packaging):

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- The smoker temperature must not exceed 90º F (32º C) (FDA).

Hot-smoked fish (Reduced Oxygen Packaging):

- The internal temperature of the fish must be maintained at or above 145º F (63º C) throughout the fish for at least 30 min.
- Must have 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).
- The product must not be exposed to temperatures above 50º F (10º C) for more than 12 hours; nor to temperatures above 70º F (21º C) for more than 4 hours; excluding time above 140º F (60º C).
- 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).
- 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.

Critical aspects of processes. Critical aspects of reduced oxygen packaged smoking processes may include:

- brine strength;
- brine to fish ratio;
- brining time;
- brining temperature;
- flesh thickness,
- texture,
- fat content,
- quality, and species of fish;
- drying time;
- input/output air temperature, humidity, and velocity;
- smoke density;
- drier loading;
- 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.

VACUUM AND MODIFIED ATMOSPHERE PACKAGED FISH AND FISHERY PRODUCTS

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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. Examples are products packed in hermetically sealed containers such as cans, deep containers where air is expressed, and packed in oil.

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 Checklists. Guidelines for auditing fish and fishery products establishments are contained in the following Table H-I through H-IV checklists.

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TABLE H-I.

APPENDIX A PARAGRAPH	Seafood general requirements checklist REQUIREMENTS as specified in: CFR Title 21, Parts 123 and 172 Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP) The Fish & Fisheries Products Hazards and Controls Guidance (FDA Guide)
B2	Processing rooms are separated/segregated to eliminate contamination. (FGMP, 2.1 (a))
C1, 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))
B2, E2	Sanitary zones are established around areas in which processed fish is handled/stored. (FGMP, 2.2 (c))
B8, C1	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))
E1	Fish or fishery products are obtained from approved sources as required. (21 CFR 123.12)
E1, E2	Fresh and frozen fish received are inspected and adequately washed before processing. (FGMP, Sec. 4.1 (a))
E2, E3, E7	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))
E2, 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))
B9, 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))
B2, 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))
E2, E6	Sodium nitrite content meets regulatory requirements and product is labeled declaring such use. (FGMP) (FDA Guide, Chapter 19)
E4	Incoming shrimp or lobsters are tested for the presence of sulfite residues at 10 ppm or below OR a supplier's certificate stating the lack of sulfiting agents is presented upon receipt. (FDA Guide, Chapter 19)
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))

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TABLE H-I – Continued.

E2, H6, H8	Lots received are accompanied by harvest vessel records that show fish are placed in ice or refrigerated seawater or brine at 40° F (4.4° C) or less within 12 hours of death or at 50° F (10° C) within 9 hours of death OR fish delivered refrigerated are accompanied by transportation records that show the fish were held at or below 40° F (4.4° C) during transportation OR upon receipt by primary processor, sensory examination of a representative sample of fish shows no more than 2.5% decomposition, and of fish held iced or refrigerated on board the vessel and delivered 24 or more hours after death the internal temperature should be 40° F (4.4° C) or below or for fish held iced or refrigerated on board the vessel and delivered from 12 to 24 hours after death with an internal temperature of 50° F (10° C) or below. (FDA Guide)
E2, E6	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))
E2, E6	The use of sodium nitrite is permitted only with those species of fish allowed by regulation (salmon, sable, shad, chub and tuna). (FGMP, 5.1 (g)) and (21 CFR 172.175 and 172.177)
E2, E3, E6	The finished products are properly cooled to 70º F (21° C) within 2 hours and further cooled to 40º F (4.4° C) within an additional 4 hours. Finished products are then maintained at 40º F (4.4° C). Where the control of nonproteolytic *Clostridium botulinum* is a factor during storage, products are stored at 38º F (3.0° C). (FDA Guide) (FGMP, 5.5)
H6, H8	Records are kept of every transaction involving the sale and distribution of processed fish. (FGMP, 4.3 (a))
H6, H8	Fish processing records are legibly written in English and identify the processing procedures, the product processed, process time, temperature, and the results of 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))
H6, H8	Records are maintained for the chemical examination of finished product for the purpose of validating the water phased salt and sodium nitrite requirements. (FGMP, 4.3 (c))
H6, 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))
H6, 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. (21 CFR 123.9)

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TABLE H-II.

APPENDIX A PARAGRAPH	Smoked, dried, and brined product checklist REQUIREMENTS as specified in: Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP)
C7, C10	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, E11	All fish are free of viscera prior to processing. (FGMP, 4.1 (g))
E2, E6	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. (FGMP, 4.2 (d))
E2, E6	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, E2	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, E6	For hot processed smoked fish to be air packaged, a controlled process is used to heat the fish. (FGMP, 5.3 (b))
E2, E6	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))
E2, E6	Brining operations are performed IAW the appropriate time and temperature parameters. (FGMP, 5.1 (a))
E2, E6	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	Brines are not reused without an adequate process available to return the brine to an acceptable microbiological level. (FGMP, 5.1 (d))
B9, 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))
C7, E2, H3	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))
C10, E2, E4, E6	For 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))

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TABLE H-II – Continued.

C10, E2, E4, E6	For 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))

TABLE H-III.

APPENDIX A PARAGRAPH	MAP packaged checklist REQUIREMENTS as specified in: Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP)
E2	The vacuum packaging or modified atmosphere packaging of processed fish is conducted only within the facilities of the manufacturer. (FGMP, 4.2 (e))
C10, 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))

TABLE H-IV.

APPENDIX A PARAGRAPH	Shellfish checklist REQUIREMENTS as specified in: Good Manufacturing Practices CFR Title 21, Part 123 National Shellfish Sanitation Program (NSSP)
E1	Molluscan shellfish will be derived from shellstock received from harvesters or processors that shuck, ship, or reship or pack shellfish are certified by a shellfish control authority. (21 CFR 123.28)
E1, H6, H8	Identification tags on in-shell and shucked molluscan shellfish, containing all required information are affixed to each container. (NSSP CH X.05), (21 CFR 123.28)
E3	Chilled or iced shucked shellstock maintained at 45°F during storage and transport. (21 CFR 123.11)
E2, E3	Shucked shellfish from different lots are not commingled. (21 CFR 123.11)
B9, E7	Ice used to store shellstock will be potable. (21 CFR 123.11)
H1, H2, H3	Mandatory Critical Control Points Identified by the NSSP Model Ordinance are addressed in the HACCP Plan. (NSSP CH XI.01, XII.01, XIII.01, XIV.01)
H6, H8	HACCP records are maintained for at least one year. (NSSP CH X.01.H.2)

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TABLE H-IV – Continued.

E4, H3	Critical limits will include those listed in Chapter XI. 01, Chapter XII. 01, Chapter XIII. 01, and Chapter XIV. 01, as applicable. As an alternative the dealer may establish other critical limits, which the dealer has demonstrated, provide equivalent public health protection with the exception of receiving which will always be considered as a critical control point. In any case, the critical limits identified in Chapter XI. 01, Chapter XII. 01, Chapter XIII. 01, and Chapter XIV. 01, will be met as components of good manufacturing practices. (NSSP)
H6, H8	Transaction records will be sufficient to: Document that the shellfish are from a source authorized under this Ordinance (the NSSP); Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken; Permit a lot (or commingled lots) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, and if possible, the harvester or group of harvesters. (NSSP CH X.08.B.3)

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PASTEURIZED, REFRIGERATED JUICES

J.1 SCOPE

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

J.2 APPLICABLE DOCUMENTS

J.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

J.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 120.

Federal Register Volume 66, Number 13, Pages 6137-6202.

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

FOOD AND DRUG ADMINISTRATION (FDA)

FDA Guidance for Industry, "Juice HACCP Hazards and Controls Guidance, First Edition", Mar 2004.

(Available on-line at: http://www.cfsan.fda.gov/~dms/juicgu10.html.)

U.S. DEPARTMENT OF AGRICULTURE

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), "Requisite Scientific parameters for Establishing the Equivalence of Alternative Methods of Pasteurization", Aug 2004.

(Available on-line at: http://www.fsis.usda.gov/ophs/nacmcf/2004/nacmcf_pasteurization_082704.pdf.)

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J.3 DEFINITIONS

J.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

Pasteurized Juice – a juice which has been processed (treated) to achieve the FDA mandated 5-log reduction the level of the pertinent microorganism in the juice

J.4 GUIDELINES

J.4.1 General. This appendix does not apply to aseptic fill, acidified, non-refrigerated juices. For these products, reference CFR Title 21, Part 114 and the FDA Juice HACCP Guidance.

All juice produced for DOD procurement will be pasteurized 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.

A validated HACCP plan is compulsory for all pasteurized, refrigerated juice manufacturers.

Processors of juice products will include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (i.e., 10\5\) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The most commonly found pathogens in unpasteurized juices are *E.coli* O157:H7 (bacteria), *Salmonella* (bacteria), and *Cryptosporidium* (parasite). The following juice processors are exempt from this requirement:

(1) A juice processor that is subject to the requirements of part 21 CFR Parts 113 or 114; and

(2) a juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by 21 CFR 120.7.

DAIRY JUICE PRODUCERS. When pasteurizing equipment is used for both milk and juice, the 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.

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- 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 (e.g., "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 CFR Title 21, Part 120 HACCP requirements.

- IAW CFR Title 21, Part 120, producers may obtain a copy of water test results from the community sources. However, 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. Subsequently, juice is cooled to room temperature and filled under aseptic conditions into pre-sterilized containers.

HEAT PASTEURIZATION. The 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

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microorganism of concern (based on juice type/fruit) and the composition of the juice, i.e., 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 will be 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-spore forming, acid tolerant microorganisms are destroyed at 150° F. 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 of microorganisms that will develop under usual storage conditions. This does not completely destroy all microorganisms.

- High Heat Short Time 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: This may increase the heat transfer rate and allow for faster contact times.

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- Vertical Tube Banks 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-pasteurized acid products may be "commercially 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 settling 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° , 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.

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- Black Currant Juice: Steam heat to 176° F, dilute, filter and flash to 170° F. 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 minus 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 establishments are contained in the following Table J-I checklist.

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TABLE J-I.

APPENDIX A PARAGRAPH	Pasteurized, refrigerated juices checklist REQUIREMENTS as specified in: CFR Title 21, Part 120
A11, H2	HACCP plan will be validated and signed every 12 months by trained individuals. (21 CFR 120.11)
E1, H1	Imported juice will originate from processors in countries with either (1) an active MOU with the FDA that covers that juice and documents the equivalency of that countries inspection system or (2) validated and documented HACCP plans, and each delivery will be accompanied by Certificates of Conformance (COC) from government officials. (21 CFR 120.14)
C10, E2, E4, E6, H8, H10	HACCP plans include control measures that will consistently produce, at a minimum, a 5 log reduction in the product, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism and records of routine examination will be available for review. (21 CFR 120.24) and (21 CFR 120.11)
E4, H1	Juice processors will reassess the adequacy of their 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. (21 CFR 120.7)
C10, H6, H8	Records of equipment validation available. (21 CFR 120.11)
H5	Customer complaint process will be in place to determine whether complaints relate to the performance of the HACCP plan or reveal unidentified CCPs . (21 CFR 120.11)
E4	Juice processor's that rely on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of 21 CFR 120.24 will analyze the finished product for biotype I Escherichia coli per 21 CFR 120.25.
E2, H1	A hazard analysis will be conducted for all food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during and after harvest, and be subject to record keeping requirements. (21 CFR 120.7)
E2, H11	Each processor will have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. (21 CFR 120.6)
H11	Establishment will maintain sanitation control records, monitor sanitary conditions and practices, and correct any insanitary conditions in a timely manner. (21 CFR 120.10) and (21 CFR 120.12)

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BOTTLED WATER

K.1 SCOPE

K.1.1 Scope. This appendix contains food safety and related guidelines for bottled water processing establishments. The information contained herein is intended for guidance.

K.2 APPLICABLE DOCUMENTS

K.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

K.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 129 and 165.

CFR Title 40, 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, or online at: http://www.gpoaccess.gov/cfr/index.html.)

K.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

International Bottled Water Association (IBWA)

(Available online at: http://www.bottledwater.org/.)

K.3 DEFINITIONS

K.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

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.

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Natural Mineral Water – means microbiologically wholesome water originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits. Natural mineral water can be clearly distinguished from ordinary drinking water:

- by its nature, which is characterized by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;
- by its original state, both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.

Purified Water – is the name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition, which in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. Alternatively, the water may be called ‘‘deionized water’’ if the water has been processed by deionization, ‘‘distilled water’’ if it is produced by distillation, ‘‘reverse osmosis water’’ if the water has been processed by reverse osmosis, and “_____drinking water’’ with the blank being filled in with one of the defined terms describing the water in this paragraph (e.g., ‘purified drinking water’’ or ‘‘deionized drinking water”).

Sparkling Bottled Water – is the name of water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source.

Spring Water – is the name of water derived from an underground formation from which water flows naturally to the surface of the earth. It will be collected only at the spring or through a bore hole tapping the underground formation feeding the spring. There will be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring will be identified. Spring water collected with the use of an external force will be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and will have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring’s natural orifice. Plants will demonstrate, on request, to appropriate regulatory officials, using a hydrogeologically valid method that an appropriate hydraulic connection exists between the natural orifice of the spring and the bore hole.

Coliforms – are naturally present in the environment; as well as feces; fecal coliforms and E. coli only come from human and animal fecal waste. These bacterial are not normally considered health threats in themselves, but are used to indicate whether other potentially harmful pathogens (e.g., parasites, protozoa, bacteria, or viruses) may be present. Fecal Coliform and E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Disease-causing microbes (pathogens) in these wastes can cause

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diarrhea, cramps, nausea, headaches, or other symptoms. These pathogens may pose a special health risk for infants, young children, and people with severely compromised immune systems.

Sample – a sample normally consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified.

Analytical Unit – is the portion(s) of material taken from a subsample of a sample for the purpose of analysis.

K.4 GUIDELINES

K.4.1 General. Soft drink establishments will be audited in accordance with Appendix A and not this Appendix.

When auditing a bottled water establishment, the auditor should verify the following key points during the audit:

- Source of water is from an adequate (safe) 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.

Label Statements:

If the Total Dissolved Solids (TDS) content of mineral water is below 500 ppm, or if it is greater than 1,500 ppm, the statement ‘‘low mineral content’’ or the statement ‘‘high mineral content’’, respectively, will appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch. If the TDS of mineral water is between 500 and 1,500 ppm, no additional statement need appear.

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When bottled water comes from a community water system, as defined in CFR Title 40, Part 141.2, the label will state ‘‘from a community water system’’ or, alternatively, ‘‘from a municipal source’’ as appropriate, on the principal display panel or panels. This statement will immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter.

When the label or labeling of a bottled water product states or implies (e.g., through label statements or vignettes with references to infants) that the bottled water is for use in feeding infants, and the product is not commercially sterile under § 113.3(e) (3) (i) of CFR 165, the product’s label will bear conspicuously and on the principal display panel the statement: “Not sterile. Use as directed by physician or by labeling directions for use of infant formula.”

K.4.2 Microbiological Criteria. For source water that must meet EPA drinking water standards, no more than 5.0% of the samples may be total coliform-positive in a month. For water systems that collect fewer than 40 routine samples per month, no more than one sample can be total coliform-positive per month. Every sample that has total coliform (TC) must be analyzed for either fecal coliforms or E. coli. If two consecutive samples are TC-positive, and one is also positive for E. coli or fecal coliforms, the system has an acute Maximum Contaminant Level violation. See the EPA Total Coliform Rule for more details and assistance.

Heterotrophic Plate Count (HPC) has no health effects; it is an analytic method used to measure the variety of bacteria that are common in water. The lower the concentration of bacteria in drinking water, the better maintained the water system is. For drinking water, EPA's surface water treatment rules require systems using surface water or ground water under the direct influence of surface water to (1) disinfect their water, and (2) filter their water or meet criteria for avoiding filtration so that the HPC is no more than 500 bacterial colonies per milliliter.

For bottled water tested with the multiple-tube fermentation method, not more than one of the analytical units in the sample will have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit will have an MPN of 9.2 or more coliform organisms per 100 milliliters. For bottled water tested with the membrane filter method, not more than one of the analytical units in the sample will have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample will not exceed one coliform organism per 100 milliliters.

K.4.3 Checklist. Guidelines for auditing bottled water establishments are contained in the following Table K-I checklist.

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TABLE K-I.

APPENDIX A PARAGRAPH	Bottled water checklist REQUIREMENTS as specified in: CFR Title 21, Parts 129 and 165
B2	The bottling room is separated from 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 area and are positioned to minimize post-sanitization contamination. (21 CFR 129.20)
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. (21 CFR 129.20)
B10, E2	Product in process, in other than sealed piping systems under pressure is protected from back-siphonage and other sources of contamination. (21 CFR 129.20)
B2	Processing, washing, and storage rooms are not directly connected to room(s) used for domestic household purposes. (21 CFR 129.20)
E1, H8	Product water used for bottling will be from an adequate (safe) source, properly located, protected, and operated and will be easily accessible, adequate, and of a safe, sanitary quality which will be in conformance at all times with the laws and regulations of the government agencies having jurisdiction. (21 CFR 129.35 (a))
E4, H8	Representative bacteriological samples tested weekly for each type of finished product water produced during a day's production. (21 CFR 129.80 (g)) and (21 CFR 165.110)
E4, H8	Representative chemical, physical, and radiological samples analyzed annually for each type of finished product water. (21 CFR 129.80 (g)) and (21 CFR 165.110)
E4, H8	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. (21 CFR 129.35 (a))
E4, H8	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 will be tested for the residual disinfectants and disinfection by-products (DBP's) listed in 21 CFR 165.110(b)(4)(iii)(h). (21 CFR 129.35(a)(4)) and (21 CFR 129.80(g))
B8, C1, C6	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. (21 CFR 129.37 (a))
B8, 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. (21 CFR 129.37(c))
E2	Filling, capping, closing, sealing, and packaging are done in a sanitary manner. (21 CFR 129.37(d))

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TABLE K-I – Continued.

C1, C6	Storage tanks closed to exclude all foreign matter. Filtered vents provided. Filters are readily cleanable or have replaceable elements. (21 CFR 129.40)
E2, E6, 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. (21 CFR 129.80(a))
E4, E6, 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. (21 CFR 129.80(a))
E2, E10	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. (21 CFR 129.80(b))
C5, H6, H8	Mechanical washers are inspected. Records of physical maintenance, inspections, conditions found, and performance of the mechanical washer, are maintained by the plant. (21 CFR 129.80(b))
B8, E3	Multi-service shipping cases are maintained to assure that they will not contaminate primary containers or the product. (21 CFR 129.80(b))
B8, E6	Sanitizing operations meet requirements contained in 21 CFR 129.80(d).
H6, H8	Records of the intensity of the sanitizing agent and the contact time duration will be maintained by the plant. (21 CFR 129.80(c) and (d))
E6	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. (21 CFR 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. (21 CFR 129.80(e))
E10	Containers and closures are nontoxic and comply with applicable standards. (21 CFR 129.80(f))
E2	Filling, capping, and sealing are monitored. Filled containers are visually or electronically inspected. (21 CFR 129.80(f))
E4, H6, H8	A swab and/or rinse bacterial count performed quarterly on four containers and closures immediately prior to filling the containers and meets the microbiological criteria in accordance with 21 CFR 129.80(f).
E4, H6, H8	Records are maintained of sampling date, type of product, production code, and results of each analysis. (21 CFR 129.80(h))
H6, 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. (21 CFR 129.80(h))

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OFF POST CATERERS, CIVILIAN RESTAURANTS AND READY-TO-EAT MANUFACTURED PRODUCTS

L.1 SCOPE

L.1.1 Scope. This appendix contains food safety and related guidelines for auditing off post caterers, civilian restaurant and other Ready-to-Eat (or Heat and Eat) establishments. The information contained herein is intended for guidance.

L.2 APPLICABLE DOCUMENTS

L.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

L.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) Food Code.

(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 online at: http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

L.3 DEFINITIONS.

L.3.1 Definitions. General definitions are contained in this handbook.

L.4 GUIDELINES

L.4.1 General. This appendix applies to manufacturers of Ready-to-Eat (RTE) and “Heat & Eat” (H&E) manufactured convenience foods. This also includes products which are processed, cooked, cooled or frozen and then distributed to the consumer for re-heating prior to consumption, unless another appendix that identifies the product by-name specifically applies (e.g., Appendix U, Sous-vide / Cook-chill, Appendix H, Fish & Fishery Products, etc.).

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This appendix 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 findings in catering, restaurant and RTE manufacturing establishments. 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 establishment. Your appearance is important. Be sure to wear a clean over-garment to over your street cloths. Always wear a head cover when walking through the establishment. 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). PHF's 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, civilian restaurants and Ready-to-Eat manufactured product establishments are contained in the following Table L-I checklist.

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TABLE L-I.

APPENDIX A PARAGRAPH	Off post caterers, civilian restaurants and ready-to-eat manufactured products checklist REQUIREMENTS as specified in: FDA Food Code
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)
A10, C1, 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, E3	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, E2	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 FDA Food Code. Fruits and vegetables may be washed by using chemicals IAW established guidance. (3-302.15) and (7-204.12)
E2, E7	Ice used as an external coolant is not used as food. (3-303.11)
C1, 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)
E2, E3	During preparation, unpackaged food is protected from environmental sources of contamination. (3-305.14)
E2, E6	Raw animal foods comply with cooking requirements listed in the Food Code. (3-401.11/12)
E2, E6	Fruits and vegetables that are cooked for hot holding are cooked to the internal temperature and time as stated in the FDA Food Code. (3-401-13)
E2, E6	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)

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TABLE L-I – Continued.

E2, E6	Potentially hazardous foods (PHFs) that are cooked, cooled, and reheated for hot holding are reheated so that all parts of the food reach a temperature of at least the internal temperatures and stated time as indicated in the FDA Food Code with exceptions as noted in the reference. (3-403.11)
E6, H3, H8	When a HACCP / Food Safety Program is in place, critical limits are in accordance with the Food Code or have deviations validated by competent authority. (8.201.13 and 8.201.14)
E2, E6	Reheating for hot holding is accomplished as stated in the Food Code. (3-403.11)
E2, E6	Frozen PHF is slacked under refrigeration below 41° F (5° C) with exceptions as noted in the reference. (3-501.12)
E2, E6	Frozen PHF is thawed under proper refrigeration; proper running water technique; proper cooking techniques; and for proper time periods. (3-305.13).
E2, E6	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, E6	PHF is maintained in accordance with proper hot and cold holding procedures. (3-501.16/19)
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, E6, H6	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	Ware washing machines are equipped with proper temperature and pressure indicating devices and are operated in accordance with manufacturers instructions. (4-203.13 and 4-204.115)

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SLAUGHTER AND FABRICATION OF MEAT PRODUCTS OCONUS

M.1 SCOPE

M.1.1 Scope. This appendix contains food safety and related guidelines for auditing meat slaughter and fabrication establishments OCONUS. The information contained herein is intended for guidance.

M.2 APPLICABLE DOCUMENTS

M.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

M.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 9, Parts 53, 54, 71, 72, 75, 94, 307, 309, 310, 313, 327 and 416.

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, or online at: http://www.gpoaccess.gov/cfr/index.html.)

USDA, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

National Center for Import and Export Veterinary Services (NCIE) Programs, List of USDA-Recognized Animal Health Status of Countries/Regions Regarding Specific Livestock or Poultry Diseases, or Acceptable Commodities.

(Available on-line at: http://www.aphis.usda.gov/NCIE/country.html.)

USDA, FOOD SAFETY AND INSPECTION SERVICE

Foreign Establishments Certified to Export Meat, Poultry and Egg Products to the United States.

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(Available on-line at:
http://www.fsis.usda.gov/regulations_&_policies/eligible_foreign_establishments/index.asp.)

M.3 DEFINITIONS

M.3.1 Definitions. General definitions are contained in this 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. BSE is becoming an increasing public health concern/threat in livestock in the US, UK, Canadian, etc. Animals infested with ticks or exposed to severe tick infestation should not be slaughtered for food or human consumption. Auditors must be knowledgeable of the signs of medical conditions in order to ensure wholesome meat products are procured. Regional Public Health Officials should be able to provide information on their region's status concerning herd health; therefore, good communications should be maintained between overseas health authorities and the Army Veterinary Service.

Ante-mortem inspections are performed on each animal prior to slaughter for the purpose of eliminating those unfit for the preparation of food. Competent ante-mortem inspection gives the only assurance that unfit animals will not enter the slaughter establishment (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 diseased 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 examined 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.

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The slaughter line is a dangerous area to work around. Auditors should never enter the slaughter area directly from the holding pens without first washing their 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 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 to the carcass. Also, pay special attention to the water being used to wash the floor. In an effort to make the establishment 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 are twenty minutes and from the 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, 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 objective for slaughtering animals is 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 (i.e., 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 45° F (7° 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).

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This portion was written to acquaint you with livestock (meat) slaughtering and fabrication and was not intended for use with poultry. For poultry slaughter and processing, use Appendix O. You will find numerous variations of slaughtering and dressing procedures throughout the world. 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 MACOM Veterinarian.

M.4.2 Checklist. Guidelines for auditing of meat slaughter and fabrication establishments OCONUS are contained in the following Table M-I checklist.

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TABLE M-I.

APPENDIX A PARAGRAPH	Slaughter and fabrication of meat products OCONUS checklist REQUIREMENTS as specified in: CFR Title 9, Parts 94, 110, 307, 309, 310, 313 and 416
E2	Handling of livestock from the unloading ramps to the stunning area is done in a humane manner. (9 CFR 313)
B2, C1	Pens, chutes and alleys are paved, drained and supplied with adequate hose connections for cleanup purposes. (9 CFR 307.2)
E2	Livestock entering the establishment 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, B5	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 has 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. If held longer than 24 hours, feed is provided. (9 CFR 313.2)
E1, E11	Seriously crippled animals, “downers," are not slaughtered for human consumption (BSE requirement). (9 CFR 309.2)
E1, E11	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, E11	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, C1	Floors of livestock pens, ramps, and driveways are constructed and maintained as to provide good footing for livestock. (9 CFR 313.1)
B2, E1	Humane methods of slaughter are applied within an appropriate stunning area. (9 CFR 313)
E1, E2	Animals are adequately stunned prior to being shackled, hoisted, thrown, cast, or cut (bleeding). (9 CFR 313.2)
E1, E2	A careful post-mortem examination and inspection is made of carcasses and parts of all livestock slaughtered. (9 CFR 310.1)
E1, 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)

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TABLE M-I – Continued.

E2	Identification devices (i.e., ear tags) are removed from the animal's hide or ear by an establishment's employee and are properly affixed to the corresponding carcass. Supervising veterinarian may allow alternate methods of tracing carcasses back to live animal records. (9 CFR 310.2)
E2, E11	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 veterinary final inspection has been completed. Retained carcasses are not washed or trimmed unless authorized by veterinary official. (9 CFR 310.3)
E2, E11	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, E11	Spermatic cords and pizzles are removed from all carcasses. Preputial diverticuli are removed from hog carcasses. (9 CFR 310.7)
E2, E11	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, E11	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, E11	The sternum of each carcass is split and abdominal and thoracic viscera are removed at the time of slaughter in order to allow proper inspection. (9 CFR 310.12)
E2, E11	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 and disinfected immediately and disinfected. (9 CFR 310.9)
E2, E11	The kidney capsule is opened to expose the kidneys for the purpose of inspection. (9 CFR 310.19)
E2, E11	Partially skinned carcasses are not stimulated. (9 CFR 416.12)
B8, C1	For hide-off stimulation, the carcass contact surfaces of equipment are disinfected between carcasses. (9 CFR 416.12)
E2, E3	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. (9 CFR 310.14)
C1, C4	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)

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TABLE M-I – Continued.

E2, E11	Carcass contamination of edible tissue by stomach contents, feces and/or urine is unacceptable. (9 CFR 416.12) To prevent this contamination, any of the following are used prior to electrical stimulation: a. Leave the sphincter muscles intact. b. Cut the rectum (scalp the bung) and the urethra free from surrounding tissue and securely tie each off. c. Partially open the mid-line and/or slay the brisket to reduce pressure on the visceral organs. d. Any other pressure-relieving or discharge-restricting alternative acceptable to the chief veterinary inspector. e. Rod (separate the esophagus from the surrounding tissue) and tie it off.
B3, B8, C1, C6, E2, E11	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: a. Knives are immediately disinfected after contamination (i.e., after sticking, head removal, following the initial cut through the hide/skin, after removal of an abscess, bruise or contamination). b. No water is placed onto a carcass until the entire hide has been removed and the carcass inspection has been performed. c. Manual hide removal begins at the hind leg and proceeds downward allowing the hide to be laid back away from the flesh. d. The final wash is begun at the highest point of the carcass and works downward. e. No portion of the forequarters comes in contact with eviscerating/inspection tables. f. Overhead rails are free of flaking rust or grease. g. Carcasses do not come in contact with walls, pillars, dividers or other features that will result in cross-contamination. h. Adequate separation is provided between offal rooms and product areas. i. Pressurized water used to wash down equipment and facilities are only used when carcasses are not in the location (to avoid splash contamination). j. Ventilation is provided at the location of a mechanical hide puller. k. Condensation does not drip onto carcasses. l. Carcasses are washed immediately after the final inspection and prior to being placed into a cooler. m. The floor area (dry landing) within the stunning box is maintained in a reasonably dry condition.
E2, B10	Nonpotable water lines are clearly identified. (9 CFR 416.12(g))

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TABLE M-I – Continued.

B10, E2	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. (9 CFR 416.12 (g)
B9	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 416.12(g)
B9, B10	A supply of potable, running water at a suitable temperature and under pressure as needed, must be provided in all areas when required (for cleaning rooms and equipment, utensils, and packaging facilities and for employee sanitary facilities, etc. (9 CFR 416.2)
B2, C6, E2	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 416.2-3)
A4, B13, E2, E11	Workers 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 416.5)
B6, B8, C1	Equipment and/or utensils 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 416.3, 4, 6 and 12)
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 416.2)
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 416.2)
B5, B6, C7, C10, E4, H6	Hot water disinfecting units are maintained above 180° F (82° C), allow immersion of the hilt and are adequately located. Chemical disinfectants may be used during production when used in accordance with manufacturer's instructions and/or approved by the MACOM Veterinarian. (9 CFR 416.2)
C1, C2	Cutting boards and tables are solid, clean and sanitary. (9 CFR 416.3)
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 416.5)
A2, A3	Aprons, frocks, and other outer clothing worn by persons who handle product are clean and are changed each day. (9 CFR 416.5)
C1, C2	Scabbards are constructed of a smooth impervious material. (9 CFR 416.4)

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TABLE M-I – Continued.

C7, C10, E2, E3, H6	All food manufacturing, including packaging and storage, will be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or the contamination of food. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, will be held in a manner that prevents the food from becoming adulterated. Compliance for fabrication areas may be accomplished by maintaining these areas at or below 50° F (10° C) unless local regulations authorize a higher temperature. In any case, processes should ensure that fresh meat does not exceed 45° F (7° C) during fabrication. (21 CFR 110.80)
E4, E6, E11, H8	Livestock must be tested for Escherichia coli Biotype 1 (E. coli) at a minimum of one sample during each week of operation. (9 CFR 310.25 (a)(2))
B2, E2, E6, E11, H3	In establishments where multiple species of animals are processed, separate processing areas and worker procedures must be in place to prevent cross-contamination between species. This is especially important in countries where ruminant animals are not free of BSE and other significant animal diseases. (9 CFR 416.3-5 and 12-13) (9 CFR 94)

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DRY DAIRY PRODUCTS

N.1 SCOPE

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

N.2 APPLICABLE DOCUMENTS

N.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

N.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 131 and 173.

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) 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, 5100 Paint Branch Parkway, College Park, MD 20740-3835.)

N.2.3. Non-Government publications. The following documents form a part of this document to the extent specified herein.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

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

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

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/.)

N.3 DEFINITIONS

N.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

Dry Milk Products – products resulting from the frying of milk or milk products and any product resulting from the combination of dry milk products with other wholesome dry ingredients.

Grade "A" Dry Milk Products – products which comply with the applicable provisions of the FDA PMO.

Dry Whey Products – products resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome ingredients.

Grade "A" Concentrated (Condensed) and Dry Whey Products – products which comply with the applicable provision of the FDA PMO.

N.4 GUIDELINES

N.4.1 General.

Pasteurization Systems. The establishment 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.

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- 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, sanitizers.
- Determine if equipment is constructed and maintained to protect the product from dust and environmental contamination.
- 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 hot wells 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.
- Potential for plumbing back-flow. For example, can water used to produce vacuum be back siphoned into the plant's water supply?
- Evaluate air filtration system and determine the air-flow throughout the plant. Consider the following:
    - The 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, i.e., entering and leaving drying chamber.

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- Establishment's 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, i.e., in sanitizing and packaging rooms.
- Clean, adequately filtered air should be supplied to product dryers, product coolers, dry product handling and sanitizing 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.
- 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 procedures 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 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.

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- 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, i.e., 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, i.e., 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 the PMO.
- Determine the disposition of powder and dust collected during plant cleanup.
- Milk powder recovered from bag collectors and other places in the sanitizing process (other than "fines" which are recirculated) may be fed back into the system, but, unless rehydrated and pasteurized prior to recycling since 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:

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a. It is produced in a state of the United States, or
b. The source is listed in the *Worldwide 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*.

N.4.3 Checklist. Guidelines for auditing dry dairy product establishments are contained in the following Table N-I checklist.

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TABLE N-I.

APPENDIX A PARAGRAPH	Dry dairy products checklist REQUIREMENTS as specified in: USPHS/FDA Pasteurized Milk Ordinance (PMO)
E1	Milk originates from farms that meet the requirements or intent of the PMO and herds that meet the annual health requirements as specified in Section 8 (Animal Health) of the PMO or equivalent program as determined by the MACOM Veterinarian. (PMO, Sec. 8)
B9, E1	The source of water (to include reclaimed water), vitamins, flavorings, etc., meets standards. (PMO, Sec. 7 and Appendix G)
H6, H8	A system of tagging or recording tanker trucks that have been cleaned and sanitized is established and maintained for 15 days. (PMO, Sec. 7)
E1, E4, H6, H8	Upon arrival, raw milk and/or raw products for pasteurization complies with bacteriological, chemical and temperature standards. (PMO, Sec. 7).
E4, H6, H8	Raw milk and milk products are screened for drug and pesticide residue. (PMO, Sec. 6 and Table 1)
E3	Raw milk and milk products are held at 45° F (7° C) or less until processed. (PMO, Sec. 7, Item 17p)
E3	Condensed milk is held at 45º F (7° C) or less. (PMO, Sec. 7)
E3	Whey for condensing is maintained at 45º F (7° C) or less; or 145º F (63º C) or greater until processed. (PMO, Sec. 7)
E6	Condensed whey is cooled during the crystallization process to 45º F (7° C) or less within 18 hours of condensing. (PMO, Sec. 7)
C1, C6, E6	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). (PMO, Sec. 7)
C4	Welded portions of food contact surfaces are smooth and free from pits, cracks, or inclusions. (PMO, Sec. 7)
C1	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. (PMO, Sec. 7)
C1, C5	Equipment is designed to protect against surface and overhead contamination. (PMO, Sec. 7)
C1, C6	Raw milk storage tanks are cleaned when emptied and should be emptied at least every 72 hours. (PMO, Sec. 7)
C7, C9	Storage tanks used to store raw milk or heat-treated milk products are equipped with a 7-day temperature recording device. (PMO, Sec. 7)
C1, C5	Pasteurizing equipment complies with the sanitary design and construction standards of the PMO or equivalent in OCONUS. (PMO, Sec. 7)

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TABLE N-I – Continued.

C10, E4, E6, H6, H8	Pasteurization equipment and controls testing is performed in accordance with the PMO. (PMO, Appendix F)
H6, H8	Pasteurization recording charts are maintained on file at the processing plant. (PMO, Sec. 7)
C7, C10, H6, H8	Thermometers meet requirements. (PMO, Sec. 7 and Appendix E)
E2, H6, H8	Temperature and pH recording charts are complete and maintained. (PMO, Sec. 7 and Appendix H)
C1	Equipment is constructed to ensure static accumulations are limited. (PMO, Sec. 7)
B2, B8	Rollers and collectors are located in a room separate from other operations to prevent airborne contamination. (PMO, Sec. 7)
B8, C1, E2	Conveying equipment is cleaned at least daily. (PMO, Sec. 7)
C1	Sifter screens are easily removed and kept clean. (PMO, Sec. 7)
B5	The plant air filtration system meets requirements. (PMO, Sec. 7)
E2	Cooling water used in a cooling tower is not used where it will come in direct contact with products (cooling products). (PMO, Sec. 7)
E2, E6	Safeguards are in place to preclude the contamination of finished products during filling. (PMO, Sec. 7)
E2	The topping off of containers to obtain the proper weight is done in a sanitary manner. (PMO, Sec. 7)
E1, E2	Ingredients from damaged containers are reprocessed prior to being repackaged. (PMO, Sec. 7)
C8	Culinary steam is in accordance with PMO. (PMO, Sec. 7 and Appendix D)
B6, C1	Boiler water additives comply with FDA PMO, Appendix H.
C8	Air under pressure is in accordance with 3-A Accepted Practices. (PMO, Appendix C)
E2	There are no cross-connection or direct contamination of pasteurized milk or milk product (raw with pasteurized). (PMO, Sec. 7)
B8, C1, E5	All openings, including valves, pipes, milk tanker trucks, etc. are capped or otherwise protected when not in use. (PMO, Sec. 7)
B10, E2, E5	Re-circulated cooling water is protected from contamination. (PMO, Sec. 7)
E4	Re-circulated cooling water is tested once per six-month period. (PMO, Appendix D)

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TABLE N-I – Continued.

C6, C7, E6	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 which the line or equipment is exposed to cleaning and sanitizing solution (retained for 3 months). (PMO, Sec. 7)
H6, H7, H8, H9	Record of CIP cleaning process is maintained for recirculating cleaning systems. (PMO, Sec. 7)
B2, 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. (PMO, Sec. 7)
E4, H6, 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. This is recorded and records maintained. (PMO, Sec. 7)
E4, H6, H8	Residual bacteria counts for multi-use and single-service containers meet the standards listed in the PMO. This is recorded and records maintained. (PMO, Sec. 7)
B6, E3	Poisonous or toxic materials are not stored in any room where milk or milk products are received, processed, pasteurized or stored. (PMO, Sec. 7)
B6	Only approved pesticides are used. (PMO, Sec. 7)
A2, A8, A10, A11	Employee habits and dress, particularly the use of special clothing while handling or in contact with products or product contact surfaces, is appropriate. (PMO, Sec. 7)

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SLAUGHTER AND FABRICATION OF POULTRY PRODUCTS OCONUS

O.1 SCOPE

O.1.1 Scope. This appendix contains guidelines for auditing poultry slaughter and processing establishments OCONUS. The information contained herein is intended for guidance.

O.2 APPLICABLE DOCUMENTS

O.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

O.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 9, Parts 381, 416 and 417.

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

O.3 DEFINITIONS

O.3.1 Definitions. General definitions are contained in this handbook.

O.4 GUIDELINES

O.4.1 General. Establishments utilizing forced air chilling of the product will ensure the Food Safety Program addresses the environmental as well as the proper carcass chilling temperature and time concerns.

A validated HACCP plan is compulsory for poultry processing establishments in accordance with 9 CFR Part 417.

This guideline has been written for military procurement overseas. Therefore, it is extremely important that an auditor know about the prevalence of diseases afflicting poultry in the region the flocks are kept in. In general, flocks are kept within a short drive of the plant

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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 Tuberculoses, diseases of the leukosis complex, septicemia or toxemia, airsacculitis, inflammatory processes, tumors, and parasites.

Auditors must be knowledgeable of the signs of the medical conditions listed above in order to ensure 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 herd; 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 the preparation of food. Competent ante-mortem inspection gives the only assurance that unfit animals will not enter the slaughter establishment. 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 diseased 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. The viscera may be removed and left attached to the carcass. 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. 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 you are clean. Stay clear of electrical stimulation devices, if you are working in a wet area and possibility of an electrical problem does exist.

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

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

2. BLEEDING: Birds are bled immediately after stunning (animals must die by exsanguination). Kosher/Halal birds are killed by bleeding without previous stunning simultaneously by severing the trachea and major blood vessels.

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). Too high of a temperature 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 can be accomplished manually or mechanically. Post-mortem examination may be accomplished after the abdominal cavity is opened and prior to evisceration, however it will normally be conducted after 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 come in direct contact with carcasses which makes this medium a potential source of contamination. Salmonella and other microorganisms may build-up 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

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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 poultry slaughter and processing establishments are contained in the following Table O-I checklist.

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TABLE O-I.

APPENDIX A PARAGRAPH	Slaughter and fabrication of poultry products OCONUS checklist REQUIREMENTS as specified in: CFR Title 9, Part 381 and 416
E1, E11	Birds originate from healthy flocks. Birds are free of communicable disease. Birds from a quarantine region are processed in that region. (9 CFR 381.36)
B1, B2, 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 will be 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, B4	Batteries, coops or other facilities in which live poultry are presented for ante-mortem inspection will be arranged, constructed and lighted so that the inspector can carry out the inspection. (9 CFR 381.36)
E2, E11	Post-mortem inspection will be made on a bird-by-bird basis or per country requirements. Facilities for post-mortem inspection will comply with minimum facility requirements for the system of postmortem inspection employed. Maximum inspection rate allowed for the system of postmortem inspection employed must be adhered to, as specified. (9 CFR 381.36) and (9 CFR 381.76)
E2	Body cavity will be opened to permit post-mortem inspection. No viscera will be removed prior to post-mortem inspection, unless identity with the rest of the carcass is maintained. (9 CFR 381.76)
E2, E11	The presence of the following conditions will result in condemnation of the carcass: tuberculosis; leukosis complex; septicemia; toxemia; air sacculitis; tumors; parasites; bruises affecting the whole carcass; over scald (flesh has a cooked appearance); cadavers (died prior to bleeding); decomposition; any disease characterized by presence of organisms/toxins, in the edible portions, dangerous to the consumer. (9 CFR 381.80 thru 381.93)
B14, E2, E6	Condemned carcasses will be disposed of in accordance with one of the approved methods of described in reference requirements. (9 CFR 381.95)
E2	Blood from the killing operation will be confined to a relatively small area. (9 CFR 381.65)
E2	Birds will have been thoroughly bled and have stopped breathing prior to scalding. (9 CFR 381.65)
B8, C1	Chilling tanks will be cleaned and operated in a manner consistent with meeting the pathogen reduction performance standards set forth in 9 CFR 381.94 and the provisions of the establishment's HACCP plan. (9 CFR 381.66)
B9, E7	Only potable water or potable ice may be used in chill tanks. (9 CFR 381.66)

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TABLE O-I – Continued.

E2, E11	Poultry carcasses contaminated with visible fecal material will be prevented from entering the chilling tank. (9 CFR 381.65)
E2, E6	Major portions of poultry carcasses will be chilled to not more than 40° F (4.4° C) within the following times: less than 4 pounds (1.814 kg) - 4 hours; 4 - 8 pounds (3.629 kg) - 6 hours; over 8 pounds - 8 hours. The HACCP plan will specifically address this potential hazard for carcasses over 8 pounds. (9 CFR 381.66)
E2, E6	Giblets will be chilled to 40° F (4.4° C) or lower within 2 hours after separation from the inedible viscera, unless they remain attached to the carcass. (9 CFR 381.66)
E2, E6	Poultry which is further processed after slaughter may have a temperature no higher than 55° F (13° C) during further processing and packaging. (9 CFR 381.66)
E2, E6	Fresh poultry which is to be held at the establishment in excess of 24 hours will be held in a room at a temperature of 36° F (2.2° C) or less. (9 CFR 381.66)
E2, E11	”Ready-to-cook poultry’ will be free of from protruding pin feathers and vestigial feathers. The head; feet; crop; oil glands; trachea; esophagus; entrails and lungs will have been removed. Final product will be suitable for cooking without need of further processing. (9 CFR 381.1)
B9	Non-potable 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 or other uses as described in reference regulation. (9 CFR 416)
B9	Non-potable water is not permitted for use in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions. (9 CFR 416)
B9, B10	In all cases, non-potable water lines are clearly identified. (9 CFR 416)
B6	If hot water is used for sanitizing, it is at a temperature of not less than 170° F (77° C) with a minimum 30 second contact time. Chemical sanitizers may be used (as allowed under 21 CFR 178.1010) provided they provide the equivalent bactericidal effect of a solution containing at least 50 ppm available chlorine as a hypochlorite at 75° F (24° C) for 1 minute. Other approved sanitizing methods may be used, as described in reference regulations or as approved by the MACOM Veterinarian. (9 CFR 381.10)
H3	Establishment addresses (HACCP) pathogen reduction performance standards set forth in 9 CFR 381.94.

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FRESH-CUT FRUITS AND VEGETABLES

P.1 SCOPE

P.1.1 Scope. This appendix contains guidelines for auditing fresh-cut fruit and vegetable establishments. The information contained herein is intended for guidance.

P.2 APPLICABLE DOCUMENTS

P.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

P.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 110 and 173.

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

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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

(Available on-line at: http://www.foodsafety.gov/~dms/prodguide.html/.)

Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables, Draft Guidance, March 2007, U.S. Department of Health and Human Services, Food and Drug Administration, CFSAN.

(Available on-line at: http://www.cfsan.fda.gov/~dms/prodgui3.html/.)

Methods to Reduce/Eliminate Pathogens from Fresh and Fresh-Cut Produce, Sep 01, U. S. Department of Health and Human Services, Food and Drug Administration, CFSAN.

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(Available on-line at: http://www.cfsan.fda.gov/~comm/ift3-5.html/.)

Microbiological Safety of Controlled and Modified Atmosphere Packaging of Fresh and Fresh-Cut Produce, 2001, U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition.

(Available on-line at: http://www.cfsan.fda.gov/~comm/IFT3-6.html/.)

P.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

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

(Application for copies should be addressed to United Fresh Produce Association, 1901 Pennsylvania Ave. NW, Suite 1100, Washington, DC 20006.)

Fresh-Cut Products: Maintaining Quality and Safety, 2006.

(Application for copies should be addressed to University of California, Davis, Dept. of Plant Sciences, Mail Stop 2 (Wickson Ave), One Shields Avenue, Davis, CA 95616-8683, or online at: http://postharvest.ucdavis.edu/Pubs/Pub_desc_10-06.pdf/.)

Post-harvest Chlorination - Basic Properties and Key Points for Effective Distribution, 1997.

(Application for copies should be addressed to University of California, Davis, Dept. of Plant Sciences, Mail Stop 2 (Wickson Ave), One Shields Avenue, Davis, CA 95616-8683, or online at: http://vric.ucdavis.edu/selectnewtopic.foodsafety.htm/.)

P.3 DEFINITIONS

P.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

Processing water – water used for post harvest handling of produce, such as washing, cooling, waxing, or product transport.

P.4 GUIDELINES

P.4.1 General. Fresh-cut Fruits and Vegetables (commonly referred to as minimally processed) include the following items (not all inclusive):

- Peeled and sliced potatoes.

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- Shredded lettuce and cabbage.
- Washed and trimmed spinach.
- Chilled peach, mango, melon and other fruit slices.
- Vegetable snacks (celery/carrot sticks, broccoli/cauliflower florets, and baby carrots).
- 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 post harvest 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. Approved water disinfectants and their amount allowed during processing (see checklist) and the pH of the product determine the final efficacy of the disinfectants on fresh-cut-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 an antimicrobial agent, as well as the amount that should be used, depends on the treatment conditions, such as water

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temperature, acidity [pH], water hardness, contact time, amount of organic material, and the resistance of pathogens to the particular antimicrobial agent. 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 manufacturer's 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. For example, the antimicrobial activity of a chlorine-based disinfectant depends on the amount of hypochlorous acid (also called "free chlorine") present in the water. The amount of hypochlorous acid in the water depends upon the pH of the water, the amount of organic material in the water, and to some extent, the temperature of the water. If the amount of hypochlorous acid is not maintained when the amount of organic material increases, the antimicrobial agent may lose effectiveness in maintaining water quality. If a fresh-cut processor uses a chlorine containing compound as a disinfectant, the processor should monitor the processing water for free chlorine or hypochlorous acid concentrations. The fresh-cut processors should consider options for maintaining the safety of water most appropriate for their individual operations. See 21 CFR 173.315, "Chemicals used in washing or to assist in the peeling of fruits and vegetables," for additional information about chemicals approved for use in wash water.

- Fresh-cut processors should also consider the following regarding water quality maintenance:

  - Following the manufacturer's directions for correct mixing of antimicrobial agents to obtain effective concentrations and to minimize safety hazards.
  - Monitoring disinfectant levels frequently in water used for various processing operations to ensure appropriate concentrations are maintained.
  - Test strips or test kits may be useful for monitoring some disinfectant levels.
  - Minimizing the build up of organic material in wash water For some operations, filtering recirculating water or using a net to scoop plant material or other debris from tanks may help reduce the build up of organic material.
  - Following contact between produce and processing water containing antimicrobial chemicals with a clean water rinse to remove any treatment residues where appropriate and according to and consistent with the manufacturer's direction.

- 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 (cabbage) may be washed separately from others. Certain types of produce (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

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pulled into produce. A number of methods can be employed to achieve adequate lethality for the pathogen of greatest concern. Examples are as follows:

- For some operations, a series of washes may be more effective than a single wash. An initial wash treatment may be used to remove the bulk of field soil from produce followed by an additional wash or washes containing an antimicrobial chemical.
- Using appropriate wash methods. Vigorous washing of produce not easily bruised or injured increases the likelihood of pathogen removal. Different methods may be used to wash different types of produce, including submersion, spray, or both. Regardless of the method used, maintaining the quality of the wash water is important in order to minimize the potential for contamination.
- Maintaining the efficacy of wash treatments.
- Using wash water of an appropriate temperature. For many types of produce, removing field heat is a primary consideration in maintaining quality. However, some types of produce such as cantaloupe, mangoes, and tomatoes are susceptible to infiltration of wash water if warm produce is placed in water that is cooler than the produce. Such infiltration occurs when the temperature difference creates a pressure differential causing air spaces inside the fruit or vegetable to contract, thereby allowing water to be pulled into the fruit or vegetable. Thus pathogens that may be present on the surface of the produce or in the water may be drawn into the produce. If pathogens are pulled into the produce, subsequent washing will not reduce levels of these pathogens. For products that may be susceptible to pathogen internalization, the recommended temperature differential (e.g., temperature difference between the wash water and the temperature of the fresh produce) may be achieved by cooling produce before immersion. When it is not practical to reduce the temperature differential between the water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. If product is washed or cooled in a submersion system, care must be taken to control the rate of product flow to minimize the amount of product that is submerged at a greater depth as well as the time sufficient to accomplish the process.
- When recommended ranges are either not met or exceeded, the auditor should request supplemental research to support the food safety program.

- 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.

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Sanitizer dip stations for cutting utensils and employee hands should be accessible. Product internal temperatures should be maintained at 40º F (4.4º C).

- 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 increase the shelf life and quality. The key parameter for any Modified Atmosphere Packaging (MAP) is 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 fruit and vegetable establishments are contained in the following Table P-I checklist.

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TABLE P-I.

APPENDIX A PARAGRAPH	Fresh-cut fruits and vegetables checklist REQUIREMENTS as specified in: CFR Title 21, Part 110 Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables Food Safety Guidelines for the Fresh-Cut Produce Industry Methods to Reduce/Eliminate Pathogens from Fresh and Fresh-Cut Produce Microbiological Safety of Controlled and Modified Atmosphere Packaging of Fresh and Fresh-Cut Produce
E2	Trimming, coring, cutting and culling operations are performed in a sanitary manner. (21 CFR 110.35, 110.37, 110.40)
E2, E4, E6, H6, H8	Wash water disinfectant level established and pH (if applicable) monitored to include but not limited to: - Chlorine level parameter is established and monitored at 50-200 ppm total chlorine contact time; pH 6.0-7.5, final rinse required. - Hydrogen peroxide level not to exceed 59 ppm in wash water; final rinse required. - Peroxyacetic acid level not to exceed 80 ppm in wash water; pH range 1.0 – 8.0. - 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. - Chlorine dioxide level not to exceed 3 ppm residual followed by a final rinse of adequate quality water; pH range 6.0-10.0. - Ultraviolet (UV) light effective at 240-260 nanometer wavelength range. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables) (Methods to Reduce/Eliminate Pathogens from Fresh and Fresh-Cut Produce) (Food Safety Guidelines for the Fresh-Cut Produce Industry) Note: If another disinfection program is in use, the establishment must provide evidence of acceptable water safety.
E2, E6, H3, H6, H8	Product contact time is established and monitored IAW established FSP (dump tank, submersion, sprayer, flume, hydrocooler method). (Food Safety Guidelines for Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E2, E6, H6, H8	Water recirculation method is established and monitored (filtration, displacement, replacement). (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
B6, E11	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) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)

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TABLE P-I – Continued.

E2, H6	Dewatering, centrifugation, or drying methods established (when applicable) to ensure removal of free surface moisture after washing. (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E5, H6, H8	Method(s) to exclude physical contaminants are established and monitored (including but limited to metal detector, visual screening, and sieves). (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E2, E6, H3	Holding time throughout the entire process, especially post-wash and prior to packaging (weighing, transporting, collecting), is minimized. (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E2, E10, 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. (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E2, E6, H3, H6, H8	Parameters for modified atmosphere(s) packaging are established and monitored (e.g., 1 - 5% oxygen). (Microbiological Safety of Controlled and Modified Atmosphere Packaging of Fresh and Fresh-Cut Produce) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E2, E6	Each retail and food service package has a “USE BY DATE” or distinguishable coding and a “KEEP REFRIGERATED” label. (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E3	Product temperatures maintained at 4.4º C (40º F) or below during storage and distribution. (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables)
E4, H3, H6, H8	All product contact water have established and monitored disinfectant parameters to include filtration and recirculation methods. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables) (Food Safety Guidelines for the Fresh-Cut Produce Industry) (Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables) Note: Recycled water should run counter flow to produce (i.e., final rinse water may be used as cooling water).
E6	Establishment has traceforward and traceback capabilities. (Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables)

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MANUFACTURED EGG PRODUCTS

Q.1 SCOPE

Q.1.1 Scope. This appendix contains guidelines for auditing manufactured egg product establishments. The information contained herein is intended for guidance.

Q.2 APPLICABLE DOCUMENTS

Q.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

Q.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 110.

CFR Title 7, Parts 56 and 59.

CFR Title 9, Part 590.

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

U.S. DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE

Egg Product Inspectors Handbook.

(Available through USDA, FSIS, Technical Service Center (TSC), Omaha, Nebraska (800) 233-3935.)

U.S. DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE

Shell Egg Inspections Handbook.

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(Available through USDA, AMS, Standardizations Branch, Washington, DC.)

Q.3 DEFINITIONS

Q.3.1 Definitions. General definitions are contained in this handbook

Q.4 GUIDELINES

Q.4.1 General. These guidelines have been written for military procurement overseas.

It is important to understand that manufactured eggs are a growth industry. An ever-increasing number of shell eggs are raised specifically for manufactured egg products as opposed to shell eggs. It is also important to understand that shell eggs from which manufactured eggs are derived, may be contaminated with food pathogens, particularly Salmonella and that liquid egg is an excellent growth media for pathogens.

Raw Materials: A common perception is that dirty or so-called “loss” eggs that are unacceptable for sale as shell eggs may be diverted to egg breaking plants. Loss eggs may be used for animal feed or for uses other than as human food. Eggs used for human food should be Grade B or higher. Definitions for loss eggs and egg quality grades can be found in the USDA, AMS shell egg inspection handbook. If it is legal to do so, eggs should be washed. There are specific guidelines to safely and effectively wash eggs in 9 CFR 590.515. However, it is illegal to wash eggs in some OCONUS nations. Nevertheless, excessive dirt and filth adhering to the shell egg exteriors would be considered adulteration if allowed to be incorporated into the liquid egg product. Eggs should be relatively clean, with no clumps or loosely adhering dirt or filth. Eggs should be broken in such a way as to minimize contact between the eggshell exterior and the egg contents. Afterwards, the establishment must use screens, filtration and other methods to detect and remove small blood spots and meat spots, shell particles and foreign materials.

Additive Ingredients: Substances or ingredients used in the manufacture or preparation of any product capable of use as human food will be clean, wholesome and unadulterated.

Egg Breaking Operations: Eggs will be broken in a sanitary and satisfactory manner and reexamined by a qualified person before being released into tank or churns. Small blood spots, small meat spots and shell particles must be removed with a spoon or other approved instrument. Following breaking, egg contents must be cooled unless pasteurized immediately. The acceptable temperature varies with the type of product and how long it will be held until pasteurization. The requirements are found in 9 CFR 590. These requirements are summarized in Table I of this appendix.

Egg Packaging Operations: Packaging rooms will have a filtered, positive air ventilation system unless product is packaged by an automatic closed packaging system.

Pasteurization: Every particle of liquid eggs must be heat treated to the extent necessary to ensure that the eggs are free of Salmonella and other pathogens. Egg pasteurization

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equipment is very similar to milk pasteurization equipment. 9 CFR 590.570 prescribes that continuous flow pasteurization equipment include a holding tube, automatic flow diversion valve, thermal controls, and recording devices to ensure proper pasteurization. The establishment must have a program for ensuring the proper operation of the pasteurization equipment. Proper pasteurization times and temperatures for different types of products are shown in Table II of this appendix.

Egg Cooling (after pasteurization): Once broken or pasteurized, eggs must be cooled to an acceptable temperature within 2 hours. Adding previously processed egg to increase the rate of cooling is not an acceptable method. The acceptable temperature varies with the type of product. The requirements are found in 9 CFR 590. They are summarized in Table III of this appendix.

Egg Freezing: Frozen eggs will be frozen solid or reduced to a temperature of 10° F or lower within 60 hours of pasteurization.

Salmonella Testing: Salmonella is a public health threat for manufactured egg products. Therefore a comprehensive program for laboratory surveillance of product for the presence of Salmonella is required for liquid egg, frozen egg, and dried egg products. All lots must be Salmonella negative. The sampling program for this surveillance should be on a lot-by-lot basis. A lot may be considered a day's production for each category of egg product for a continuous thermal processing operation. Although OCONUS areas may have different legal requirements, the USDA, FSIS Egg Products Inspectors Handbook offers the following guidance for reducing the frequency of Salmonella testing:

- No History of Testing – Every lot must be tested until 60 consecutive lots are found to be Salmonella negative.
- Level 1 – 1 lot sampled for every 2 lots produced.
- Level 2 – 1 lot sampled for every 4 lots produced.
- Level 3 – 1 lot sampled for every 8 lots produced.

To reduce the sampling frequency from 100 percent to Level 1, 60 consecutive lots within a product category must be Salmonella negative.

To reduce the sampling frequency from Level 1 to Level 2, 60 consecutive lots within a product category must be Salmonella negative.

To reduce the sampling frequency from Level 2 to Level 3, 60 consecutive lots within a product category must be Salmonella negative.

If a Salmonella positive lot is found at any reduced sampling level, the plant must be immediately begin sampling the entire product category at 100%.

If the country of origin or the manufactured egg products establishment has a sampling frequency that is less severe than the sampling plan shown above, consult the MACOM

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Veterinarian as to whether it is acceptable. Some countries are certified Salmonella free and therefore may not have testing programs in place.

TABLE Q-I.

Egg Cooling Requirements within 2 hours after Breaking, and before Pasteurization.			
Liquid Egg Product	Liquid w/o salt Held 8 hours or less	Liquid w/o salt Held more than 8 hours	Liquid Product with salt
Whites, (not to be stabilized)	NMT 55° F (12.8° C)	NMT 45° F (7.2° C)	
Whites, (to be stabilized)	NMT 70° F (21.1° C)	NMT 55° F (12.8° C)	
All other product, except product with 10% or more added salt	NMT 45° F (7.2° C)	NMT 40° F (4.4° C)	
Liquid egg product with 10% or more added salt			If to be held 30 hours or less, 65° F (18.3° C) or lower. If to be held in excess of 30 hours, 45° F (7.2° C) or lower.

Note: Stabilization means subjecting the egg to a desugaring process IAW 9 CFR 590.5.

TABLE Q-II.

Pasteurization Requirements.		
Liquid Egg Product	Minimum Temperature Requirements (°F / °C)	Minimum Holding Time Requirements (Minutes)
Albumin (without the use of chemicals)	134 / 56.7 132 / 55.6	3.5 6.2
Whole egg	140 / 60.0	3.5
Whole egg blends (less than 2% added non-egg ingredients)	142 / 61.1 140 / 60.0	3.5 6.2
Fortified Whole Egg and blends (24-38% egg solids, 2-12 % added non-egg ingredients)	144 / 62.2 142 / 61.1	3.5 6.2
Salt whole egg (with 2% or more salt added)	146 / 63.3 144 / 62.2	3.5 6.2
Sugar whole egg (with 2% or more sugar added)	142 / 61.1 140 / 60.0	3.5 6.2

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TABLE Q-II – Continued.

Plain yolk	142 / 61.1 140 / 60.0	3.5 6.2
Sugar yolk (2% or more sugar added)	146 / 63.3 144 / 62.2	3.5 6.2
Salt yolk (2-12% salt added)	146 / 63.3 144 / 62.2	3.5 6.2

TABLE Q-III.

Egg Cooling Requirements after Pasteurization.		
Liquid Egg Product	Temperature within 2 hours after pasteurization	Temperature within 3 hours after pasteurization
Whites, (not to be stabilized)	NMT 45° F (7.2° C)	
Whites, (to be stabilized)	NMT 55° F (12.8° C)	
All other product, except product with 10% or more added salt	If to be held 8 hours or less, 45° F (7.2° C) or lower. If to be held for more the 8 hours, 40° F (4.4° C) or lower	If to be held 8 hours or less, 45° F (7.2° C) or lower. If to be held for more the 8 hours, 40° F (4.4° C) or lower
Liquid egg product with 10% or more added salt	NMT 65° F (18.3° C)	

Note: Stabilization means subjecting the egg to a desugaring process IAW 9 CFR 590.5.

Q.4.2 Checklist. Guidelines for auditing manufactured egg product establishments are contained in the following Table Q-IV checklist.

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TABLE Q-IV.

APPENDIX A PARAGRAPH	Manufactured egg products checklist REQUIREMENTS as specified in: CFR Title 9, Part 590 Egg Product Inspectors Handbook
B2, B7	Buildings must be of sound construction and maintained in such a way as to preclude the entry of pests and vermin. (9 CFR 590.500)
B2, B5, B13	Breaking rooms will meet the requirements of 9 CFR 590.520 to include adequate ventilation, sanitary construction, lighting, hand washing facilities and a suitable container conspicuously identified for the disposal of rejected liquid. (9 CFR 590.520)
C7, E2, E6, H6, H8	If eggs are washed, the temperature of the wash water must be 90° F (32.2° C) or higher, and will be at least 20° F (-6.7° C) warmer than the temperature of the eggs to be washed. (9 CFR 590.515)
E2	If eggs are washed, wash water must be changed approximately every four hours or more often if necessary. (9 CFR 590.515)
B6, E2	If eggs are washed, an approved cleaning compound will be used in the wash water. (9 CFR 590.515)
B6, E2	If eggs are washed, wash water must be added continuously to the wash water to maintain a continuous overflow. Rinse water and chlorine sanitizing rinse may be used as part of the replacement water. Iodine may not be used. (9 CFR 590.515)
E2	If eggs are washed the washing operating will be continuous. Eggs will not be allowed to stand or soak in water. Immersion type washers will not be used. (9 CFR 590.515)
E2	If eggs are washed, shell eggs will not be washed in the breaking room or any other room where edible products are processed. (9 CFR 590.515)
E2	Shell eggs having strong odors or eggs received in cases having strong odors will be candled and broken separately to determine their acceptability. (9 CFR 590.510)
E1, E6, E11	Eggs, presented for breaking will be of edible interior quality and free of exterior dirt and foreign material except that: a. Checks on eggs with a portion of the shell missing may be used so long as the membrane is not ruptured and the shell is free of adhering dirt and foreign material. b. Eggs with clean shells which are damaged during candling or transfer may be used so long as the yolk is not broken and the contents of the egg are not exuding over the outside shell. Such eggs will be placed in leaker trays and broken immediately. c. Eggs with meat or blood spots may be used if the spots are removed in an acceptable manner. (9 CFR 590.510)
E2	The contents of any breaking cup which contains one or more inedible or loss eggs will be rejected. (9 CFR 590.522)
B8, C1, E2	Whenever an inedible egg is broken, the affected breaking equipment will be cleaned and sanitized. (9 CFR 590.522)

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TABLE Q-IV – Continued.

C7, E2, E6, H8	Once broken or pasteurized, egg contents must be cooled to an acceptable temperature within 2 hours. (9 CFR 590, Table I)
C7, E2, E6	If liquid eggs are frozen, they must be frozen solid or reduced to a temperature of 10° F (-12.2° C) or lower within 60 hours of pasteurization. (9 CFR 590.536)
E2, E6	If frozen eggs are defrosted, this should be accomplished in an acceptable manner. (9 CFR 590.539)
B8, C1, C2, E2, E3	Pasteurizers and equipment must be cleaned and sanitized daily (minimum). Hand-held utensils and screens and filters used for removing dirt and other foreign materials require a mid-shift clean-up (minimum). Liquid egg holding tanks and containers (including tank trucks) used for hauling liquid egg will be cleaned and sanitized after each use. (9 CFR 590.522)
C6, C7, C10, E6, H6, H8	For pasteurized egg, every particle of egg must be heat treated to the required time and temperature, properly operating equipment, where cross contamination of raw and pasteurized product is precluded. (9 CFR 590.570)
E4, E6, H8	To ensure adequate pasteurization, pasteurized egg products and heat treated dried egg products will be analyzed for the presence of Salmonella at an acceptable frequency. (9 CFR 590.580) (Section 8, Egg Product Inspectors Handbook)
E4, H3, H11	If the establishment does not test every lot of liquid egg, frozen egg, or dried egg, then the establishment must have an acceptable reduced sampling Plan. (9 CFR 590.580)
E2, E4, E6, E11	Lots found to be Salmonella positive must be placed in a hold status pending retesting, reprocessing, or destruction. (Section 9, Egg Products Inspectors Handbook)
E2, E4, E6, E11	If a lot is found to be Salmonella positive, it must be reprocessed, retested, and found to be Salmonella negative before it can be released for use as human food. (Section 9, Egg Products Inspectors Handbook)
B3, E3	If frozen, freezing rooms will be kept clean and free from objectionable odors. (9 CFR 590.536)
C7, C10, E2, E6	If frozen, liquid eggs will be solidly frozen to a temperature of 10° F (-12.2° C) or lower from time of breaking (if not pasteurized) or from time of pasteurization. (9 CFR 590.536)
B8, E3	The outside of liquid egg containers will be clean and free from evidence of liquid egg. (9 CFR 590.536)
E2, E11	Frozen eggs will receive a sensory evaluation to determine fitness for human food. (9 CFR 590.536)

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MUSHROOMS

R.1 SCOPE

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

R.2 APPLICABLE DOCUMENTS

R.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

R.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 110.

CFR Title 40, Part 141.

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

R.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

Good Management Practices for Safe Growing, Harvesting, and Packing of Fresh Mushrooms.

(Available on-line at: http://www.americanmushroom.org/gmp.rtf.)

Other useful sites:

(Available on-line at:http://www.mushroomcouncil.com; http://www.agf.gov.bc.ca/mushroom/; http://www.attra.org/attra-pub/mushroom.html; http://mushgrowinfo.cas.psu.edu/; and http://www.americanmushroom.org/index.htm.)

R.3 DEFINITIONS

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R.3.1 Definitions. General definitions are contained in this 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:

1. Prevention of food safety hazards is favored over reliance on corrective actions once a problem has occurred.

2. To minimize food safety hazards in mushroom products, growers, packers, and distributors should use good management practices in those areas over which they have control.

3. Mushrooms can become contaminated at any point between growing and receipt by the customer.

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

5. The use of animal manures in substrate preparation should be managed carefully to minimize the potential for microbial contamination of mushrooms.

6. Worker hygiene and sanitation practices during growing, harvesting, and handling play a critical role in minimizing the potential for microbial contamination of mushrooms.

7. 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.

8. Accountability at all levels of the agricultural environment (growing, packing distribution, and transportation operations) is an important component in a successful food safety program. There must be qualified personnel and effective monitoring to ensure that all elements of the program function correctly and to help track products back through the distribution channels to the producer.

9. Control of food safety hazards in mushroom growing, harvesting, packing, and distribution operations is best achieved through a systematic, preventative, and well documented food safety program based on established Hazard Analysis Critical Control Point (HACCP) principles.

10. Additional information. Sanitation audits of mushroom establishment’s are similar to “on-farm” audits. To minimize food safety hazards in mushroom products, growers, packers, and distributors must use good manufacturing practices over those areas which they have control. Mushrooms can become contaminated at any point between growing and receipt by the

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customer. Control of food safety hazards in mushroom growing, harvesting, packing, and distribution operations is best achieved through a systematic, preventative, and well documented food safety program based on established HACCP principles.

At a minimum, the following eleven control areas should be described in the methodology section of the audit report:

1. Facilities and plant layout.
2. Equipment design and maintenance.
3. Receiving and storage of raw materials.
4. Water quality.
5. Cleaning and Sanitation.
6. Pest control.
7. Worker hygiene and sanitary facilities.
8. Transportation.
9. Product traceback and recall.
10. Training.
11. Process controls.

Mushroom Farming:

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 that develop in the substrate (pasteurized compost) after the spawn and supplement are added. After the mycelium is formed, a thin layer of casing (mixture of peat moss and sugar beet lime) is spread over the surface of the mycelium. The cased compost is watered for several days until the tiny white protrusions called fruiting bodies, form on the mycelium and push up through the peat moss (pinning). It takes 17 to 25 days to produce mature mushrooms from the time the peat moss was placed over the white protrusions.

Mushrooms may be grown in buckets, bags, on logs, or on trays (metal and even wood). Some farms may be located underground in limestone caves (ideal temperature and humidity conditions). You may discover that smaller farms perform several of the steps in one room (or house) or you may find that different rooms are used for each of the major steps and the trays are moved (usually by conveyor or forklift) several times during the process.

Mushroom harvesting takes place over a period of several weeks, usually in three crops referred to as “breaks”. After harvesting, each growing house 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, which are further described below:

1. Phase I: Making mushroom compost.
2. Phase II: Finishing the Compost.
3. Spawning.

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4. Casing.
5. Pinning & Growth.
6. Cropping.

Step #1: Phase I usually takes place outdoors. A concrete slab, often referred to as a wharf, is required for the beginning of the composting process. Composting is initiated by mixing and wetting the ingredients (wheat straw, cotton seed hulls, dried poultry waste or horse manure etc.) and leaving them on the wharf until they start to decompose. Then, the compost mixture is stacked in rectangular piles with tight sides and loose centers (called "ricks"). Nitrogen and gypsum supplements are added, as needed, to the tip of the bulk ingredients and are thoroughly mixed by a compost turner. Adequate moisture, oxygen, nitrogen, and carbohydrates result in the activity of microorganisms producing heat and some heat-releasing chemical reactions. Turning of the compost is important to prevent conditions favorable for the growth of anaerobes in the center of the compost pile. Some farms are installing and using aerated bunkers (large cement building with built-in air lines that force air up through the compost pile) in place of the more traditional practice of turning the ricks mechanically.

Step #2: Phase II is the finishing of the compost (or pasteurization). Phase II generally takes 10 - 14 days to complete. 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. There are two (high-temperature and low-temperature), Phase II temperature protocols typically used in the mushroom industry. The high temperature Phase II process involves and initial pasteurization period of ~140^{o} F (62^{o} C) lasting four-six hours; after which the temperature of the compost is then lowered 2-3 degrees a day until the ammonia is dissipated. The low temperature Phase II process allows the compost to obtain a temperature of 126^{o} F (52^{o} C) (range 125^{o} F - 130^{o} F / 52^{o} C - 54^{o} C)). Higher pasteurization temperatures are not generally used by the industry because they may negatively affect the yield. Pasteurization may occur in tunnels, where steam is injected into the room and the compost is then put into trays, bags or buckets; or pasteurization may occur in the trays in a room that is flushed with steam. This is a very important step in the production of safe mushrooms and must be closely monitored by the facility. Typically, the pasteurization is computer controlled, computer monitored and thorough records are kept (chart recorders, logs etc). Temperatures may be recorded manually using thermometers or by the placement of thermocouples or other temperature monitoring devices in various places in the pasteurization tunnel or room. Records should include all of the details about the time and temperature of the pasteurization; including the duration of peak heat (e.g., 2 hours at 135 ^{o} F).

Step #3: Spawning is the process of inoculating the compost with mushroom spawn and possibly a spawn supplement. Spawn is commercially produced mycelium that is mixed into the substrate and is essentially the beginning of a mushroom. After the spawn is mixed with the substrate, the mixture is held under controlled conditions (temperatures and atmospheric conditions may vary) and this is referred to as the spawn run.

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Step #4: 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, and sugar beet lime. Some facilities may include spent mushroom substrate (SMS), which is the leftover growing material from a previous crop. After casing, the crop is watered very heavily (but carefully) to ensure that the mushrooms have enough water to grow throughout the crop cycle. Casing acts as a water reservoir and is the place where rhizomorphs (thicker mushroom mycelia) form. Mushroom initials, primordia, or "pins" form when the rhizomorphs change from vegetative growth to fruiting growth and the pins push up through the casing layer. Casing may be pasteurized to eliminate insects and pathogens it may be carrying. Pasteurization of casing may be done at the processing facility, or by a commercial supplier prior to receipt. Supplier certificates of pasteurization should be available upon request. Recent research conducted jointly by industry, academia and the government indicates that pasteurization of casing may destroy naturally occurring competitive microorganisms that may inhibit the growth of *Listeria monocytogenes*.

Step #5: Pinning & Growth is the careful management of temperature and humidity during the maturation of the pins. This step may also be referred to as airing-out as fresh air is introduced to each crop (referred to as "houses") to initiate the pinning.

Step #6: Cropping is the harvesting of mushrooms at various growth stages. Cropping may also be performed as a method of thinning out the crop. A full harvest of mature mushrooms is often referred to as "breaks". Mushrooms are usually harvested in a 7 to 10 day cycle, typically in three breaks. This may be longer or shorter depending on the temperature, humidity, cultivars and stage when they are picked.

Mushroom farming is an art form and must be performed under controlled conditions. Auditors will find that each farm does things a little differently. Keep an open mind and remember that this is essentially a raw agricultural product. Many of the fruits and vegetables we enjoy everyday are grown outside where the product may be exposed to all types of environmental conditions. Mushroom farms are essentially an indoor farming operation. There are several key things to focus on during the audit (especially water quality, Phase II pasteurization, traffic control, post-production contamination, slicing and packaging), including:

- Water safety & quality (especially if the farm uses well water)
- Sanitary plumbing (cross-connections, back-flow preventers etc.).
- Waste water handling (drainage away from well-heads; placement of the lagoon; location of septic drain fields in relation to wells).
- Compost preparation (watering, turning and isolation of "raw" compost).
- Traffic controls on the plant grounds (isolate or limit movement of wharf workers into growing, harvesting and packaging areas). Placement and use of footbaths.
- Pasteurization of the compost (time & temperature of Phase II).
- Controls to ensure that pasteurized compost is not cross-contaminated by equipment or personnel that handle or move unpasteurized or raw compost materials.
- Application of pesticides and fungicides to the crop.

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- Hand washing and employee hygiene.
- Harvesting operations (contamination from employees).
- Protection from overhead contamination (from condensation or glass bulb breakage).
- Handling during packaging and slicing.
- Inspection of slicer blades and/or metal detection for sliced mushrooms.
- Packaging (must have holes in packages to prevent creation of an anaerobic environment).
- Cleaning of growing rooms between crops.

Mushroom Types:

There are several types of mushrooms that are grown and marketed, including: crimini, portabella, oyster, shiitake, enoki, beech, and maitake. The procedures and methods are similar, and the audit can be approached in the same manner for each. A short description of several types of mushrooms follows:

White Mushrooms: White mushrooms are the most commonly available mushroom and are referred to simply as button, or common mushrooms (typically *Agaricus* spp.). The process described above details the process for white mushrooms.

Crimini Mushrooms: Crimini mushrooms are grown and harvested in the same manner as the white mushroom. The reason they have a darker color and slightly denser texture is that they come from a different strain of spores.

Portabella Mushrooms: Portabella mushrooms are also grown like the white mushrooms. Actually, the Portabella is a mature Crimini. It's usually three to seven days older than the Crimini when harvested. As a result of their longer growing period, Portabellas develop much larger caps-ranging up to six inches in diameter.

Oyster Mushrooms: Like other mushrooms, Oyster mushrooms are grown in mushroom houses but they require a bit more humidity and fresh air than the white variety. They grow well on a range of agricultural and wood waste products including hardwood chips, chopped cereal straws or corn cobs. After the growing medium is pasteurized and cooled it is inoculated, that is, mixed with spawn and packed into long, tubular shaped plastic bags. Holes are punched in the bags to allow the mycelia to breathe and the bags are hung up or set on racks in the growing rooms. After about 14 days, the mushrooms pop out through the holes and can be harvested. If straw is used as a growing medium, the substrate can be used as fertilizer after mushroom production is completed.

Shiitake Mushrooms: Shiitake mushrooms were originally cultivated on natural oak logs, a process which took two to four years before the mycelium colonized the wood sufficiently to produce fruiting. Shiitakes were harvested on a seasonal basis (spring and fall) for about six years. Now, however, oak sawdust is packed into poly bags, sterilized, inoculated with spawn and placed in environmentally controlled rooms. These man-

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made "logs" produce Shiitakes in seven weeks. The total process, from spawning to the end of harvesting takes about four months as compared to the six year cycle on natural logs.

Enoki Mushrooms: For the Enoki, current technology uses automated systems to fill plastic bottles with substrate usually ground corn cob pellets along with other ingredients such as wheat bran and soybean meal. The bottles are sterilized, inoculated with the mushroom culture and placed in growing houses. When the substrate is fully colonized with mycelium, the bottles are moved to an area where a plastic collar is attached to the mouth of the bottle. This collar guides the forming mushrooms to grow straight up to help control Carbon Dioxide. Enokis require a colder environment, 45^{o} F compared to growing temperatures of about 60^{o} F, which other varieties require. After about 90 days, the mushrooms are harvested. The collars are removed, the Enokis plucked from the mouth of the bottle and usually packaged in shrink-wrapped bags. The remaining substrate is recycled, since Enokis only produce one set of fruiting bodies per crop.

Beech Mushrooms: In some ways growing Beech mushrooms is similar to growing Enokis. Plastic bottles are sterilized, inoculated, with mushroom culture and then placed in growing houses to allow the substrate to colonize with the mycelium. However, Beeches require a temperature of 60 to 64^{o} F in order for the culture to fully develop. It takes about 100 days to produce a mature crop. Afterward, the mushrooms are harvested and packaged for sale. Since Beeches only produce one set of fruiting bodies per crop, the remaining substrate is recycled for agri-business products.

Maitake Mushrooms: The cultivated Maitake starts out as a mushroom "culture"- piece of mushroom tissue grown on special sterile media in a Petri plate in a laboratory. The culture is used to make mushroom spawn- a series of steps to make a lot of mushroom tissue out of a little. The mushroom spawn is used to inoculate Maitake production logs, which are made out of sawdust supplemented with grain byproducts such as bran. The logs go through a "spawn run" where the mushroom spawn colonizes the sawdust and supplements and knits them together in a solid mass. This takes about 30 days. The logs are incubated in special mushroom houses with temperature, humidity and air flow carefully controlled. Once the logs start to pin (small mushrooms begin to form) the logs are moved into "fruiting" houses which are also very carefully controlled to provide the best environment for mushroom formation. Like the Enoki mushroom, Maitake produces only one time, and then the substrate is recycled into agri-business products. The whole process from lab to table takes from 10 to 14 weeks.

R.4.2 Checklist. Guidelines for auditing mushroom establishments are contained in the following Table R-I checklist.

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TABLE R-I.

APPENDIX A PARAGRAPH	Mushrooms checklist REQUIREMENTS as specified in: CFR Title 21, Part 110 Good Management Practices for Safe Growing, Harvesting, and Packing of Fresh Mushrooms. Note: Cross-referenced by Page # (Pg.), Principle (Pr.) and Preventive Measure (PM)
C1, E2, E4	Pre-operational inspections, audits, or microbial sampling of the environment or of food contact surfaces is conducted to ensure cleaning and sanitizing procedures are effective. (Pg. 10, Pr 5, PM 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 areas where mushrooms are grown, harvested, and packed. (Pg. 4, Pr. 1, PM 1)
B2	Separate areas are provided for the receipt of raw materials and mushroom loading and shipping areas. (Pg. 4, Pr. 1, PM 1)
A4, A10, B8	Traffic patterns for employees and equipment are established to avoid contamination of pasteurized substrate, casing materials, and mushrooms with raw manure and unpasteurized substrate. Where workers and equipment enter and exit the building between phase one and other plant operations, methods of control exist for employee's feet, hands and portable (personal) equipment (knives). (Pg. 4, Pr.1, PM 1)
B2	In rooms that are not steam pasteurized, floors will be constructed of washable, nonporous materials and adequately sloped to allow drainage. (Pg. 4, Pr. 1 PM 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, Pr. 1, PM 3)
B2, B5	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, Pr. 1, PM 3)
C1, C6, E2	Equipment for moving, mixing, or otherwise handling unpasteurized substrate is not used for handling pasteurized substrate, casing materials, or mushrooms and equipment is cleaned as needed to protect against contamination of the premises. (Pg. 6, Pr. 2, PM 1).
C7, C10	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, Pr. 2, PM 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, Pr. 3, PM 1)
E1, H6, H8	Appropriate records are kept to monitor the performance of suppliers and if necessary for traceback of sources of contamination. (Pg. 7, Pr. 3, PM 1)
B2, E2, E3	Raw materials and unpasteurized substrate are in separate areas from where mushrooms are grown, harvested, packed, and stored. (Pg. 8, Pr. 3, PM 2)

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TABLE R-I – Continued.

B9	Water that directly contacts mushrooms or surfaces that come into contact with mushrooms is potable and meets federal drinking water standards. (Pg. 9, Pr. 4, PM 1).
B9, E4	Water supply tested periodically for fecal contamination. (Pg. 9, Pr. 4, PM 2)
B6, B9, E4	The concentration of antimicrobial chemicals in treated water is routinely monitored and recorded to ensure they are maintained at appropriate concentrations. (Pg. 9, Pr.4, PM 3)
B6	Properly labeled pesticides fungicides, cleaners, sanitizers and disinfectants are safe under the conditions of use and are approved for use in mushroom growing and packing operations. (Pg. 7, Pr. 3, PM 1)
E10	Packaging materials are made of approved food grade materials. (Pg. 7, Pr. 3, PM 1)
B5	Adequate lighting should be provided in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where mushrooms are harvested, packed, stored, and transported. (Pg. 5, Pr. 1, PM 3)
B4	Safety-type light bulbs that prevent contamination of mushrooms with glass should be used and regularly cleaned. (Pg. 5, Pr. 1, PM 3)
B3, C1, C6	Refrigeration and heating units, mixers, conveyers, compressors, fans, trucks, forklifts, and any other equipment used in growing, packing, distribution, and transportation of mushrooms are properly maintained and kept in proper working order. (Pg. 6, Pr. 2, PM 2)
E3	Mushrooms are maintained at appropriate temperature during loading, are carefully loaded to prevent damage or contamination, and are loaded onto clean conveyances. (Pg. 14, Pr. 8, PM 1, 2 and 3)
E2, E6, E11, J5	Biosecurity procedures or controls are in place to ensure that the premises, raw materials, facilities, equipment, water source and/or finished product is not contaminated or adulterated when spent compost is picked up by third-parties. (21 CFR 110.5 and 110.80)
B6, B7, H6, H8	Application of approved pesticides is undertaken by or under the supervision of a licensed pest control applicator. 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 includes dates of inspection, inspection reports, and steps taken to eliminate any problems. (Pg. 11, Pr. 6, PM 1 and Pg. 7, Pr. 3, PM 1)
E3, H8	The label on all packages for wholesale or retail sale includes all items required by federal, state, and local regulations including: the name, street address, city, state, zip code, and product code that enable traceback to the point at which the mushrooms were grown and the date they were processed. (Pg. 15, Pr. 9, PM 1)
E2, E3, H8	Written procedures are developed in the event that a mushroom grower or processor wishes to remove a product from the marketplace. (Pg. 15, Pr. 9, PM 2)

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TABLE R-I – Continued.

E6	Time and Temperature controls during Phase II pasteurization are adequate to kill mesophilic human pathogens. (Pg. 17, Pr. 11, PM 1)
E5	Where slicing blades are used, continuous monitoring of metal in packaged mushrooms is achieved using an online detector. (Pg. 18, Pr. 11, PM 3)
E6, E10	For soil (or compost) grown mushrooms, 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, Pr. 11, PM 4)
E3, C7, C10	Refrigerators holding harvested mushrooms are maintained at 40^{o} F (4.4 ^{o} C) or below and are properly maintained and thermometers are calibrated. (Pg. 18, Pr. 11, PM 5)
B2, E3	Raw material storage areas are protected from rainfall, runoff or flooding by covering the materials or the runoff is collected using barriers or physical containment measures such as concrete blocks, soil berms, pits, lagoons or wharfs. (Pg. 8, Pr. 3, PM 2)
B3, H8	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, Pr. 5, PM 1)
B8, C1, E2	A regularly scheduled and “as needed” program is implemented that ensures all parts of the operation are appropriately clean and sanitary. (Pg. 10, Pr. 5, PM 1)
A10, A11, H8	Training records are maintained of employee hand washing training. (Pg. 13, Pr. 6, PM 2)
B4, E6, H6	Glass & brittle inspection policy in place and monitored. (Pg. 13, Pr. 6, PM 2)
E3, H6, H8	Label placed on containers to trace source (grower), the name of the company, name of product, lot #, and date of harvest during storage and transfer of product within the company or between packers. (Pg. 15, Pr. 9, PM 1)
A11, H8	Management and workers are trained to maintain proficiency in mushroom production methods. (Pg. 16, Pr. 10, PM 2)
B6, E2, H8	When chemicals and pesticides are directly applied to mushrooms, adequate controls are maintained to ensure that pesticides are applied IAW manufacturer’s instructions and application is properly diluted and recorded. (Pg. 17, Pr. 10, PM 2)

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VEGETABLE SPROUTS

S.1 SCOPE

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

S.2 APPLICABLE DOCUMENTS

S.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

S.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 110 and 179.

CFR Title 40, Part 141.

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

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

FDA, “Reducing Microbial Food Safety Hazards For Sprouted Seeds”, Oct 1999.

FDA, “Microbiological Safety Evaluations and Recommendations on Sprouted Seeds”, May 1999.

(Available on-line at: http://www.cfsan.fda.gov/~mow/sprouts2.html.)

FDA Guidance for Industry, “Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production”, Oct 1999.

(Available on-line at: http://www.cfsan.fda.gov/~dms/sprougd2.html.)

S.3 DEFINITIONS

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S.3.1 Definitions. General definitions are contained in this handbook.

S.4 GUIDELINES

S.4.1 General. While fresh produce, including sprouts, can serve as a potential source of many types of foodborne pathogens (e.g., bacterial, viruses, protozoa, fungi, and helminths) (NACMCF, 1998), bacterial pathogens are of particular concern with sprouts. This reflects the fact that the environmental conditions and nutrients present during sprout production provide excellent conditions for the outgrowth of most pathogenic bacteria, if present. Pathogens can grow to elevated levels since there are no inherent steps in the production of sprouts that either prevent bacterial growth or eliminate them entirely. Pathogenic bacteria could be introduced to sprouted seed by a number of pathways, including via the seeds, the water used during germination and sprouting, unsanitary production practices, or mishandling by the consumer (Patterson and Woodburn, 1980). However, epidemiological investigations suggest that seed are the likely source in most, if not all, sprout-associated illness outbreaks (Puohiniemi et al., 1991; CDC, 1997; Mahon et al., 1997).

Little information is available on how seeds become contaminated with bacterial pathogens. Since seeds are raw agricultural products, they could be contaminated by a variety of potential sources of fecal contamination, including contaminated agricultural water, use of inadequately treated manure as a fertilizer, location of fields near animal rearing facilities, access by feral animals, and inadequate agricultural worker hygiene (NACMCF, 1998).

Once present on or in seed, pathogens are likely to survive for extended periods of time. Studies have shown that *Salmonella* can survive for months under dry conditions such as those used to store alfalfa seeds (Mistcherlich and Marth, 1984).

Common Varieties: Seed sprouts include alfalfa, mung bean, broccoli, mustard, cress, soybean, wheatgrass and radish.

Seed Production: Many of the sources of contamination described above (e.g., untreated or improperly treated water, animal waste or manure, poor sanitation of equipment and poor personal hygiene) could also be potential sources of contamination for seeds or sprouts at the sprouting facility. Although seeds are suspected to be the most likely source of contamination, contamination of water used during sprouting could be a source of initial contamination or a vehicle for subsequent cross contamination. When only the roots of fully developed radish sprouts were immersed in water containing *E. coli* O157:H7, the pathogen was found throughout the edible portion (Hara-Kudo et al., 1997). Likewise, *E. coli* O157:H7 was found both on the outer surfaces and the inner tissue of radish sprouts grown from artificially inoculated seeds (Itoh et al., 1998).

The key aspect of sprouts that increases the risk of foodborne disease compared to other fresh produce is the exponential growth of bacteria during sprouting. Microorganisms on seeds

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can grow quickly under the favorable conditions of the sprouting process (e.g., water activity, temperature, pH, time, and nutrients).

Plants for seed production are grown in typical agricultural environments and should be grown and harvested using Good Agricultural Practices (GAPs). Seeds are generally treated as a raw agricultural product. Potential sources of contamination in the field include agricultural water, improperly managed animal manure, contact with wild animals, and inadequate worker hygiene. In addition, domestic animals may be allowed to graze on alfalfa fields. While such contact is not likely to be a significant problem for the primary use of seed, i.e., seed for forage production, even low level, sporadic contamination of seed for food use may result in significant public health concerns because the sprouting process amplifies pathogen levels.

This overview focuses on alfalfa seed production, though many aspects of production (e.g., GAPs in the field and Good Manufacturing Practices (GMPs) during conditioning) would be equally applicable to other types of seed. Some growers may modify some of these practices depending on many factors, such as the needs of the crop, resources of the operation, and requirements, if any, imposed by the buyer or distributor.

Harvesting procedures expose the seed to a substantial amount of dirt and debris and likely spread localized contamination throughout the harvested seed. The processes used to sort, clean, store, and package seeds at seed mills may reduce, but are unlikely to eliminate pathogenic microorganisms. If performed incorrectly, these steps could serve as a source of contamination or cross contamination. There is the possibility that damage to seeds, either inadvertently or purposefully to change the seeds' germination characteristics (e.g., scarification), could aggravate contamination by making removal of pathogenic microorganisms during subsequent steps more difficult.

For most crops, only a small proportion of harvested seed goes to sprout manufacturers. Further, the decision whether to direct seed to agricultural uses or to sprouting is often not made until after harvest. Thus, the seed grower does not necessarily know whether seed will be sold for food use and, therefore, may have little incentive for following GAPs. Finally, seed processing, shipping and selling practices often involve mixing multiple lots of seeds of different origins, complicating traceback and providing an opportunity for cross contamination.

Scarification: Some legume seed has a hard seed coat that is more impermeable to water compared to other ("non-hard") seed. Consequently, this hard seed does not readily absorb the moisture needed for germination. Mechanical scarification, or scratching the seed coat, improves percent and uniformity of germination of hard seed. Seed is generally scarified only if it has a high hard seed percentage. The proportion of hard seed in a seed lot varies with the type of seed and where the seed is grown.

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

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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: 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, from receipt of bags of seed to shipment of finished product.

Seed Treatment: Seeds for sprouting may be treated with one or more treatments (such as 20,000 ppm calcium hypochlorite) that have been researched and 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.

Note: Some sprouters may be receiving irradiated seed. Irradiated seed cannot be subjected to > 8.0 KGy of ionizing irradiation and be used in food (Ref: 21 CFR, Part 179.26). Sprouters should have documentation from the seed supplier indicating that the seed was treated with irradiation and the dose. Additionally, the bags of SEED (not the retail or wholesale packages of sprouted seeds) must be marked with the “Radura” symbol and labeled as follows:

Irradiated seed will be labeled with the statement, "Treated with radiation" or "Treated by irradiation" in addition to information required by other regulations. The logo will be placed prominently and conspicuously in conjunction with the required statement. The radiation disclosure statement is not required to be more prominent than the declaration of ingredients required under 21 CFR Part 101.4. As used in this provision, the term "radiation disclosure statement" means the written statement that discloses that a food has been intentionally subject to irradiation.

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.

Typically, the steps involved in sprouting seeds involve:

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- Receipt of seed: Seed is received in woven bags (often cloth) from a seed supplier. Seed may originate from the United States or may be imported from OCONUS. It is important that the sprout producer perform receipt inspections of the bags of seed placing special emphasis on identifying any possible contamination by rodents (e.g., UV light inspection to detect rodent urine and an inspection for rodent feces or evidence of feeding.)

- Seed storage: Seed may be stored in a dry storage warehouse or under refrigeration. It is important to store the seed in a manner to protect the seed from infestation by rodents. The seed should be placed on pallets (may be shelved) in a clean, well-built facility or structure that is designed to preclude the entry of rodents and has a well-developed Integrated Pest Prevention Program.

- Disinfection: Seed may be soaked in an approved sanitizer (IAW 21 CFR, Part 173) to reduce the microbial load of the seed prior to sprouting. The FDA Guidance Document for Sprouted Seeds recommends a 5-minute soak in a 20,000 ppm calcium hypochlorite solution to minimize the potential of *Salmonella* spp. and *E. coli* O157:H7 or a similar process that achieves 5-log reduction of the aforementioned pathogens. Many sprouters use a lower concentration of sanitizer and a longer soak due to concerns with worker exposure and environmental considerations of the waste water discharge (which may be heavily regulated by the municipality). Some sprouters may be experimenting with different sanitizers, concentrations and contact times. The seed will probably be soaked in a bin or tub and may be agitated during soaking.

- Pre-germination soak: Seeds may be soaked for several hours in potable or lightly chlorinated water to soften the seed hull and prepare the seed for sprouting.

- Rinse: Pre-soaked seed is rinsed with potable water (usually 0.5 to 3.0 ppm chlorine) to remove any residual chlorine before being placed in the growing bins or drums.

- Germination and growth: Seeds are sprouted for 3-10 days depending on the type of seed. During sprouting, the seeds are watered every 15-20 minutes in a room that is held at ~80°F and that is kept dark. Temperature and humidity are usually closely monitored by most growers as these factors have a direct impact on yield. There is no public health controls required related to the temperature or humidity of the growing room – they are quality factors. These are precisely the factors that lead to growth of pathogens, but the risks are minimized and or monitored during other steps in the process. Seed grown in drums may be constantly rotated or may be rotated on some frequency (every 15 minutes, every hour etc). Occasionally, some seed may be started in a bin or drum (up to ~60%) and growing is “finished” in the retail tray or clamshell.

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During germination and growth, samples of the irrigation water are collected (usually after 48-72 hours) for submission to the laboratory for analysis. Irrigation water is normally tested for the presence of *Salmonella* spp. and *E. coli* O157:H7. Many plants carefully time their growing cycles and irrigation water sampling so that the laboratory results are received prior to packaging and shipping of the product.

- Harvest, Wash and Drain: Sprouts are removed from the growing bins or drums by hand or by employees using plastic pitch forks. The sprouts may be transferred by flume or manually to a wash tank where they may be washed, "scrubbed", or agitated with air bubbles to remove the seed hulls. The sprouts are then drained on a shaker table, or may be placed in mesh bags and a plastic barrel before being run through the spin dryer (centrifuge) to spin off excess water or they move directly to packaging.

- Packaging, Cooling and Storage: The sprouts are usually packaged by hand into plastic clam-shell containers (retail) or into plastic bags (bulk). The packages are coded and labeled (retail) and placed in cases for storage until distribution. Sprouts should be stored, shipped and displayed at less than 41° F to prevent the growth of pathogenic microorganisms. The temperature of the storage room should be closely monitored as sprouts in storage are living organisms that emit a significant amount of heat as they continue to grow and respire.

Soil-grown sprouts: Some producers grow sprouts in soil and sometimes, these firms also produce hydroponically grown sprouts. Typically, soil-grown and hydroponic products are grown in separate rooms.

Sprouts are planted and grown in plastic trays containing a composted soil that is mixed to the producer's preferences. In one case, the soil mix included composted horse manure, bone meal, and oyster shell flour.

Seed used for soil trays was soaked and rinsed as described above for hydroponic operations. After rinsing, wet seed was held for 12 to 24 hours in buckets to allow for initial germination. Meanwhile, plastic trays (approximately 2' by 3') were filled with soil. When the seeds were ready, they were spread on top of the soil and leveled out. Growing usually took place in a green house. Water was sprayed on trays two times daily, usually by an automated pipe system overhead. Sprouts can take 5 to 10 days for optimal growth in wintertime, or 3 to 10 days in summertime.

Most soil-grown sprouts are harvested at the facility, washed, packaged, and delivered to the customer. Typically, soil-grown products are brought into the cutting and packaging room in soil trays. They are often there at the same time as the hydroponic items.

Alternatively, some processors deliver the product as is, in the tray, directly to the retailer. At the retailer the tray is inserted in a plastic bag and placed in a cooler. Typical

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retailers of this product were juice blending shops. These shops cut sprouts, primarily wheat grass, directly from the tray and drop them into a blender with other fruits, vegetables, and various ingredients. Apparently, some sprout producers and retailers view product that is allowed to continue growing in soil and is not harvested until just before use as more healthy and organic compared to product that is harvested and packaged by the producer.

When the retailer is finished cutting/snipping sprouts from the tray, the tray of soil with remaining product (e.g., roots) is returned to the sprout producer. The producer may pick up these trays while delivering new trays of freshly grown, uncut product. Soil and remaining spout parts were then deposited into a compost mound. The soil may be eventually reused for subsequent sprout production.

S.4.2 Checklist. Guidelines for auditing vegetable sprouts establishments are contained in the following Table S-I checklist.

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TABLE S-I.

APPENDIX A PARAGRAPH	Vegetable sprouts checklist REQUIREMENTS as specified in: CFR Title 21, Parts 110 and 179 FDA, “Microbiological Safety Evaluations and Recommendations on Sprouted Seeds” (FDA, MSE) FDA, “Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production” (FDA, SMT)
E1, H6, H8	Appropriate records are kept to monitor the performance of suppliers and when necessary for traceback of sources of contamination. (FDA, MSE, Finding 5, Recommendation e.)
E2	Seeds are subjected to a potable water rinse after washing, before germination (FDA, MSE, Finding 4, Recommendations a. and c.)
B6, B8	Containers (bins, trays or drums) that are used for germination and growth are cleaned and disinfected prior to use. (FDA, MSE, Finding 6, Recommendation e.)
B9	Water, to include irrigation water that directly contact sprouts or surfaces that come in contact with sprouts is potable and meets federal drinking water standards. (21 CFR 110.37(a))
A10, E2, E11	Adequate measures are taken to protect against any contamination during harvesting and packaging. (FDA, MSE) and (21 CFR 110.80)
E2, E4	Wash water is adequately chilled and chlorinated. (FDA, MSE)
B8	Wash tank and collection bins are cleaned and disinfected as needed. (FDA, MSE, Finding 6, Recommendation e.)
E5	Methods to exclude physical contaminants are established and monitored (metal detector, visual screening, sieves, or other means). (21 CFR 110.80)
E3, E6	Chill storage and distribution temperature will be less than 40° F +/- 4° F. (FDA, MSE)
E3	Incoming raw materials and finished products are dated and stock rotation is controlled to ensure proper rotation. (FDA, MSE, Appendix 2, Para 1)
E4, E6	Testing of irrigation water for pathogens is conducted after the initial 48 hour growing period for each batch within the growing cycle IAW FDA or recognized (AOAC) sampling guidelines. (FDA, SMT)

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LOW-ACID CANNED FOODS (LACF)

T.1 SCOPE

T.1.1 Scope. This appendix contains guidelines for auditing low-acid canned food processing establishments. The information contained herein is intended for guidance.

T.2 APPLICABLE DOCUMENTS

T.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

T.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

Title 21 CFR, Parts, 110, 113, and 173.

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

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Guide to Inspections of Low-Acid Canned Food Manufacturers.

(Available on-line at: http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt101.html.)

T.3 DEFINITIONS

T.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

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

T.4 GUIDELINES

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T.4.1 General. Auditors should verify the pH and Aw of the food to ensure low-acid classification prior to using this appendix to conduct an audit.

When a food product is acidified to a pH of 4.6 or less (acid to high acid foods), inhibition of the growth of C. botulinum is assured by the acid level and these products are regulated under 21 CFR 114, not this appendix.

When a product meets the definition of low-acid they are regulated following 21 CFR 113. Auditors must be prepared to audit the firm's compliance with 21CFR Part 113. 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 firms processing authority. A scheduled process designed to achieve commercial sterility for a LACF, is formula, process, retort, and can/package size/style specific. Any change from these specifics requires an evaluation by a recognized process authority or qualified persons having expert knowledge of thermal process requirements and adequate equipment for making such determinations to ensure commercial sterilization is achieved.

Improper commercial sterilization creates a condition for potential C. botulinum growth and toxin formation. 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. Improperly processed LACF can provide this favorable environment. The thermal retort process is the primary means used to achieve commercial sterility. It is imperative that equipment provide proper heat distribution for a period of time and at a temperature scientifically determined to be adequate to ensure destruction C. botulinum and other microorganisms of public health significance.

T.4.1.1 Summary Guidelines for Inspection of LACF Processors using Retort Systems.

To fully understand the importance of items listed in the LACF checklist of this Appendix , auditors should review and become familiar with the information contained in publications cited in sections 2.1 and 2.2. Additionally, each auditor assigned to audit LACF manufacturing plants should consider attending a formal LACF course, routinely offered by the FDA, Office of Regulatory Affairs and various university food science departments. The following list extracted from the GUIDE TO INSPECTION OF LOW-ACID CANNED FOOD MANUFACTURER'S, Parts I, II and III, and has been compiled in an effort to suggest minimum information necessary to make a valid assessment of a processor’s operations. Auditors should include but are not limited to, all applicable items during an audit.

I. Product Preparation, Filling and Closing Operations

A. Product Formulation and Specifications

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

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B. Product preparation.
   1. Blanching equipment and conditions (i.e., time and temperature) and control thereof.
   2. Preparation and holding kettles and tanks; times and temperatures and controls.
   3. Preparation of packing medium.

C. Containers - Source, type and size(s) used.

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

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

F. Closing Operations
   1. Closing machine model and make.
   2. Closure examinations; specifications, frequency and recording of visual and tear-down examinations.
   3. 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.
   4. Coding method and information.

II. Thermal Processing Schedules, Operations and Equipment.

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

B. Operations
   1. Scheduled processes and operating procedures (e.g., venting, come-up) posted or on file.
   2. Use of heat sensitive indicators and retort traffic control.

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3. Initial temperature, method and frequency of measurement.
4. Type and accuracy of process timing devices.
5. Operating under the supervision of a person who has attended a school of instruction as per 21 CFR 113.10.
6. Actual venting or come-up procedures used.
7. Actual retort operations, time(s), and temperature(s).
8. Actual cooling practices.

C. Equipment and Procedures

1. Type, size and number of retorts.
2. Mercury-in-glass (MIG) Thermometer specifications, date of accuracy checks, accuracy at time of check, standard used, method used to check accuracy.
3. Temperature recording device(s); specifications of chart, installation, accuracy of timing mechanism, agreement with MIG thermometer.
4. Retort temperature and pressure controllers; type (e.g., mechanical, air operated, computer controlled etc.) description of operation.
5. Pressure gauges and pressure relief valve; specifications, installation and location if applicable.
6. Steam entry, description of steam spreaders, steam injectors, heat exchangers etc.
7. Retort crates, divider plates, container orientation, etc. complies with regulations and filed scheduled process requirements.
8. 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.

D. Retort Unique Requirement

1. Still steam retorts
    a. Crate supports, vertical retorts.
    b. Bleeders; specifications, location, installation and use.
    c. 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.
2. Still water immersion retorts
    a. Crate supports and guides in vertical retorts.
    b. Drain valve, type, screened.
    c. Water level indicators, type, use.
    d. Air supply and control.
    e. Method of water circulation, compliance with regulations, temperature distribution studies.
    f. Cooling water supply.
    g. Location of control temperature sensing probe.
3. Continuous agitating steam retorts
    a. Capacity and number of steps in reel.
    b. Vents and bleeders specifications and locations.
    c. Method of removing condensate, condensate bleeder.

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d. Retort speed timing method and frequency, tamper proof.
e. Procedures for handling emergency stops and temperature drops.

4. Discontinuous agitating steam retorts
   a. Capacity and number of steps in reel.
   b. Retort speed timing method and frequency.
   c. Procedures for removing condensate.
   d. Vents and bleeder specifications, locations.
   e. Procedures for handling emergency stops and temperature drops.
5. Discontinuous agitating water retorts
   a. RPM's timing and control.
   b. Over-pressure supply and control.
   c. Method of heating water.
   d. Come-up steps to heat to processing temp.
6. Hydrostatic retorts
   a. Type, number of chains and number of flights in steam, timing of container carrier.
   b. 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.
   c. Vents and bleeders, specifications and location
   d. Disposition of stray containers.
7. Cascading/spray water retorts
   a. Method of heating water (e.g., heat exchanger, direct injection of steam into water, steam distribution pipes).
   b. Come-up steps in process.
   c. Water flow, measurement, (e.g., flow meter, pressure, none) is flow the same as that during temperature distribution studies.
   d. Method used to insure water distribution system is not clogged (e.g., examination of water distribution manifold and sprays, physical cleaning, chemical cleaning).
   e. Water Pump size, inlet diameter, and horsepower.
   f. Location of water inlet into shell.
   g. Timing of RPM's on rotational models.
8. Steam-air
   a. Percent steam/air mixture, is it the same as that used during temperature distribution studies.
   b. Fan operation, method of checking.
   c. Timing of RPM's on rotational models.

III. Processing and Production Records.

A. Production Records
   1. Frequency of measurement and recording of critical factors.
   2. Evidence of critical factors not within established limits.

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B. Processing Records
   1. Thermal processing records maintained as per 21 CFR 113.100.
   2. Thermal processing charts and records can be correlated.
   3. 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

IV. Finished Product.

A. Warehouse
   1. Evidence and extent of spoilage and/or abnormal containers
   2. Incubation practices

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

C. Product Recalls
   1. Nature of recall, date of recall
   2. Disposition of product

D. Process Deviations
   1. Procedures for handling
   2. Disposition is documented.

T.4.2 Checklist. Guidelines for auditing low-acid canned food establishments are contained in the following Table T-I checklist.

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TABLE T-I.

APPENDIX A PARAGRAPH	Low-acid canned foods checklist REQUIREMENTS as specified in: CFR Title 21, Parts 110, 113 and 173
E1, E2, E3	Raw materials are handled in a manner that protects against contamination, adulteration, and minimizes deterioration; does not allow the growth of microorganisms to a level that challenges the lethality of the thermal process; and does not cause food product to spoil under normal conditions of canning and storage. (21 CFR 110.80(a)(1) – (7))
A11	Trained personnel supervise the operators of processing systems, retorts, systems, and container and closure inspections. (21 CFR 113.10)
A11, E2, E6, H1, H3	Scheduled processes for low-acid foods have been established by qualified persons having expert knowledge of thermal process requirements and having adequate facilities for making such determinations. Critical factors (e.g., minimum headspace; consistency; maximum fill or drained weight; Aw; pH; initial product temperature; type of filling; specific can size/style; etc.) will be specified in the scheduled process. (21 CFR 113.83)
H6, H7, H8, H9	Processing and production information is entered on forms/mandatory records specific to the process and retort used and includes: company name, date, product, production code, retort number, container size, number of containers produced per coding interval, initial temp, time steam on, time vent closed, vent temp, time temp up, time steam off, actual processing time, mercury-in-glass (MIG) and recorder chart temperatures and other appropriate processing/critical factor data. Records are reviewed by qualified personnel, reviews are documented when required; and records maintained as required. (21 CFR 113.100(a) – (e))
E1, E2, E6, H3, H8	Processor ensures raw materials and ingredients are suitable for use before using raw materials and ingredients susceptible to microbiological contamination. Process steps are controlled to ensure critical factors are met, as noted on the scheduled process. (21 CFR 113.81)
E2, E6, H3	Critical factors specified in the scheduled process should be measured and recorded on the processing record at intervals not exceeding 15 min. (21 CFR 113.40 (13))
E2, E4, E6, H4, H6, H8	When ever any process is less than the scheduled process or when critical factors are out of control, that low-acid food is fully reprocessed or food is evaluated and substantiated by a qualified scientific authority as free of any potential hazard to public health prior to release. (21 CFR 113.89)
E2, E6	Container size and type are the same as those identified on the scheduled process for each item being produced. (21 CFR 113.83)
E2, E4, E6	When pH is the basis for a scheduled process, processor ensures equilibrium pH of the finished product. (21 CFR 113.81(e))
E2, E10, H3	Containers must meet container specifications and be free of gross closure defects (21 CFR 113.60(a))

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TABLE T-I – Continued.

A11, E2, E4	Visual seam inspections are conducted by a qualified individual 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 by a qualified individual at least every 4 hours. (21 CFR 113.60(a) - (1))
C4, E6, H6, H8	Required can seam measurements during can seam teardown are performed using the Micrometer Method (in 3 places about 120^0 apart {Required: cover hook, body hook, width, tightness, and thickness)} or the Seam Scope/Seam Projector Method {in 2 places about 180^0 apart) (Required: body hook, overlap, tightness, thickness). (21 CFR 113.60(a) - (1))
C6, C7	Specific retort type is properly fitted with: indicating thermometers, temperature recorders, pressure gauges, steam controls, spreaders and bleeders. Steam inlets and crate supports are of proper design and location. (21 CFR 113.40(a) – (j))
C7, C10, H6, H8	Each retort is equipped with at least one MIG thermometer properly installed and tested for accuracy against a known accurate standard at installation and at least once per year thereafter. Calibration records are annotated and thermometers are identified. MIG divisions are readable to 1 degree F and temperature range does not exceed 17 degrees F per inch of graduated scale. (21 CFR Part 113.40(a)(1))
C7, C10, E6	Each retort is equipped with accurate temperature recording device with appropriate degree graduations. The temperature recording device will be adjusted to agree with the MIG thermometer, but in no event higher the MIG thermometer. A means of preventing unauthorized adjustments will be provided (e.g., seals, etc.). (21 CFR 113.40(a)(2))
C7, C10	Each retort is equipped with a pressure gauge (graduated in divisions of 2 pounds or less) and an automatic steam controller (to properly control steam temperature). (21 CFR 113.40(a)(3) – (4))
C6	Retort steam inlets are of proper design and enter the retort at a location opposite of the retort vent. (21CFR 113.40(a)(5))
C1, C6, E2	Crate supports, steam spreaders, bleeders, stacking equipment, air valves water valves and vents are of proper design, installed, and maintained as required by the specific type of retort being used. (21 CFR 113.40(a)(6) – (12))
C6, E2, E6	Dividers between the layers of containers should be perforated approximately the equivalent of 1-inch holes on 2-inch centers (or as otherwise specified in the scheduled process) to promote steam flow. (21 CFR 113.40(a)(9))
E2, E6	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 113.87(a))
E2, E6	Product traffic control 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 113.87(b))

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TABLE T-I – Continued.

C7, E6	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 113.87(b))
E2, E6, H3, H6, H8	Initial temperature of the contents of the containers to be processed in the retort is determined and recorded. Product initial temperature (e.g., the temperature of the potentially coldest container in the retort about to begin a process) is not lower than the minimum initial temperature specified in the scheduled process. (21 CFR 113.87(c))
C10, E6	Timing device used to record processing and venting times is accurate to the extent needed. Pocket or wrist watches are not considered satisfactory for timing purposes. Clock times on recording-temperature charts should reasonable correspond to time of day entered on other processing records. (21 CFR 113.87(d) & (e))
B9, E2, H3	Water used for cooling must be potable. Container cooling water will be chlorinated or otherwise sanitized, as necessary, for cooling canals and for recirculating water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler. (21 CFR 113.60(b))
B6, B9, E2	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. (21 CFR 173.310)

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COOK/CHILL AND SOUS VIDE PROCESSING

U.1 SCOPE

U.1.1 Scope. This appendix contains guidelines for auditing Cook Chill and Sous Vide processing establishments. The information contained herein is intended for guidance.

U.2 APPLICABLE DOCUMENTS

U.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

U.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

CODE OF FEDERAL REGULATIONS (CFR)

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, or online at: http://www.gpoaccess.gov/cfr/index.html.)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) Food Code.

(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); available on-line at: http://vm.cfsan.fda.gov/~dms/foodcode.html/.)

U.3 DEFINITIONS

U.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

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Cook/chill – a food cooking "manufacturing process" where food is cooked to a "just done" status. The hot cooked food is immediately packaged into a plastic bag, air is expelled, and the bag is closed with a plastic or metal crimp. Subsequently, a reduced oxygen environment develops. The bagged food is then immediately chilled (but not frozen) for storage and reheating at a later time.

Sous Vide – a specialized reduced oxygen process (ROP) for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

(a) Preparation of the raw materials (may include partial cooking of some or all ingredients);
(b) Packaging of the product, application of vacuum, and sealing of the package;
(c) Pasteurization of the product for a specified and monitored time/temperature;
(d) Rapid and monitored cooling of the product at or below 38º F (3º C) or frozen; and
(e) Heating of the packages to a specified temperature to complete the cooking process, before opening and service.

U.4 GUIDELINES

U.4.1 General. Cook/chill offers today's food service operators a cost effective means of providing quality foods while reducing overhead costs. Sous vide is a partial cooking process that uses lower temperatures and does not reduce bacterial load to the same level as cook chill processing times and temperatures.

The basic cooking concept centers on the fact that food-borne organisms that cause spoilage and illness grow rapidly between 41° F (4.4° C) and 135° F (60° C). Foods are cooked to the proper temperatures, killing most organisms and microbes, followed by rapidly chilling the product down through the temperature range of 135° F (60° C) to 41° F (4.4° C). The cooked food is then stored as close to the freezing point as practical without allowing it to actually freeze, optimizing product quality.

There are two methods for product cooling: blast chilling and water bath chilling utilizing tumble chillers and other mechanical equipment. Blast chilling uses cold air, blown over the food in containers (usually shallow pans) while the water bath chilling method submerses sealed casings of cooked food in very cold water. Blast chilling produces products with a much shorter shelf life than when cooled with bath chilling.

The primary difference of the cook/chill and sous vide systems compared to more common kitchen food preparation techniques are in the final cooking, chilling and storage methods. The goal is ideally to automate and control everything in these stages so that the prepared food manufacturing can occur as a steady process, rather than the more typical peak-and-valley method of most kitchens. This steady operation can fine-tune food quality through

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strict adherence to standardized recipes and procedures to ensure a consistent product. These systems may also permit "centralized" regional food service opportunities. This is proving extremely popular in school systems.

It is important that the kitchen or central kitchen facility be designed specifically for this food preparation concept. Conventional walk-in refrigeration units cannot reduce food temperatures quickly enough. In addition, much of the equipment that will automatically transfer, portion control, and package finished food products is specialized.

These systems start with the centralized bulk purchase and storage of ingredients. All pumpable recipes (foods with chunks smaller than about 1" in diameter) are fed to specially made jacketed kettles with mixer/agitator attachments. Large non-pumpable foods such as cut up chicken and meat are either purchased in a ready-to-cook state or are processed into vacuum-sealed packages for the "slow cook" process.

Next, the pumpable hot products are metered into special casings, sealed, and labeled without human or utensil contact and immediately loaded into a tumble chiller or blast cooler for rapid cooling. Most casings hold 1 to 2 gallons of product. The food product is brought to 38°F/3.3°C or lower within 2 hours, and then placed in standard walk-in refrigerators that will hold the food very close to, but just above, freezing.

Food is distributed from these holding areas to operating kitchens that will reheat (otherwise called "re-thermalize") them as needed. This reheating can be done in convection ovens, combi-oven/steamers, convection steamers, pressure steamers, steam jacketed kettles, and/or tilting skillets and braising pans.

A least one barrier or multiple hurdles resulting in a barrier need to be incorporated into the production process for these products. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth, is necessary to ensure food safety.

Processors should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. For these items with extended shelf-life (greater than 14 days), a temperature of 38° F (3.3° C) or lower must be strictly maintained at all times to prevent outgrowth of *Clostridium botulinum* and the subsequent production of toxin.

Listeria monocytogenes can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Barriers or hurdles, such as low pH, Aw, short shelf life, and/or proper temperature control inhibit growth. Any one hurdle, or a combination of several, may be used to control pathogenic outgrowth.

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Some products contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, Aw, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

Bacteria, with the exception of those that can form spores, are eliminated by proper/effective pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-processing contamination occurs.

An anaerobic environment, usually created by reduced oxygen packaging of these products, provides the potential for growth of several important pathogens. Some of these are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, telltale signs signaling that the product is no longer fit for consumption will not occur.

Target microorganisms of concern in sous vide and cook/chill processing include *Salmonella spp., Listeria monocytogenes, Staphylococcus aureus, Clostridium perfringens, Clostridium botulinum* and *Bacillus cereus.* Scheduled process control and HACCP plans will include: time temperature controls, finished product laboratory analyses, and verification procedures to ensure a pathogen free product.

Sous vide processed products have a shelf life of 1 to 6 weeks, depending upon the severity of the cooking or pasteurisation step and storage temperatures. For a short shelf life product (<10 to 14 days), the significant microbiological risk is the presence of vegetative pathogens, and the heat treatment should achieve at least a 6-log reduction (150° F (70° C) for 2 min in the lowest heating point) in the numbers of pathogens. For longer shelf life products, the thermal process must eliminate any spores capable of germination and outgrowth during prolonged storage and must be at least equal to 6-D for psychrotrophic *Clostridium botulinum* [194° F (90° C) for 10 min] or greater if spores of pyschrotrophic *Bacillus* species must also be eliminated. Manufacturers will re-evaluate and validate the process and shelf life of products annually. Any change in recipe, ingredients or major pieces of equipment will also require re-evaluation and verification.

HACCP plans are required for all cook/chill and sous vide retail production operations and applicable records must be maintained for all phases of production.

U.4.2 Checklist. Guidelines for auditing cook/chill and sous vide food processing establishments are contained in the following Table U-I checklist.

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TABLE U-I.

APPENDIX A PARAGRAPH	Cook/chill and sous vide processing checklist REQUIREMENTS as specified in: CFR Title 21, Part 110 FDA Food Code
E1, E2, E3	Raw materials are handled in a manner that protects against contamination, adulteration, and minimizes deterioration; does not allow the growth of microorganisms to a level that challenges the lethality of the thermal process; and does not cause food product to spoil under normal conditions of packaging and storage. (21 CFR 110.80 (a) (1) – (7))
E1, H6	Materials and ingredients are suitable for use in processing, as verified by any effective means to include purchasing under a supplier guarantee or certification. (21 CFR 110.80(a)(2) – (3))
A11	Employees will have documented proof of training concerning the reduced oxygen packaging (ROP) process and the hazards associated with these processes. (21 CFR 110.10(c)) and (FDA Food Code, Annex 6)
E2, E6, H6, H8	Heat processes should be designed as a minimum to ensure that all vegetative pathogens are destroyed by a pasteurization process. Microbiological or challenge studies should be performed by an appropriate process authority (qualified individual) validating the pasteurization process. (21 CFR 110.80 (b) (2)) and (FDA Food Code, Annex 6)
E2, E6, H6	ROP product must be cooled in a manner that prevents the growth of pathogenic organisms or toxin formation, ensuring a uniform and safe cooling process. (21 CFR 110.80(b)(1) – (17)) and (FDA Food Code, Annex 6)
B9, H6, H8	Ice and water used for cooling must be potable. (21 CFR 110.37, 110.80(b)(16)) and (FDA Food Code, Annex 6)
C7, E2, E6	Internal product temperatures will be monitored and recorded throughout the process using appropriate temperature measuring devices. (FDA Food Code, Annex 6)
C10	All scales, meters, thermometers and weights will be calibrated IAW manufacturer's instructions. (FDA Food Code, Annex 6)
E2, E6, H6	Effective separation procedures will be in place to prevent cross contamination between raw and cooked foods. (21 CFR 110.80(b)(2)) and (FDA Food Code, Annex 6)
A11, E2	Access to the processing areas will be limited to responsible trained personnel. (FDA Food Code, Annex 6)
E6, H6	Each container will bear a use by date, "keep refrigerated at 41° F (5° C)" or "keep frozen" statement, and date of manufacture in addition to minimum labeling required by Federal Law. (FDA Food Code, Annex 6)
E6, H8	Processed foods that exceed use-by date cannot be sold or used in any form, and must be disposed of properly. (FDA Food Code, Annex 6)

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TABLE U-I – Continued.

E1, H6, H8	Traceability and recall program is required and validated. (FDA Food Code, Annex 6)
E3, E6, H6, H8	Finished product must be stored and distributed at a core temperature of 38° F or 41° F (or lower), depending on product shelf life (41° F for 14 days or less, or 38° F for 14 days or more). Microbiological or challenge studies should be performed by an appropriate process authority (qualified individual) validating the cooling process. For food safety considerations, this product may be produced and held in a frozen state, and the shelf life/temperature parameters above do not apply. (21 CFR 110.80(b)(2)) and (FDA Food Code, Annex 6)
H3	A record of process safety barrier verifications should be updated annually. (FDA Food Code, Annex 6)
E6	Processed fish and smoked fish products will not be manufactured unless specifically approved by the appropriate government regulatory agency. (FDA Food Code, Annex 6)

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FRESH FRUIT AND VEGETABLE SUPPLIERS (UNPROCESSED) IN OCONUS AREAS

W.1 SCOPE

W.1.1 Scope. This appendix contains guidelines for auditing suppliers of fresh fruit and vegetable suppliers (unprocessed) in OCONUS Areas. The information herein is intended for guidance.

W.2 APPLICABLE DOCUMENTS

W.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

W.2.2 Other Government documents and publications. The following other Government documents and publications form a part of this document to the extent specified therein.

NAVAL MEDICINE PUBLICATION

Manual of Naval Preventive Medicine, NAVMED P5010. Chapter 1 (P5010-1) is Food Safety.

TECHNICAL BULLETIN, MEDICAL, U.S. ARMY

TB Med 530, Food Service Sanitation.

(Available online at http://chppm-www.apgea.army.mil/tbm.htm.)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Mar. 07, U. S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN).

(Available on-line at: http://www.cfsan.fda.gov/~dms/prodgui3.html.)

U.S. ENVIRONMENTAL PROTECTION AGENCY

EPA’s Registered Sterilizers, Tuberculocides, and Antimicrobial Products Against Certain Human Public Health Bacteria and Viruses

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(Available on-line at: http://epa.gov/oppad001/chemregindex.htm.)

W.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

Food Safety Begins on the Farm.

(Available online at: http://www.sfc.ucdavis.edu/pubs/articles/foodsafetybeginsonthefarm.pdf.)

Improving the Safety and Quality of Fresh Fruits and Vegetables.

(Available online at: http://www.jifsan.umd.edu/PDFs/GAPS_English/english.pdf.)

Setting Tolerances for Pesticide Residues in Foods (Pesticides: Topical and Chemical Fact Sheet).

(Available online at: http://www.epa.gov/pesticides/factsheets/stprf.htm.)

W.3 DEFINITIONS

W.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below:

Agricultural water – refers to water used in the growing environment (for example, field, orchard or vineyard) for agronomic reasons. It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers or pesticides. Occasionally a more specific term may be used, such as “irrigation water.” Typical sources of agricultural water include flowing surface water from rivers, streams, irrigation ditches, open canals, impoundments (such as ponds, reservoirs, and lakes). Additionally, agricultural water may include wells and municipal supplies.

Chlorine contact time – the period of time the product/surface is in direct contact with an effective concentration of chlorine.

Chlorine demand – the amount of chlorine dosage, which reacts with and is consumed by organic material, bacteria, and other materials in the water.

Chlorine dosage – the amount of chlorine added to water to satisfy the chlorine demand as well as to provide a residual after a specified time.

Chlorine residual – the amount of the chlorine dosage remaining after the demand has been satisfied. Dosage minus demand equals residual.

Free available chlorine – the total available residual chlorine present at the end of a specified contact period.

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Fresh fruits and vegetables – refers to fresh produce that is likely to be sold to consumers in an unprocessed (i.e., raw) form. Fresh produce may be intact, such as strawberries, whole carrots, radishes, and fresh market tomatoes, or cut during harvesting, such as celery, broccoli, and cauliflower.

Fresh salad-type fruits and vegetables – refers to fresh fruits and vegetables that normally are not peeled, pared, or cooked prior to eating.

Composting – refers to a managed process in which organic materials, including animal manure and other wastes are digested by anaerobic or aerobic microbial action.

Field heat – many fresh fruits and vegetables will deteriorate soon after harvest, unless they are rapidly cooled. Field heat is a term used to describe the temperature of the produce at time of harvest. Rapid cooling immediately after harvest is often referred to as “removing the “field heat”. This process reduces the rate of transpiration in the harvested produce. Removing field heat increases the shelf life of the produce. There are several methods for removing field heat such as vacuum cooling, icing, and cold-water immersion.

Packing Shed – a facility that is used for washing, culling, trimming, and packing of fresh fruits and vegetables before delivery to the U.S. Armed Forces.

Processing water – water used for post-harvest treatment of produce such as washing, cooling, waxing, and product transport.

Produce - fresh fruits and vegetables grown for the market.

W.3.2 Risks associated with different categories of fresh fruits and vegetables.

Fresh fruits – Fresh fruits can be an important vehicle in the transmission of disease to man. Therefore, increased emphasis must be placed upon proper surveillance of the areas of procurement of fresh fruits, which can be easily contaminated and difficult to clean (e.g., strawberries by parasitic ova). Fresh fruits that are normally eaten with the skin on such as apples, peaches, and pears should be thoroughly washed and scrubbed with a brush before they are eaten. Washing and scrubbing may help remove and/or reduce the presence of pesticides that may be on the fruit. Fresh fruit, in which skin has been broken or the stem pulled, should be washed thoroughly and the defective area cut out with a knife prior to consumption.

Microbiology of fresh fruits – Three groups of microorganisms commonly found on fresh fruits are spoilage organisms, fermentation organisms, and pathogenic organisms. Many organisms that cause intestinal diseases can be found in soil and water; therefore, an excellent opportunity exists for fresh fruits to become contaminated. The disease-causing organisms most likely to be found on fresh fruits are those that cause cholera, dysentery, and typhoid fever. Since the meat of fresh fruits is normally sterile, the disease-transmission potential is derived primarily from external contamination. This contamination will usually result from contact with

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the soil and water on the farm or from handling at the packing shed, including the use of polluted water to “freshen” the product.

Fresh vegetables – Fresh vegetables are often implicated in the transmission of disease to man. Microorganisms ubiquitous to soil and water therefore present a greater opportunity to contaminate vegetables which are grown in or near the ground. It is recommended that water chestnuts, watercress, lotus, water bamboo, and other aquatic plants not be procured from local sources where intestinal and hepatic flukes are prevalent. Spinach greens, if consumed as a fresh salad-type vegetable, should be disinfected prior to consumption.

Fresh non-salad-type vegetables – Fresh non-salad-type vegetables include: potatoes, sweet potatoes, string beans, okra, and eggplant. These fresh vegetables include those that are usually consumed after they have been cooked. Therefore, the disease-transmission potential of this type of fresh vegetable is not as great as that of the fresh salad-type. However, care must be taken to assure that handling of fresh non-salad-type vegetables does not result in contamination of the kitchen, prepared foods, fresh salad-type vegetables, and/or utensils.

Microbiology of fresh vegetables – Spoilage and pathogenic organisms are found on fresh vegetables. As with fresh fruits, the tissues of fresh vegetables are normally sterile. Surface contamination usually results from contact with the soil, irrigation water, or unsanitary handling and packing practices. The washing of fresh vegetables removes soil contamination but does little to remove bacterial contamination. Fresh salad-type vegetables are most likely to be involved in disease transmission since they are eaten raw. Intestinal diseases and viruses such as Hepatitis A may be transmitted by contaminated fresh vegetables. Transmissible intestinal diseases include intestinal parasites, cholera, dysentery, typhoid, and paratyphoid fever.

W.4 GUIDELINES

W.4.1 General.

Pre-Audit Research – In many parts of the world suppliers of unprocessed produce are exempt from *Worldwide Directory* listing. In OCONUS areas, the MACOM Veterinarian may require audit, approval, and *Worldwide Directory* listing of these commercial suppliers. If produce suppliers are to be audited, generally the supplier is located in a country that may not maintain the same standards as the United States. Therefore, it is important that the auditor determine the extent of host country oversight of the produce industry. This would include areas such as pesticide regulation, pesticide residue testing programs, and testing of agricultural waters. If the country belongs to, or exports to multi-national trade organizations such as the European Union (EU), it is recommended that the auditor check with that organization to see if there are any restrictions on produce from the host country. It is also recommended that the auditor contact the USDA Foreign Agricultural Service (FAS) to determine if the United States has any restrictions on importing produce from the host country.

Scope of the audit – Most produce supply companies receive their produce from many different farms or orchards. Therefore, it is necessary for the produce supplier to be responsible

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for the wholesomeness of the fresh fruits and vegetables that are being sold to U.S. Forces. It is usually not possible for the auditor to audit all the potential growing fields. When time permits, visiting a few farms can be a good opportunity for the auditor to evaluate local agricultural practices. The produce supplier should have a grower certification program. If there is an adequate government regulatory authority, the establishment may rely on local government requirements and enforcement. At a minimum, the produce supplier/local government should have guidelines/requirements that are monitored and enforced with the growers. The supplier certification should cover growing field environment, agricultural water, fertilizers, sanitation for agricultural workers, and the use of pesticides. The auditor will determine the extent and acceptability of growing areas. This can be accomplished by reviewing the grower certification program (to include records review) and/or through discussion with the local government health authority. The auditor will then observe and audit the packing shed and distribution system for adherence to sanitation requirements.

W.4.2 Guidelines for Reviewing Grower Certification.

Growing environment and agricultural water – The growing fields for agricultural water should be studied along with its relative potential for being a source of pathogens. Agricultural water should not be readily contaminated by run-off from livestock, wildlife, industrial or human sources. Wells should be in good repair. Agricultural water should be subjected to laboratory testing not less than annually. Agricultural water should be free of pathogens. Tolerance for fecal coliform is 2.2 cfu/100 ml. Although it may not need to be tested as often, protozoa and virus should not be ignored in the design of a testing program. Pesticide residues should be within tolerances for normal agricultural applications. Turbidity and total plate count requirements are not applicable.

Fertilizers – Chemical-type fertilizers should be used in accordance with the manufacturer's instructions on the label. Equine or bovine manure fertilizers are acceptable if they have been composted or otherwise treated so that living intestinal pathogens and parasites are not released into the growing field environment. If bovine or equine manure is not composted, it should be added to the growing field at least two weeks prior to planting. Do not harvest produce until 120 days after application of manure. Use of untreated manure, as a fertilizer is not acceptable. Use of untreated manure, as a fertilizer is not acceptable. Human waste, as incorporated into a program of municipal bio-solids management is acceptable in accordance with guidelines of 40 CFR Section 503. Use of vegetative matter as a fertilizer is acceptable.

Sanitation for agricultural workers – Field workers should continuously have convenient access to sanitary toilets and hand washing facilities, particularly during harvest. Hand-washing water should be potable. Outdoor toilets should be of sanitary construction so as not to contaminate the growing fields. Workers will follow safe food handling procedures and be free of communicable disease.

Pesticides – The Environmental Protection Agency (EPA) is responsible for the regulation of pesticides used within the United States. Certain pesticides are not permitted for

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use in the U.S. When procuring produce OCONUS for U.S. Forces, growers will use pesticides within the parameters allowed for U.S. growers. The auditor will inspect the label on the container of any pesticide to be used to ensure that the label states (1) that the pesticide is authorized for use on the plant and/or crop to be purchased for human consumption; (2) provides information on timing of last application prior to harvest; and (3) whether or not any restriction on the number of applications or volume of finished pesticide preparation which can be applied is stated. Restrictions stated on the label, or as provided by a consulting entomologist must be followed. The supplier or the local government will have a program for monitoring pesticide residues on produce imported from outside sources. The grower or supplier will have records available for review by the auditor. Records should include crop data, name of pesticides used, place of application, dosage, application data, period of time, prior to harvest, name of pesticide application operator, date of applicator calibration.

W.4.3 Sanitation Audit of Post-harvest Operations.

Sources of contamination post-harvest (packing, storage, and distribution). Packing sheds/houses generally create a product that can be easily sold in boxes of uniform weight and sorted into uniform sizes. Cases are easily palletized and distributed. Because of their seasonal nature, and that the product is maintained as intact fruits and vegetables, unprocessed produce is often handled with less attention to sanitation than other food products. The lack of minimum sanitary standards for packing sheds has allowed some establishments to operate in a manner that disregards consideration of food risk. Consequently, packing sheds have been implicated in the spread of foodborne illness. Consider the following when evaluating post-harvest operations:

- Hygiene of packing house employees – Workers will be clean and free of communicable disease. They will have convenient access to sanitary toilet and hand washing facilities. Hands will be washed after using toilets and before working with product. It is not necessary for employees to wear hairnets. Clean outer garments will be worn.

- Facility construction, maintenance – Packing sheds are generally not expected to meet the same standards as other commercial food processing establishment's. Exterior openings may remain open during processing hours, but they should be shut when not processing. The buildings and grounds will be free of pest harborages. The building will be free of openings or holes that allow the entrance of pests when the shed is not in operation.

- Proper operation and sanitation of equipment – Food contact surfaces should be constructed of stainless steel or other approved sanitarily acceptable, easily cleanable material. Food contact surfaces should be cleaned and sanitized as appropriate for the type of operation. Conduits and reservoirs for processing water should be clean and sanitary. Food handling equipment must have smooth surfaces and be placed in locations that facilitate adequate cleaning. Food handling equipment should not have loose bolts, knobs, or removable parts that should fall off. If equipment is painted, the paint should be approved for food processing

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equipment and be free of chips. Rust should be removed so that it does not flake off on product. Only food grade oil and lubricants will be used.

- Transport containers – Bins or containers used for transporting produce from the growing fields will be segregated from bins or containers used for transporting clean product. Otherwise containers used to transport produce from the growing field will be thoroughly cleaned prior to being loaded with washed produce.

- Processing Water – Water used during the post harvest handling of fruits and vegetables often involves a high degree of water to product contact. Processing water is recommended to meet the same standard as U.S. Environmental Protection Agency (EPA) requirements for drinking water. However 21 CFR 110.19 carries an exemption to water quality standards for establishments engaged solely in the harvesting, storage or distribution of raw agricultural commodities. Since water is often used for soil removal it is recommended that clean water flows counter to the movement of produce during different unit operations. In other words, the water in the final rinse will be clean and sanitary compared to water used for soil removal. Produce will be washed in a freely circulating chlorine solution that maintains sufficient chlorine residual to prevent the widespread contamination of produce during the washing process. Depending on the type of product, chlorine is used in a range of 50 - 200 ppm, at a pH of 6.0 to 7.5, with a contact time of 1 - 2 minutes. Anti-microbial agents other than chlorine may be used if shown to be effective. In addition to chlorine, other anti-microbial treatments that have been researched include chlorine dioxide, irradiation, tri-sodium phosphate, lactic acid and acetic acid. In the case of unprocessed produce, a one to two log reduction in surface microbes is considered effective. The cleanliness of the final rinse water and the concentration of the anti-microbial agent will be regularly or continuously monitored. Unsanitary wash water can allow the spread of pathogens throughout the product lot.

- Cooling – The process of removing field heat helps to maintain product quality. There are several methods for cooling produce including water, ice and forced air. In most instances cooling with forced air (such as vacuum coolers or fans) poses the least risk of spreading contamination across a product lot. Water and ice used during cooling are a potential source of contamination; and will be treated with the same care as processing water used for washing. The cleanliness of cooling water or ice will be monitored and maintained.

- Washing – Vigorous washing of produce not subject to bruising or injury may increase pathogen removal. Brush cleaning is more effective than washing without brushes. Spray methods may cause the spread of pathogens by splashing or aerosol. It may be more effective to have a series of washes rather than a single wash. An example of this would be an initial wash, followed by a sanitizing dip, followed by a clean water rinse. It is important to note that for the majority of produce items, the temperature of the water will be greater than the temperature of the produce to

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prevent the water from being pulled into the plant tissue. Denser products, such as carrots, do not appear to be affected by water temperature differences. Reducing the temperature difference can be accomplished by heating the water, or by air-cooling the produce prior to washing.

- Waxing/Coating – If produce is not clean prior to waxing, pathogens will be sealed between the outer surface and the wax coating. Wax reservoirs and applicators should be maintained, cleaned and sanitized, and not provide a means of spreading contamination.

- Packing/labeling – Packing must include marking that allows product to be traced back to its origin in the event of a foodborne outbreak or recall. Packing materials must be free of contamination.

- Storage/Distribution – Some types of produce are subject to chill injury at refrigeration temperatures. These types of products should be stored at their appropriate temperature. Whenever appropriate for the type of produce, refrigeration reduces the growth rate of pathogens. Storage areas will be clean and enclosed to prevent pest access. Conveyances will be clean, free of odors, visible dirt and traces of organic matter, and refrigerated when appropriate. Storage areas and conveyances will not be used for the storage and transport of harmful chemicals, raw meat, fish, eggs, and other commodities that are significant sources of foodborne contaminants or pathogens, unless the containers are adequately cleaned and sanitized.

- Phytosanitary requirements – The term phytosanitary inspection is an international effort to protect natural flora and plant products from pests and pest products that can damage crops and the agriculture of countries or regions. It may require the produce supplier or local government to thoroughly inspect produce for destructive pests. These inspections may include conveyances, containers, storage places and soil as well as produce. This may be an issue if produce is procured from a supplier and shipped to U.S. Forces in another area.

Restrictions to product listing – In order to better ensure the food safety of produce delivered to U.S. Forces, the auditor may restrict the produce items that a supplier is approved for. This may include only produce that must be peeled, or imported from more advanced countries. Another possible stipulation is that produce must be dipped in a chlorine solution at destination. If the packing shed receives washed produce from plants that have poor sanitary control, the auditor may recommend that only unwashed produce be accepted. The auditor should consider the types of produce that may be procured and discuss possible stipulations with his chain of command. U.S. Forces policy requires produce to be disinfected prior to consumption, typically in a chorine solution of 200 ppm (Army) or 50 to 100 ppm (Navy). The cleaning and disinfecting of fresh fruits and vegetables required in TB Med 530 (Occupational Health Food Sanitation) is primarily concerned with the destruction of disease-producing organisms. However, it is also a definite aid in removing pesticide residues that may be present.

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W.4.4 Checklist. Guidelines for auditing Fresh Fruit and Vegetable Suppliers (unprocessed) in OCONUS areas are contained in the following Table W-I checklist.

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TABLE W-I.

APPENDIX A PARAGRAPH	Fresh fruit and vegetable suppliers (unprocessed) in OCONUS areas checklist REQUIREMENTS as specified in: Guide to Minimize Microbial Hazards of Fresh Fruits and Vegetables (Guide)
B9, E7	Water and ice used in cooling operations does not introduce food safety hazards. (Guide, Chapter II, Section 2.4)
B6, E4	Produce establishment or local government has a pesticide residue-monitoring program in place. (Guide, Chapter II)
B8, E1, E2	Bins or containers used for transporting produce from the growing fields are segregated from bins or containers used for transporting clean product. If this is not the case, containers used to transport produce from the growing field are thoroughly cleaned prior to being loaded with clean produce. (Guide, Chapter VII, Section 1.0)
B6, E2, E4, E6	Produce washed in a freely circulating chlorine solution that maintains sufficient chlorine residual to prevent contamination of produce during the washing process. Anti-microbial chemicals utilized in the processing water are monitored and maintained at the proper concentration. Depending on the type of product, chlorine is used in a range of 50 - 200 ppm, at a pH of 6.0 to 7.5, with a contact time of 1- 2 minutes. (Guide, Chapter II, Section 2.2 and 2.3)
E2, E4, E6	Temperature of wash water is greater than that of produce to ensure that the pressure differential does not cause water to be pulled into the product, causing pathogens that may be present on the produce surface or the water to be internalized. (Guide, Chapter II, Section 2.2)
E1, H6, H8	Products from establishment can be traced back to their source (growers, packers). (Guide, Chapter IX)
E3	Storage areas are maintained at the appropriate temperature to reduce the risk of microbial hazards. (Guide, Chapter II, Section 2.4)
E3	Distribution and transportation operations maintain adequate temperature controls to ensure the safety of fresh produce. (Guide, Chapter VIII)

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FOOD DEFENSE PROGRAM

Y.1 SCOPE

Y.1.1 Scope. This appendix contains guidelines for auditing the food defense program within establishments. The information contained herein is intended for guidance.

Y.2. APPLICABLE DOCUMENTS

Y.2.1 General. The Government and non-Government publications listed in this particular section are applicable to this appendix. However, this particular section does not include: (1) documents cited in other sections of this *handbook*; (2) documents recommended for additional information; or (3) documents recommended as examples. While every effort has been made to ensure the completeness of the publication lists in this particular section, users are cautioned that all other specified documents {(1) through (3) above} cited in this appendix still apply, whether they are listed below or not.

Y.2.2 Other Government publications. The following other Government publications form a part of this document to the extent specified therein.

DEPARTMENT OF DEFENSE INSTRUCTION

Subject: DOD Antiterrorism (AT) Standards. Number 2000.16, October 2, 2006. Incorporating through Change 2, December 8, 2006.

(Available online at: http://www.dtic.mil/whs/directives/corres/pdf/200016p.pdf.)

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE / HSPD – 7, 9 & 10

HSPD – 7, Critical Infrastructure Identification, Prioritization, and Protection.

HSPD – 9, Defense of United States Agriculture and Food.

HSPD – 10, Biodefense for the 21st Century.

(Available online at: http://www.whitehouse.gov/news/releases/2003/12/20031217-5.html and http://www.whitehouse.gov/news/releases/2004/02/20040203-2.html.)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Law No: 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act of 2002).

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(Available online at: http://tis.eh.doe.gov/biosafety/library/PL107-188.pdf and http://www.fda.gov/oc/bioterrorism/bioact.html.)

Y.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein.

AIB INTERNATIONAL

AIB Food Security Guidelines.

(Application for copies should be addressed to the AIB International, 1213 Bakers Way, P.O. Box 3999, Manhattan, KS 66505-3999: Available on-line at: https://www.aibonline.org/foodsafetyeducation/FoodDefense/resources/guidelines/foodsecurityguidancel.pdf.)

The AIB Guide to Food Defense.

(Application for copies should be addressed to the AIB International, 1213 Bakers Way, P.O. Box 3999, Manhattan, KS 66505-3999: Available on-line at: http://www.aibonline.org/.)

Y.3 DEFINITIONS

Y.3.1 Definitions. General definitions are contained in this handbook. Appendix specific definitions are listed below.

For Official Use Only (FOUO) - a designation that is applied to *unclassified* information that may be exempt from mandatory release to the public under the Freedom of Information Act (FOIA).

Y.4 GUIDELINES

Y.4.1 General. This appendix has been adopted from AIB International's *Food Security Guidelines* (with permission). Most of the guidelines developed by AIB have been incorporated. The AIB guidelines also incorporate industry recommendations, FDA Guidance documents, and security guidelines.

Y.4.2 Systems Approach. When performing the audit on an establishment's food defense program, the audit will comprise of six general systems/areas:

- Food Defense Policy (MIL-STD-3006C Table Y-I)
- Outside Grounds and Roof Areas (MIL- STD-3006C Table Y-II)
- Employee and Visitor Programs (MIL- STD-3006C Table Y-III)
- Material Receiving (MIL- STD-3006C Table Y-IV)
- Facility Operations (MIL- STD-3006C Table Y-V)
- Finished Goods Storage/Shipping (MIL- STD-3006C Table Y-VI)

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The Food Defense appendix is a critical component of a complete sanitary audit program. Identified findings/vulnerabilities need to be addressed to further strengthen the establishment's food defense program.

The AIB reference documents (with modified scoring criteria) must be used in conjunction with this appendix in order to properly assess an establishment's food defense program. There are specific deviations from the *AIB Food Security Guidelines* reference manual in the MIL-STD-3006C Food Defense Appendix, most notably (not all inclusive):

- The *AIB Food Security Guidelines* reference manual lists evaluation criteria as Ideal, Fair, and Weakness. This is due to how the document is used and implemented. The MIL-STD adopts the guidelines (modified) as requirements to be scored.

- Paragraph 1.4 - States a six-month frequency for mock recalls. The MIL-STD does not prescribe/require a frequency.

- Paragraph 1.6 - States a quarterly frequency for food security (self) inspections. The MIL-STD does not prescribe/require a frequency.

- Paragraph 1.7 - List of key regulatory and law enforcement officials. There is no deviation from this requirement.

- Paragraph 5.4 - Water potability testing (omitted). This item is covered in other areas of the MIL-STD.

- Paragraph 5.5 - Water treatment and/or filter systems (omitted). This item is covered in other areas of the MIL-STD.

- Paragraph 5.7 - Air supply systems (omitted). This item is covered in other areas of the MIL-STD.

- When a guideline exists in the AIB reference document that states *documented*, but the MIL-STD does not list a documentation requirement, the component does not have to be documented.

Y.4.3 Scoring.

When scoring food defense, utilize Critical, Major, and Observation for findings. Auditors must assess each component listed in the applicable MIL-STD Table (Y-I through Y-VI) under Finding codes J1 through J6, and determine the overall level of adequacy and compliance. If an establishment has an equivalent policy, practice or procedure that meets the component requirement, it is considered adequate.

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In some cases, it is recognized that not all Finding codes (components) listed in the tables will apply to a certain establishment. These components may be considered "NA" (Non-Applicable) by the auditor. In deciding whether or not an item is Non-Applicable versus scoreable, the auditor must establish the need for the particular barrier to the vulnerability in question based upon all other factors relating to the establishment. For example under appendix paragraph J2, the component, "Documented system in place to control and identify vehicles authorized to enter and/or park on premises (Para 2.7)", may not apply to a small operation that is located within a public shopping strip mall. If the auditor determines the item to be Non-Applicable, it will be scored as an Observation, and comments will be made in the Finding why the item does not apply.

Once the assessment of all components for a particular table is completed, only one Finding code (if found) will be scored for the entire table. In other words, when scoring each table, the severity of each component Finding is not looked at in terms of whether it is a Critical, Major, or Observation. The auditor must judge whether the totality of all components assessed constitutes a finding for the overall table. At this point a score will be given for the entire table.

In the sanitation audit report, address all findings for each specific MIL-STD Table (Y-I through Y-VI) under the scoreable finding (J1 – J6). Food defense program findings are totaled with the sanitation audit findings to determine the overall sanitation rating. Specific food defense findings will be annotated on paper and handled as “For Official Use Only (FOUO)”. Auditors will prepare, review and leave, a copy (hand-written if necessary) listing the specific food defense findings with the establishment’s management for all Initial, Routine, Special, and Directed Routine audits, prior to departing the establishment. Do not record specific (detailed) food defense findings in the Lotus Notes Audit Management database for audit reports, but rather use components listed in the applicable MIL-STD Table (Y-I through Y-VI) under Finding codes J1 through J6.

Y.4.4 Checklist. Guidelines for auditing food defense programs are contained in the following Table Y-I through Y-VI checklists.

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TABLE Y-I.

APPENDIX A PARAGRAPH	Food defense policy checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J1	An over-arching *Food Defense Policy* is implemented that adequately reduces food defense vulnerabilities. Components of the system include the following (either as stated or in an equivalent manner): • A Food Operational Risk Management (FORM) program; or equivalent assessment has been completed for the establishment and validated on a yearly basis and is documented. (AIB, Para. 1.1) • A crisis management team or alternative system for dealing with crises is established. (AIB, Para. 1.2) • A product recall program is in place; mock recalls are conducted. (AIB, Para's. 1.3, 1.4) • Food defense responsibilities are assigned to a specific individual or team. (AIB, Para. 1.5) • Food defense inspections are conducted by establishment personnel on a pre-scheduled frequency. (AIB, Para. 1.6) • A list of key regulatory and law enforcement contacts is maintained. (AIB, Para. 1.7) • A method exists to ensure company controlled off-site warehousing, manufacturing, and distribution are included in food defense programs. (AIB, Para 1.10) • There are procedures to investigate alleged tampering issues, within the customer/consumer complaint program. (AIB, Para. 1.11) • Written procedures and policies are in place for a contracted or in-house security service, if utilized. (AIB, Para. 1.12)

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TABLE Y-II.

APPENDIX A PARAGRAPH	Food defense, outside grounds and roof areas checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J2	A system is in place and implemented to adequately reduce food defense vulnerabilities from *Outside Grounds and Roof* areas. Components of the system include the following (either as stated or in an equivalent manner): • Secured perimeters to restrict access to establishment and related outbuildings. (AIB, Para. 2.1) • Security cameras utilized at key locations around facilities and outbuildings. (AIB, Para. 2.2) • Regular documented patrols conducted outside grounds and roof area. (AIB, Para. 2.3) • Access restricted and locked to roof, silos, outbuildings with food safety-sensitive materials, bulk storage tanks, bulk receiving stations, etc. (AIB, Para. 2.4) • Potential hiding places for persons or intentional contaminants are minimized. (AIB, Para. 2.5) • Adequate exterior lighting provided around grounds to include parking lots, doorways, loading docks, bulk storage areas, silos, etc. (AIB, Para. 2.6) • Documented system in place to control and identify vehicles authorized to enter and/or park on premises. (AIB, Para. 2.7) • Program in place to address any unusual security issues noted on outside grounds. (AIB, Para. 2.8) • Entrances to establishment are minimized and monitored. (AIB, Para. 2.9) • Metal or metal-clad doors utilized on entrances to establishment. (AIB, Para. 2.10)

TABLE Y-III.

APPENDIX A PARAGRAPH	Food defense, employee and visitor program checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J3	An *Employee and Visitor* program is in place and implemented to adequately reduce food defense vulnerabilities. Components of the system include the following (either as stated or in an equivalent manner): • A formal pre-hiring screening program in place for all employees and contracted personnel; no employees or contracted personnel are working without pre-hiring screening being completed and approved. (AIB, Para's. 3.1, 3.2)

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TABLE Y-III – Continued.

	• Positive identification and recognition system in place for all personnel entering the establishment. (AIB, Para. 3.3) • System in place to restrict employee access inside and outside of establishment to authorized areas only. (AIB, Para 3.4) • Documented employee training program is in place to cover food defense, including identification of potential signs and evidence of tampering. (AIB, Para. 3.5) • Traffic patterns restricted to welfare areas for arriving employees. (AIB, Para. 3.6) • Employee welfare areas provided for personal belongings. (AIB, Para. 3.7) • No evidence of personal belongings outside designated areas. (AIB, Para. 3.8) • Formal uniform or outer garment program in place. (AIB, Para. 3.9) • Employees not allowed outside of establishment or designated outside break areas during work hours. (AIB, Para. 3.10) • Employee lockers in locker rooms and other personal storage areas inspected on a regular basis. (AIB, Para. 3.11) • Visitors, contractors, etc., report to designated entrance/sign in. (AIB, Para. 3.12) • Establishment policies are provided to visitors, contractors, guests, etc., and plant-issued identification provided with the date of issue and expiration. (AIB, Para. 3.13). • Visitors, contractors, guests, etc., comply with the company dress policy. (AIB, Para. 3.14) • Program to accompany visitors in establishment and verify access to food-sensitive areas. (AIB, Para. 3.15)

TABLE Y-IV.

APPENDIX A PARAGRAPH	Food defense, material receiving checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J4	A system is in place and implemented to adequately reduce food defense vulnerabilities from the *Material Receiving* area(s). Components of the system include the following (either as stated or in an equivalent manner): • Suppliers provide documented evidence of their food defense programs. (AIB, Para. 4.1) • Supplier guarantees on file for all ingredients and packaging. (AIB, Para. 4.2) • Formalized ingredient and packaging testing programs are in place (in-plant testing, outside source testing, or certificates of analysis). (AIB, Para 4.3)

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TABLE Y-IV – Continued.

	Paragraphs 4.4 through 4.11 apply to BULK Materials (Ingredients, Chemicals, Gases, etc.) If N/A, skip to the item covering Paragraph 4.12. • Procedures are in place to cover receipt of all BULK materials. (AIB, Para. 4.4) • Arrival of truck at establishment verified and driver identification verified, for BULK materials. (AIB, Para. 4.5) • Bill of lading, receiving document, truck seals and seal numbers verified for BULK materials. (AIB, Para. 4.6) • BULK material truck or trailer inspection conducted by trained establishment personnel. (AIB, Para. 4.7) • Unloading equipment for BULK materials (hoses, pipes, caps, augers, etc.) secured and inspected prior to use. (AIB, Para. 4.8) • Unloading process for BULK materials conducted in a secured area or monitored during entire process. (AIB, Para. 4.9) • Trailer for BULK materials is inspected after unloading and all unloading equipment re-secured. (AIB, Para. 4.10) • Actual amount of BULK product/materials received is verified (weights, meters, etc.) against the receiving document. (AIB, Para. 4.11) Non-BULK Received Materials (Paragraph's 4.12 through 4.20). • Procedures in place to cover receipt of all received materials. (AIB, Para. 4.12) • Arrival of truck at establishment verified and driver identification verified. (AIB, Para. 4.13) • Bill of lading, receiving documents, amount of seals, and seal numbers verified. (AIB, Para. 4.14) • Truck and trailer inspection conducted by trained establishment personnel before and after unloading. (AIB, Para 4.15) • Product(s), amounts, labels, lot numbers, etc., verified at time of receipt. (AIB, Para. 4.16) • Procedures in place for handling damaged or rejected materials. (AIB, Para. 4.17) • Less-than-load (LTL)/Partial load shipments have a food security system in place. (AIB, Para. 4.18) • Procedures in place to address quarantine and release, irregularities in amounts outside a predetermined range, evidence of tampering, or counterfeiting of goods received. (AIB, Para. 4.19) • Documented requirement for tamper-resistant/evident packaging for received materials, when feasible. (AIB, Para. 4.20)

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TABLE Y-V.

APPENDIX A PARAGRAPH	Food defense, facilities operations checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J5	Processes within *Facility Operations* adequately reduce food defense vulnerabilities. Components of the system include the following (either as stated or in an equivalent manner): • Documented assessment conducted to indicate sensitive areas; access restricted to authorized individuals in sensitive areas identified. (AIB, Para's. 5.1 and 5.2) • Water supply and related critical components are secured. (AIB, Para. 5.3) • Plan to address and react to a possible water safety issue. (AIB, Para. 5.6) • Appropriate access control, CCTV monitoring, and/or supervision present at key manufacturing and storage locations. (AIB, Para. 5.8) • Access to bulk ingredient, gas, or chemical storage vessels are controlled to limit unauthorized access to hatches, filters, vents, etc. (AIB, Para. 5.9) • Physical barriers in place and/or access restricted to hazardous compounds. (AIB, Para. 5.10) • Controls in place to prevent intentional contamination by contractors of maintenance, pest control, or sanitation crews. (AIB, Para. 5.11) • Program to identify any sample or opened ingredient containers; employees aware of program and understand procedures. (AIB, Para. 5.12) • Traceability provided for all ingredients, direct contact packaging and rework. (AIB, Para. 5.13) • Access to food safety manufacturing components limited and controlled. (AIB, Para. 5.14) • Unprocessed goods segregated from processed goods, and a program to prevent deliberate mixing of these goods. (AIB, Para. 5.15) • Food safety detection devices monitored and inspected on a regular frequency to ensure proper function. (AIB, Para. 5.16) • Tamper-resistant/evident packaging and/or seals provided for finished goods as applicable. (AIB, Para. 5.17) • All finished goods have appropriate lot identification. (AIB, Para. 5.18) • Labels held in a secure area; program exists to destroy all obsolete or defective labels; labels provided on containers are verified to inhibit intentional use of allergens. (AIB, Para's. 5.19, 5.20, 5.21) • Equipment design evaluated to minimize possible product tampering. (AIB, Para. 5.22) • In-house laboratories secured and access restricted to authorized personnel. (AIB, Para. 5.23) • Positive control cultures of pathogens kept secure. (AIB, Para. 5.24)

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TABLE Y-VI.

APPENDIX A PARAGRAPH	Food defense, finished goods storage/shipping checklist REQUIREMENTS as specified in: AIB Food Security Guidelines (AIB)
J6	A system is in place and implemented to adequately reduce food defense vulnerabilities from the *Finished Goods Storage/Shipping* area(s). Components of the system include the following (either as stated or in an equivalent manner): • Finished goods appropriately segregated from raw materials or hazardous chemicals. (AIB, Para. 6.1) • Quantities of finished goods are tracked and program in place to investigate missing or extra stock. (AIB, Para. 6.2) • Public storage warehousing and shipping companies utilized by the establishment practice food defense. (AIB, Para. 6.3) • Procedures exist for inspection of all vehicles prior to loading. (AIB, Para. 6.4) • Inspections conducted of all outbound vehicles prior to loading. (AIB, Para. 6.5) • Wash certificates and/or seals verified with trailers. (AIB, Para. 6.6) • Trailer sweepings or other removed materials handled appropriately. (AIB, Para. 6.7) • Amounts and lot numbers of materials verified during loading. (AIB, Para. 6.8) • Outbound driver identification verified. (AIB, Para. 6.9) • Security of trucks and trailers maintained during transport to include multiple stops or deliveries. (AIB, Para. 6.10)

CONCLUDING MATERIAL

Custodians:
Army - MD2
Navy - SA
Air Force- 03

Preparing Activity:
Army - MD2
Project No. 89GP-2008-005

Review activities:
Navy - MS, MC
DLA - SS

NOTE: The activities listed above were interested in this document as of the date of this document. Since organizations and responsibilities can change, you should verify the currency of the information above using the ASSIST Online database at http://assist.daps.dla.mil.