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DEPARTMENT OF DEFENSE STANDARD PRACTICE

SANITATION REQUIREMENTS FOR FOOD ESTABLISHMENTS

AMSC N/A FSG 89GP

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FOREWORD

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

2. The DOD is committed to the acquisition of food products produced, handled and stored in clean, sanitary food establishments in order to prevent the transmission of contaminants and foodborne disease to members of the Armed Forces. The requirements contained herein are based on available national food and drug regulatory requirements, industry and trade standards, and scientific guidelines published by various professional societies. These requirement documents are selectively applied herein to provide a scientific basis upon which to evaluate the safety of commercial food production purchased by the United States Armed Forces. This minimum set of standards can be augmented by the Major Command (MACOM) Veterinarian.

3. In keeping with DOD policy to use industry practices, the requirements for food establishments contained in this standard are based on industry standards applicable to the product identified in each appendix. While the appendices identify requirements selected from the appropriate industry standards, they do not contain all of the requirements from these standards. The requirements cited herein are not all-inclusive, verification during an audit may include other requirements from the cited document(s) at the discretion of the auditor.

4. This standard establishes the enforcement of Current Good Manufacturing Practices (CGMPs) requirements, as provided in United States Code of Federal Regulations (CFR), Title 21, Part 110 as basic sanitation standards for food establishments requiring listing in the *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*. This standard also provides more detailed product specific requirements in the appendices.

5. This standard is applicable to all establishments supplying subsistence to DOD, whether in the Continental United States (CONUS) or outside the Continental United States (OCONUS). Detailed standards relating to specific types of food establishments are located in the appendices to this standard. This standard is also applicable to military owned/leased establishments where foods are stored (excluding retail operations), utilizing 21 CFR Part 110, General Requirements only. The auditing of military retail establishments is conducted utilizing the United States Food and Drug Administration (FDA) Food Code.

6. In OCONUS locations, the MACOM Veterinarian may supplement this document. This standard is not used to determine an establishment's capabilities to comply with product specifications or other purchase requirements. 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. Good Manufacturing Practice (CGMP) documents provided by industry and recognized by the FDA, the United States Department of Agriculture (USDA) or the United States Department of Commerce (USDC), may be used in conjunction with 21 CFR Part 110, with MACOM Veterinarian

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approval.

7. 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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CONTENTS

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1. SCOPE

1.1 Scope. This standard establishes sanitation and food defense requirements for establishments that produce, process, or store various types of food products before or after final acceptance by an element of the Department of Defense.

2. APPLICABLE DOCUMENTS

2.1 General. The documents listed in this section are specified in sections 3, 4, or 5 of this standard. This section does not include documents cited in other sections of this standard or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements of documents cited in sections 3, 4, or 5 of this standard, whether or not they are listed.

2.2 Government Documents.

2.2.1 Handbook. The following handbook forms a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

DEPARTMENT OF DEFENSE STANDARD

MIL-HDBK-3006C, Guidelines for Auditing Food Establishments.

(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 publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

MILITARY PUBLICATIONS

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/.)

2.3 Order of Precedence. In the event of a conflict between the text of this document and the references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specified exemption has been obtained.

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3. DEFINITIONS

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

3.2 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).

3.3 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.

3.4 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.

3.5 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, processing, packaging, packing, warehousing or distribution.

3.6 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.

3.7 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.

3.8 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. A HACCP plan supports, but does not substitute a FORM assessment.

3.9 Food Safety and Defense. A food is deemed safe when it has been 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 prevent or reduce the

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

3.10 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.

3.11 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.

3.12 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.

3.13 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.

3.14 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.

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

3.16 Routine Sanitation Audit. An evaluation to determine the current sanitary status and overall status of the sanitation and food defense program of an establishment listed in the *Worldwide Directory*. 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.

3.17 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.

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

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

3.20 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”.

3.21 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.

3.22 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.

3.23 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).

4. GENERAL REQUIREMENTS

4.1 Listing of Establishments. Compliance with this standard is mandatory for listing of establishments in the *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement* (see 6.6).

4.2 Appendices. The general requirements in the appendices contained herein shall apply to the appropriate food establishment.

4.3 Sanitation Audit. Compliance with the requirements of this standard and the applicable appendices shall be verified by an audit of the food establishment (see 6.4). The audit shall examine and evaluate the adequacy of an establishment's food safety, food defense, and

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other applicable control systems to include an examination of the methods used to receive, handle, process and store and transport food. The sanitation audit shall be performed in the presence of management or a designated representative. Results of the audit shall be documented.

4.4 Laboratory Testing. All food products in the establishment are subject to laboratory testing. If a product is selected for laboratory testing, the sanitation audit report will not be considered final until laboratory results are received.

4.5 Sanitation Audit Rating. A sanitation audit shall be rated either "Acceptable" or "Unacceptable". A Critical finding will result in an “Unacceptable” rating. More than three Major findings will result in an “Unacceptable” rating. It is possible to have multiple ‘unrelated’ findings with the same reference code listed (scored) separately. It is also possible to have multiple ‘related’ findings listed under the same score (i.e., Observation, Major, or Critical). 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.

4.6 Corrective Action Request. Establishments receiving a Corrective Action Request (CAR) will provide feedback as to the root cause of the finding as well as the action(s) taken to correct and prevent recurrence of the finding(s) (See 6.5).

5. DETAILED REQUIREMENTS

5.1 General. The following appendices contain specific requirements related to the cited reference document, but are not intended to be all-inclusive.

APPENDIX A - General Requirements
APPENDIX B - Bakery
APPENDIX C - Manufactured Cheese Products
APPENDIX D - Pasteurized Milk Products
APPENDIX E - Shell Eggs
APPENDIX F - Frozen Desserts
APPENDIX G - Ice
APPENDIX H - Fish and Fishery Products
APPENDIX J - Pasteurized, Refrigerated Juices
APPENDIX K - Bottled Water
APPENDIX L - Off Post Caterers, Civilian Restaurants, and Ready-to-Eat Manufactured Products
APPENDIX M - Slaughter and Fabrication of Meat Products OCONUS
APPENDIX N - Dry Dairy Products
APPENDIX O - Slaughter and Fabrication of Poultry Products OCONUS
APPENDIX P - Fresh-Cut Fruits and Vegetables
APPENDIX Q - Manufactured Egg Products
APPENDIX R - Mushrooms

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APPENDIX S - Vegetable Sprouts
APPENDIX T - Low-acid Canned Food (LACF)
APPENDIX U - Cook/chill and Sous Vide Processing
APPENDIX W - Fresh Fruit and Vegetable Suppliers (unprocessed) in OCONUS Areas
APPENDIX Y - Food Defense Program

6. NOTES

6.1 Intended Use. This standard is intended to ensure that food products procured by DOD for use by Armed Forces personnel are safe.

6.2 Issue of DODISS. When this standard is used in acquisition of products, the applicable issue of the DODISS must be cited in the solicitation.

6.3 Tailoring Guidance. To ensure proper application of this standard, invitations for bids, requests for proposals, and contractual statements of work should tailor the requirements in section 5 of this standard to exclude any unnecessary requirements. For example, if the requirement applies to a bakery establishment, only the requirements contained in this standard and in the bakery appendix should be mandated.

6.4 Audit Guidelines. The Government will perform audits of contractors' premises based on guidelines contained in MIL-HDBK-3006C, Guidelines for Auditing Food Establishments. 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.

6.5 Corrective Actions. Follow the guidelines in MIL-HDBK-3006C for establishments that receive Corrective Action Requests.

6.6 Listing of Establishments. Establishments in compliance with this standard may be listed in the *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement* (http://www.veterinaryservice.army.mil/). Requests for listing in the Directory should be directed to the appropriate procurement agency. Information related to its use should be directed to the appropriate MACOM Veterinarian.

6.7 Subject Term (keyword) Listing.

Sanitation Audit Report
Corrective Action Request
Auditing Personnel
Initial Audit
Routine Audit
Special Audit
Directed Routine Sanitation Audit
Methodology

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Laboratory Audit
Recommendation for Deletion
Request for Removal
Food Safety
Food Defense
Worldwide Directory

6.8 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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GENERAL PROVISIONS

A.1 SCOPE

A.1.1 Scope. This appendix establishes the general sanitation requirements for auditing food processing and food warehousing establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 documents and publications. The following other Government documents and publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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 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/.)

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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.)

A.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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

The definitions in section 3 of this standard apply to this appendix.

A.4 GENERAL REQUIREMENTS

This section is not applicable to this appendix.

A.5 DETAILED REQUIREMENTS

A.5.1 General. The requirements in Tables A-I through A-VII shall be as specified in the individual Tables, but are not intended to be all-inclusive. The requirements herein relate to personnel safety and cleanliness, building and facilities, equipment and utensils, raw materials and operations, defect action levels, hazard analysis (HACCP)/food safety program (FSP) and the food defense program to ensure the adequacy and safety of food products.

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TABLE A-I.

GENERAL PROVISIONS Subpart A – Personnel 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 shall 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 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 shall 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. (21 CFR 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 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 shall 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 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 shall 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 shall 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 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 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 shall be made from water that is of adequate sanitary quality and shall 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 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 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) 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 and 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 and when the HACCP or FSP plan 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 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 establishes the food safety and related requirements for bakery establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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 this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. The definitions in section 3 of this standard apply to this appendix.

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B.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

B.5 DETAILED REQUIREMENTS

B.5.1 General. The requirements in Table B-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE B-I.

APPENDIX A PARAGRAPH	Bakery 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 shall be filtered or washed to remove particles 5 microns or larger, and shall 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 shall provide a floor clearance of at least 6 inches (150mm) or shall be accessible for cleaning. (BISSC 3.2.6)
C3	Where lubrication is required, the design and construction shall 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 shall be readily removable or appropriately fitted for in-place cleaning. (BISSC 4.5.1.8)
E2	Potable water inlet lines shall 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 shall be minimum mesh 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 establishes the food safety and related requirements for manufactured cheese establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO).

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(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.3 DEFINITIONS

C.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

C.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

C.5 DETAILED REQUIREMENTS

C.5.1 General. The requirements in Table C-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE C-I.

APPENDIX A PARAGRAPH	Manufactured cheese products 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 shall 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 shall be of USDA Extra grade (or equivalent) except for moisture (Processed cheese). (7 CFR 58.716, and 58.717)
B8	Conveyors, grinders/shredders, and cookers maintained cleaned to prevent contamination. (7 CFR 58.707, 58.708, and 58.709)
E2	Fats/oils used on the surface of the cheese shall be of food grade. (21 CFR 133)

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PASTEURIZED MILK PRODUCTS

D.1 SCOPE

D.1.1 Scope. This appendix establishes the food safety and related requirements for pasteurized milk establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

D.3 DEFINITIONS

D.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

D.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

D.5 DETAILED REQUIREMENTS

D.5.1 General. The requirements in Table D-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE D-I.

APPENDIX A PARAGRAPH	Pasteurized milk products 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)
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)
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)

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E4	Recirculated cooling water is tested once per six-month period. (PMO, Sec. 7)

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 establishes the food safety and related requirements for shell egg establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 7, Part 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.3 DEFINITIONS

E.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

E.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

E.5 DETAILED REQUIREMENTS

E.5.1 General. The requirements in Table E-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE E-I.

APPENDIX A PARAGRAPH	Shell eggs 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(a))
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(b)(1) and (2))
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 shall be at least 20° F (-6.7° C) warmer than the temperature of the eggs to be washed. Temperatures shall 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 shall be continuous. Eggs shall not be allowed to stand or soak in water. Immersion type washers shall 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 establishes the food safety and related requirements for frozen dessert establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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 (Most current version).

U.S. Public Health Service (USPHS)/Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO).

(Application for copies should be addressed to: U.S. 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. The definitions in section 3 of this standard apply to this appendix.

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F.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

F.5 DETAILED REQUIREMENTS

F.5.1 General. The requirements in Table F-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE F-I.

APPENDIX A PARAGRAPH	Frozen desserts 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 blowers, 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 shall 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 coliform; and not more than 20 cfu/g coliform 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 shall 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 establishes the food safety and related requirements for ice establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. The definitions in section 3 of this standard apply to this appendix.

G.4 GENERAL REQUIREMENTS

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See Appendix A requirements in Tables A-I through A-VII.

G.5 DETAILED REQUIREMENTS

G.5.1 General. The requirements in Table G-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE G-I.

APPENDIX A PARAGRAPH	Ice 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall be adequately installed and identifiable so that it is readily distinguishable from piping that carries potable water. (PIQCS, Sec 2)
B10	Plumbing shall 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 shall be located, installed, and maintained to prevent a source of contamination of ice, equipment, and utensils. (PIQCS, Sec 2)
B2, B10, B11	Floor drains shall be functional and properly trapped. Floor drainage shall 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 shall 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 shall be those that are necessary for cleaning and sanitizing or for the plant's operation. Cleaning and sanitizing substances shall be free from undesirable microorganisms, and be safe for the conditions of use (where applicable food grade approved). All toxic materials shall be clearly identified, held and stored as labeled. (PIQCS, Sec 3)
B6, B7	The use of insecticides and rodenticides shall be in accordance with appropriate regulations. All chemicals should be clearly labeled. Inspections for infestations shall 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 shall be allowed in any area of the plant. (PIQCS, Sec 3)
B8	Single service supplies shall be stored, dispensed, and handled in a sanitary manner and shall be used only once. (PIQCS, Sec 3)
B8, C1, C5	All portable equipment and utensils shall be stored in a suitable means that provides protection from contamination when not in use. When equipment and utensils become soiled they shall 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 shall be of impervious material and shall 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 shall be conducted at least monthly. Ice shall 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 shall be maintained for two years. (PIQCS, Sec 5 and 7)
A6, E2	Adequate provisions (such as sanitary gloves) shall be made so that hands shall not come in direct contact with the ice at any time during manufacturing, processing, packaging, and storage. (PIQCS, Sec 5)
E1, E10	Packaging shall be accomplished with non-toxic materials and in a sanitary manner. The bags shall be of sound strength and quality to prevent fracture or tearing during handling. They shall 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 shall 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 shall 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 shall be placed upstream from the compressor and shall 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 shall be used as needed to produce ice free of rust or other foreign materials. (PIQCS, Sec 8)
B9, E2	Only potable water shall be used in sprays and in the thaw tanks for the removal of ice from cans. Ice shall not come in direct contact with water in dipping wells. (PIQCS, Sec 8)
C1, C2	Ice cans shall be leak proof and the inner surfaces of such containers shall be free of corrosion. (PIQCS, Sec 8)
B3, C1, C5	Freezing tank covers of acceptable materials shall 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, shall 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 establishes the food safety and related requirements for fresh or frozen processed fish, retorted seafood and specialty fishery product establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 documents and publications. The following other Government documents and publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 123, and 172.

(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.)

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

Guide for the Control of Molluscan Shellfish (2005 version).

(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

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no changes were made, can be accessed via the 2003 Guide at: http://www.cfsan.fda.gov/~ear/nss2-toc.html.)

H.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

Cured, Salted and Smoked Fish Establishments Good Manufacturing Practices (FGMP). 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.)

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

N.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

H.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII. A validated HACCP plan is compulsory for all seafood operations.

H.5 DETAILED REQUIREMENTS

H.5.1 General. The requirements in Tables H-I through H-IV shall be as specified in the Tables, but are not intended to be all-inclusive.

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TABLE H-I.

APPENDIX A PARAGRAPH	Seafood general requirements 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 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 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 REQUIREMENTS as specified in: Good Manufacturing Practices CFR Title 21, Part 123 National Shellfish Sanitation Program (NSSP)
E1	Molluscan shellfish shall 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. (21CFR 123.11)
B9, E7	Ice used to store shellstock shall 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 shall 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 shall 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, shall be met as components of good manufacturing practices. (NSSP)
H6, H8	Transaction records shall 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 establishes the food safety and related requirements for pasteurized, refrigerated juice establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Part 120.

(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.)

J.3 DEFINITIONS

J.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

J.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII. A validated HACCP plan is compulsory for all pasteurized, refrigerated juice manufacture.

J.5 DETAILED REQUIREMENTS

J.5.1 General. The requirements in Table J-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE J-I.

APPENDIX A PARAGRAPH	Pasteurized, refrigerated juices REQUIREMENTS as specified in: CFR Title 21, Part 120
A11, H2	HACCP plan shall be validated and signed every 12 months by trained individuals. (21 CFR 120.11)
E1, H1	Imported juice shall 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 shall 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 shall be available for review. (21 CFR 120.24) and (21 CFR 120.11)
E4, H1	Juice processors shall 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 shall 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 shall analyze the finished product for biotype I Escherichia coli per 21 CFR 120.25.
E2, H1	A hazard analysis shall 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 shall 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 shall 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 establishes the food safety and related requirements for bottled water establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 129 and 165.

(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.3 DEFINITIONS

K.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

K.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

K.5 DETAILED REQUIREMENTS

K.5.1 General. The requirements in Table K-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE K-I.

APPENDIX A PARAGRAPH	Bottled water REQUIREMENTS as specified in: CFR Title 21, Parts 129 and 165
B2	The bottling room is separated from the other plant operations or storage areas by tight walls, ceilings, self-closing doors, and size of conveyor opening. Bottle washing and sanitizing are in an enclosed 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 shall be from an adequate (safe) source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall 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 shall 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 shall 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 establishes the food safety and related requirements for off post caterers, civilian restaurants and other Ready-to-Eat (or Heat and Eat) establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. The definitions in section 3 of this standard apply to this appendix.

L.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

L.5 DETAILED REQUIREMENTS

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L.5.1 General. The requirements in Table L-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE L-I.

APPENDIX A PARAGRAPH	Off post caterers, civilian restaurants and ready-to-eat manufactured products 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 establishes the food safety and related requirements for meat slaughter and fabrication establishments OCONUS. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 9, Parts 94, 110, 307, 309, 310, 313, and 416.

(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/.)

M.3 DEFINITIONS

M.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

M.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII. A validated HACCP plan is compulsory for all meat processing plants.

M.5 DETAILED REQUIREMENTS.

M.5.1 General. The requirements in Table M-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE M-I.

APPENDIX A PARAGRAPH	Slaughter and fabrication of meat products OCONUS 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 hit 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, shall 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, shall 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 establishes the food safety and related requirements for dry dairy establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.3 DEFINITIONS

N.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

N.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

N.5 DETAILED REQUIREMENTS

N.5.1 General. The requirements in Table N-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE N-I.

APPENDIX A PARAGRAPH	Dry dairy products 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. (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 recirculated 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 establishes the food safety and related requirements for poultry slaughter and processing in OCONUS establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 9, Parts 381 and 416.

(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. The definitions in section 3 of this standard apply to this appendix.

O.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII. A validated HACCP plan is compulsory for Poultry Processing Establishments.

O.5 DETAILED REQUIREMENTS

O.5.1 General. The requirements in Table O-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE O-I.

APPENDIX A PARAGRAPH	Slaughter and fabrication of poultry products OCONUS 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 shall 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 shall be arranged, constructed and lighted so that the inspector can carry out the inspection. (9 CFR 381.36)
E2, E11	Post-mortem inspection shall be made on a bird-by-bird basis or per country requirements. Facilities for post-mortem inspection shall 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 shall be opened to permit post-mortem inspection. No viscera shall 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 shall 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 shall 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 shall be confined to a relatively small area. (9 CFR 381.65)
E2	Birds shall have been thoroughly bled and have stopped breathing prior to scalding. (9 CFR 381.65)
B8, C1	Chilling tanks shall 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 shall be prevented from entering the chilling tank. (9 CFR 381.65)
E2, E6	Major portions of poultry carcasses shall 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 shall 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 shall 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’ shall be free of from protruding pin feathers and vestigial feathers. The head; feet; crop; oil glands; trachea; esophagus; entrails and lungs shall have been removed. Final product shall 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 establishes the food safety and related requirements for fresh-cut fruit and vegetable establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 documents and publications. The following other Government documents and publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. 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 2006, 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/.)

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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.

(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. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

P.3 DEFINITIONS

P.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

P.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

P.5 DETAILED REQUIREMENTS

P.5.1 General. The requirements in Table P-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE P-I.

APPENDIX A PARAGRAPH	Fresh-cut fruits and vegetables 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 establishes the food safety and related requirements for manufactured egg product establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

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.)

UNITED STATES 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.)

Q.3 DEFINITIONS

Q.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

Q.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

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Q.5 DETAILED REQUIREMENTS

Q.5.1 General. The requirements in Table Q-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE Q-IV.

APPENDIX A PARAGRAPH	Manufactured egg products REQUIREMENTS as specified in: CFR Title 9, Part 590 Egg Product Inspectors Handbook
B2, B7	Buildings be must 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 shall 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 shall 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 shall 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 shall be continuous. Eggs shall not be allowed to stand or soak in water. Immersion type washers shall not be used. (9 CFR 590.515)
E2	If eggs are washed, shell eggs shall 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 shall be candled and broken separately to determine their acceptability. (9 CFR 590.510)
E1, E6, E11	Eggs, presented for breaking shall 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 shall 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 shall be rejected. (9 CFR 590.522)
B8, C1, E2	Whenever an inedible egg is broken, the affected breaking equipment shall 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 shall 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 shall 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 shall be kept clean and free from objectionable odors. (9 CFR 590.536)
C7, C10, E2, E6	If frozen, liquid eggs shall 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 shall be clean and free from evidence of liquid egg. (9 CFR 590.536)
E2, E11	Frozen eggs shall 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 establishes the food safety and related requirements for mushroom growing and processing establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

R.2.3 Non-Government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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

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

R.3 DEFINITIONS

R.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

R.4 GENERAL REQUIREMENTS

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See Appendix A requirements in Tables A-I through A-VII.

R.5 DETAILED REQUIREMENTS

R.5.1 General. The requirements in Table R-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE R-I.

APPENDIX A PARAGRAPH	Mushrooms 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)
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 shall 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 area 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 establishes the food safety and related requirements for vegetable sprout growing and processing establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 documents and publications. The following other Government documents and publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

CODE OF FEDERAL REGULATIONS (CFR)

CFR Title 21, Parts 110 and 179.

(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, “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

S.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

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S.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

S.5 DETAILED REQUIREMENTS

S.5.1 General. The requirements in Table S-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE S-I.

APPENDIX A PARAGRAPH	Vegetable sprouts 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 shall 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 establishes the food safety and related requirements for low-acid canned food establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

T.3 DEFINITIONS

T.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

T.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

T.5 DETAILED REQUIREMENTS

T.5.1 General. The requirements in Table T-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE T-I.

APPENDIX A PARAGRAPH	Low-acid canned foods 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.) shall 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 113.40(a)(1))
C7, C10, E6	Each retort is equipped with accurate temperature recording device with appropriate degree graduations. The temperature recording device shall be adjusted to agree with the MIG thermometer, but in no event higher the MIG thermometer. A means of preventing unauthorized adjustments shall 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) and (e))
B9, E2, H3	Water used for cooling must be potable. Container cooling water shall 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 13.60(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 establishes the food safety and related requirements for Cook/Chill and Sous Vide processing establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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. The definitions in section 3 of this standard apply to this appendix.

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U.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

U.5 DETAILED REQUIREMENTS

U.5.1 General. The requirements in Table U-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE U-I.

APPENDIX A PARAGRAPH	Cook/chill and sous vide processing 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 shall 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 shall be monitored and recorded throughout the process using appropriate temperature measuring devices. (FDA Food Code, Annex 6)
C10	All scales, meters, thermometers and weights shall be calibrated IAW manufacturer's instructions. (FDA Food Code, Annex 6)
E2, E6, H6	Effective separation procedures shall 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 shall be limited to responsible trained personnel. (FDA Food Code, Annex 6)
E6, H6	Each container shall 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 shall 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 establishes the food safety and related requirements for fresh fruits and vegetable suppliers (unprocessed) in OCONUS areas. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 publications. The following other Government publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

W.3 DEFINITIONS

W.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

W.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

W.5 DETAILED REQUIREMENTS

W.5.1 General. The requirements in Table W-I shall be as specified in the Table, but are not intended to be all-inclusive.

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TABLE W-I.

APPENDIX A PARAGRAPH	Fresh fruit and vegetable suppliers (unprocessed) in OCONUS areas 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 establishes the food safety and related requirements for food defense programs within establishments. This appendix is a mandatory part of this standard. The information contained herein is intended for compliance.

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 *standard*; (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 Non-Government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

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.)

Y.3 DEFINITIONS

Y.3.1 Definitions. The definitions in section 3 of this standard apply to this appendix.

Y.4 GENERAL REQUIREMENTS

See Appendix A requirements in Tables A-I through A-VII.

Y.5 DETAILED REQUIREMENTS

Y.5.1 Scoring. When scoring food defense findings, auditors will assess each component listed in the applicable MIL-STD tables (Y-I through Y-VI) under Finding codes (J1 through J6) to determine the overall level of adequacy and compliance within the establishment.

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Where components within the tables do not apply to the establishment, components may be considered "NA" (Non-Applicable) by the auditor. In deciding whether or not an item is Non-applicable versus scoreable, the auditor will establish the need for the particular barrier to the vulnerability in question based upon all other factors relating to the establishment.

Once the assessment of all components for a particular table is completed, the auditor will score only one Finding (if found) for that specific table. The auditor will judge whether the totality and severity of all component Findings assessed constitutes a Finding for the entire table.

Y.5.2 General. The requirements in Tables Y-I through Y-VI shall be as specified in the Tables, but are not intended to be all-inclusive.

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TABLE Y-I.

APPENDIX A PARAGRAPH	Food defense policy 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. 1.8) • 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 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 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 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 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 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-2008-004

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/.