WEBER-MORGAN
HEALTH DEPARTMENT

Weber-Morgan Health Department

Regulation for

Food Service Sanitation

Adopted by the Weber-Morgan Board of Health

September 23, 2019

Under Authority of Section 26A-1-121
Utah Code Annotated, 1953, as amended

Certified Official Copy
Weber-Morgan Health Department

By_____
Brian Bennion, Director, Weber-Morgan Health Department

By_____
Neil Garner, Chair, Weber-Morgan Board of Health

1.0 Title and Purpose.

1.1 These standards shall be known as the Food Service Sanitation Regulation, hereinafter referred to as “this Regulation”.

1.2 This regulation establishes definitions; sets standards for management and personnel, food operations, equipment and facilities; sets fees; provides for food establishment plan review, permit issuance, food employee certification, food establishment inspection, employee restriction, food establishment permit suspension and facility closure to prevent foodborne illness and protect public health.

2.0 Authority.

2.1 It is the responsibility of the Weber-Morgan Health Department to provide food protection services for the citizens of Weber and Morgan Counties as legislated under Section 26A-1-106 and 26A-1-108 of the Utah Code Annotated, 1953 as amended.

2.2 The Weber-Morgan Board of Health is authorized to make standards and regulations pursuant to Subsection 26A-1-121(1) of the Utah Code Annotated, 1953 as amended.

2.3 The Weber-Morgan Board of Health is authorized to establish and collect fees pursuant to Section 26A-1-114 of the Utah Code Annotated, 1953 as amended.

2.4 All fees shall be set by the Weber-Morgan Board of Health and shall be referenced in a Department fee schedule. The Department may charge additional fees for enforcement and follow-up inspections as set by the Board of Health.

2.5 The Weber-Morgan Health Department may deny any application for a permit if it appears that the operation of the food establishment will not comply with this regulation.

3.0 Severability.

If any provision, clause, sentence, or paragraph of this Regulation or the application thereof shall be held to be invalid, such invalidity shall not affect the other provisions or applications of these standards. The valid part of any clause, sentence, or paragraph of these standards shall be given independence from the invalid provisions or application and to this end the provisions of these standards are declared to be severable.

4.0 Effective Date.

This regulation including Appendices shall become effective the day following its adoption by the Board of Health and will supersede previous food service sanitation regulations adopted by the Board of Health. Appendices may be modified by the Department without affecting the rest of this regulation.

5.0 INFORMATION TO ASSIST THE USER

The structural nomenclature of the document is as follow:

Chapter	9
Part	9-1
Subpart	9-101
Section (§)	9-101.11
Paragraph (¶)	9-101.11(A)
Subparagraph	9-01.11(A)(1)

Some sections and portions of some sections are written in italics. These provisions are requirements specific to the Weber-Morgan Health Department jurisdiction and not originally part of the 2013 Food Code.

An asterisk * after a tagline (which is the language immediately following a section number that introduces the subject of the section) indicates that all of the provisions within that section are critical unless otherwise indicated, as follows:

Any unmarked provisions within a section that has an asterisked tagline are critical. All provisions following a tagline that is not marked with an asterisk are noncritical.

The following conventions are used in the Food Code. “Shall” means the act is imperative, i.e., “shall” constitutes a command. “May not” means absolute prohibition. “May” is permissive and means the act is allowed. The term “means” is followed by a declared fact.

6.0 Incorporation by Reference.

The requirements as found in the Utah Department of Health, Food Service Sanitation Rule, R392-100, Effective Date May, 2016, are adopted and incorporated by reference with Weber-Morgan Board of Health amendments.

1. The requirements as found in the U.S. Public Health Service, Food and Drug Administration, Food Code 2013, Chapters 1 through 8, Annex 1, and Annex 2, Federal Food, Drug, and Cosmetic Act, 21, U.S.S. 342, Sec. 402 are adopted and incorporated by reference, with the exclusion of Sections 8-302.14(C) (1)(2),(D) and (E), 8-805.40, and 8-809.20; and 8-905.40.

2. With the Utah Department of Health additions or amendments.

3. The requirements of the Utah Uniform Building Standards Act Rules as found in Sections R156- 56-701(1)(c), and R156-56-803 are adopted and incorporated by reference.

6.1 Add Definition to Chapter 1 to read:

“Adequate” *means satisfactory or sufficient to accomplish the intended purpose in compliance with good public health and food safety practice as determined by the*

Department.

6.2 Add Definition to Chapter 1 to read:

"Board of Health" *means the Weber-Morgan Board of Health.*

6.3 Add Definition to Chapter 1 to read:

"Code" *means the Weber-Morgan Health Department Food Service Sanitation Regulation and related Rules and Regulations.*

6.4 Add Definition to Chapter 1 to read:

"Critical Item"

(1) ***"Critical item"*** *means a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to FOOD contamination, illness, or environmental health HAZARD.*

(2) ***"Critical item"*** *is an item that is denoted in this Code with an asterisk * .*

(3) ***"Critical item"*** *means a priority item denoted with a superscript P-* ^{P} *or a priority foundation item denoted with a subscript Pf-* ^{Pf}*.*

6.5 Add Definition to Chapter 1 to read:

"Department" *means the Weber-Morgan Health Department, Division of Environmental Health.*

6.6 Add Definition to Chapter 1 to read:

"Director" *means the Director of the Weber-Morgan Health Department or authorized representative.*

6.7 Add Definition to Chapter 1 to read:

"Food Employee Certificate" *means the document issued by the Department that authorizes a person to work at a food establishment and includes the terms Food Handler Permit, Food Service Personnel Permit, Food Employee Permit, Food Safety Permit and Food Handler Card.*

6.8 Add Definition to Chapter 1 to read:

"Food Establishment Permit" *means the document issued by the Department that authorizes a person to operate a food establishment.*

6.9 Add Definition to Chapter 1 to read:

"Food Establishment Risk Criteria*" means the criteria identified in the appendices of this regulation which establishes risk categories, inspection frequency for obtaining*

compliance with this regulation.

6.10 Add Definition to Chapter 1 to read:

"*Intermittent Food Establishment"* *means a temporary food establishment that operates for a period of time, not to exceed three (3) days per week, at a fixed location, with a fixed menu, in conjunction with a recurring event, and is restricted to a limited menu of non-complex preparation and low risk foods for a period not exceeding the length of the event.*

6.11 Add Definition to Chapter 1 to read:

"Mobile Food Establishment" *means a vehicle-mounted food establishment that reports to and operates from a commissary and is readily moveable; is a motorized wheeled vehicle; or a towed, wheeled vehicle designed and equipped to serve food.*

6.12 Add Definition to Chapter 1 to read:

"Non-complex preparation" *means food preparation using limited steps and minimal manipulation of food prior to cooking or service; excludes foods requiring extensive cutting, chopping. De-boning, marinating or combining of multiple ingredients.*

6.13 Add Definition to Chapter 1 to read:

"Non Critical item"

(1) "Non Critical item" *means a provision of this Code, that relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.*

(2) "Non Critical item" *has the same meaning as a core item in R392-100.*

6.14 Add Definition to Chapter 1 to read:

"Rule" *means the Weber-Morgan Health Department Food Service Sanitation Regulation and related rules and regulations.*

6.15 Add Definition to Chapter 1 to read:

"Seasonal Operation" *means a food establishment which is closed five (5) consecutive months of the year or more.*

6.16 Add Definition to Chapter 1 to read:

"Seasonal Temporary Food Establishment" *means a food establishment that operates for a period of not more than six (7) months during any twelve (12) consecutive months and not more than fourteen (14) consecutive days at any one location in conjunction with a single event or celebration.*

6.17 Amend section 2-102.11(A) Demonstration to read:

(A) Complying with this Code by having no violations of CRITICAL ITEMS during the current inspection;[Pf]

6.18 Add section 2-102.21 to read:

Certified Food Safety Manager.

The permit holder shall comply with Title 26-15a, Utah Food Safety Certification Act and Utah Department of Health Rule R392-101, Food Safety Manager Certification. Those food establishments required to be managed by a Certified Food Safety Manager as specified in Title 26-15a shall have said Certified Food Safety Manager registered with the Department.

6.19 Add section 2-102.22 to read:

Certified Food Safety Manager Registration.

(A) A person may become registered as a Food Safety Manager at the Department after the following requirements have been completed:

(1) Provide a completed application on a form provided by the Department;

(2) Provide to the Department acceptable documentation showing the applicant has, within the previous three years, received a passing score on a Food Safety Manager Certification Examination that has been approved by the Utah Department of Health;

(3) Is employed by a food establishment within the jurisdiction of the Department;

(4) Provide a picture I.D. when applying for certification;

(5) Submit Certified Food Safety Manager Registration fee;

(B) Upon acceptance of the registration issued by the Department:

(1) The Food Safety Manager Registration Certificate shall be posted in public view;

(2) A person may obtain a duplicate of his Certified Food Safety Manager Registration Certificate after paying a duplicate certificate fee. Duplicate certificates may be obtained in person at the Department;

(3) The Certified Food Safety Manager Registration may be suspended or revoked by the Department because of returned checks and may not be reinstated until repayment is confirmed.

(4) The Certified Food Safety Manager Registration may be suspended or revoked by the Department for failure to comply with Section 2-102.11 Demonstration.

6.20 Add section 2-103.12 to read:

Food Employee Training.*

Food employees shall be trained in food safety as required under Section 26-15-5 of the Utah Code Annotated and R-392-103 a valid food handler permit issued by a local health department:

(A) It shall be unlawful for any person to employ another person or for any person to work as a food employee in a food establishment unless that person has lawfully obtained a valid food handler permit or Food Handler Certification or is registered with the Department as the certified food safety manager;

(B) A food employee shall provide to the person-in-charge of a food service establishment or the certified food safety manager, a valid food handler permit, prior to working in the food establishment;

(C) The food handler permit will expire three (3) years from the date of issuance. The food handler permit must be renewed prior to the expiration date;

(D) The person in charge of a food establishment or the certified food safety manager shall have onsite copies of the food handler permits of all food employees working in the food establishment. Permits shall be available for inspection by the Department. The person in charge or the certified food safety manager shall not accept expired food handler permits;

(E) The Director may exempt the following individuals from the food food handler permit fee:

(1) Employees and volunteers of those charitable nonprofit establishments which may be exempt from the food establishment permit fee identified in Section 3.2(k) above,

(2) Employees, clients and volunteers of substance abuse rehabilitation facilities which are nonprofit charitable organizations and which, as a general practice, do not receive a fee or compensation from those who are served,

(3) Employees and inmates of correctional facilities,

(4) The exemption granted from the food handler permit fee does not include exemption from the requirement to receive the food employee training and to have a food handler permit;

(F) Any food handler permit may be revoked by the Department upon receipt of evidence that the certificate holder:

(1) Violates accepted sanitation procedures and practices in the processing, preparation, handling, storage or service of food offered for public consumption,

(2) Violates any part of this regulation,

(3) Is diagnosed with an infectious agent specified in 2-201.11(A),

(4) Refuses to submit to a physical examination by a physician when required by the Department,

(5) Withholds information from the Department about a food borne illness outbreak,

(6) Has submitted information required for issuance, renewal or approval of the certificate which was false, and/or

(7) Has threatened, coerced, cajoled, offered a bribe, assaulted, harangued and/or stalked a Department employee pursuant to his/her duties with the Department;

(8) Food handler permit may be suspended or revoked by the Department because of returned checks and may not be reinstated until repayment is confirmed. All returned checks will be charged a returned check handling fee.

(G) Any food employee whose permit has been revoked as provided in this section may be granted a review of findings incident to such revocation by the Director upon written application filed with the Department within ten (10) days of said revocation. Upon such review, the Director may either sustain such revocation or reinstate said certificate;

(H) Valid food handler permit issued by any other health authority in Utah will be accepted by the Department according to R-392-103

(I) The person in charge or the certified food safety manager shall immediately return the food permit to the certificate holder when he/she is no longer employed in the food establishment;

6.21 Add section 2-103.14 to read:

Communication.

The person in charge shall ensure that during all times of operation that there is a person available that speaks and reads English and is able to speak and read the predominant language spoken by food employees:

6.22 Add subsection 3-501.17 (G) to read:

(G) In a child care center, baby food, infant formula, and breast milk for infants that are brought from home for the individual child's use shall be:

(1) Marked with the name of the child and the date of bottling in the case of breast milk or opening of the container, such as a jar of baby food;

(2) Open containers of baby food, infant formula, and breast milk shall be refrigerated and stored for no more than 24 hours; and

(3) Infant formula shall be discarded after feeding or within two hours of initiating a feeding.

6.23 Add section 6-501-115 to read:

(D) A food establishment operating only in Weber or Morgan Counties may request a review and approval for dogs (other than service animals or patrol dogs) in the outdoor patio areas in accordance with the procedures for a variance modifying or waiving the requirements of the Utah Administrative Code R392-100-2 (adopting the U.S. Public Health Service Food and Drug Administration Food Code, including §8.103.10 with certain additions and amendments). Each variance request for dogs on outdoor patio areas where food is being served shall be individually reviewed and evaluated by the Director on a case-by-case basis. The Board delegates the authority to review and approve requests from food establishments for a variance allowing dogs on an outdoor patio in compliance with the requirements of this section to the Director or his/her designee.

(E) This section shall not impair or diminish the right of an individual to be accompanied by an animal where otherwise permitted by law, including but not limited to the rights of people with disabilities using guide, hearing or service animals.

1) Canine Hazard Plan (CHP). The applicant must submit a CHP plan with the variance request that includes:

a. *Type of sanitizer used to disinfect area after waste release*

b. *Method of cleanup and sanitizing the affected area*

c. *Method of solid waste disposal*

d. *Method for patio sanitation between shift changes (day and night). If the food establishment has continuous food or beverage service without designated shifts, then sanitation must be performed every six hours when a dog has been present.*

e. *Equipment, sanitizer, and container to be given to patron to remove animal waste.*

f. A site plan drawing showing where tables will be located and setback distances to entrances or other non-dog allowed areas

2) *Facility and Operational Requirements.*

a. *A separate entrance must be provided from the outside of the food establishment to the outdoor patio so a dog will have direct access to the patio without entering the interior dining, service or sales areas of the food establishment. A dog may not be allowed within ten (10) feet of any entrance to an interior area of the food establishment, except as necessary to enter or exit the patio.*

b. A patio must be constructed of smooth, durable, non-absorbent, cleanable material.

Grass, gravel or dirt are not acceptable materials.

c. Multiple establishments that utilize a shared patio space must all agree to and apply for a variance. A single variance will not be issued for shared patio spaces.

d. *A dog must be kept on a leash and remain in the control of the patron while on the outdoor patio.*

e. *Signs must be posted at the entrance of the food establishment and entrance to the patio, notifying patrons that dogs may be on the premises. The signs must state: "NOTICE to patrons, dogs may be on the premises but are restricted to the outdoor patio. Owners are responsible for keeping their animal under control at all times." Signs should be 8.5 x 11 inches and posted in an easy to see location.*

f. *Tables that allow patrons with dogs cannot be placed within 10 feet of any door leading into the restaurant.*

g. *No food preparation, including mixing drinks or service ice, may be performed in the outdoor patio area, except that a beverage glass may be filled on the patio from a pitcher or other container that has been filled or otherwise prepared and kept inside the food establishment.*

h. *The outdoor patio must be continuously maintained free of visible dog hair, dog dander, and other dog-related wastes or debris. The outdoor patio must be cleaned at the end of each shift, or every six hours if there are no designated shifts, when a dog has been present during that time. Waste water generated by cleaning the patio area must be properly disposed of in the sanitary sewer and not washed where it can enter the storm drain.*

i. *Waste produced from a dog's bodily functions must be cleaned up immediately. Restaurant staff will provide the patron with the necessary tools, containers, and sanitizer to clean up the waste. Patrons will dispose of all waste in the appropriate area determined by the restaurant through the variance review.*

j. *All dog waste must be disposed of outside of the food establishment in an appropriate waste receptacle. Equipment used to clean the outdoor patio must be kept outside of a food preparation and service area.*

k. *While on duty, wait staff or other food handlers may not have contact with any dog or dog waste.*

l. *A dog is not allowed on a seat, table, countertop, or similar surface in the outdoor patio area under any circumstance.*

m. *A dog is not allowed to have contact with any dishes or utensils used for food service or preparation at the food establishment.*

n. *A dog may not be given any food (including, but not limited to, dog kibble, biscuits, and edible treats) while in the outdoor patio area, but may be given water in a disposable container or a properly sanitized dog specific container sanitized outside of food*

preparation and service areas.

o. *If a dog shows any kind of aggression or unruly behavior that threatens the health/safety of other patrons or staff, the patron dog owner must remove the dog immediately.*

p. *The responsibility for management and control of dogs on the food premises resides between the food establishment management/ownership and the patron dog owner. Violations of the variance rules will be addressed with the establishment, not the individual dog owners.*

(3) *Compliance with other Restrictions. The applicant must demonstrate how the establishment will comply with any other local ordinances or restrictions prohibiting dogs in or about any establishment or place of business where food is sold, displayed or served, including food establishments.*

(4) *Inspections. Food establishments who obtain a variance will be inspected separate of the establishment food permit. These inspections will be conducted one time during the calendar year and are required as part of the variance approval. Owners/manager will be given copies of the report when the inspection is complete.*

(5) *Fees. Due to the additional resource commitments associated with the review of a Canine Hazard Plan and necessary follow-up inspections, the WMHD may establish and collect additional fees.*

(6) *Complaints. The WMHD will respond to complaints of dogs when received. Two separate validated complaints against any one establishment within the calendar year may result in the revocation of the variance for that establishment*

(7) *Revocation of Variance. Food establishments that do not follow the directions outlined in the variance rule are subject to variance revocation. Refunds are not issued for revoked variances. Only the Director or his/her designee may revoke a variance.*

(8) *Annual Review and Approval. Each variance shall be submitted and reviewed on an annual basis and shall be limited to the seasonal operation (May thru October) of the food establishment's outdoor areas. The food establishment must reapply for a variance on an annual basis*

(9) *Liability. The Department cannot be held liable or responsible for dog related incidences that cause harm, physical damage, or personal property damage on the premises of the food establishment.*

6.24 Add section 8-303.25 to read:

Qualifications for Obtaining a Permit, Renewing a Permit or Change of ownership.*

(A) All full time and seasonal food establishment fees shall be paid annually to the Department by the billing due date as set by the Department. The food establishment inspection intervals and permit fees shall be based on food establishment risk criteria provided in Appendix C;

(B) Should any permittee fail to obtain the permit prior to the opening of a food establishment for business the permit fee shall be three hundred percent (300%) of the normal annual fee;

(C) Should any permittee fail to renew his/her permit on or before the due date of said permit but before said permit expires, then said annual fee shall be one hundred fifty percent (150%) of the normal annual fee set forth for that particular food establishment plus an additional fee set by the Board of Health. The due date of said permit shall be thirty (30) days prior to the annual expiration date of the permit;

(D) Failure to pay the food establishment fees, by or on the expiration date of the permit shall result in revocation of the permit and forfeiture of the right to operate a food establishment;

(E) After expiration of an annual permit, the food establishment shall not be operated until a new permit is issued, unless the renewal form and annual permit fee including any additional charge, if applicable, is received by the Department on or before the expiration date of the permit;

(F) If a permit is not renewed on or prior to the expiration date, no new permit shall be issued, except upon submission of a new permit application and the applicant's compliance with all applicable provisions of this regulation for a new food establishment. The Department may then grant the existing food establishment a new permit after receiving payment of three hundred percent (300%) of the normal permit fee;

(G) No fees, or any part thereof, may be refunded or transferred;

(H) A food establishment permit may be suspended or revoked by the Department because of returned checks and may not be reinstated until payment is confirmed;

(I) Lapse of Permit: Each permit issued hereunder shall automatically lapse and be void and of no further force or effect unless the permit holder actually begins operations under said permit within three months from the time the permit is issued;

(J) Nothing in this section shall prevent the Department from exercising any other duty regarding suspension, closure, or revocation of the permit with regard to any food establishment.

6.24 Amend section 8-304.10(A) to read:

Responsibilities of the Regulatory Authority.

(A) Upon request at the time a permit is first issued, the regulatory authority shall provide to the permit holder a copy of this code, in English, so that the permit holder is notified of the compliance requirements and the conditions of retention, as specified under § 8-304.11, that are applicable to the permit.

6.25 Amend subsection 8-304.11(G) to read:

Responsibilities of the Permit Holder.

(G) Except as specified under ¶ (H) of this section, replace existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this Code if:

(1) The REGULATORY AUTHORITY directs the replacement because the facilities and EQUIPMENT constitute a public health HAZARD or nuisance or no longer comply with the criteria upon which the facilities and EQUIPMENT were accepted,

(2) The REGULATORY AUTHORITY directs the replacement of the facilities and EQUIPMENT because of a change of ownership, or

(3) The facilities and EQUIPMENT are replaced in the normal course of operation;

6.26 Amend section 8-304.11(H) to read:

(H) Upgrade or replace refrigeration EQUIPMENT as specified under Subparagraph 3-501.16(A)(2)(b), if the circumstances specified under Subparagraphs (G)(1) - (3) of this section do not occur first, and 5 years pass after the REGULATORY AUTHORITY adopts this Code;

6.27 Amend section 8-304.11(I) to read:

(I) Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies;

6.28 Amend section 8-304.11(J) to read:

(J) Accept notices issued and served by the REGULATORY AUTHORITY according to LAW; and

6.29 Add section 8-304.11(K) to read:

(K) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in LAW for failure to comply with this Code or a directive of the REGULATORY AUTHORITY, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

6.30 Amend subsection 8-401.10 (B)(2) to read:

(2) The FOOD ESTABLISHMENT is assigned a less frequent inspection based on a written RISK-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the REGULATORY AUTHORITY to ensure that the establishment manager and the nature of FOOD operation are not changed;

6.31 Amend subsection 8-401.20(A) to read:

(A) Past performance, for numerous or repeat violations of Code or HACCP PLAN requirements that are critical;

6.32 Amend subsection 8-401.20(B) to read:

(B) Past performance, for nonconformance with Code or HACCP PLAN requirements that are non critical;

6.33 Amend subsection 8-403.10(B)(3) to read:

(3) Nonconformance with CRITICAL ITEMS of this Code,

6.34 Amend section 8-405.11(A) to read:

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a violation of a CRITICAL ITEM of this Code and implement corrective actions for a HACCP PLAN provision that is not in compliance with its CRITICAL LIMIT.

6.35 Amend subsection 8-405.11(B)(1) to read:

(1) 72 hours after the inspection, for the PERMIT HOLDER to correct violations of a CRITICAL PRIORITY ITEM; or

6.36 Amend subsection subsection 8-405.11(B)(2) to read:

(2) 10 calendar days after the inspection, for the PERMIT HOLDER to correct violations of a CRITICAL PRIORITY FOUNDATION ITEM or HACCP PLAN deviations.

6.37 Amend section 8-405.20(A) to read:

(A) After observing at the time of inspection a correction of a violation of a CRITICAL ITEM or HACCP plan deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report.

6.38 Amend section 8-405.20(B) to read:

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a violation of a CRITICAL ITEM or HACCP PLAN deviation, or at the end of the specified period of time, the REGULATORY AUTHORITY shall verify correction of the violation, document the information on an inspection report, and enter the report in the REGULATORY AUTHORITY'S records.

6.39 Amend section 8-406.11(A) to read:

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall correct non critical violations by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.

6.40 Add 8-905.10(E) to read:

(E) The Department shall follow the Weber-Morgan Health Department Adjudicative Hearing Procedures where applicable.

6.41 Add Chapter 9 to read:

Chapter 9 ALTERNATIVE FOOD FACILITIES

Parts

9-1 MOBILE FOOD ESTABLISHMENTS
9-2 TEMPORARY FOOD ESTABLISHMENTS
9-3 INTERMITTENT FOOD ESTABLISHMETS

9-1 MOBILE FOOD ESTABLISHMENTS

Subparts

9-101 Requirements and Restrictions
9-102 Plan Approval
9-103 Standard Operating Procedures
9-104 Potentially Hazardous Foods
9-105 Water System
9-106 Handwashing
9-107 Toilet Facilities
9-108 Sink Compartment Requirements
9-109 Required Postings
9-110 Food and Equipment Protection

9-101.11 Requirements.

(A) The permit holder and person in charge of a mobile food establishment must comply with the requirements of this Regulation, except as otherwise provided in this section.

(B) The permit holder must obtain approval from other applicable regulating agencies prior to operating a mobile food establishment, including the City or County business license.

(C) The permit holder and person in charge of a mobile food establishment must operate the mobile food establishment from an approved commissary/servicing area and shall return to such location for supplies, thorough cleaning, and other servicing activities, as approved in a

plan of operation. When not in operation, a mobile food establishment must be stored at an approved servicing area or other approved location.

(D) All mobile food establishments shall comply with all applicable requirements outlined in this Regulation (unless otherwise noted) and any other requirements of the Regulatory Authority. The Regulatory Authority may approve a variance to some of the requirements if no health hazard will result. Such variances shall be reviewed in accordance with the procedures specified under Sections 8-103.11 and 8-103.12.

(E) Additionally, each mobile food establishment shall have its business name, address, and telephone number of the person, firm or corporation responsible for its operation legibly printed in no less than 4-inch high letters on at least two sides of the mobile food establishment. The letters shall be of a contrasting color from the color of the mobile food establishment. The letters shall be easily visible to consumers during operations and shall be in English.

(F) The mobile food establishment must be located in an area that allows convenient access to the support services by the servicing area. Safe and protected transportation of food, equipment, utensils, etc. form the servicing area to the mobile food establishment must be evaluated and

approved by the Department before operations can begin. The mobile food establishment shall return to its commissary/servicing area not less than once in each 24 hour period for servicing and maintenance and more often if necessary. The maximum distance for a daily operation shall be no greater than 50 miles from the commissary/servicing area to the mobile food establishment operation.

(G) If the mobile food establishment is used at a fair, carnival, or other event where it does not or cannot return to the servicing area, the mobile food establishment must be licensed and regulated as a temporary food establishment.

(H) All new mobile food establishment operations approved after the adoption of this regulation shall be required to own, operate or lease a commissary/servicing area, approved by the Department, which is under their direct control and from which they operate their mobile food establishment.

9-101.12 Restrictions.

The Department may impose additional requirements to protect against health hazards related to the operation of a mobile food establishment including but not limited to:

(A) Limiting the food preparation steps;

(B) Prohibiting some menu items;

(C) Restricting the mode of operation when facilities or equipment are inadequate to protect public health.

(D) Suspend the permit of the mobile food establishment if the commissary/servicing area is not available or is closed by the regulating agency for any reason;

(E) Close a mobile food establishment during inclement weather, if the handwashing sink is not functioning and food cannot be held or served in a safe manner;

(F) Close the mobile food establishment for inadequate lighting;

(G) Only allow food to be served that has been pre-approved by the Department;

(H) Suspend or revoke the mobile food establishment operating permit for falsifying any information about the mobile food establishment, its operation, its use of the commissary/servicing area, or any agreements required for the operation of the mobile food establishment, and;

(I) Suspend the operating permit of a commissary or restrict use of a commissary by a mobile food establishment for falsifying information and/or operational concerns.

(J) Prohibit catering or deliveries from a food cart.

(H) Prohibit customer seating provided by the mobile food establishment.

9-102.11 Plan review.

(A) The permit applicant shall submit a properly prepared plan of operation with specifications of the mobile food establishment, commissary, and servicing area to the Department for approval before:

(1) Construction or remodeling begins;

(2) The menu of the mobile food establishment is changed;

(3) The method of food preparation is changed;

(4) The vehicle is changed;

(5) The commissary/servicing area is changed; or

(6) The location(s) of the operation is changed.

(B) For mobile food establishments with commissaries and/or servicing areas located outside of the jurisdiction of the Department, a copy of the regulatory authority permit and/or current inspection of the commissary/servicing area may be required. The regulatory authority that regulates or permits the commissary/servicing area will determine whether it is suitable and allowable for the mobile food establishment to use.

9-102.12 Plan Contents.

The plans and specifications for a mobile food establishment shall be consistent with the criteria as specified under Sections 8-201.11 and 8-201.12 including the following:

(A) Menu and food preparation steps;

(B) Floor plan;

(C) Equipment specifications and location;

(D) Finish schedule;

(E) Proposed itinerary or sites to be served;

(F) Source of water and specifications of the on-board plumbing;

(G) Site used for sewage disposal;

(H) Availability of restrooms for employees;

(I) Operating procedures;

(J) Cleaning schedule; and

(K) An approved commissary/servicing area agreement in writing.

9-102.13 Types of Mobile Food Establishments.

The type of Mobile Food Establishment must be identified during the application review process of the operation:

***(A) Self Sufficient Vehicle or Trailer**: These mobile food establishments are capable of preparing potentially hazardous food (time/temperature control for safety food) and non-potentially hazardous food (time/temperature control for safety food), cooking, hot and cold storage, dry storage, utensil washing, hand washing, etc. on the mobile food establishment. The mobile food establishment has a self-contained potable water supply and a wastewater storage system.*

***(B) Vehicle or Trailer that is not Self-Sufficient**: These mobile food establishments are capable of dispensing hot and cold potentially hazardous food (time/temperature control for safety food) and non-potentially hazardous food (time/temperature control for safety food). They may be capable of hot and cold holding of potentially hazardous food (time/temperature control for safety food), but may not have the facilities to cook. These mobile food establishments have hand washing facilities, a potable water supply, and containment for wastewater. They may not have utensil washing facilities. The commissary/servicing area may have to be used for cooking, re-heating food for hot-holding, cold and frozen food storage, dry goods storage, utensil washing, washing the mobile food establishment, access to potable water, and the disposal of wastewater and garbage because this type of mobile food establishment may not have the facilities for conducting these activities.*

***(C) Food Cart**: These mobile food establishments are not self-propelled and must be towed or hauled by a vehicle or pushed to move them from one location to another. These types of mobile food establishments offer limited potentially hazardous food (time/temperature control*

for safety food) and non-potentially hazardous food (time/temperature control for safety food). The food carts must be designed to safely serve designated food items from the cart. These carts usually have accessory components such as coolers with ice for cold holding potentially hazardous food (time/temperature control for safety food). Hand washing stations must be built into the cart. Potable water must be available for food use and for hand washing. A wastewater containment system must be available and used. A commissary/servicing area must be available and used for cold and frozen food storage, dry goods storage, single-service/single- use storage, utensil storage, utensil washing, cart washing, access to potable water, and the disposal of wastewater and garbage.

(D) ***Limited Mobile Food Unit:*** *These mobile food establishments are not self-propelled and must be towed or hauled by a vehicle and may be stationed at a fixed location as a seasonal operation. Limited mobile food units are restricted to the sale of non-potentially hazardous foods such as flavored ice, coffee and drinks from commercial mixes that only require the addition of water. These units may serve commercially manufactured pre-packaged non- potentially hazardous food products. Limited mobile food units may not provide seating facilities for customers to use while eating or drinking. There is no on-site food preparation except for the addition of flavorings, sugar and prepackaged non-potentially hazardous condiments to the beverage items being served. All food items shall be served using disposable, single-service articles. A limited mobile food unit may not engage in food preparation unless specifically approved by the Department. A limited mobile food unit has a self-contained potable water supply and a wastewater storage system and operates in conjunction with an approved commissary/servicing area.*

9-103.11 Standard Operating Procedures.

The person in charge of a mobile food establishment shall ensure:

(A) Only employees and other persons authorized by the regulatory authority are present in the mobile food establishment;

(B) All employees are in compliance with the provisions of this regulation for obtaining and renewing valid food safety certificate, unless all foods are prepackaged and are non-potentially hazardous;

(C) All foods, including ice, are from an approved source;

(D) Potentially hazardous foods prepared on the mobile food establishment are served the same day that they are prepared;

(E) Prepackaged foods are properly labeled;

(F) Only single-service articles are provided for use by the customer;

(G) Condiments not in individual packages are provided in dispenser bottles or in other containers protected from contamination.

(H) Mobile food establishment is not used for living or sleeping purposes;

(I) Mobile food establishment is not used for any non-food establishment purposes or

business;

(J) Non-food employees, children and animals are not allowed in the mobile food establishment; and

(K) No food, food containers, wrappers, packaging materials, or utensils are stored in the driver's compartment of any mobile food establishment.

9-104.11 Food Preparation.

(A) All potentially hazardous food (time/temperature control for safety food) which is pre-cooked and pre-cooled either on the mobile food establishment or at the commissary/servicing area must be pre-approved by the Department. The Person in Charge must demonstrate that the facilities on the mobile food establishment or at the commissary/servicing area are adequate to cool potentially hazardous food (time/temperature control for safety food) in accordance with Sections 3-501.14 and 3-501.15. The Department may require time/temperature logs for potentially hazardous foods (time/temperature control for safety food) that are cooled.

(B) The Person in Charge will be responsible for the overall operation of the mobile food establishment unless the ONLY foods offered from the mobile food establishment are commercially pre-packaged non- potentially hazardous food (time/temperature control for safety food). The menu and manner for transportation, storage, cooking, preparation, and service of the food and beverage items must specifically be identified and evaluated by the Department. Any changes to the menu must be submitted to and approved by the Department prior to their service. All food and beverage items to be offered at the mobile food establishment must be identified and approved by the Department during the application process and prior to an evaluation being conducted of the structural components of the mobile food establishment.

(C) The mobile food establishments shall comply with Parts 3-4 and 3-5 regarding the required temperatures for cooking, thawing, cooling, reheating, hot holding and cold storage.

9-104.13 Leftovers.

(A) Potentially hazardous foods (time/temperature control for safety food) that have been hot held
on the mobile food establishment shall be served or discarded at the end of the business day.

(B) Potentially hazardous foods (time/temperature control for safety food) cold foods that are prepared on the mobile food establishment shall be served or discarded at the end of the business day.

9-105.11 Water System.

The person in charge must ensure that the water system on the mobile food establishment:

(A) Is supplied from an approved source of water;

(B) Is designed and constructed in an approved manner. Both hot and cold water under pressure shall be provided at every fixture. There shall be a hot water heater and tank that provides enough hot, cold and warm water when the mobile food establishment is open for service;

(C) Is filled from the approved water source through a food-grade hose;

(D) Is refilled as frequently as necessary to furnish enough hot and cold water for handwashing, food preparation, utensil cleaning, sanitizing, and facility cleaning, on the mobile food establishment;

(E) Has a water supply tank with a minimum capacity of five gallons for handwashing for vehicles or trailers that are not self sufficient and food carts, or has a water supply tank with a minimum capacity or forty gallons for handwashing, utensil washing and sanitizing purposes for self sufficient vehicles and trailers.

(F) Stores liquid waste in a wastewater retention tank with at least fifteen percent more capacity than the water supply tank; and

(G) Retains wastewater on the mobile food establishment until disposed of by an approved method.

9-106.11 Handwashing Facilities.

The person in charge of the mobile food establishment must ensure that a separate handwashing facility for employees is accessible at all times of operation and includes:

(A) A sink with potable, hot and cold, running water under pressure delivered through a mixing valve;

(B) Soap; and

(C) Paper towels.

9-106.12 Handwashing Waiver.

When only prepackaged food items are served, the Department may waive or modify requirements for handwashing on the mobile food establishment.

9-107.11 Toilet Facilities.

The permit holder must ensure approved toilet facilities are available for employees:

(A) Readily accessible within three (300) hundred feet of the mobile food establishment during times of operation, if at any one location for more than one hour; and

(B) Provided with handwashing facilities with potable, hot and cold, running water under pressure delivered through a mixing valve.

9-108.11 Warewashing Facilities.

The permit holder must ensure:

(A) A three-compartment sink is available on the mobile food establishment with potable hot and cold running water under pressure to wash, rinse, and sanitize utensils when utensils are reused on the mobile food establishment; except

(B) This requirement may be waived or modified by the regulatory authority when:

(1) Limited food preparation occurs; or

(2) Additional clean utensils are available and utensil washing takes place at an approved commissary/servicing area.

9-109.11 Business Name.

The permit holder shall provide the Department a designated business name and ensure that the name is posted on the mobile food establishment as specified under Paragraph 9-101.11(E).

9-109.12 Permit.

The permit holder shall ensure that the original current valid food establishment permit or sticker is posted on the mobile food establishment in a manner specified by the Department that is easily visible to customers during all hours of operation. Permits are non-transferable.

9-110.11 Overhead Protection.

The permit holder and person in charge shall ensure overhead protection is provided at the site of operation of the mobile food establishment for all food handling activities.

9-110.12 Food and Food Service Supplies.

The permit holder and person in charge must ensure that all food, equipment, utensils, and other food service supplies are contained on the mobile food establishment, at the approved commissary, at the approved servicing area, or as otherwise approved in the plan of operation.

9-2 TEMPORARY AND SEASONAL TEMPORARY FOOD ESTABLISHMENTS

Subparts

9-201 Requirements and Restrictions 9-

9-201.11 Requirements and Restrictions.

(A) The permit holder and person in charge of a temporary or seasonal temporary food establishment must comply with the requirements of this Regulation, except as otherwise provided in this section.

(B) The Department may impose additional requirements related to the operation of the temporary/seasonal temporary food establishment and may:

(1) Limit the food preparation steps;

(2) Prohibit some menu items; and

(3) Restrict the mode of operation when facilities or equipment are inadequate to protect public health.

(C) If necessary to protect the public health, the Director shall impose additional requirements to protect against health hazards related to the conduct of operation and prohibit the sale or giving away some or all potentially hazardous food;

(D) The owner/operator of a temporary food establishment must:

(1) Apply to the Department for a permit to operate the temporary food establishment;

(2) Allow only employees and other persons authorized by the Department to be present in the temporary food establishment; and

(3) Require the person in charge of the temporary food establishment to obtain a valid food safety certificate before beginning work;

(4) Not allow foods prepared in any home to be sold or given away.

*9-201.12 Obtaining a Temporary/Seasonal Temporary Food Establishment Permit.**

(A) A person desiring to operate temporary/seasonal temporary food establishment shall obtain a valid temporary/seasonal temporary food establishment permit issued by the Department;

(B) To qualify for a permit, an applicant shall submit an application and fee at least five (5) working days prior to start of the event, for a temporary establishment or prior to operating at the first event for a seasonal temporary establishment. Failure to do so may result in increased fee or denial of permit. Each day of application after the five (5) working days prior to the event the fee will increase by twenty five percent (25%);

(C) Permits for temporary food establishments shall be for use at a fixed location in conjunction with a single event or celebration for a period not exceeding the length of the event or celebration, or fourteen (14) days, whichever is shorter. Permit for a seasonal temporary food establishment shall be for use at a fixed location no more than three (3) days per week at recurring event or at a fixed location in conjunction with a single event or celebration for a period not exceeding the length of the event or celebration, or fourteen (14) days, whichever is shorter. Each temporary/seasonal temporary food establishment site (booth, stand, etc.) shall have a separate permit.

(D) A temporary/seasonal temporary food establishment fee shall be paid at the time application is made for a temporary/seasonal temporary food establishment permit. Three hundred percent (300%) of the normal permit fee will be assessed if a permit fee is not paid obtained prior to operating as a temporary/seasonal temporary food establishment. Permits will only be issued at the Department office location during regular business hours;

(E) Permit(s) must be posted on site and copies of the permit will not be accepted. Permits are not transferable;

(F) Fees will be set by the Board of Health and will be listed in the Department fee schedule;

(G) Unopened, commercially pre-packaged non-potentially hazardous foods requiring no food preparation. No application or fee required.

9-202.11 Standard Operating Procedures.

The person in charge of a temporary/seasonal temporary food establishment must ensure:

(A) Adequate facilities are provided at the temporary/seasonal food establishment for all necessary food preparation steps;

(B) All foods, including ice, are from an approved source;

(C) All off site food preparation is done in an approved food establishment;

(D) All storage of food and equipment is done at approved locations;

(E) Food is transported and stored in properly designed food-grade containers;

(F) Food is protected from potential contamination during transport;

(G) Only single-service articles are provided for use by consumers, unless otherwise approved by the Department; and

(H) Condiments not in individual packages are provided in dispenser bottles or in other containers protected from contamination.

9-203.11 Temperature Control.

The person in charge of a temporary/seasonal temporary food establishment must ensure that potentially hazardous foods are:

(A) Not cooled in a temporary food establishment;

(B) Properly temperature-controlled during transport to the temporary event location;

(C) Monitored by use of a stem-type thermometer or thermocouple capable of measuring all proper food temperatures;
(D) Heated, for hot holding, from 41°F to 165°F or above within one hour when cooked and cooled in an approved food establishment;

(E) Heated, for hot holding, from 41°F to 140°F or above within one hour when ready-to-eat or precooked food is produced in a food processing plant;

(F) Heated no more than one time; and

(G) Held in preheated mechanical hot holding equipment or prechilled mechanical cold holding equipment, or otherwise temperature controlled by an approved method.

9-204.11 Separation Barrier.

The person in charge of a temporary/seasonal temporary food establishment shall ensure a separation barrier or other effective method is used to protect food preparation and cooking areas from public access.

9-205.11 Handwashing and Wastewater Facilities.

The permit holder of a temporary/seasonal temporary food establishment shall ensure approved handwashing facilities are conveniently located for employees in all food preparation areas, which include:

(A) Potable, warm, running water;

(B) Soap and paper towels;

(C) A five-gallon or larger insulated container kept supplied with warm water for handwashing delivered through a continuous-flow spigot, if permanent plumbing is not available; and

(D) A wastewater retention tank sufficient in size to hold all wastewater generated by the temporary food establishment until emptied in an approved manner, if a public sewage system hookup is not available.

9-206.11 Toilet Facilities.

The permit holder of a temporary/seasonal temporary food establishment shall ensure approved toilet facilities are available for employees:

(A) Readily accessible during all times of operation; and

(B) Provided with handwashing facilities with soap, disposable towel and potable, warm, running water.

9-3 INTERMITTENT FOOD ESTABLISHMENTS

Subparts

9-301 Requirements and Restrictions
9-302 Standard Operating Procedures
9-203 Potentially Hazardous Foods
9-204 Separation Barrier
9-205 Handwashing and Wastewater Facilities
9-206 Toilet Facilities

9-301.11 Requirements and Restrictions

(A) The permit holder and person in charge of an intermittent food establishment shall comply with the requirements of this Regulation, except as otherwise provided in this section.

(B) The Department may impose additional requirements related to the operation of the intermittent food establishment and may:

(1) Limit the food preparation steps;

(2) Prohibit some menu items; and

(3) Restrict the mode of operation when facilities or equipment are inadequate to protect public health.

(C) If necessary to protect the public health, the Director shall impose additional requirements to protect against health hazards related to the conduct of operation and prohibit the sale or giving away of some or all potentially hazardous food;

(D) The owner/operator of an intermittent food establishment shall:

(1) Apply to the Department for a permit to operate the intermittent food establishment. An intermittent food establishment permit is valid until the end of the current calendar year, is not prorated and can be used for an unlimited number of events. The intermittent food establishment shall not operate for more than 3 days per week for organized events that are recurring each week throughout the season or more than 14 days in a row with an once time or once per year organized event;

(2) Allow only employees and other persons authorized by the Department to be present in

the intermittent food establishment; and
(3) Require the person in charge of the intermittent food establishment to obtain a valid food worker certificate before food operations begin;

(4) Not allow foods prepared in any home to be sold or given away.

*9-201.12 Obtaining an Intermittent Food Establishment Permit.**

(A) A person desiring to operate an intermittent food establishment shall obtain a valid intermittent food establishment permit issued by the Department;

(B) To qualify for a permit, an applicant shall:

(1) Submit application and fee prior to the first event and a projected schedule of events and/or locations of concessions booths for the calendar year. Events may be changed or added if notification is given to the Department a minimum of 10 working days prior to the proposed change including an address or locations of each event;

(2) Submit the menu of the food operation, commissary location if applicable and schedule an inspection if operating a mobile food establishment.

(C) Permits for intermittent food establishments shall be for use at a specified location in conjunction with a recurring event and is valid for operation, not to exceed three (3) days per week.
Each intermittent food establishment (booth, stand, etc.) shall have a separate permit;

(D) An intermittent food establishment fee shall be paid at the time application for a permit is made. Three hundred percent (300%) of the normal permit fee will be assessed if a permit is not obtained prior to operating as an intermittent food establishment. Permits will only be issued at the Department office location;

(E) Permit(s) must be posted on site and copies of the permit will not be accepted. Permits are not transferable;

(F) Unopened, commercially pre-packaged non-potentially hazardous foods requiring no food preparation. No application or fee required.

9-202.11 Standard Operating Procedures.

The person in charge of n intermittent food establishment must ensure:

(A) Adequate facilities are provided at the intermittent food establishment for all necessary food preparation steps;

(B) All foods, including ice, are from an approved source;

(C) All off site food preparation is done in an approved food establishment;

(D) All storage of food and equipment is done at approved locations;

(E) Food is transported and stored in properly designed food-grade containers;

(F) Food is protected from potential contamination during transport;

(G) Only single-service articles are provided for use by consumers, unless otherwise approved by the Department; and

(H) Condiments not in individual packages are provided in dispenser bottles or in other containers protected from contamination.

9-203.11 Temperature Control.

The person in charge of an intermittent food establishment must ensure that potentially hazardous foods are:

(A) Not cooled in a intermittent food establishment;

(B) Properly temperature-controlled during transport to the temporary event location;

(C) Monitored by use of a stem-type thermometer or thermocouple capable of measuring all proper food temperatures;

(D) Heated, for hot holding, from 41°F to 165°F or above within one hour when cooked and cooled in an approved food establishment;

(E) Heated, for hot holding, from 41°F to 140°F or above within one hour when ready-to-eat or precooked food is produced in a food processing plant;

(F) Heated no more than one time; and

(G) Held in preheated mechanical hot holding equipment or pre-chilled mechanical cold holding equipment, or otherwise temperature controlled by an approved method.

9-204.11 Separation Barrier.

The person in charge of an intermittent food establishment shall ensure a separation barrier or other effective method is used to protect food preparation and cooking areas from public access.

9-205.11 Handwashing and Wastewater Facilities.

The permit holder of an intermittent food establishment shall ensure approved handwashing facilities are conveniently located for employees in all food preparation areas, which include:

(A) Potable, warm, running water;

(B) Soap and paper towels;

(C) A five-gallon or larger container kept supplied with warm water for handwashing delivered through a continuous-flow spigot, if permanent plumbing is not available; and

(D) A wastewater retention tank sufficient in size to hold all wastewater generated by the intermittent food establishment until emptied in an approved manner, if a public sewage system hookup is not available.

9-206.11 Toilet Facilities.

The permit holder of an intermittent food establishment shall ensure approved toilet facilities are available for employees:

(A) Readily accessible during all times of operation; and

(B) Provided with handwashing facilities with soap, disposable towel and potable, warm, running water.

Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY
3. SUPPORTING DOCUMENTS
4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Federal Depository Library

The USC and CFR are widely available for reference and viewing in some 1300 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

GPO Customer Contact Center, Mail Stop: IDCC
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401-0001
(866) 512-1800, Fax (202) 512-2104
Email: ContactCenter@gpo.gov

(2) Internet World Wide Web Information System

The CFRs are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration Copies of Federal Regulations -Retrieve CFR by Citation Provided through the Government Printing Office Web Site -GPO Inet Services

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so by writing:

Superintendent of Documents (New Orders)
U.S. Government Printing Office
P.O. Box 371954 Pittsburgh, PA 15250-7954;

or by calling:

(202) 512-1800 from 8:00 a.m. to 5:30 p.m. eastern time, Monday-Friday (except Federal holidays. Orders may be charged to American Express, Discover, MasterCard, or Visa

Or by emailing: gpo@custhelp.com or at http://www.gpo.gov/customers/print.htm .

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec. 342
Title 21 -Food and Drugs Chapter 9 -Federal Food, Drug and Cosmetic Act
Subchapter IV -Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated

(a) Poisonous, insanitary, etc., ingredients

A food shall be deemed to be adulterated

(a) Poisonous, insanitary, etc., ingredients (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1]

(2) (A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains **(i)** any food additive that is unsafe within the meaning of section 348 of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives
If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e (a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and— **(1)** has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

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(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety (1) If it is a dietary supplement or contains a dietary ingredient that— **(A)** presents a significant or unreasonable risk of illness or injury under—
(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or
(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is

adulterated. The court shall decide any issue under this paragraph on a de novo basis. **(2)** Before the Secretary may report to a United States attorney a violation of paragraph [2] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices (1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission
If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381 (a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

[1] So in or". original. The period probably should be ";

[2] So in original. Probably should be "subparagraph". (As amended by Congress, 2002 – Subsec. (h).

Pub. L. 107-188 added subsec. (h).)

2. BIBLIOGRAPHY

The following bibliography is a compilation of documents that were taken into consideration in developing the Food Code.

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Chapter 1 Purpose and Definitions

1-201.10 Statement of Application and Listing of Terms

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2-102.12 Certified Food Protection Manager.

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2-201.12 Exclusions and Restrictions.

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2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

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3. Code of Federal Regulations, Title 40 Part 152.500 Pesticide registration and classification procedures, Requirements for devices found at http://edocket.access.gpo.gov/cfr_2009/julqtr/pdf/40cfr152.500.pdf

4. Code of Federal Regulations, Title 40 Part 156.10 Labeling requirements for pesticides and devices found at http://edocket.access.gpo.gov/cfr_2009/julqtr/pdf/40cfr156.10.pdf

5. EPA's Good Laboratory Practices Standards (GLPS) found at http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html

6. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Sections 2(q)(1) and 12 found at http://www.epa.gov/pesticides/regulating/laws.htm

7. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

8. Miller, M.P., Principal Investigator, 1985. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Addendum to Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

9. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB

4-602.11 Equipment Food-Contact Surfaces and Utensils.

1. Tauxe, R.V., M.D., Chief, Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Disease and M.L. Cohen, M.D., Director, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, memo dated January 10, 1996 re: "Bacterial Contamination of Iced Tea," to State and Territorial Epidemiologists and State and Territorial Public Health Laboratory Directors. Memo includes two fact sheets by the Tea Association of the U.S.A., Inc.

4-703.11 Hot Water and Chemical.

1. Miller, M.P., Principal Investigator, 1984. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. contract No. 223-80-2295.

2. Miller, M.P., Principal Investigator, 1985. Relationship of Factors Affecting Bactericidal Effectiveness of Chlorine Sanitizing Solutions. Addendum to Final Report. National Sanitation Foundation, Ann Arbor, MI., subcontract No. 9013-092-108-H0620101; Booz, Allen & Hamilton, Inc. contract no. 223-80-2295.

3. National Sanitation Foundation, Ann Arbor, MI. November, 1990. Report on the Bacterial Effectiveness of a Chlorine Sanitizing Solution at Contact Times of Less than Ten Seconds. Purchase Order #FDA 665531-00-90-RB.

4-901.11 Equipment and Utensils, Air-Drying Required.

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.

Chapter 5 Water, Plumbing, and Waste

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (food-contact surface sanitizing solutions), before contact with food.

2. Code of Federal Regulations, Title 21, Part 129 – Processing and Bottling of Bottled Drinking Water.

3. International Association of Plumbing and Mechanical Officials, 2003 Uniform Plumbing Code, Walnut, CA. Available for sale at http://publications.iapmo.org/categories.asp?id=1.

4. International Code Council. 2003 International Plumbing Code, Falls Church, VA. Available for sale at http://www.iccsafe.org/Pages/SearchResults.aspx?cat=StoreSearch&q=2003%20international%20plumbing%20code

5-102.12 Nondrinking Water.

1. FDA, Program Information Manual, Retail Food Protection, Storage and Handling of Tomatoes, posted 10/05/07, updated 09/25/08. Available at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm

2. FDA, Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables, posted 10/26/98, updated 08/19/03, 02/2008. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm

5-202.12 Handwashing Facility, Installation.

1. American Society for Testing and Materials, Designation: E 1838-02, Standard Test Method for Determining the Virus-Eliminating Effectiveness of Liquid Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Volunteers. ASTM, Philadelphia, PA.

2. American Society for Testing and Materials, Designation: E 2011-99, Standard Test Method for Evaluation of Handwashing Formulations for Virus-Eliminating Activity Using the Entire Hand. ASTM, Philadelphia, PA.

3. American Society for Testing and Materials, Designation: E 1327-90 (reapproved 2000), Standard Test Method for Evaluation of Health Care Personnel Handwash Formulations by Utilizing Fingernail Regions. ASTM, Philadelphia, PA.

4. American Society for Testing and Materials, Designation: E 1174-00, Standard Test Method for Evaluation of Health Care Personnel or Consumer Handwash Formulations. ASTM, Philadelphia, PA.

5. Code of Federal Regulations, Title 21, Part 129 Processing and Bottling of Drinking Water.

5-203.13 Service Sink.

1. Barker, J. and Bloomfield, S. F., 2000. Survival of *Salmonella* in bathrooms and toilets in domestic homes following salmonellosis. Journal of Applied Microbiology, 89, 137-144.

2. Barker, J. and Jones, M.V., 2005. The potential spread of infection caused by aerosol contamination of surfaces after flushing a domestic toilet. Journal of Applied Microbiology, 99, 339-347.

3. Barker, J., Vipond, I. B, and Bloomfield, S. F., 2004. Effects of cleaning and disinfection in reducing the spread of Norovirus contamination via environmental surfaces. Journal of Hospital Infection, 58, 42-49.

4. Cheesbrough, J. S., Green, J., Gallimore, C. I., and Wright, P.A., 2000. Widespread environmental contamination with Norwalk-like viruses (NLV) detected in a prolonged hotel outbreak of gastroenteritis. Epidemiol. Infect., 125, 93-98.

5. Gerba, C. P., C. Wallis, and J.L. Melnick, 1975. Microbiological Hazards of Household Toilets: Droplet Production and the Fate of Residual Organisms. Appl. Microbiology, 30(2):229-237.

6. Mokhtari, A. and Jaykus, L. (2009). Quantitative exposure model for the transmission of norovirus in retail food preparation. *International Journal of Food Microbiology,* 133 (1-2), 38-47.

5-203.15 Backflow Prevention Device, Carbonator.

1. American Society of Sanitary Engineering, ASSE Product Performance Standards , Standard 1022. ASSE International Office, 901 Canterbury, Suite A, Westlake, OH 44145. Available at: http://www.asse-plumbing.org/standards.html

Chapter 6 Physical Facilities

6-202.15 Outer Openings, Protected.

1. National Fire Protection Association, NFPA 101 Life Safety Code, 2009 Edition, Quincy, MA. Available for sale at: http://www.nfpa.org/aboutthecodes/aboutthecodes.asp?docnum=101

2. National Fire Protection Association, NFPA 101 Life Safety Code Handbook, 2009 Edition, Quincy, MA.

6-303.11 Intensity.

1. Illuminating Engineering Society of North America, 2000. Lighting Handbook, 9th Ed., IESNA Publications Dept., New York, NY. 900+ pp.

6-301.12 Hand Drying Provision

1. D. R. Patrick, G. Findon and T. E. Miller (1997). Residual moisture determines the level of touch-contact-associated bacterial transfer following hand washing. *Epidemiology and Infection,* **119**, pp 319-325 .

6-501.18 Cleaning Plumbing Fixtures

1. Barker, J. and Bloomfield, S. F., 2000. Survival of *Salmonella* in bathrooms and toilets in domestic homes following salmonellosis. Journal of Applied Microbiology, 89, 137-144.

2. Barker, J. and Jones, M.V., 2005. The potential spread of infection caused by aerosol contamination of surfaces after flushing a domestic toilet. Journal of Applied Microbiology, 99, 339-347.

3. Barker, J., Vipond, I. B, and Bloomfield, S. F., 2004. Effects of cleaning and disinfection in reducing the spread of Norovirus contamination via environmental surfaces. Journal of Hospital Infection, 58, 42-49.

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6-501.111 Controlling Pests.

1. Monica Pava-Ripoll, Rachel E. Goeriz Pearson, Amy K. Miller, and George C. Ziobro. 2012. **Prevalence and Relative Risk of *Cronobacter* spp., *Salmonella* spp., and *Listeria monocytogenes* Associated with the Body Surfaces and Guts of Individual Filth Flies.** Applied and Environmental Microbiology 78 (22): 7891-7902. http://aem.asm.org/content/78/22.toc?etoc

Chapter 7 Poisonous or Toxic Materials

7-202.12 Conditions of Use.

1. Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act found at http://www.epa.gov/opp00001/regulating/fifra.pdf.

7-204.11 Sanitizers, Criteria.

1. Code of Federal Regulations, Title 40, Part 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions) found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.940.pdf

2. Code of Federal Regulations, Title 40 Part 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance-Non-Food determinations found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.2020.pdf

3. Code of Federal Regulations, Title 29 Part 1910.1000 Occupational Safety and Health Standards found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/29cfr1910.1000.pdf

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables.

2. Code of Federal Regulations, Title 21, Part 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

7-204.13 Boiler Water Additives, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.310, Boiler water additives.

7-204.14 Drying Agents, Criteria.

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.

2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.

3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.

4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.

5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.

6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.

7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.

8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.

9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.

10. Code of Federal Regulations, Title 21, Part 170.30, Eligibility for classification as generally recognized as safe (GRAS)

11. Code of Federal Regulations, Title 21, Part 174, Indirect Food Additives: General.

12. Federal Food Drug and Cosmetic Act, Section, 409 (h), http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct FDCAct/default.htm

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13. Federal Food Drug and Cosmetic Act, Section 201(s)(4)
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct FDCAct/default.htm

14. Food Contact Notification, Ingredients and Packaging,
http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm

7-205.11 Incidental Food Contact, Criteria.

1. Code of Federal Regulations, Title 21, Part 178.3570, Lubricants with incidental food contact.

7-206.11 Restricted use Pesticides, Criteria.

1. Code of Federal Regulations, Title 40, Part 152 Subpart I, Classification of Pesticides.

3. SUPPORTING DOCUMENTS

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

A. Voluntary National Retail Food Regulatory Program Standards
B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
E. Food Establishment Plan Review Guide
F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
G. Growing Sprouts in a Retail Food Establishment
H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety
I. Evaluation and Definition of Potentially Hazardous Foods
J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004
K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003
M. Comprehensive Guidelines for Food Recovery Programs
N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.
O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens
P. Employee Health and Personal Hygiene Handbook
Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions
R. Parameters for Determining Inoculated Pack/Challenge Study Protocols
S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response
T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

A. Voluntary National Retail Food Regulatory Program Standards

This document can be accessed at the following web site:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ default.htm and was formulated from ideas and input by Federal, State, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;
- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and
- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

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The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

B. FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found by accessing the following web site: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm2006814.htm. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.

FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

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C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

The Operator's Manual can be found by accessing the following web site: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system. This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your Federal, State, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Annex 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee turnover and communication barriers must be considered when designing a HACCP plan.

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Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems

The Regulator's Manual can be found by accessing the following website: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm. This document provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides recommendations for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

The utilization of voluntary food safety management systems by industry and the incorporation of risk-based methodology into regulatory inspection programs are important elements in reaching the goals established by the Healthy People 2010 health improvement strategy and FDA retail program goals.

In 2004, the Conference for Food Protection (CFP) endorsed both documents with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

A Federal Register notice announcing the availability of these documents was published July 21, 2005 (Docket No. 2005D-0274).

E. Food Establishment Plan Review Guide

This document can be found at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm. This Food Establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
- Industry to establish an organized and efficient flow of food.
- Regulatory agencies to eliminate code violations prior to construction.

F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the “FDA Baseline Report.” The Baseline Report is available from FDA through the following website: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional*

Foodservice, Restaurant, and Retail Food Store Facility Types (2004. This second report is available from FDA through the following website: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm089696.htm. An additional data collection project is planned for 2008.

G. Growing Sprouts in a Retail Food Establishment

This document, Growing Sprouts in a Retail Food Establishment, can be found at the web site http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm078758.htm . There were 25 reported outbreaks associated with raw and lightly cooked seed sprouts in the United States between January 1996 and December 2003. No single treatment so far has been shown to completely eliminate pathogens on seeds or sprouts without affecting germination or yield; therefore a combination of factors is used to eliminate and control potential pathogens and assure a safe, ready-to-eat food product. Seeds or beans grown using Good Agricultural Practices (GAPs) and conditioned, transported, and stored according to GMPs reduce the potential for seed to serve as a source of contamination. Retail Sprouting Industry Best Practices help ensure that no further contamination occurs and precautionary measures are taken to prevent high levels of bacteria from growing on the seeds or sprouts. Seeds for sprouting or sprouts should receive a chemical disinfection treatment that has been approved by EPA for reduction of pathogens. Other treatments such as irradiation of seeds [21 CFR 179.26(b)(10)] have been approved. Because no treatments are known to completely eliminate pathogens without adversely affecting germination or yield, microbial testing of spent irrigation water from the sprouting process is also necessary to verify that no pathogens are present. Raw sprouts are considered time/temperature control for safety food (TCS) and therefore, require refrigeration.

H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety

These documents are available for purchase at minimum cost from the Association of Food and Drug Officials (AFDO) at the website http://www.afdo.org/. These guides were funded by USDA through the University of Florida in cooperation with Florida A&M University and the Association of Food and Drug Officials and developed by experts from academic, regulatory, and industry areas. Nine guides help retailers and regulatory personnel understand the food safety controls to implement in retail food and food service operations in order to process and sell safe food products. They can also be used as a reference in applying for or reviewing a variance and HACCP Plan, where required, for retail processing of beef jerky, cured and hot smoked sausage, cured and smoked ham, fermented and dried sausage, fresh-cut produce, fresh juice, reduced oxygen packaging (ROP), smoked seafood, and sushi.

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Each guide provides a definition of terms, a flow diagram, and a detailed check list for operations including receiving, food storage, preparation, and display. Information in the Appendices helps identify specific food safety hazards associated with that product, necessary equipment calibrations, product labeling, recommended record keeping with sample log sheets, and a daily SOP check list. Authoritative sources are also referenced such as FDA's "Fish and Fisheries Products Hazards & Controls Guidance" and 21 CFR 101 for labeling requirements.

These guides are not intended to replace or duplicate existing regulations within the jurisdictions of the regulatory authority or food establishment but they offer information and references for more uniform practices.

I. Evaluation and Definition of Potentially Hazardous Foods

This document can be found at the web site

http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm0 94141.htm .

The Institute of Food Technologists (IFT) prepared and submitted this report as part of a contract with FDA. It contains responses to various questions posed by FDA about time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term TCS and recommended a change to time/temperature control for safety (TCS) food as well as a science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is non-TCS.

The IFT Science and Technology Expert Panel reviewed the two protocols used by NSF International and the American Baking Association for determining if a food is a TCS and proposed an alternate approach. The report examines intrinsic factors such as a_w, pH, redox potential, natural and added antimicrobials and competitive microorganisms, and extrinsic factors such as packaging, atmospheres, storage conditions, processing steps, and new preservation technologies that influence microbial growth. The report also analyzes microbial hazards related to time/temperature control of foods for safety.

The IFT developed a framework that could be used to determine whether a food is a TCS food or not. Part of the framework includes two tables that consider the interaction of pH and a_w in a food, whether the food is raw or heat-treated, and whether it is packaged. When further product assessment is required, the application of microbiological challenge testing (inoculation studies) is discussed along with pathogen modeling programs and reformulation of the food. An extensive reference list is included in the report.

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J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004

The guide is designed to assist restaurants and other food service employers in complying with the employment provisions of the Americans with Disabilities Act (ADA). The EEOC worked extensively with the Food and Drug Administration in developing this new publication.

Available online at http://www.eeoc.gov/facts/restaurant_guide.html, http://www.eeoc.gov/facts/restaurant_guide_summary.html, and www.fda.gov, the guide covers such topics as how the FDA Food Code provisions about restricting and excluding sick employees interact with the ADA's requirements; types of reasonable accommodations, including the use of service animals; and what an employer should do if a charge of discrimination is filed against the employer's business.

Title I of the ADA, which prohibits employment discrimination against people with disabilities in the private sector and State and local governments, and the Rehabilitation Act's prohibitions against disability discrimination in the federal government. The EEOC enforces Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex, and national origin; the Age Discrimination in Employment Act, which prohibits discrimination against individuals 40 years of age or older; the Equal Pay Act; and sections of the Civil Rights Act of 1991.

K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" at http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES. On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=0225504-filed.pdf, in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli* O157:H7 contamination.
USDA/FSIS announced in 2002 that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

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Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback contaminated product that is in commerce to its source and to remove it from commerce. In the Spring of 2004, FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities as well as at import facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infections with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published "Sanitation Guidance for Beef Grinders" which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.

The following information would be used to facilitate traceback of contaminated ground beef products:

- The manufacturer name of source material used for product produced.
- The type of product or description of the purchased or received article(s).
- The establishment information from the label of source product used such as the name, address, and establishment number
- The supplier lot numbers, product code or production or pack date of source materials used.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records and amount (in pounds) and lot/batch numbers, production codes, name and package size of the products produced.

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In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products.
4. Best Practices for Raw Ground Products.
5. FSIS Sanitation Performance Standards Compliance Guide.
6. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 (http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES)

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003

This document can be found at http://www.foodprotect.org/guides/ . Permanent Outdoor Cooking Establishments (POCE) include a wide range of facilities from barbecue pits at beach resorts to campfire meals at dude ranches, pig roasts and clam bakes, and multi-menu food service sites in amusement and theme parks. It is essential that the equipment and physical facility requirements be based upon a menu review of the items to be prepared, cooked, held, and served. Many of these POCEs are high risk operations engaging in extensive preparation of raw ingredients: processes that include the cooking, hot and cold holding, and reheating of time/temperature control for safety foods. These guidelines provide the basis on which regulatory authorities can evaluate and permit permanent outdoor cooking establishments.

M. Comprehensive Guidelines for Food Recovery Programs

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

With bipartisan support, Congress passed the Bill Emerson Good Samaritan Food Donation Act in 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to hungry individuals. The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct.

The *Guidelines* are intended to provide guidance to those who want to participate in food recovery programs as donors and receiving operations as well as to those who oversee standards compliance as regulators or peer inspectors.

The *Guidelines* also give advice on implementing a food recovery program, various ways to contribute to food recovery programs, choosing suitable partners, and laying the foundation for a successful program. This includes food safety provisions in alignment with the FDA Food Code, guidelines for monitoring food recovery programs, and handling of donations of game animals. For simple recordkeeping, the *Guidelines* contain sample forms designed to facilitate the management of a variety of aspects of food recovery programs.

For in-depth information, see the *Comprehensive Guidelines for Food Recovery Programs* available via the Conference for Food Protection web page at http://www.foodprotect.org/guides/
N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.

This document can be found at the web site:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm

The Retail Food Protection Program Information Manual, Storage and Handling of Tomatoes provides safe storage and handling practices for cut tomatoes and additional rationale for including cut tomatoes in the definition of time/temperature control for safety food in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. Since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes. From 1998 – 2006, outbreaks associated with tomatoes made up 17% of the produce-related outbreaks reported to FDA. *Salmonella* has been the pathogen of concern most often associated with tomato outbreaks. Recommendations are being offered to prevent contamination in food service facilities and retail food stores and to reduce the growth of pathogenic bacteria when contamination of fresh tomatoes may have already occurred (regardless of the location where the contamination occurred).

O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens.

This document can be found at:
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm.

Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of time/temperature for safety food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41ºF (5ºC) or less inhibits growth and promotes general die off in some pathogens such as *E. coli* O157:H7. *Salmonella, E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers. Recommended handling instructions for leafy greens during purchasing and receiving, storage, food employee handling fresh produce, washing fresh produce, preparation for sale or service and display for sale or service are attached to the document.

P. Employee Health and Personal Hygiene Handbook

This document can be found at:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm.

The Employee Health and Personal Hygiene Handbook was developed to encourage practices and behaviors that can help prevent food employees from spreading foodborne pathogens to food. Information is provided in a question-andanswer format and includes easy references to forms and tables that food service and retail food establishments and the public health community may find useful when training staff and addressing employee health and hygiene matters. This handbook highlights a combination of three interventions that can be effective in prevention of the transmission of foodborne viruses and bacteria in food establishments. These interventions include: (a) restricting or excluding ill food employees from working with food; (b) using proper handwashing procedures; and (c) eliminating bare hand contact with foods that are ready-to-eat (RTE). Concurrent use of each intervention will help prevent the transmission of viruses, bacteria and protozoan oocysts from food employees to consumers through contaminated food. **Note that the recommendations provided are not to be construed as medical advice or directions to diagnose a medical condition.**

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The person in charge and the food employee always have the option to seek professional medical attention as warranted by the situation at hand.

Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions

These documents can be found at:
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/default.htm.

FDA developed a set of definitions and a qualitative risk assessment process to redesignate the Food Code provisions and work with the CFP Critical Items Committee of stakeholders for feedback. It changed “critical” and “non-critical” to risk designations which include “priority item,” “ priority foundation item” and “core item” to link the provision to hazards associated with foodborne illness or injury. The method used is described in “**Risk Assessment Process to Redesignate Food Code Provisions**” and the decision-making process recorded in the Excel spreadsheet for transparency. The risk assessment decision-making process explained in the instructions provides a science-based rationale for each redesignation. It is internally consistent and consistent with peer-reviewed publications.

The process considered the general and specific hazards that each provision is intended to address. An initial risk designation was made based on the definitions for “priority item,” “ priority foundation item”, and “core item”, to show how directly the provision eliminated, prevented or reduced to an acceptable level, the hazards associated with foodborne illness or injury. To further refine the designation, the virulence or severity of the hazard in the absence of control by this Code provision was also examined. Contributing factors (contamination factors, proliferating/amplification factors, survival factors and method of preparation) identified for foodborne outbreaks reported to the Centers for Disease Control and Prevention were also considered. The risk designation was then re-evaluated in terms of meeting the definition, characteristics of the potential hazards, size and/or number of outbreaks caused by the haz ard in conjunction with non-application of this Code provision and the contributing factors. The final determination was based on the term which most closely defined that provision, taking into account any weighting due to severity and infectivity of the hazard. Additional comments and references to explain or support this determination were included on the spreadsheet.
R. Parameters for Determining Inoculated Pack/Challenge Study Protocols

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in response to questions posed by FDA, developed guidelines for conducting challenge studies on pathogen inhibition and inactivation studies in a variety of foods. The guidelines are available at:

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http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdz9TfQLsh0VAfb5Y5I!/?1dmy&current=true&urile=wcm%3Apath%3A%2Ffsiscontent%2Finternet%2Fmain%2Ftopics%2Fdata-collection-andreports%2Fnacmcf%2Fcurrent-subcommittees%2Fparameters-for-inoculated-packchallenge-study-protocols%2Fct_index9

The document is intended for use by the food industry, including food processors, food service operators and food retailers; federal, state and local food safety regulators; public health officials; food testing laboratories; and process authorities. The document is focused on, and limited to, bacterial inactivation and growth inhibition and does not make specific recommendations with respect to public health. NACMCF concluded that challenge studies should be designed considering the most current advances in methodologies, current thinking on pathogens of concern, and an understanding of the product preparation, variability and storage conditions. Studies should be completed and evaluated under the guidance of an expert microbiologist in a qualified laboratory and should include appropriate statistical design and data analyses.

This document provides guidelines for choice of microorganisms for studies, inoculum preparation, inoculum level, methods of inoculation, incubation temperatures and times, sampling considerations, and interpreting test results. Examples of appropriately designed growth inhibition and inactivation studies are provided. The NACMCF report, through tables and appendices, also provides sources of accepted laboratory methods, considerations for selecting a laboratory, pathogens of concern with control methods for food product categories, relevant Food Code definitions and food product checklists that test the protocol. It also includes recommended minimum expertise for designing, conducting and evaluating microbiological studies; potential pathogens of concern for growth studies based on pH and a_w; examples of mathematical growth and inactivation models and their application to different foods; pathogen growth ranges used in CommBase and Pathogen Modeling Program models; and limits for growth when other conditions are near optimum.

S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response

This document can be found at: http://www.cifor.us/CIFORGuidelinesProjectMore.cfm

The Guidelines for Foodborne Outbreak Response describe the overall approach to foodborne disease outbreaks, including preparation, detection, investigation, control and follow-up. The Guidelines also describe the roles of all key organizations in foodborne disease outbreaks. The Guidelines are targeted at local, state and federal agencies that are responsible for preventing and managing foodborne disease.

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T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

In 2009, the Council to Improve Foodborne Outbreak Response (CIFOR) convened a workgroup comprised of representatives from the food industry and l ocal, state and Federal government for the purpose of creating guidelines and tools specific for industry response to foodborne illness. The resulting document, called the CIFOR *Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines),* was developed as *voluntary* guidance for managers of Food Establishments ("Industry") to help outline, clarify, and explain Industry's recommended role in a foodborne illness outbreak investigation. These CIFOR Industry Guidelines:

- Provide a step-by-step approach including Preparation, Illness Complaints, Investigation, Control, and Follow-up
- Describe what to expect when first notified of potential illnesses or outbreak
- Provide Tools to guide Industry through the regulatory investigation process.

This document is available for download at: http://www.cifor.us/index.cfm

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

FDA Publications:

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food under their control, from tampering or other malicious, criminal, or terrorist actions:

- **Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance** at

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm

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- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm

- **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083049.htm.

- **Importers and Filers: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm078978.htm.

- The **Bioterrorism Act of 2002** at: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm.

USDA Publications:

- **Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors** at http://www.fsis.usda.gov/wps/portal/searchhelp/sitemap/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdx9jfQLsh0VAcILpdM!/?1dmy&current=true&urile=wcm%3Apath%3A%2Ffsiscontent%2Finternet%2Fmain%2Ftopics%2Ffood-defense-and-emergencyresponse%2Fpreparation-and-prevention%2Fguidance-documents%2Fguidancedocuments

- **FSIS Guidelines "Keep America's Food Safe"** at http://www.fsis.usda.gov/wps/portal/frame-redirect?url=/wps/wcm/connect/FSISContent/fsis-questionable-content/security-guidelines/keep-americas-foodsafe/CT_Index.

  This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.

FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products at: http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergencyresponse/preparation-and-prevention/guidance-documents/guidance-documents.

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This guidance contains recommendations to ensure the security of food products through all phases of the distribution process.

Additional information on FSIS food security guidance publications is available over the Internet at http://www.fsis.usda.gov.

Industry Publications:

• **National Restaurant Association**. Information for restaurants can be found on the National Restaurant Association's web page at http://www.restaurant.org.

• **Food Marketing Institute** (FMI) Security Information and Resources web page at http://www.fmi.org/foodsafety/ provides access to security information and guidelines targeted specifically to food retailers.

Guidance on Responding to Food Emergencies:

• Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at http://www.bt.cdc.gov/.

• USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at http://fsrio.nal.usda.gov/emergency-preparedness-andmanagement/response/foodservice-and-retail.

FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.

Food Defense and Emergency Guidance of Interest to Schools:

• **A Biosecurity Checklist for School Foodservice: Developing a Biosecurity Management Plan**

The document is from the USDA – Food and Nutrition Service and provides information for school food service managers. It can be found at http://fsrio.nal.usda.gov/emergency-preparedness-and-management/preventionand-preparation/foodservice-and-retail. The exact link to the checklist is http://healthymeals.nal.usda.gov/hsmrs/biosecurity.pdf . Currently the checklist is only available in an electronic format.

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- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at: http://fsrio.nal.usda.gov/emergency-preparedness-and-management/preventionand-preparation/foodservice-and-retail

Defense Guidance of Interest to Consumers:

- **Food Safety and Security: What Consumers Need to Know**, at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/getanswers/food-safety-fact-sheets/emergency-preparedness/food-safety-and-securitywhat-consumers-need-to-know .

- **Food Tampering: An Extra Ounce of Caution**, at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079137.htm

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Appendix A: 4 of 4

Chart 4-A

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Raw Eggs prepared for immediate service **Commercially Raised Game Animals and Exotic Species of Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Raw Eggs not prepared for immediate service **Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats** **Mechanically Tenderized Meats**	70°C (158°F) **68°C (155°F)** 66°C (150°F) 63°C (145°F)	< 1 second **15 seconds** 1 minute 3 minutes
Poultry **Baluts** **Stuffed Fish; Stuffed Meat;** **Stuffed Pasta;** **Stuffed Poultry; Stuffed Ratites** **Stuffing Containing Fish, Meat, Poultry, or Ratites** **Wild Game Animals**	**74°C (165°F)**	**15 seconds**
Food Cooked in A Microwave Oven	**74°C (165°F)**	**and hold for 2 minutes after removing from microwave oven**

Chart 4-B

Summary Chart for Minimum Food Temperatures and Holding Times Required by Chapter 3 for Reheating Foods for Hot Holding

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) and (D) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) and (D) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after reheating	2 hours
¶ 3-403.11(C) and (D) Food that is taken from a commercially processed, hermetically sealed container or intact package	57°C (135°F)	No time specified	2 hours
Roasts: Option A ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Not applicable
Roasts: Option B ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	74°C (165°F)	15 seconds	2 hours

Chart 4-C

Summary Chart
Ready-to-Eat, Time/temperature Control for Safety Food
Date Marking § 3-501.17(A) – (E) and Disposition of § 3-501.18

"IF" → **"THEN"**

(A) or (B) On site preparation and held >24 hours, or commercial container is opened → @ ≤ 41°F for ≥ 7 days

or

(A) or (B) Remove from freezer → @ ≤ 41°F 7 days minus*

*Time from preparation, or opening of commercial container, to freezing.

Example: The morning of October 1, a chicken was cooked, then cooled, refrigerated for 2 days at 41°F and then frozen. If the chicken is thawed October 10, the food must be consumed or discarded no later than midnight of October 14.

Date	Shelf Life Day	Action
Oct. 1	1	cook/cool
Oct. 2	2	cold hold at 41°F
Oct. 3		freeze
Oct. 10	3	thaw to 41°F
Oct. 11	4	cold hold
Oct. 12	5	cold hold
Oct. 13	6	cold hold
Oct. 14	7	consume or discard

Appendix C: Risk Assessment Worksheet
(12/10/02 Revision)

Permit No.	Establishment Name	Address City Zip	Score
1. **Past History (1 Year):** Critical violation dealing with Food Protection or Personnel (**2.0**), Other critical violations and/or repeat violations (**1.0**), No Critical violations (**0.5**)			
2. Are potentially hazardous food (PHF) items served? 5 or more items (**2.0**), 1-4 items (**1.0**), None (**0.5**)			
3. Are raw foods handled with multiple-step preparation? **Y (1.5) N (0.5)**			
4. Are hand washing, refrigeration, hot/cold holding facilities adequate/maintained? **Y (0.5) N (1.5)**			
5. Are PHFs cooked and then cooled and/or reheated? **Y (1.5) N (0.5)**			
6. Are PHFs prepared and held before service? >4 hours (**1.5**), 2 to 4 hours (**1.0**), <2 hours (**0.5**)			
7. Is date marking required or time as a public health control used? **Y (1.5) N (0.5)**			
8. Can demonstrate knowledge* and/or implementation of good food safety practices? **Y (0.5) N (1.5)**			
9. What is the average number of meals served per day? 1-150 **(0.5),** 151-400 **(1.0),** 400+ **(1.5)**			
10. Is a highly susceptible population served? (day-care, elem school, senior nutrition site) **Y (1.5) N (0.5)**			
11. Are raw PHFs handled (raw meat, eggs, seafood or food items containing raw PHFs)? **Y (1.5) N (0.5)**			
***No Certified Food Safety Manager would also apply here.**		**Total Points**	

Total points _____ divided by 10 = _____

Public Health Risk Priority:
Risk Category 4 (>1.1 and previous enforcement actions in the past 2 years, hearings, notice issued or foodborne illnesses)
Risk Category 3 (>1.1)
Risk Category 2 (.8 - 1.1)
Risk Category 1 (<.8)
THE PUBLIC HEALTH RISK CATEGORY FOR THIS ESTABLISHMENT IS: _____

Risk Category	Maximum Inspection Interval	Comments
1	12 months	
2	6 months	
3	4 months	
4	3 months	

Environmental Health Specialist Date

Program Manager Date