Annex

2 References

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
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Washington, DC 20401-0001
(866) 512-1800, Fax (202) 512-2104
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(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:	or	by calling:
Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;		(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;

(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.

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[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).)

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Chapter 2 Management and Personnel

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

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Chapter 5 Water, Plumbing, and Waste

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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.

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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/Stds%20Prog%20Info/Product%20Standards.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.

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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).

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.

7-204.13 Boiler Water Additives, Criteria.

2. 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.

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"
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

A. Voluntary National Retail Food Regulatory Program Standards

This document can be accessed at the following web site:

http://www.fda.gov/Food/FoodSafety/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.

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/FoodSafety/RetailFoodProtection/InspectionsQualityAssurance/Standardization/default.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.

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/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.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.

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/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.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/FoodSafety/RetailFoodProtection/ComplianceEnforcement/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/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123544.htm . 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/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/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/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/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 potentially hazardous food (PHF)/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/afdo/publication/index.cfm. 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.

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/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm094141.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 potentially hazardous food (PHF)/time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term PHF 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 nonpotentially hazardous/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 PHF 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 PHF (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.

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/oppde/rdad/fsisdirectives/10.010.1.pdf. 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=02-25504-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 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.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback *E. coli* O157:H7 contaminated product that is in commerce to its source and to remove it from commerce. In March 2004, the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf. In this Directive, the Agency stated that, effective May 17, 2004, it would conduct 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.

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 *E. coli* O157:H7 ground beef in a product, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

The following information would be adequate for meeting federal transaction requirements:

- The name or description of the purchased or received article(s).
- The name, address, and establishment number of the seller of the articles purchased or received.
- The supplier lot numbers and production dates of the articles purchased or received.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce.

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.

2. 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 *Escherchia coli* O157:H7

   http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010 1/ecolio157h7dirguid4-13-04.pdf.

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 potentially hazardous foods (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/FoodSafety/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 potentially hazardous food (time/temperature control for safety food) in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-PHF (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/RetailFoodProtection.

Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of potentially hazardous 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/FoodSafety/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-and-answer 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. 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/RetailFoodProtection.

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 hazard 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:
http://www.fsis.usda.gov/PDF/NACMCF_Inoculated_Pack_2009F.pdf

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.

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/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm082751.htm

- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at
  http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/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/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083049.htm .

- **Importers and Filers: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/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/Food_Defense_&_Emergency_Response/FSIS_Security_Guidelines_for_Food_Processors/index.asp

- **FSIS Guidelines "Keep America's Food Safe"** at http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Keep_Americas_Food_Safe/index.asp .

  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/OA/topics/transportguide.htm .

  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://www.fns.usda.gov/fns/food_foodsafety.htm .

  FDA's Office of Emergency Operations at 301-796-8240 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 on the Healthy School Meals Resource System website at http://schoolmeals.nal.usda.gov/Safety/FNSFoodSafety.htm. 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.

- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at: http://healthymeals.nal.usda.gov/nal_display/index.php?info_center=14&tax_level=3&tax_subject=265&topic_id=1289&level3_id=5223

or directly link to the document at:
http://www.olemiss.edu/depts/nfsmi/information/e-readinessguide.pdf

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Defense Guidance of Interest to Consumers:

- **Food Safety and Security: What Consumers Need to Know**, at http://www.fsis.usda.gov/OA/topics/foodsec_cons.htm.

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