Food Code

U.S. Public Health Service

2001

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

Washington, DC 20204

Food Code

2001 Recommendations of the
United States Public Health Service
Food and Drug Administration

The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model.

This guidance represents FDA's current thinking on safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. This guidance is being issued in accordance with FDA's Good Guidance Practices regulation (21 CFR 10.115; 65 FR 56468; September 19, 2000).

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Previous Editions of Codes
Recommended by The
United States Public Health Service
for
Regulating Operations Providing Food Directly to the Consumer

1934 - *Restaurant Sanitation Regulations,*
Proposed by the U.S. Public Health Service in cooperation with the Conference of State and Territorial Health Officers and the National Restaurant Code Authority

1935 - *An Ordinance Regulating Food and Drink Establishments*
(Recommended by U.S. Public Health Service), December 1935, Mimeographed

1938 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the U.S. Public Health Service,* March 1938, Mimeographed

1940 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended* by the U.S. Public *Health Service,* June 1940, Mimeographed

1943 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the United States Public Health Service,* 1943, FSA, Public Health Bulletin No. 280 (Republished in 1955, DHEW, PHS Publication No. 37)

1957 - *The Vending of Foods and Beverages - A Sanitation Ordinance and Code, 1957 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 546

1962 - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance and Code, 1962 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 934

1965 - *The Vending of Food and Beverages - A Sanitation Ordinance and Code, 1965 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 546

1976 - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance, 1976 Recommendations of the Food and Drug Administration,* DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091

1978 - *The Vending of Food and Beverages Including A Model Sanitation Ordinance, 1978 Recommendations of the Food and Drug Administration,* DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091

1982 - *Retail Food Store Sanitation Code, 1982 Recommendations of the Association of Food and Drug Officials and U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration,* AFDO/HHS Publication

1993 - *Food Code, 1993 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB94-113941

1995 - *Food Code, 1995 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB95-265492

1997 - *Food Code, 1997 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB97-133656

1999 - *Food Code, 1999 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB-99-115925

JOINT INTRODUCTION to the 2001 FOOD CODE

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) are pleased to release the 2001 edition of the Food Code. As in the past, this edition of the Food Code provides practical, science-based guidance and manageable, enforceable provisions for mitigating risk factors known to cause foodborne illness. The Code is a reference document for regulatory agencies that oversee food safety in food service establishments, retail food stores, other food establishments at the retail level, and institutions, such as nursing homes and child care centers. Food safety is a top priority for DHHS and USDA, and we strongly endorse and encourage adoption of the Code.

First published in 1993, we have revised and updated the Food Code every two years. As of December 2000, thirty states and one territory have adopted one of the four editions of the Food Code. Fifteen additional states and one territory are in the process of adoption. Many Federal agencies and tribal governments have adopted the Code as well. We commend these jurisdictions and agencies and urge others to act. We also encourage all jurisdictions to examine the level of food safety protection their current rules and implementation strategies provide and take the steps necessary to increase that level in light of the 2001 Food Code. Food Code adoption and implementation in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system.

Ensuring safe food is an important public health priority for our nation. An estimated 76 million illnesses, 323,914 hospitalizations, and 5,194 deaths are attributable to foodborne illness in the United States each year. The estimated cost of foodborne illness is $10 - $83 billion annually. For some consumers, foodborne illness results only in mild, temporary discomfort or lost time from work or other daily activity. For others, especially pre-school age children, older adults, and those with impaired immune systems, foodborne illness may have serious or long-term consequences, and most seriously, may be life threatening. The risk of foodborne illness is of increasing concern due to changes in the global market, aging of our population, increasing numbers of immunocompromised and immunosuppressed individuals, and changes in food production practices.

In this context, DHHS and USDA are increasing efforts to educate food service workers about food safety principles. One example is our collaborative Foodborne Illness Education Information Center, which houses a database of videos, software, course books, posters, and brochures to teach restaurant food workers how to prepare and serve food safely in order to prevent foodborne illness.

Significantly, food safety is a priority action area of *Healthy People 2010,* the comprehensive, nationwide set of health promotion and disease prevention objectives

designed to serve as a 10-year strategy for improving health in the United States. *Healthy People 2010* objectives include reducing infections caused by foodborne pathogens, reducing outbreaks of foodborne illness, and improving food employee behaviors and food preparation practices that directly relate to foodborne illnesses in retail food establishments. We intend to measure progress through public health data collection systems and data collected on Food Code interventions.

DHHS and USDA, along with state and local and other federal and tribal government agencies and the food industry, share responsibility for ensuring that our food supply is safe. DHHS and USDA, in partnership with numerous others, will continue to take progressive steps to strengthen our nation's food safety system. We look forward to achieving uniform and effective standards of food safety for food services, retail stores, and other retail-level establishments nationwide.

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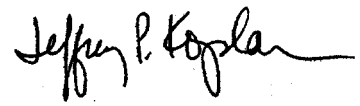

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Preface

1. FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS

Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. Meade et. al. (1999) estimated that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.

For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs are estimated to be $10 - $83 billion. As stated by Meade et. al., the nature of food and foodborne illness has changed dramatically in the United States over the last century. While technological advances such as pasteurization and proper canning have all but eliminated some disease, new causes of foodborne illness have been identified. Surveillance of foodborne illness is complicated by several factors. The first is underreporting. Although foodborne illnesses can be severe or even fatal, milder cases are often not detected through routine surveillance. Second, many pathogens transmitted through food are also spread through water or from person to person, thus obscuring the role of foodborne transmission. Finally, pathogens or agents that have not yet been identified and thus cannot be diagnosed cause some proportion of foodborne illness.

Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness:

- Improper holding temperatures,
- Inadequate cooking, such as undercooking raw shell eggs,

- Contaminated equipment,
- Food from unsafe sources, and
- Poor personal hygiene

The Food Code addresses controls for risk factors and further establishes 5 key public health interventions to protect consumer health. Specifically, these interventions are: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination; time and temperature parameters for controlling pathogens, and the consumer advisory. The first two interventions are found in Chapter 2 and the last three in Chapter 3.

Healthy People 2000 and Healthy People 2010 are national initiatives that work through the cooperative federal-state-private sector and which establish 10-year objectives to improve the health of all Americans through prevention. Food Safety Objective 10-6 in Healthy People 2010 is: *Improve food employee behaviors and food preparation practices that directly relate to foodborne illnesses in retail food establishments*. This includes food operations such as retail food stores, food service establishments, health care facilities, and other "food establishments" as defined in the Food Code.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 12 million.

2. PHS MODEL CODES HISTORY, PURPOSE, AND AUTHORITY

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption. Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of these, which is now titled *Grade A Pasteurized Milk Ordinance - 1999 Recommendations of the PHS/FDA,* was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on page iii. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

Today, FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry. The retail segment includes those establishments or locations in the food distribution chain where the consumer takes possession of the food.

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A list of jurisdictions that have reported to FDA their status in adopting the Food Code is available on the FDA CFSAN Web Page at http://www.cfsan.fda.gov under Federal/State Food Programs - Retail Food Safety References. The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

Providing model food codes and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food control agency, promotes uniform implementation of national food regulatory policy among the several thousand federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations.

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part:
"... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (4)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies such as the General Services Administration and the Indian Health Service.

Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

3. PUBLIC HEALTH AND CONSUMER EXPECTATIONS

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak or in the transmission of communicable disease. This shared responsibility extends to ensuring that consumer expectations are met and that food is unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's 1997 Mission Statement the agency is responsible for ensuring that:

> Foods are safe, wholesome, and sanitary...; regulated products are honestly, accurately, and informatively represented; and, these products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

4. ADVANTAGE OF UNIFORM STANDARDS

The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.

Industry conformance with acceptable procedures and practices is far more likely where regulatory officials "speak with one voice" about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted.

Model codes provide a guide for use in establishing what is required. They are useful to business in that they provide accepted standards that can be applied in training and quality assurance programs. They are helpful to local, state, and federal governmental bodies that are developing or updating their own codes.

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes. Federal performance standards in effect define public food safety expectations for the product, usually in terms of lethality to a pathogenic microorganism of particular concern. Use of performance standards as the measure of regulatory compliance means establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches, such as specified cooking times and temperatures, that achieve the same end.

Federally inspected establishments demonstrate compliance with performance standards by showing that their process adheres to an appropriately designed, validated HACCP plan.

Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the Regulatory Authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to the regulatory authority.

5. MODIFICATIONS AND IMPROVEMENTS IN THIS EDITION

The revisions contained in this edition largely reflect the recommendations developed during the 2000 meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

The needed clarifications and missing Code provisions were identified by FDA and others during standardization and certification activities, State Training Team courses, regional food protection seminars, the deliberations of food equipment standards organizations, and the verbal and written requests for clarification received by FDA field and headquarters components.

Changes in provisions related to federal laws and regulations administered by other federal agencies such as the United States Department of Agriculture were jointly developed with those agencies.

A summary of changes is provided at the end of the Food Code. General enhancements include:

(1) Added and improved definitions that are more precise and more consistent with terminology and definitions found in related laws and regulations;

(2) Modified provisions to make them more consistent with national requirements and standards administered by other federal agencies and international bodies; more flexible without compromising public health; and more internally consistent with other Food Code provisions;

(3) Clarified other provisions regarding their intent, thereby reducing confusion and the potential for inconsistent application;

(4) Improved user aids contained in the Annexes such as added references and updated

public health reasons, model forms, guides, and lists; and

(5) Expanded the Index with additional terms to assist a broader base of users in finding topics of interest.

6. DISCUSSION OF THE CODE AS A HACCP MODEL AND THE INTENTION TO INCORPORATE OTHER MODELS

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997. Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans mandated by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be potentially hazardous and for which retail production would otherwise be prohibited.

To assist food establishments in applying HACCP principles at retail, FDA has issued a draft document entitled: Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level. This document is available from FDA and can be found on the FDA Web Page at http://vm.cfsan.fda.gov/~ear/retail.html.

Under the Fish and Fishery Products regulation, every seafood processor is required to perform a hazard analysis, and must have and implement a written HACCP Plan whenever a hazard analysis reveals a food safety hazard that is reasonably likely to occur. HACCP plans developed pursuant to the Fish and Fishery Products regulation are for all products in the class and are not for products for which production is presently prohibited. Plans will be reviewed on site, with records available to judge, among other things, the adequacy of past corrective actions.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced.

HACCP plans are key to the use of performance standards as measures of regulatory compliance. Performance standards issued by the Food Safety and Inspection Service are applicable to a broad range of meat, poultry, and egg products. Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for processing various products. Federal performance standards may be used to determine the safety of a product or process under the Food Code if authorized under a Variance granted in accord with the Code's Variance provisions, and demonstrated by adherence to a validated HACCP plan, consistent with the Code's HACCP provisions.

7. CODE ADOPTION/CERTIFIED COPIES

The model Food Code is provided for use by food regulatory jurisdictions at all levels of government. At the state and local levels the model may be:

(A) Enacted into statute as an act of the state legislative body;

(B) Promulgated as a regulation, if the state legislative body has delegated rule-making authority to a governmental administrative agency; or

(C) Adopted as an ordinance, if the local legislative body has been delegated rule-making authority or regulatory powers.

Typically, code adoption bodies publish a notice of their intent to adopt a code, make copies available for public inspection, and provide an opportunity for public input prior to adoption. This is usually done in one of two ways.

The recommended method is the "short form" or "adoption by reference" approach where a simple statement is published stating that certified copies of the proposed code are on file for public review. This approach may be used by governmental bodies located in states that have enabling laws authorizing the adoption of codes by reference. An advantage to this approach is a substantial reduction in the cost of publishing and printing.

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food and Interstate Travel Team, HFS-627, 200 C Street, SW, Washington, DC 20204-0001. Refer to 2. *(A)* of this Preface to access a listing of jurisdictions' adoptions.

The alternative method is the "long form" or "section-by-section" approach where the proposed code is published in its entirety.

Both methods of adoption allow for the modification of specific provisions to accommodate existing law, administrative procedure, or regulatory policy. Annex 7 contains model adoption forms for use by governmental bodies who wish to use either of these methods.

8. INFORMATION TO ASSIST THE USER

Many of the improvements contained in the model Food Code as listed under item 5. above are provided to make the document easier to use. Other characteristics of the new edition, if they are understood by the user, make it easier to follow and apply. These include structure, nomenclature, and methodology.

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4, 5, 6, 7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the table of contents together with the Inspection Guide (Annex 7) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas.

The structural nomenclature of the document is as follows:

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

Internal cross referencing is widely used throughout the document to eliminate the need for restating provisions. For example, fixtures and devices necessary for handwashing are relevant to both the plumbing (Chapter 5) and the facilities (Chapter 6) portions. To alert the reader to relevant information and provide a system by which each violation is recorded under the one most appropriate provision, the Code uses the phrase "...as specified under (followed by a Code cite such as a section or paragraph)." It must be determined within the context of the provision whether the cross reference simply provides information to explain the requirement or whether the observed violation is properly recorded against the provision that is cited after the word "under."

The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

Portions of some sections are written in *italics.* These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance.

Requirements contained in the Food Code are presented as being in one of 3 categories of importance: critical; "swing" (i.e., those that may or may not be critical depending on the circumstances); and noncritical. 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 provisions that are "swing" items, are followed by the bold, superscripted letter **S** and any provisions that are noncritical are followed by the bold, superscripted letter **N**.

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.

Defined words and terms are capitalized in the text of the Food Code chapters to alert the reader to the fact that there is a specific meaning assigned to those words and terms and that the meaning of a provision is to be interpreted in the defined context. A concerted effort was also made to capitalize all forms and combinations of those defined words and terms that were intended to carry the weight of the definition.

The annexes located at the back of the document can provide tremendous assistance to those charged with applying Food Code provisions. No reference is made in the text of a provision to the annexes which support its requirements. This is necessary in order to keep future laws or other requirements based on the model Food Code "clean." However, the annexes are provided specifically to assist the regulatory authority apply the provisions uniformly and effectively.

It is, therefore, important for users to preview the subject and essence of each of the annexes before using the document. Some of the annexes (e.g., References, Public Health Reasons) are structured to present the information by the specific Food Code item number to which they apply. Other annexes provide information and materials intended to be helpful to the user such as model forms that can be used, a delineation of the principles of HACCP, guidelines for establishment inspection, and criteria for certain food processes for use in evaluating proposed HACCP plans.

9. THE CODE REVISION PROCESS

(A) Food Code Revision and Publication Cycles

FDA is revising the Food Code every 2 years. The revision will issue either as a supplement to the existing edition or as a new edition based on the extent of revision. Each new edition will incorporate the provisions of supplements issued between editions.

(B) Submission of Food Code Change Suggestions

FDA will continue to receive concerns and recommendations for modification of the Food Code from any individual or organization.

Given the purpose of the document as discussed in item 2. above, the Agency will be especially interested in addressing problems identified by those in government and industry who are responsible for implementing the Food Code. FDA will also be especially responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns.

Included are organizations that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates. The Conference for Food Protection (retail food issues), the National Conference on Interstate Milk Shipments (milk and dairy products issues), and the Interstate Shellfish Sanitation Conference (molluscan shellfish issues) are examples of such organizations. These organizations receive problems submitted by any interested individual, but specify the forms on which the issues must be detailed and provide specific time frames during which they may be submitted.

FDA encourages interested individuals to consider raising issues and suggesting solutions involving the federal-state cooperative programs based on FDA's model codes through these organizations.

10. ACKNOWLEDGMENTS

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations. It is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those whose contribution to public health and food safety via the Food Code will span well into the next century.

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- **b) Form 1-B Food Employee Reporting Agreement**
- **c) Form 1-C Applicant and Food Employee Medical Referral**
- **d) Guide 1-D Exclusions and Restrictions**
- **e) Guide 1-E Removal of Exclusions and Restrictions**
- **f) List 1-F Worldwide Status of *Salmonella* Typhi, *Shigella* spp., *Escherichia coli* O157:H7, and Hepatitis A Virus by Geographical Area**

2) Adoption information

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- **b) Form 2-B Adoption by Section-by-Section Reference**

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- **c) Guide 3-C Inspectional Guide**

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Chapter

1 Purpose and Definitions

Parts

1-1 TITLE, INTENT, SCOPE

Subparts

Title

1-101.10 Food Code.

These provisions shall be known as the Food Code, hereinafter referred to as "this Code."

Intent

1-102.10 Food Safety, Illness Prevention, and Honest Presentation.

The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is safe, unADULTERATED, and honestly presented.

Scope

1-103.10 Statement.

This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE RESTRICTION, and PERMIT suspension.

1-2 DEFINITIONS

Subpart 1-201 Applicability and Terms Defined

Applicability and Terms Defined **1-201.10 Statement of Application and Listing of Terms.**

(A) The following definitions apply in the interpretation and application of this Code.

(B) Terms Defined.

(1) **Accredited program.**

(a) **"Accredited program"** means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(b) **"Accredited program"** refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(c) **"Accredited program"** does not refer to training functions or educational programs.

(2) **Additive.**

(a) **"Food additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.

(b) **"Color additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.

(3) **"Adulterated"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

(4) **"Approved"** means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

(5) **"a_w"** means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

(6) **"Beverage"** means a liquid for drinking, including water.

(7) **"Bottled drinking water"** means water that is SEALED in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(8) **"Casing"** means a tubular container for sausage products made of either natural or artificial (synthetic) material.

(9) **"Certification number"** means a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH dealer according to the provisions of the National Shellfish Sanitation Program.

(10) **CIP.**

(a) **"CIP"** means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.

(b) ***"CIP"*** *does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.*

(11) **"CFR"** means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.

(12) **"Code of Federal Regulations"** means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:

(a) Is published annually by the U.S. Government Printing Office; and

(b) Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries rules in 50 CFR.

(13) **"Commingle"** means:

(a) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or

(b) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates.

(14) **Comminuted.**

(a) **"Comminuted"** means reduced in size by methods including chopping, flaking, grinding, or mincing.

(b) **"Comminuted"** includes FISH or MEAT products that are reduced in size and restructured or reformulated such as gefilte FISH, gyros, ground beef, and sausage; and a mixture of 2 or more types of MEAT that have been reduced in size and combined, such as sausages made from 2 or more MEATS.

(15) **"Confirmed disease outbreak"** means a FOODBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the FOOD as the source of the illness.

(16) **"Consumer"** means a PERSON who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

(17) **"Corrosion-resistant material"** means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the FOOD to be contacted, the normal use of cleaning compounds and SANITIZING solutions, and other conditions of the use environment.

(18) **"Critical control point"** means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health RISK.

(19) **Critical Item.**

(a) **"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.

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

(20) **"Critical limit"** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the RISK that the identified FOOD safety HAZARD may occur.

(21) **Drinking Water.**

(a) **"Drinking water"** means water that meets 40 CFR 141 National Primary Drinking Water Regulations.

(b) **"Drinking water"** is traditionally known as "potable water."

(c) **"Drinking water"** includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

(22) **"Dry storage area"** means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not POTENTIALLY HAZARDOUS and dry goods such as SINGLE-SERVICE items.

(23) **Easily Cleanable.**

(a) **"Easily cleanable"** means a characteristic of a surface that:

(i) Allows effective removal of soil by normal cleaning methods;

(ii) Is dependent on the material, design, construction, and installation of the surface; and

(iii) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

(b) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified under Subparagraph (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(i) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for CONSUMER dining; or

(ii) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the CONSUMER dining area.

(24) **"Easily movable"** means:

(a) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EQUIPMENT for cleaning; and

(b) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the EQUIPMENT to be moved for cleaning of the EQUIPMENT and adjacent area.

(25) **"Egg"** means the shell EGG of the domesticated chicken, turkey, duck, goose, or guinea.

(26) **"Employee"** means the PERMIT HOLDER, PERSON IN CHARGE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

(27) **"EPA"** means the U.S. Environmental Protection Agency.

(28) **Equipment.**

(a) **"Equipment"** means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(b) ***"Equipment"*** *does not include items used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.*

(29) **"Exclude"** means to prevent a PERSON from working as a FOOD EMPLOYEE or entering a FOOD ESTABLISHMENT except for those areas open to the general public.

(30) **"FDA"** means the U.S. Food and Drug Administration.

(31) **Fish.**

(a) **"Fish"** means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(b) **"Fish"** includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

(32) **"Food"** means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(33) **"Foodborne disease outbreak"** means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

(34) **"Food-contact surface"** means:

(a) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or

(b) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:

(i) Into a FOOD, or

(ii) Onto a surface normally in contact with FOOD.

(35) **"Food employee"** means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

(36) **Food Establishment.**

(a) **"Food establishment"** means an operation that stores, prepares, packages, serves, vends, or otherwise provides FOOD for human consumption:

(i) Such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and

(ii) That relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(b) **"Food establishment"** includes:

(i) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location *unless the vending or feeding location is PERMITTED by the REGULATORY AUTHORITY*; and

(ii) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(c) **"*Food establishment*"** *does not include:*

(i) *An establishment that offers only pre*PACKAGED FOODS *that are not* POTENTIALLY HAZARDOUS;

(ii) *A produce stand that only offers whole, uncut fresh fruits and vegetables*;

(iii) *A* FOOD PROCESSING PLANT;

(iv) *A kitchen in a private home if only* FOOD *that is not* POTENTIALLY HAZARDOUS *is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by* LAW *and if the* CONSUMER *is informed by a clearly visible placard at the sales or service location that the* FOOD *is prepared in a kitchen that is not subject to regulation and inspection by the* REGULATORY AUTHORITY;

(v) *An area where* FOOD *that is prepared as specified in Subparagraph (c)(iv) of this definition is sold or offered for human consumption*;

(vi) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers* FOOD *to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the* CONSUMER *is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the* FOOD *is prepared in a kitchen that is not regulated and inspected by the* REGULATORY AUTHORITY; *or*

(vii) *A private home that receives catered or home-delivered* FOOD.

(37) **Food Processing Plant.**

(a) **"Food processing plant"** means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption and does not provide FOOD directly to a CONSUMER.

(b) ***"Food processing plant"*** *does not include a* FOOD ESTABLISHMENT *as defined under Subparagraph 1-201.10(B)(36).*

(38) **Game Animal.**

(a) **"Game animal"** means an animal, the products of which are FOOD, that is not classified as cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Subchapter A - Mandatory Meat Inspection, Part 301, as Poultry in 9 CFR Subchapter C - Mandatory Poultry Products Inspection, Part 381, or as FISH as defined under Subparagraph 1-201.10(B)(31).

(b) **"Game animal"** includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(c) **"Game animal"** does not include ratites such as ostrich, emu, and rhea.

(39) **"General use pesticide"** means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

(40) **"Grade A standards"** means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" and "Grade A Condensed and Dry Milk Ordinance" with which certain fluid and dry milk and milk products comply.

(41) **"HACCP plan"** means a written document that delineates the formal procedures for following the HAZARD Analysis CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(42) **"Hazard"** means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

(43) **"Hermetically sealed container"** means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

(44) **"Highly susceptible population"** means PERSONS who are more likely than other people in the general population to experience foodborne disease because they are:

(i) Immunocompromised; preschool age children, or older adults; and

(ii) Obtaining FOOD at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(45) **"Imminent health hazard"** means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice,

circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(i) The number of potential injuries, and

(ii) The nature, severity, and duration of the anticipated injury.

(46) **"Injected"** means manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as by processes which may be referred to as "injecting," "pinning," or "stitch pumping."

(47) **"Juice"**, when used in the context of FOOD safety, means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée. JUICE includes JUICE as a whole BEVERAGE, an ingredient of a BEVERAGE and a purée as an ingredient of a BEVERAGE.

(48) **"Kitchenware"** means FOOD preparation and storage UTENSILS.

(49) **"Law"** means applicable local, state, and federal statutes, regulations, and ordinances.

(50) **"Linens"** means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(51) **"Meat"** means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, *except fish, poultry, and wild game animals as specified under Subparagraphs 3-201.17(A)(3) and (4).*

(52) **"mg/L"** means milligrams per liter, which is the metric equivalent of parts per million (ppm).

(53) **"Molluscan shellfish"** means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle*.

(54) **Packaged.**

(a) **"Packaged"** means bottled, canned, cartoned, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(b) ***"Packaged"*** *does not include a wrapper, carry-out box, or other nondurable container used to containerize* FOOD *with the purpose of facilitating* FOOD *protection during service and receipt of the* FOOD *by the* CONSUMER.

(55) **"Permit"** means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

(56) **"Permit holder"** means the entity that:

(a) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and

(b) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

(57) **"Person"** means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

(58) **"Person in charge"** means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

(59) **Personal Care Items.**

(a) **"Personal care items"** means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a PERSON'S health, hygiene, or appearance.

(b) **"Personal care items"** include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(60) **"pH"** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

(61) **"Physical facilities"** means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(62) **"Plumbing fixture"** means a receptacle or device that:

(a) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or

(b) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

(63) **"Plumbing system"** means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

(64) **"Poisonous or toxic materials"** means substances that are not intended for ingestion and are included in 4 categories:

(a) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) Pesticides, *except SANITIZERS*, which include substances such as insecticides and rodenticides;

(c) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and

(d) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.

(65) **Potentially Hazardous Food.**

(a) **"Potentially hazardous food"** means a FOOD that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

(i) The rapid and progressive growth of infectious or toxigenic microorganisms;

(ii) The growth and toxin production of ***Clostridium botulinum***; or

(iii) In raw shell EGGS, the growth of ***Salmonella* Enteritidis**.

(b) **"Potentially hazardous food"** includes an animal FOOD (a FOOD of animal origin) that is raw or heat-treated; a FOOD of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(c) **"*Potentially hazardous food*"** *does not include:*

(i) An air-cooled hard-boiled EGG with shell intact, or a shell EGG that is not hard-boiled, but has been treated to destroy all viable ***Salmonellae****;*

(ii) A FOOD with an a_w value of 0.85 or less;

(iii) A FOOD with a pH level of 4.6 or below when measured at 24°C (75°F);

(iv) A FOOD, in an unopened HERMETICALLY SEALED CONTAINER, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

(v) A FOOD for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of ***S.*** **Enteritidis** *in EGGS or* ***C. botulinum*** *can not occur, such as a FOOD that has an a_w and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or*

(vi) A FOOD that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the FOOD may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

(66) **Poultry.**

(a) **"Poultry"** means:

(i) Any domesticated bird (chickens, turkeys, ducks, geese, or guineas), whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations; and

(ii) Any migratory waterfowl, game bird, such as pheasant, partridge, quail, grouse, or guinea, or pigeon or squab, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Program.

(b) **"Poultry"** does not include ratites.

(67) **"Premises"** means:

(a) The physical facility, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or

(b) The physical facility, its contents, and the land or property not described under

Subparagraph (a) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(68) **"Primal cut"** means a basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(69) **"Public water system"** has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

(70) **Ready-to-Eat Food.**

(a) **"Ready-to-eat food"** means FOOD that:

(i) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under ¶ 3-401.11(A) – (C) or § 3-401.12 or 3-402.11; or

(ii) Is a raw or partially cooked animal FOOD and the consumer is advised as specified under Subparagraphs 3-401.11(D)(1) and (2); or

(iii) Is prepared in accordance with a variance that is granted as specified under Subparagraphs 3-401.11(D)(1) and (3); and

(iv) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(b) **"Ready-to-eat food"** includes:

(i) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

(ii) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(iii) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(iv) All POTENTIALLY HAZARDOUS FOOD that is cooked to the temperature and time required for the specific food under Subpart 3-401 and cooled as specified in § 3-501.14;

(v) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(vi) Substances derived from plants such as spices, seasonings, and sugar;

(vii) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;

(viii) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and

(ix) FOODS manufactured according to 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

(71) **Reduced Oxygen Packaging.**

(a) **"Reduced oxygen packaging"** means:

(i) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and

(ii) A process as specified in Subparagraph (a)(1) of this definition that involves a FOOD for which ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form.

(b) **"Reduced oxygen packaging"** includes:

(i) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE, such as sous vide;

(ii) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen; and

(iii) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained,

such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(72) **"Refuse"** means solid waste not carried by water through the SEWAGE system.

(73) **"Regulatory authority"** means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

(74) **"Restrict"** means to limit the activities of a FOOD EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through FOOD and the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS; and unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

(75) **"Restricted egg"** means any check, dirty EGG, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

(76) **"Restricted use pesticide"** means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(77) **"Risk"** means the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

(78) **"Safe material"** means:

(a) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any FOOD;

(b) An additive that is used as specified in § 409 or 706 of the Federal Food, Drug, and Cosmetic Act; or

(c) Other materials that are not ADDITIVES and that are used in conformity with applicable regulations of the Food and Drug Administration.

(79) **"Sanitization"** means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

(80) **"Sealed"** means free of cracks or other openings that allow the entry or passage of moisture.

(81) **"Service animal"** means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

(82) **"Servicing area"** means an operating base location to which a mobile FOOD ESTABLISHMENT or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding FOOD.

(83) **"Sewage"** means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(84) **"Shellfish control authority"** means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and dealers for interstate commerce.

(85) **"Shellstock"** means raw, in-shell MOLLUSCAN SHELLFISH.

(86) **"Shiga toxin-producing *Escherichia coli*"** means any ***E. coli*** capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins). This includes, but is not limited to, ***E. coli*** reported as serotype O157:H7, O157:NM, and O157:H-.

(87) **"Shucked shellfish"** means MOLLUSCAN SHELLFISH that have one or both shells removed.

(88) **"Single-service articles"** means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

(89) **Single-Use Articles.**

(a) **"Single-use articles"** means UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded.

(b) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

(90) **"Slacking"** means the process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as spinach.

(91) **"Smooth"** means:

(a) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(b) A nonFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(92) **"Table-mounted equipment"** means EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(93) **"Tableware"** means eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(94) **"Temperature measuring device"** means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

(95) **"Temporary food establishment"** means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

(96) **"USDA"** means the U.S. Department of Agriculture.

(97) **"Utensil"** means a FOOD-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

(98) **"Variance"** means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

(99) **"Vending machine"** means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

(100) **"Vending machine location"** means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

(101) **"Warewashing"** means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

(102) **"Whole-muscle, intact beef"** means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Chapter

2 Management and Personnel

Parts

2-1 SUPERVISION

Subparts

Responsibility

2-101.11 Assignment.*

The PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.

Knowledge

2-102.11 Demonstration.*

Based on the RISKS of foodborne illness inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code;

(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM; or

(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;

(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;

(3) Describing the symptoms associated with the diseases that are transmissible through FOOD;

(4) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD and the prevention of foodborne illness;

(5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH;

(6) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD including MEAT, POULTRY, EGGS, and FISH;

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD;

(8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(a) Cross contamination,

(b) Hand contact with READY-TO-EAT FOODS,

(c) Handwashing, and

(d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair;

(9) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:

(a) Sufficient in number and capacity, and

(b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

(10) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;

(11) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

(12) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW;

(13) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;

(14) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the establishment; and

(15) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE,

(b) PERSON IN CHARGE, and

(c) REGULATORY AUTHORITY.

Duties **2-103.11 Person in Charge.**

The PERSON IN CHARGE shall ensure that:

(A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111;

(B) PERSONS unnecessary to the FOOD ESTABLISHMENT operation are not allowed in the FOOD preparation, FOOD storage, or WAREWASHING areas, except that brief visits and tours may be authorized by the PERSON IN CHARGE if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination;

(C) EMPLOYEES and other PERSONS such as delivery and maintenance PERSONS and pesticide applicators entering the FOOD preparation, FOOD storage, and WAREWASHING areas comply with this Code;

(D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing;

(E) EMPLOYEES are visibly observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from contamination, unADULTERATED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt;

(F) EMPLOYEES are properly cooking POTENTIALLY HAZARDOUS FOOD, being particularly careful in cooking those FOODS known to cause severe foodborne illness and death, such as EGGS and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B);

(G) EMPLOYEES are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling;

(H) CONSUMERS who order raw or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;

(I) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING;

(J) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;

(K) Except when otherwise approved as specified in ¶ 3-301.11(B), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT; and

(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties.

2-2 EMPLOYEE HEALTH

Subpart

2-201 Disease or Medical Condition

Disease or Medical Condition
employer requires employee reporting of:

2-201.11 Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants.*

The PERMIT HOLDER shall require FOOD EMPLOYEE applicants to whom a conditional offer of employment is made and FOOD EMPLOYEES to report to the PERSON IN CHARGE, information about their health and

activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or applicant shall report the information in a manner that allows the PERSON IN CHARGE to prevent the likelihood of foodborne disease transmission, including the date of onset of jaundice or of an illness specified under ¶ (C) of this section, if the FOOD EMPLOYEE or applicant:

health status

employee is ill

(A) Is diagnosed with an illness due to:

(1) ***Salmonella* Typhi**,

(2) ***Shigella*** spp.,

(3) SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, or

(4) Hepatitis A virus;

employee has symptom of:

(B) Has a symptom caused by illness, infection, or other source that is:

• *intestinal illness*

(1) Associated with an acute gastrointestinal illness such as:

(a) Diarrhea,

(b) Fever,

(c) Vomiting,

(d) Jaundice, or

(e) Sore throat with fever, or

• *Boil or infected wound*

(2) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(a) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,

(b) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover*, or

employee previously ill

(c) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage*;

(C) Had a past illness from:

(1) ***S.* Typhi** within the past three months,

(2) ***Shigella*** spp. within the past month,

(3) SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, within the past month; or

(4) Hepatitis A virus;

activities

(D) Meets one or more of the following high-RISK conditions:

employee at high risk of becoming ill:
• prepared or consumed food that caused disease

(1) Is suspected of causing, or being exposed to, a CONFIRMED DISEASE OUTBREAK caused by ***S***. **Typhi**, ***Shigella*** spp., SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, or hepatitis A virus including an outbreak at an event such as a family meal, church supper, or festival because the FOOD EMPLOYEE or applicant:

(a) FOOD implicated in the outbreak,

(b) Consumed FOOD implicated in the outbreak, or

(c) Consumed FOOD at the event prepared by a PERSON who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent,

• lives with ill person

(2) Lives in the same household as, and has knowledge about, a PERSON who is diagnosed with a disease caused by ***S***. **Typhi**, ***Shigella*** spp., SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, or hepatitis A virus, or

• lives with person involved in disease outbreak

(3) Lives in the same household as, and has knowledge about, a PERSON who attends or works in a setting where there is a confirmed disease outbreak caused by ***S.* Typhi**, ***Shigella*** spp., SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, or hepatitis A virus.

2-201.12 Exclusions and Restrictions.*

The PERSON IN CHARGE shall:

excluding ill employees

(A) EXCLUDE a FOOD EMPLOYEE from a FOOD ESTABLISHMENT if the FOOD EMPLOYEE is diagnosed with an infectious agent specified under ¶ 2-201.11(A);

restricting employees: (serving general population)

(B) Except as specified under ¶ (C) or (D) of this section, RESTRICT a FOOD EMPLOYEE from working with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES, in a FOOD ESTABLISHMENT if the FOOD EMPLOYEE is:

• with symptom of illness or

(1) Suffering from a symptom specified under ¶ 2-201.11(B)(1)(a), (b), (c), and (e), or

of past illness

(2) Not experiencing a symptom of acute gastroenteritis specified under Subparagraph 2-201.11(B)(1) but has a stool that yields a specimen culture that is positive for ***Salmonella* Typhi**, ***Shigella*** spp., or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI;***

excluding employees: (serving high-risk population)

(C) If the population served is a HIGHLY SUSCEPTIBLE POPULATION, EXCLUDE a FOOD EMPLOYEE who:

• with symptom of illness or

(1) Is experiencing a symptom of acute gastrointestinal illness specified under Subparagraph 2-201.11(B)(1)(a), (b), (c), or (e) and meets a high-RISK condition specified under Subparagraphs 2-201.11(D)(1)-(3),

of past illness

(2) Is not experiencing a symptom of acute gastroenteritis specified under Subparagraph 2-201.11(B)(1) but has a stool that yields a specimen culture that is positive for ***S*. Typhi**, ***Shigella*** spp., or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI*** ,

(3) Had a past illness from ***S*. Typhi** within the last 3 months, or

(4) Had a past illness from ***Shigella*** spp. or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI*** within the last month; and

excluding and restricting jaundiced employees

(D) For a FOOD EMPLOYEE who is jaundiced:

(1) If the onset of jaundice occurred within the last 7 calendar days, EXCLUDE the FOOD EMPLOYEE from the FOOD ESTABLISHMENT, or

(2) If the onset of jaundice occurred more than 7 calendar days before:

(a) Exclude the food employee from a food establishment that serves a highly susceptible population, or

(b) RESTRICT the FOOD EMPLOYEE from activities specified under ¶ 2-201.12(B), if the FOOD ESTABLISHMENT does not serve a HIGHLY SUSCEPTIBLE POPULATION.

2-201.13 Removal of Exclusions and Restrictions.

*reinstating an **excluded** employee who is:*

(A) The PERSON IN CHARGE may remove an EXCLUSION specified under ¶ 2-201.12(A) if:

(1) The PERSON IN CHARGE obtains approval from the REGULATORY AUTHORITY; and

(2) The PERSON EXCLUDED as specified under ¶ 2-201.12(A) provides to the PERSON IN CHARGE written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, that specifies that the EXCLUDED PERSON may work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT, including an establishment that serves a HIGHLY SUSCEPTIBLE POPULATION, because the PERSON is free of the infectious agent of concern as specified in § 8-501.40.

- *no longer ill*

or

- *free of jaundice*

reinstating a restricted employee who is

(B) The PERSON IN CHARGE may remove a RESTRICTION specified under:

- *free of symptoms*

(1) Subparagraph 2-201.12(B)(1) if the RESTRICTED PERSON:

(a) Is free of the symptoms specified under ¶ 2-201.11(B)(1)(a), (b), (c), or (e) or (2) and no foodborne illness occurs that may have been caused by the RESTRICTED PERSON,

(b) Is suspected of causing foodborne illness but:

(i) Is free of the symptoms specified under ¶ 2-201.11(B)(1)(a), (b), (c), or (e) or (2), and

• free of suspected infectious agent

(ii) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, stating that the RESTRICTED PERSON is free of the infectious agent that is suspected of causing the PERSON'S symptoms or causing foodborne illness, as specified in § 8-501.40, or

• has symptoms that are not caused by an infectious agent

(c) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis; or

• no longer a shedder

(2) Subparagraph 2-201.12(B)(2) if the RESTRICTED PERSON provides written medical documentation from a physician, licensed to practice medicine, or, if allowed by LAW, a nurse practitioner or physician assistant, according to the criteria specified in § 8-501.40 that indicates the stools are free of ***Salmonella* Typhi**, ***Shigella*** spp., or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, whichever is the infectious agent of concern.

reinstating an excluded employee serving: high-risk population

(C) The PERSON IN CHARGE may remove an EXCLUSION specified under ¶ 2-201.12(C) if the EXCLUDED PERSON provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant:

(1) That specifies that the PERSON is free of the infectious agent of concern as specified in § 8-501.40, or

(2) If the PERSON is EXCLUDED under Subparagraph 2-201.12(C)(1), stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.

reinstating an employee who is:

(D) The PERSON IN CHARGE may remove an EXCLUSION specified under Subparagraph 2-201.12(D)(1) and Subparagraph 2-201.12(D)(2)(a) and a RESTRICTION specified under Subparagraph 2-201.12(D)(2)(b) if:

• not suspect source of illness

(1) No foodborne illness occurs that may have been caused by the EXCLUDED or RESTRICTED PERSON and the PERSON provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, that specifies that the PERSON is free of hepatitis A virus as specified in Subparagraph 8-501.40(D)(1); or

• suspect source of illness

(2) The EXCLUDED or RESTRICTED PERSON is suspected of causing foodborne illness and complies with the requirements in Subparagraphs 8-501.40(D)(1) and (D)(2).

2-201.14 Responsibility of a Food Employee or an Applicant to Report to the Person in Charge.*

A FOOD EMPLOYEE or a PERSON who applies for a job as a FOOD EMPLOYEE shall:

(A) In a manner specified under § 2-201.11, report to the PERSON IN CHARGE the information specified under ¶¶ 2-201.11(A)-(D); and

(B) Comply with EXCLUSIONS and RESTRICTIONS that are specified under ¶¶ 2-201.12(A)-(D).

2-201.15 Reporting by the Person in Charge.*

The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY that a FOOD EMPLOYEE is diagnosed with an illness due to ***Salmonella* Typhi**, ***Shigella*** spp., SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI***, or hepatitis A virus.

2-3 PERSONAL CLEANLINESS

Subparts

Hands and Arms

2-301.11 Clean Condition.*

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.

2-301.12 Cleaning Procedure.*

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms (or surrogate prosthetic devices for hands or arms) for at least 20 seconds, using a cleaning compound in a lavatory that is equipped as specified under § 5-202.12.

(B) FOOD EMPLOYEES shall use the following cleaning procedure:

(1) Vigorous friction on the surfaces of the lathered fingers, finger tips, areas between the fingers, hands and arms (or by vigorously rubbing the surrogate prosthetic devices for hands or arms) for at least 10 to 15 seconds, followed by;

(2) Thorough rinsing under clean, running warm water; and

(3) Immediately follow the cleaning procedure with thorough drying of cleaned hands and arms (or surrogate prosthetic devices) using a method as specified under § 6-301.12.

(C) FOOD EMPLOYEES shall pay particular attention to the areas underneath the fingernails during the cleaning procedure.

(D) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, an automatic handwashing facility may be used by food employees to clean their hands.*

2-301.13 Special Handwash Procedures.*

Reserved.

2-301.14 When to Wash.*

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms;

(B) After using the toilet room;

(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in ¶ 2-403.11(B);
(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;

(E) After handling soiled EQUIPMENT or UTENSILS;

(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;

(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD;

(H) Before donning gloves for working with FOOD; and

(I) After engaging in other activities that contaminate the hands.

2-301.15 Where to Wash.

FOOD EMPLOYEES shall clean their hands in a handwashing lavatory or APPROVED automatic handwashing facility and may not clean their hands in a sink used for FOOD preparation or WAREWASHING, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

2-301.16 Hand Sanitizers.

(A) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:

(1) Comply with one of the following:

(a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness; or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, or

(2) Comply with one of the following:

(a) Have components that are exempted from the requirement of being listed in federal FOOD ADDITIVE regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles; or

(b) Comply with and be listed in:

(i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a FOOD ADDITIVE with conditions of safe use, or

(ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with FOOD; and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12.

(B) If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with FOOD or by the use of gloves; or

(2) Limited to situations that involve no direct contact with FOOD by the bare hands.

(C) A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine.

Fingernails **2-302.11 Maintenance.**

(A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(B) *Unless wearing intact gloves in good repair*, a FOOD EMPLOYEE may not wear fingernail polish or artificial fingernails when working with exposed FOOD.

Jewelry **2-303.11 Prohibition.**

While preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms and hands. *This section does not apply to a plain ring such as a wedding band.*

Outer Clothing **2-304.11 Clean Condition.**

FOOD EMPLOYEES shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-4 HYGIENIC PRACTICES

Subparts

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.*

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.

(B) *A FOOD EMPLOYEE may drink from a closed BEVERAGE container if the container is handled to prevent contamination of:*

(1) *The EMPLOYEE'S hands;*

(2) *The container; and*

(3) *Exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.*

2-401.12 Discharges from the Eyes, Nose, and Mouth.*

FOOD EMPLOYEES experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

Hair Restraints

2-402.11 Effectiveness.

(A) Except as provided in ¶ (B) of this section, FOOD EMPLOYEES shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *This section does not apply to* FOOD EMPLOYEES *such as counter staff who only serve* BEVERAGES *and wrapped or* PACKAGED *FOODS, hostesses, and wait staff if they present a minimal* RISK *of contaminating exposed* FOOD*; clean* EQUIPMENT, UTENSILS, *and* LINENS*; and unwrapped* SINGLE-SERVICE *and* SINGLE-USE ARTICLES.

Animals

2-403.11 Handling Prohibition.*

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES may not care for or handle animals that may be present such as patrol dogs, SERVICE ANIMALS, or pets that are allowed as specified in Subparagraphs 6-501.115(B)(2)-(5).

(B) *F*OOD EMPLOYEES *with* SERVICE ANIMALS *may handle or care for their* SERVICE ANIMALS *and* FOOD EMPLOYEES *may handle or care for* FISH *in aquariums or* MOLLUSCAN SHELLFISH *or crustacea in display tanks if they wash their hands as specified under § 2-301.12 and ¶ 2-301.14(C).*

Chapter

3 Food

Parts

3-1 CHARACTERISTICS

Subparts

3-101 Condition

Condition

3-101.11 Safe, Unadulterated, and Honestly Presented.*

FOOD shall be safe, unADULTERATED, and, as specified under § 3-601.12, honestly presented.

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

Subparts

Sources

3-201.11 Compliance with Food Law.*

(A) FOOD shall be obtained from sources that comply with LAW.

(B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.

(C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.

(D) *Fish, other than MOLLUSCAN SHELLFISH, that are intended for consumption in their raw form and allowed as specified in Subparagraph 3-401.11(C)(1) may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(C) shall be:

(1) Obtained from a FOOD PROCESSING PLANT that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF, or

(2) Deemed acceptable by the REGULATORY AUTHORITY based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF, and

(3) If individually cut in a FOOD ESTABLISHMENT:

(a) Cut from WHOLE-MUSCLE INTACT BEEF that is labeled by a FOOD PROCESSING PLANT as specified in Subparagraph (1) or identified as specified in Subparagraph (2) of this section,

(b) Prepared so they remain intact, and

(c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled as specified in Subparagraph (1) or identified as specified in (2) of this section.

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(G) Shell EGGS that have not been specifically treated to destroy all viable ***Salmonellae*** shall be labeled to include safe handling instructions as specified in LAW, including 21 CFR 101.17(h).

3-201.12 Food in a Hermetically Sealed Container.*

FOOD in a HERMETICALLY SEALED CONTAINER shall be obtained from a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

3-201.13 Fluid Milk and Milk Products.*

Fluid milk and milk products shall be obtained from sources that comply with GRADE A STANDARDS as specified in LAW.

3-201.14 Fish.*

(A) FISH that are received for sale or service shall be:

(1) Commercially and legally caught or harvested; or

(2) APPROVED for sale or service.

(B) MOLLUSCAN SHELLFISH that are recreationally caught may not be received for sale or service.

3-201.15 Molluscan Shellfish.*

(A) MOLLUSCAN SHELLFISH shall be obtained from sources according to LAW and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(B) MOLLUSCAN SHELLFISH received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

3-201.16 Wild Mushrooms.*

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identification expert.

(B) *This section does not apply to:*

(1) *Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or*

(2) *Wild mushroom species if they are in PACKAGED form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.*

3-201.17 Game Animals.*

(A) If GAME ANIMALS are received for sale or service they shall be:

(1) Commercially raised for food and:

(a) Raised slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, and
(c) Raised, slaughtered, and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee;

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" in accordance with 9 CFR 352 Voluntary Exotic Animal Program or rabbits that are "inspected and certified" in accordance with 9 CFR 354 Rabbit Inspection Program;

(3) As allowed by LAW, for wild GAME ANIMALS that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, and

(b) Slaughtered and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee; or

(4) As ALLOWED by LAW, for field-dressed wild GAME ANIMALS under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an APPROVED veterinarian or veterinarian's designee, or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(c) Are processed according to LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

Specifications for Receiving

3-202.11 Temperature.*

(A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD shall be at a temperature of 5°C (41°F) or below when received.

(B) *If a temperature other than 5°C (41°F) for A POTENTIALLY HAZARDOUS FOOD is specified in LAW governing its distribution, such as LAWS governing milk and MOLLUSCAN SHELLFISH, the FOOD may be received at the specified temperature. .*

(C) Raw shell EGGS shall be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

(D) POTENTIALLY HAZARDOUS FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 60°C (140°F) or above.
(E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.

(F) Upon receipt, POTENTIALLY HAZARDOUS FOOD shall be free of evidence of previous temperature abuse.

3-202.12 Additives.*

FOOD may not contain unAPPROVED FOOD ADDITIVES or ADDITIVES that exceed amounts specified in 21 CFR 170-180 relating TO FOOD ADDITIVES, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

3-202.13 Shell Eggs.*

Shell EGGS shall be received clean and sound and may not exceed the RESTRICTED EGG tolerances for U.S. CONSUMER Grade B as specified in 7 CFR Part 56 – Voluntary Grading of Shell Eggs and United States Standards, Grades, and Weight Classes for Shell Eggs, and 9 CFR Part 590 – Inspection of Eggs and Egg Products.

3-202.14 Eggs and Milk Products, Pasteurized.*

(A) Liquid, frozen, and dry EGGS and EGG products shall be obtained pasteurized.

(B) Fluid and dry milk and milk products complying with GRADE A STANDARDS as specified in LAW shall be obtained pasteurized.

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen Desserts.

(D) Cheese shall be obtained pasteurized *unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and Related Cheese Products, for curing certain cheese varieties.*

3-202.15 Package Integrity.*

FOOD packages shall be in good condition and protect the integrity of the contents so that the FOOD is not exposed to ADULTERATION or potential contaminants.

3-202.16 Ice.*

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER.

3-202.17 Shucked Shellfish, Packaging and Identification.

(A) Raw SHUCKED SHELLFISH shall be obtained in nonreturnable packages which bear a legible label that identifies the:

(1) Name, address, and CERTIFICATION NUMBER of the shucker-packer or repacker of the MOLLUSCAN SHELLFISH; and

(2) The "sell by" date for packages with a capacity of less than 1.87 L (one-half gallon) or the date shucked for packages with a capacity of 1.87 L (one-half gallon) or more.

(B) A package of raw SHUCKED SHELLFISH that does not bear a label or which bears a label which does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

3-202.18 Shellstock Identification.*

(A) SHELLSTOCK shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:

(1) Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order:

(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The date of harvesting,

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested,

(d) The type and quantity of shellfish, and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days;" and

(2) Except as specified in ¶ (D) of this section, on each dealer's tag or label, the following information in the following order:

(a) The dealer's name and address, and the CERTIFICATION

NUMBER assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The original shipper's CERTIFICATION NUMBER including the abbreviation of the name of the state or country in which the shellfish are harvested,

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."

(B) A container of SHELLSTOCK that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a dealer's name, address, and CERTIFICATION NUMBER, the dealer's information shall be listed first.

(D) *If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual dealer tags or labels need not be provided.*

3-202.19 Shellstock, Condition.

When received by a FOOD ESTABLISHMENT, SHELLSTOCK shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or SHELLSTOCK with badly broken shells shall be discarded.

3-202.110 Juice Treated.

Pre-PACKAGED JUICE shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120;

(B) Be obtained pasteurized or otherwise treated to attain a 5-log

reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24; or

(C) Bear a warning label as specified in 21 CFR Section 101.17(g).

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) and (C) of this section, MOLLUSCAN SHELLFISH may not be removed from the container in which they are received other than immediately before sale or preparation for service.

Original Containers and Records

(B) *For display purposes, SHELLSTOCK may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a CONSUMER may be removed from the display or display container and provided to the CONSUMER if:*

(1) *The source of the SHELLSTOCK on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and*

(2) *The SHELLSTOCK are protected from contamination.*

(C) *SHUCKED SHELLFISH may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a CONSUMER'S request if:*

(1) *The labeling information for the shellfish on display as specified under § 3-202.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and*

(2) *The shellfish are protected from contamination.*

3-203.12 Shellstock, Maintaining Identification.*

(A) Except as specified under Subparagraph (B)(2) of this section, SHELLSTOCK tags shall remain attached to the container in which the shellstock are received until the container is empty.

(B) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date the container is emptied by:

(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the SHELLSTOCK are sold or served; and

(2) If SHELLSTOCK are removed from their tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under Subparagraph (B)(1) of this section, and

(b) Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container before being ordered by the consumer.

Clarification of ¶ 3-301.11(B) of the Food Code

with respect to the phrase "*Except...when otherwise APPROVED*"...

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

In response to a 1996 Conference for Food Protection (CFP) Recommendation that ¶ 3-301.11(B) be modified to include the phrase "or when otherwise APPROVED," the 1997 Code was amended accordingly. A 1998 CFP Recommendation further suggested clarification of that added language.

This insert page is provided to alert the reader that FDA has issued, with this Code, clarification of that phrase and its application. Included in Annex 3 is a full discussion of both the Public Health Reasons associated with § 3-301.11 and Administrative Guidelines regarding the criteria under which bare hand contact with ready-to-eat food may be deemed acceptable in meeting the intent of § 3-301.11.

A HACCP-based approach is applied in the clarification in order to establish a system to control the principal hazard (i.e., fecal-oral transmission of foodborne pathogens) that is the target of the Code provision.

A second 1998 CFP Recommendation was made to consult the National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) for its scientific recommendations surrounding the transmission of pathogens from food workers to consumers via ready-to-eat foods.

In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods reported that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and they agreed that the transmission could be interrupted. The NACMCF found that science does not support an absolute ban at this time on bare hand contact of ready-to-eat food, and it is the Agency's position that NACMCF's recommendation is in harmony with the Food Code.

- The Food Code does not provide a blanket prohibition to "Bare Hand Contact with Ready-to-Eat Foods."

- The guidance for "*when otherwise approved*" is provided in the Annex for situations where bare hand contact with ready-to-eat foods is deemed necessary by the retail food establishment *(Annex 3, 1999 Food Code, p.266).*

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

Subparts

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under § 3-302.15 or when otherwise APPROVED*, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.

(C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.[S]

3-301.12 Preventing Contamination When Tasting.*

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.*

(A) FOOD shall be protected from cross contamination by:

(1) Separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as vegetables, and

(b) Cooked READY-TO-EAT FOOD;

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, and

(c) Preparing each type of FOOD at different times or in separate areas;

(3) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received PACKAGED together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) *Subparagraph (A)(4) of this section does not apply to:*

(1) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

(2) *PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon that are hung on clean, SANITIZED hooks or placed on clean, SANITIZED racks;*

(3) *Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages that are placed on clean, SANITIZED racks;*

(4) *FOOD being cooled as specified under Subparagraph 3-501.15(B)(2); or*

(5) *SHELLSTOCK*.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD *except that containers holding FOOD that can be readily and unmistakably recognized such as dry pasta need not be identified*.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Pasteurized EGGS or EGG products shall be substituted for raw shell EGGS in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and EGG-fortified BEVERAGES that are not:

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or

(B) Included in ¶ 3-401.11(D).

3-302.14 Protection from Unapproved Additives.*

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES; and

(2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES.

(B) A FOOD EMPLOYEE may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B_1; or

(2) Serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT, *except that grapes need not meet this subparagraph*.

3-302.15 Washing Fruits and Vegetables.

(A) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form except as specified in ¶ (B) of this section and *except that whole, raw fruits and vegetables that are intended for washing by the CONSUMER before consumption need not be washed before they are sold*.

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD.

3-303.12 Storage or Display of Food in Contact with Water or Ice.

(A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(B) Except as specified in ¶¶ (C) and (D) of this section, unPACKAGED FOOD may not be stored in direct contact with undrained ice.

(C) *Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.*

(D) *Raw chicken and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.*

Preventing Contamination from Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

FOOD shall only contact surfaces of EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code.

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

(A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;

(B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;

(E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or

(F) In a container of water if the water is maintained at a temperature of at least 60°C (140°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 Linens and Napkins, Use Limitation.

LINENS and napkins may not be used in contact with FOOD *unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER*.

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths that are in use for wiping FOOD spills shall be used for no other purpose.

(B) Cloths used for wiping FOOD spills shall be:

(1) Dry and used for wiping FOOD spills from TABLEWARE and carry-out containers; or

(2) Wet and cleaned as specified under ¶ 4-802.11(D), stored in a chemical sanitizer at a concentration specified in § 4-501.114, and used for wiping spills from FOOD-CONTACT and nonFOOD-CONTACT SURFACES of EQUIPMENT.

(C) Dry or wet cloths that are used with raw animal FOODS shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal FOODS shall be kept in a separate sanitizing solution.

(D) Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of FOOD debris and visible soil.

3-304.15 Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

(C) *Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove, or a SINGLE-USE glove*.

(D) Cloth gloves may not be used in direct contact with FOOD *unless the FOOD is subsequently cooked as required under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT*.

3-304.16 Using Clean Tableware for Second Portions and Refills.

(A) Except for refilling a CONSUMER'S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container, FOOD EMPLOYEES may not use TABLEWARE, including SINGLE-SERVICE ARTICLES, soiled by the CONSUMER, to provide second portions or refills.

(B) Except as specified in ¶ (C) of this section, self-service CONSUMERS may not be allowed to use soiled TABLEWARE, including SINGLE-SERVICE ARTICLES, to obtain additional FOOD from the display and serving EQUIPMENT.

(C) *Drinking cups and containers may be reused by self-service CONSUMERS if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D)*.

3-304.17 Refilling Returnables.

(A) A take-home FOOD container returned to a FOOD ESTABLISHMENT may not be refilled at a FOOD ESTABLISHMENT with a POTENTIALLY HAZARDOUS FOOD.

(B) Except as specified in ¶ (C), a take-home FOOD container refilled with FOOD that is not POTENTIALLY HAZARDOUS shall be cleaned as specified under ¶ 4-603.17(B).

(C) *Personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D)*.

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (B) and (C) of this section, FOOD shall be protected from contamination by storing the FOOD:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) *FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling EQUIPMENT as specified under § 4-204.122*.

(C) *Pressurized BEVERAGE containers, cased FOOD in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture*.

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

(A) In locker rooms;

(B) In toilet rooms;

(C) In dressing rooms;

(D) In garbage rooms;

(E) In mechanical rooms;

(F) Under sewer lines that are not shielded to intercept potential drips;

(G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(H) Under open stairwells; or

(I) Under other sources of contamination.

3-305.13 Vended Potentially Hazardous Food, Original Container.

POTENTIALLY HAZARDOUS FOOD dispensed through a VENDING MACHINE shall be in the package in which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

3-305.14 Food Preparation.

During preparation, unPACKAGED FOOD shall be protected from environmental sources of contamination.

Preventing Contamination by Consumers

3-306.11 Food Display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption, FOOD on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar FOOD guards; display cases; or other effective means.

3-306.12 Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected FOOD displays provided with the proper UTENSILS, original containers designed for dispensing, or individual packages or portions.

(B) Condiments at a VENDING MACHINE LOCATION shall be in individual packages or provided in dispensers that are filled at an APPROVED location, such as the FOOD ESTABLISHMENT that provides FOOD to the VENDING MACHINE LOCATION, a FOOD PROCESSING PLANT that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the VENDING MACHINE LOCATION.

3-306.13 Consumer Self-Service Operations.*

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. *This paragraph does not apply to CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish; ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked* MEATS *or CONSUMER-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster*.

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from contamination.[N]

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures.[N]

3-306.14 Returned Food and Reservice of Food.*

(A) Except as specified in ¶ (B) of this section, after being served or sold and in the possession of a CONSUMER, FOOD that is unused or returned by the CONSUMER may not be offered as FOOD for human consumption.

(B) Except as specified under ¶ 3-801.11(C), *a container of FOOD that is not POTENTIALLY HAZARDOUS may be transferred from one CONSUMER to another if:*

(1) *The FOOD is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or*

(2) *The FOOD, such as crackers, salt, or pepper, is in an unopened original PACKAGE and is maintained in sound condition*.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

Cooking

3-401.11 Raw Animal Foods.*

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal FOODS such as EGGS, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw shell EGGS that are broken and prepared in response to a CONSUMER'S order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (3) and ¶ (B) of this section, FISH, MEAT, and pork including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section:

Minimum

Temperature °C (°F)	Time
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for POULTRY, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed ratites, or stuffing containing FISH, MEAT, POULTRY, or ratites.

(B) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham, shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity[1]	121°C (250°F) or less	121°C (250°F) or less

[1] Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

;and

(2) As specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature:

Temperature °C (°F)	Time[1] in Minutes	Temperature °C (°F)	Time[1] in Seconds
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		
[1]*Holding time may include postoven heat rise*.			

(C) *A raw or undercooked* WHOLE-MUSCLE, INTACT BEEF *steak may be served or offered for sale in a* READY-TO-EAT *form if:*

(1) *The* FOOD ESTABLISHMENT *serves a population that is not a* HIGHLY SUSCEPTIBLE POPULATION,

(2) *The steak is labeled to indicate that it meets the definition of "*WHOLE-MUSCLE, INTACT BEEF*" as specified under ¶ 3-201.11(E), and*

(3) *The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.*

(D) *A raw animal* FOOD *such as raw* EGG, *raw* FISH, *raw-marinated* FISH, *raw* MOLLUSCAN SHELLFISH, *or steak tartare; or a partially cooked* FOOD *such as lightly cooked* FISH, *soft cooked* EGGS, *or rare* MEAT *other than* WHOLE-MUSCLE, INTACT BEEF *steaks as specified in ¶ (C) of this section, may be served or offered for sale in a* READY-TO-EAT *form if:*

(1) *The* FOOD ESTABLISHMENT *serves a population that is not a* HIGHLY SUSCEPTIBLE POPULATION, *and*

(2) *The CONSUMER is informed as specified under § 3-603.11 that to ensure its safety, the FOOD should be cooked as specified under ¶ (A) or (B) of this section; or*

(3) *The REGULATORY AUTHORITY grants a VARIANCE from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP PLAN that:*

(a) *Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,*

(b) *Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe FOOD, and*

(c) *Verifies that EQUIPMENT and procedures for FOOD preparation and training of FOOD EMPLOYEES at the FOOD ESTABLISHMENT meet the conditions of the VARIANCE.*

3-401.12 Microwave Cooking.*

Raw animal FOODS cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and

(D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F).

Freezing

3-402.11 Parasite Destruction.*

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH other than MOLLUSCAN SHELLFISH shall be:

(1) Frozen and stored at a temperature of -20°C (-4°F) or below for 168 hours (7 days) in a freezer; or

(2) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) for 15 hours.

(B) *If the fish are tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern), the FISH may be served or sold in a raw, raw-marinated, or partially cooked READY-TO-EAT form without freezing as specified under ¶ (A) of this section.*

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, the PERSON IN CHARGE shall record the freezing temperature and time to which the FISH are subjected and shall retain the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.

(B) *If the FISH are frozen by a supplier, a written agreement or statement from the supplier stipulating that the FISH supplied are frozen to a temperature and for a time specified under § 3-402.11 may substitute for the records specified under ¶ (A) of this section.*

Reheating

3-403.10 Preparation for Immediate Service.

Cooked and refrigerated FOOD that is prepared for immediate service in response to an individual CONSUMER order, such as a roast beef sandwich au jus, may be served at any temperature.

3-403.11 Reheating for Hot Holding.*

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

(B) Except as specified under ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

(C) READY-TO-EAT FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD PROCESSING PLANT that is inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 60°C (140°F) for hot holding.

(D) Reheating for hot holding shall be done rapidly and the time the FOOD is between the temperature specified under ¶ 3-501.16(A)(2) and 74°C (165°F) may not exceed 2 hours.

(E) *Remaining unsliced portions of roasts of beef that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

Other Methods

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.12(B) – (E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:

(1) As specified under § 3-602.11, and

(2) As specified in 21 CFR 101.17(g) with the phrase, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-501 Temperature and Time Control
3-502 Specialized Processing Methods

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Potentially Hazardous Food, Slacking.

Frozen POTENTIALLY HAZARDOUS FOOD that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(A)(2)(b); or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, POTENTIALLY HAZARDOUS FOOD shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(A)(2)(b); or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) *Using any procedure if a portion of frozen READY-TO-EAT FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.*

3-501.14 Cooling.*

(A) Cooked POTENTIALLY HAZARDOUS FOOD shall be cooled:

(1) Within 2 hours from 60ºC (140ºF) to 21ºC (70°F); and

(2) Within 6 hours from 60ºC (140ºF) to 5ºC (41°F) or less, or to 7ºC (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).

(B) POTENTIALLY HAZARDOUS FOOD shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

(C) Except as specified in ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16(A)(2)(b).

(D) Raw shell EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

(1) Placing the FOOD in shallow pans;

(2) Separating the FOOD into smaller or thinner portions;

(3) Using rapid cooling EQUIPMENT;

(4) Stirring the FOOD in a container placed in an ice water bath;

(5) Using containers that facilitate heat transfer;

(6) Adding ice as an ingredient; or

(7) Other effective methods.

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

(1) Arranged in the EQUIPMENT to provide maximum heat transfer

through the container walls; and

(2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

(A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-501.19,* and except as specified in ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD shall be maintained:

(1) At 60°C (140°F) or above, *except that roasts cooked to a temperature and for a time specified under ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F)*; or

(2) At a temperature and time specified in the following:

(a) At 5°C (41°F) or less for a maximum of 7 days; or

(b) At 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) for a maximum of 4 days in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:

(i) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and

(ii) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

(B) Shell EGGS that have not been treated to destroy all viable **Salmonellae** shall be stored in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*

on-premises preparation
• prepare and hold cold

(A) Except as specified in ¶ (D) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ 3-501.16(A)(2). The day of preparation shall be counted as Day 1.

commercially processed food
• open and hold cold

(B) Except as specified in ¶¶ (D) and (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ 3-501.16(A)(2); and

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1; and

(2) The day or date marked by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.

(C) A refrigerated, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine, may be marked as specified in ¶ (A) or (B) of this section, or by an alternative method acceptable to the REGULATORY AUTHORITY.

(D) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or rePACKAGED for sale from a bulk container upon a consumer's request.

(E) Paragraph (B) of this section does not apply to the following when the face has been cut, but the remaining portion is whole and intact:

(1) Fermented sausages produced in a federally inspected FOOD PROCESSING PLANT that are not labeled "Keep Refrigerated" and which retain the original CASING on the product;

(2) Shelf stable, dry, fermented sausages; and

(3) Shelf stable salt-cured products such as prosciutto and Parma (ham) produced in a federally inspected FOOD PROCESSING PLANT that are not labeled “Keep Refrigerated”.

(F) A refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD ingredient or a portion of a refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest-prepared or first-prepared ingredient.

3-501.18 Ready-to-Eat, Potentially Hazardous Food, Disposition.*

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(1) Exceeds either of the temperature and time combinations specified in ¶ 3-501.16(A)(2), except time that the product is frozen;

(2) Is in a container or PACKAGE that does not bear a date or day; or

(3) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in ¶ 3-501.16(A)(2).

(B) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in ¶ 3-501.16(A)(2).

3-501.19 Time as a Public Health Control.*

(A) Except as specified under ¶ (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is displayed or held for service for immediate consumption:

(1) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control,

(2) The FOOD shall be cooked and served, served if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control,

(3) The FOOD in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and

(4) Written procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request, that ensure compliance with:

(a) Subparagraphs (A)(1)-(4) of this section, and

(b) § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;

(B) Curing FOOD;

(C) Using FOOD ADDITIVES or adding components such as vinegar:

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS;

(D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method *except as specified under § 3-502.12 where a barrier to* ***Clostridium botulinum*** *in addition to refrigeration exists*;

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store and display shellfish that are offered for human consumption;

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; or

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE.

***Clostridium botulinum* Controls**

3-502.12 Reduced Oxygen Packaging, Criteria.*

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall ensure that there are at least two barriers in place to control the growth and toxin formation of ***C. botulinum****.*

(B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the FOOD to be PACKAGED;

(2) Limits the FOOD PACKAGED to a FOOD that does not support the growth of ***Clostridium botulinum*** because it complies with one of the following:

(a) Has an a_w of 0.91 or less,

(b) Has a pH of 4.6 or less,

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the U.S.D.A. using substances specified

in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in poultry products and is received in an intact package, or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT or raw POULTRY;

(3) Specifies methods for maintaining FOOD at 5°C (41°F) or below;

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the FOOD at 5°C (41°F) or below, and

(b) For FOOD held at refrigeration temperatures, discard the FOOD if within 14 calendar days of its packaging it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;

(5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(6) Includes operational procedures that:

(a) Prohibit contacting FOOD with bare hands,

(b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and

(7) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:

(a) Concepts required for a safe operation,

(b) EQUIPMENT and facilities, and

(c) Procedures specified under Subparagraph (B)(6) of this section and ¶ 8-201.14(D).

(C) *Except for FISH that is frozen before, during, and after packaging*, a FOOD ESTABLISHMENT may not package FISH using a REDUCED OXYGEN PACKAGING method.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food Labeling, and 9 CFR 317 Labeling, Marking Devices, and Containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3)-(5), nutrition labeling as specified in 21 CFR 101 - FOOD Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(6) For any salmonid FISH containing canthaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

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Current Status of Consumer Advisory Language
Regarding § 3-603.11

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. It is inserted here to provide a summary of recent events surrounding the matter of a consumer advisory, addressed in § 3-603.11 of the Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

A consensus as to what constitutes satisfactory compliance with § 3-603.11 was reached at the 1998 Conference for Food Protection (CFP) meeting. A third option for the consumer "reminder" was added later. This insert page is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Included in Annex 3 is a full discussion of the evolution of the 1998 CFP consensus, satisfactory compliance, applicability of the Code provision, and the meaning and application of the phrase that appears in § 3-603.11, i.e., "or otherwise processed to eliminate pathogens."

There are two components to satisfactory compliance: Disclosure and Reminder.
Disclosure is satisfied when:

(1) Items are described, such as:
    (a) Oysters on the half-shell (raw oysters),
    (b) Raw-EGG Caesar salad, and
    (c) Hamburgers (can be cooked to order); or

(2) Items are asterisked to a footnote that states that the items:
    (a) Are served raw or undercooked, or
    (b) Contain (or may contain) raw or undercooked ingredients.

Reminder is satisfied when the items requiring disclosure are asterisked to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;[1]

(2) Consuming raw or undercooked meats, poultry, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked meats, poultry, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

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[1]Essential criteria for such written information are available, with a downloadable model brochure, on the CFSAN Web Page at http://www.cfsan.fda.gov. All brochures must meet these essential criteria.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*

Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(D), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a READY-TO-EAT form as a deli, menu, vended, or other item; or as a raw ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased RISK associated with certain especially vulnerable CONSUMERS eating such FOODS in raw or undercooked form.

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.*

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be reconditioned according to an APPROVED procedure or discarded.

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 through .17 shall be discarded.

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § 2-201.12 shall be discarded.

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Reservice, and Prohibited Food.*

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) – (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.

(B) Pasteurized shell EGGS or pasteurized liquid, frozen, or dry EGGS or EGG products shall be substituted for raw shell EGGS in the preparation of:

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and EGG-fortified BEVERAGES, and

(2) Except as specified in ¶ (E) of this section, recipes in which more than one EGG is broken and the EGGS are combined;

(C) FOOD in an unopened original package may not be re-served; and

(D) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare,

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw shell EGGS, and meringue, and

(3) Raw seed sprouts.

(E) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS;*

(2) *The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP PLAN that:*

(a) *Identifies the FOOD to be prepared,*

(b) *Prohibits contacting READY-TO-EAT FOOD with bare hands,*

(c) *Includes specifications and practices that ensure*:

(i) ***Salmonella* Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella* Enteritidis** *is destroyed by cooking the EGGS according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of READY-TO-EAT FOOD with raw EGGS, and*

(ii) *Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES,* and

(e) *Describes the training program that ensures that the FOOD EMPLOYEE responsible for the preparation of the FOOD understands the procedures to be used.*

Chapter

4 Equipment, Utensils, and Linens

Parts

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Multiuse

4-101.11 Characteristics.*

Materials that are used in the construction of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT may not allow the migration of deleterious substances or impart colors, odors, or tastes to FOOD and under normal use conditions shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonabsorbent;[N]

(C) Sufficient in weight and thickness to withstand repeated WAREWASHING;[N]

(D) Finished to have a SMOOTH, EASILY CLEANABLE surface;[N] and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.[N]

4-101.12 Cast Iron, Use Limitation.

(A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

(B) *Cast iron may be used as a surface for cooking.*

(C) *Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.*

4-101.13 Lead in Ceramic, China, and Crystal Utensils, Use Limitation.

Ceramic, china, crystal UTENSILS, and decorative UTENSILS such as hand painted ceramic or china that are used in contact with FOOD shall be lead-free or contain levels of lead not exceeding the limits of the following UTENSIL categories:

Utensil Category	Description	Maximum Lead mg/L
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls 1.1 L (1.16 QT)	1
Small Hollowware	Bowls < 1.1 L (1.16 QT)	2.0
Flat Utensils	Plates, Saucers	3.0

4-101.14 Copper, Use Limitation.*

(A) Except as specified in ¶ (B) of this section, copper and copper alloys such as brass may not be used in contact with a FOOD that has a pH below 6 such as vinegar, fruit JUICE, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(B) *Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.*

4-101.15 Galvanized Metal, Use Limitation.*

Galvanized metal may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT that are used in contact with acidic FOOD.

4-101.16 Sponges, Use Limitation.

Sponges may not be used in contact with cleaned and SANITIZED or in-use FOOD-CONTACT SURFACES.

4-101.17 Lead in Pewter Alloys, Use Limitation.

Pewter alloys containing lead in excess of 0.05% may not be used as a FOOD-CONTACT SURFACE.

4-101.18 Lead in Solder and Flux, Use Limitation.

Solder and flux containing lead in excess of 0.2% may not be used as a FOOD-CONTACT SURFACE.

4-101.19 Wood, Use Limitation.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

(B) *Hard maple or an equivalently hard, close-grained wood may be used for:*

(1) *Cutting boards; cutting blocks; bakers' tables; and UTENSILS such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and*

(2) *Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.*

(C) *Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.*

(D) *If the nature of the FOOD requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw FOOD may be kept in:*

(1) *Untreated wood containers; or*

(2) *Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.*

4-101.110 Nonstick Coatings, Use Limitation.

Multiuse KITCHENWARE such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching UTENSILS and cleaning aids.

4-101.111 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of a CORROSION-RESISTANT, nonabsorbent, and SMOOTH material.

Single-Service and Single-Use

4-102.11 Characteristics.*

Materials that are used to make SINGLE-SERVICE and SINGLE-USE ARTICLES:

(A) May not:

(1) Allow the migration of deleterious substances, or

(2) Impart colors, odors, or tastes to FOOD;[N] and

(B) Shall be:

(1) Safe, and

(2) Clean.[N]

4-2 DESIGN AND CONSTRUCTION

Subparts

Durability and Strength

4-201.11 Equipment and Utensils.

EQUIPMENT and UTENSILS shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 Food Temperature Measuring Devices.*

FOOD TEMPERATURE MEASURING DEVICES may not have sensors or stems constructed of glass, *except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used*.

Cleanability

4-202.11 Food-Contact Surfaces.*

(A) Multiuse FOOD-CONTACT SURFACES shall be:

(1) Smooth;

(2) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;

(3) Free of sharp internal angles, corners, and crevices;

(4) Finished to have SMOOTH welds and joints; and

(5) Except as specified in ¶ (B) of this section, accessible for cleaning and inspection by one of the following methods:

(a) Without being disassembled,

(b) By disassembling without the use of tools, or

(c) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

(B) *Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes*.

4-202.12 CIP Equipment.

(A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that:

(1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES, and

(2) The system is self-draining or capable of being completely drained of cleaning and SANITIZING solutions; and

(B) CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

4-202.13 "V" Threads, Use Limitation.

Except for hot oil cooking or filtering EQUIPMENT, "V" type threads may not be used on FOOD-CONTACT SURFACES.

4-202.14 Hot Oil Filtering Equipment.

Hot oil filtering EQUIPMENT shall meet the characteristics specified under § 4-202.11 or § 4-202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

4-202.15 Can Openers.

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

4-202.16 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

4-202.17 Kick Plates, Removable.

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(A) Removable by one of the methods specified under Subparagraph 4-202.11(A)(5) or capable of being rotated open; and

(B) Removable or capable of being rotated open without unlocking EQUIPMENT doors.

4-202.18 Ventilation Hood Systems, Filters.

Filters or other grease extracting EQUIPMENT shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Accuracy

4-203.11 Temperature Measuring Devices, Food.

(A) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^{o}C$ in the intended range of use.

(B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to $\pm 2^{o}F$ in the intended range of use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

(A) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to $\pm 1.5^{o}C$ in the intended range of use.

(B) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to $\pm 3^{o}F$ in the intended range of use.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water SANITIZING rinse shall have increments of 7 kilopascals (1 pounds per square inch) or smaller and shall be accurate to $\pm$ 14 kilopascals ($\pm$ 2 pounds per square inch) in the 100-170 kilopascals (15-25 pounds per square inch) range.

Functionality

4-204.11 Ventilation Hood Systems, Drip Prevention.

Exhaust ventilation hood systems in FOOD preparation and WAREWASHING areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-204.12 Equipment Openings, Closures and Deflectors.

(A) A cover or lid for EQUIPMENT shall overlap the opening and be sloped to drain.

(B) An opening located within the top of a unit of EQUIPMENT that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).

(C) Except as specified under ¶ (D) of this section, fixed piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT shall be provided with a watertight joint at the point where the item enters the EQUIPMENT.

(D) If a watertight joint is not provided:

(1) The piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the FOOD; and

(2) The opening shall be flanged as specified under ¶ (B) of this section.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

In EQUIPMENT that dispenses or vends liquid FOOD or ice in unPACKAGED form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the FOOD shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the FOOD;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of EQUIPMENT used to vend liquid FOOD or ice in unPACKAGED form to self-service CONSUMERS shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the EQUIPMENT is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or

(2) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE; and

(D) The dispensing EQUIPMENT actuating lever or mechanism and filling device of CONSUMER self-service BEVERAGE dispensing EQUIPMENT shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

4-204.14 Vending Machine, Vending Stage Closure.

The dispensing compartment of a VENDING MACHINE including a machine that is designed to vend prePACKAGED snack FOOD that is not POTENTIALLY HAZARDOUS such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE.

4-204.15 Bearings and Gear Boxes, Leakproof.

EQUIPMENT containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

4-204.16 Beverage Tubing, Separation.

BEVERAGE tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice. *This section does not apply to cold plates that are constructed integrally with an ice storage bin*.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 Condenser Unit, Separation.

If a condenser unit is an integral component of EQUIPMENT, the condenser unit shall be separated from the FOOD and FOOD storage space by a dustproof barrier.

4-204.19 Can Openers on Vending Machines.

Cutting or piercing parts of can openers on VENDING MACHINES shall be protected from manual contact, dust, insects, rodents, and other contamination.

4-204.110 Molluscan Shellfish Tanks.

(A) Except as specified under ¶ (B) of this section, MOLLUSCAN SHELLFISH life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the CONSUMER that the shellfish are for display only.

(B) MOLLUSCAN SHELLFISH life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a VARIANCE granted by the REGULATORY AUTHORITY as specified in § 8-103.10 and a HACCP PLAN that:

(1) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11; and

(2) Ensures that:

(a) Water used with FISH other than MOLLUSCAN SHELLFISH does not flow into the molluscan tank,

(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and

(c) The identity of the source of the SHELLSTOCK is retained as specified under § 3-203.12.

4-204.111 Vending Machines, Automatic Shutoff.*

(A) A machine vending POTENTIALLY HAZARDOUS FOOD shall have an automatic control that prevents the machine from vending FOOD:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain FOOD temperatures as specified under Chapter 3; and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3.

(B) When the automatic shutoff within a machine vending POTENTIALLY HAZARDOUS FOOD is activated:

(1) In a refrigerated VENDING MACHINE, the ambient temperature may not exceed any time/temperature combination as specified under ¶ 3-501.16(A)(2) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or

(2) In a hot holding VENDING MACHINE, the ambient temperature may not be less than 60°C (140°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

4-204.112 Temperature Measuring Devices.

(A) In a mechanically refrigerated or hot FOOD storage unit, the sensor of a TEMPERATURE MEASURING DEVICE shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot FOOD storage unit.

(B) Except as specified in ¶ (C) of this section, cold or hot holding EQUIPMENT used for POTENTIALLY HAZARDOUS FOOD shall be designed to include and shall be equipped with at least one integral or permanently affixed TEMPERATURE MEASURING DEVICE that is located to allow easy viewing of the device's temperature display.

(C) *Paragraph (B) of this section does not apply to EQUIPMENT for which the placement of a TEMPERATURE MEASURING DEVICE is not a practical means for measuring the ambient air surrounding the FOOD because of the design, type, and use of the EQUIPMENT, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated FOOD transport containers, and salad bars*.

(D) TEMPERATURE MEASURING DEVICES shall be designed to be easily readable.

(E) FOOD TEMPERATURE MEASURING DEVICES and water TEMPERATURE MEASURING DEVICES on WAREWASHING machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

A WAREWASHING machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications including the:

(A) Temperatures required for washing, rinsing, and SANITIZING;

(B) Pressure required for the fresh water SANITIZING rinse *unless the machine is designed to use only a pumped SANITIZING rinse;* and

(C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

4-204.114 Warewashing Machines, Internal Baffles.

WAREWASHING machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

A WAREWASHING machine shall be equipped with a TEMPERATURE MEASURING DEVICE that indicates the temperature of the water:

(A) In each wash and rinse tank; and

(B) As the water enters the hot water SANITIZING final rinse manifold or in the chemical SANITIZING solution tank.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

If hot water is used for SANITIZATION in manual WAREWASHING operations, the SANITIZING compartment of the sink shall be:

(A) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

A WAREWASHING machine that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be designed and equipped to:

(A) Automatically dispense detergents and SANITIZERS; and

(B) Incorporate a visual means to verify that detergents and SANITIZERS are delivered or a visual or audible alarm to signal if the detergents and SANITIZERS are not delivered to the respective washing and SANITIZING cycles.

4-204.118 Warewashing Machines, Flow Pressure Device.

(A) WAREWASHING machines that provide a fresh hot water SANITIZING rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the WAREWASHING machine; and

(B) If the flow pressure measuring device is upstream of the fresh hot water SANITIZING rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(C) *Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated SANITIZING rinse.*

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.

Sinks and drainboards of WAREWASHING sinks and machines shall be self-draining.

4-204.120 Equipment Compartments, Drainage.

EQUIPMENT compartments that are subject to accumulation of moisture due to conditions such as condensation, FOOD or BEVERAGE drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

4-204.121 Vending Machines, Liquid Waste Products.

(A) VENDING MACHINES designed to store BEVERAGES that are PACKAGED in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(B) VENDING MACHINES that dispense liquid FOOD in bulk shall be:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(C) Shutoff devices specified under Subparagraph (B)(2) of this section shall prevent water or liquid FOOD from continuously running if there is a failure of a flow control device in the water or liquid FOOD system or waste accumulation that could lead to overflow of the waste receptacle.

4-204.122 Case Lot Handling Equipment, Moveability.

EQUIPMENT, such as dollies, pallets, racks, and skids used to store and transport large quantities of PACKAGED FOODS received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available EQUIPMENT such as hand trucks and forklifts.

4-204.123 Vending Machine Doors and Openings.

(A) VENDING MACHINE doors and access opening covers to FOOD and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or one-sixteenth inch by:

(1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1.5 millimeters or one-sixteenth inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;

(2) Being effectively gasketed;

(3) Having interface surfaces that are at least 13 millimeters or one-half inch wide; or

(4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(B) VENDING MACHINE service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with Parts 4-1 and 4-2 of this chapter.

4-3 NUMBERS AND CAPACITIES

Subparts

Equipment

4-301.11 Cooling, Heating, and Holding Capacities.

EQUIPMENT for cooling and heating FOOD, and holding cold and hot FOOD, shall be sufficient in number and capacity to provide FOOD temperatures as specified under Chapter 3.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

(A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and SANITIZING EQUIPMENT and UTENSILS.

(B) Sink compartments shall be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT as specified in ¶ (C) of this section shall be used.

(C) *Alternative manual WAREWASHING EQUIPMENT may be used when there are special cleaning needs or constraints and its use is APPROVED. Alternative manual WAREWASHING EQUIPMENT may include:*

(1) *High-pressure detergent sprayers;*

(2) *Low- or line-pressure spray detergent foamers;*

(3) *Other task-specific cleaning EQUIPMENT;*

(4) *Brushes or other implements;*

(5) *2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or*

(6) *Receptacles that substitute for the compartments of a multicompartment sink.*

(D) Before a 2-compartment sink is used:

(1) The PERMIT HOLDER shall have its use APPROVED; and

(2) The PERMIT HOLDER shall limit the number of KITCHENWARE items cleaned and SANITIZED in the 2-compartment sink, and shall limit WAREWASHING to batch operations for cleaning KITCHENWARE such as between cutting one type of raw MEAT and another or cleanup at the end of a shift, and shall:

(a) Make up the cleaning and SANITIZING solutions immediately before use and drain them immediately after use, and

(b) Use a detergent-SANITIZER to SANITIZE and apply the detergent-SANITIZER in accordance with the manufacturer's label instructions and as specified under § 4-501.115, or

(c) Use a hot water SANITIZATION immersion step as specified under ¶ 4-603.16(C).

(E) A 2-compartment sink may not be used for WAREWASHING operations where cleaning and SANITIZING solutions are used for a continuous or intermittent flow of KITCHENWARE or TABLEWARE in an ongoing WAREWASHING process.

4-301.13 Drainboards.

Drainboards, UTENSIL racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary UTENSIL holding before cleaning and after SANITIZING.

4-301.14 Ventilation Hood Systems, Adequacy.

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

4-301.15 Clothes Washers and Dryers.

(A) Except as specified in ¶ (B) of this section, if work clothes or LINENS are laundered on the PREMISES, a mechanical clothes washer and dryer shall be provided and used.

(B) *If on-PREMISES laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under § 4-901.12, a mechanical clothes washer and dryer need not be provided.*

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

A FOOD dispensing UTENSIL shall be available for each container displayed at a CONSUMER self-service unit such as a buffet or salad bar.

4-302.12 Food Temperature Measuring Devices.

(A) FOOD TEMPERATURE MEASURING DEVICES shall be provided and readily accessible for use in ensuring attainment and maintenance of FOOD temperatures as specified under Chapter 3.

(B) A TEMPERATURE MEASURING DEVICE with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin FOODS such as MEAT patties and FISH filets.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

In manual WAREWASHING operations, a TEMPERATURE MEASURING DEVICE shall be provided and readily accessible for frequently measuring the washing and SANITIZING temperatures.

4-302.14 Sanitizing Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in mg/L of SANITIZING solutions shall be provided.

4-4 LOCATION AND INSTALLATION

Subparts

Location

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *A storage cabinet used for LINENS or SINGLE-SERVICE or SINGLE-*

USE ARTICLES may be stored in a locker room.

(C) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

Installation

4-402.11 Fixed Equipment, Spacing or Sealing.

(A) EQUIPMENT that is fixed because it is not EASILY MOVABLE shall be installed so that it is:

(1) Spaced to allow access for cleaning along the sides, behind, and above the EQUIPMENT;

(2) Spaced from adjoining EQUIPMENT, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(3) SEALED to adjoining EQUIPMENT or walls, if the EQUIPMENT is exposed to spillage or seepage.

(B) TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be installed to allow cleaning of the EQUIPMENT and areas underneath and around the EQUIPMENT by being:

(1) SEALED to the table; or

(2) Elevated on legs as specified under ¶ 4-402.12(D).

4-402.12 Fixed Equipment, Elevation or Sealing.

(A) Except as specified in ¶¶ (B) and (C) of this section, floor-mounted EQUIPMENT that is not EASILY MOVABLE shall be SEALED to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the EQUIPMENT.

(B) *If no part of the floor under the floor-mounted EQUIPMENT is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches)*.

(C) *This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the CONSUMER shopping areas of a retail FOOD store, if the floor under the units is maintained clean*.

(D) Except as specified in ¶ (E) of this section, TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the EQUIPMENT.

(E) *The clearance space between the table and TABLE-MOUNTED EQUIPMENT may be*:

(1) *7.5 centimeters (3 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 50 centimeters (20 inches) from the point of access for cleaning; or*

(2) *5 centimeters (2 inches) if the horizontal distance of the table top under the EQUIPMENT is no more than 7.5 centimeters (3 inches) from the point of access for cleaning*

4-5 MAINTENANCE AND OPERATION

Subparts

Equipment

4-501.11 Good Repair and Proper Adjustment.

(A) EQUIPMENT shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2.

(B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(C) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate FOOD when the container is opened.

4-501.12 Cutting Surfaces.

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and SANITIZED, or discarded if they are not capable of being resurfaced.

4-501.13 Microwave Ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

4-501.14 Warewashing Equipment, Cleaning Frequency.

A WAREWASHING machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing EQUIPMENT, UTENSILS, or raw FOODS, or laundering wiping cloths; and drainboards or other EQUIPMENT used to substitute for drainboards as specified under § 4-301.13 shall be cleaned:

(A) Before use;

(B) Throughout the day at a frequency necessary to prevent recontamination of EQUIPMENT and UTENSILS and to ensure that the EQUIPMENT performs its intended function; and

(C) If used, at least every 24 hours.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

(A) A WAREWASHING machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(B) A WAREWASHING machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

4-501.16 Warewashing Sinks, Use Limitation.

(A) A WAREWASHING sink may not be used for handwashing as specified under § 2-301.15.

(B) If a WAREWASHING sink is used to wash wiping cloths, wash produce, or thaw FOOD, the sink shall be cleaned as specified under § 4-501.14 before and after each time it is used to wash wiping cloths or wash produce or thaw FOOD. Sinks used to wash or thaw FOOD shall be SANITIZED as specified under Part 4-7 before and after using the sink to wash produce or thaw FOOD.

4-501.17 Warewashing Equipment, Cleaning Agents.

When used for WAREWASHING, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

4-501.18 Warewashing Equipment, Clean Solutions.

The wash, rinse, and SANITIZE solutions shall be maintained clean.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F);

(2) For a stationary rack, dual temperature machine, 66°C (150°F);

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F).

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F).

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If immersion in hot water is used for SANITIZING in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F); or

(2) For all other machines, 82°C (180°F).

(B) *The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.*

4-501.113 Mechanical Warewashing Equipment, Sanitization

Pressure.

The flow pressure of the fresh hot water SANITIZING rinse in a WAREWASHING machine may not be less than 100 kilopascals (15 pounds per square inch) or more than 170 kilopascals (25 pounds per square inch) as measured in the water line immediately downstream or upstream from the fresh hot water SANITIZING rinse control valve.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

A chemical SANITIZER used in a SANITZING solution for a manual or mechanical operation at exposure times specified under ¶ 4-703.11(C) shall be listed in 21 CFR 178.1010 Sanitizing solutions, shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:

(A) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;

Minimum Concentration	Minimum Temperature	
mg/L	pH 10 or less ^{o}C (^{o}F)	pH 8 or less ^{o}C (^{o}F)
25	49 (120)	49 (120)
50	38 (100)	24 (75)
100	13 (55)	13 (55)

(B) An iodine solution shall have a:

(1) Minimum temperature of 24^{o}C (75^{o}F),

(2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and

(3) Concentration between 12.5 mg/L and 25 mg/L;

(C) A quaternary ammonium compound solution shall:

(1) Have a minimum temperature of 24°C (75°F),

(2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and

(3) Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;

(D) If another solution of a chemical specified under ¶¶ (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED; or

(E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

If a detergent-SANITIZER is used to SANITIZE in a cleaning and SANITIZING procedure where there is no distinct water rinse between the washing and SANITIZING steps, the agent applied in the SANITIZING step shall be the same detergent-SANITIZER that is used in the washing step.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.

Utensils and Temperature

4-502.11 Good Repair and Calibration.

and Pressure Measuring Devices

(A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded.

(B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use.

(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

A FOOD ESTABLISHMENT without facilities specified under Parts 4-6 and 4-7 for cleaning and SANITIZING kitchenware and TABLEWARE shall provide only SINGLE-USE KITCHENWARE, SINGLE-SERVICE ARTICLES, and SINGLE-USE ARTICLES for use by FOOD EMPLOYEES and SINGLE-SERVICE ARTICLES for use by CONSUMERS.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

(B) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells may not be used more than once as serving containers.

4-6 CLEANING OF EQUIPMENT AND UTENSILS

Subparts

Objective

4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.*

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be clean to sight and touch.

(B) The FOOD-CONTACT SURFACES of cooking EQUIPMENT and pans shall be kept free of encrusted grease deposits and other soil accumulations.[N]

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.[N]

Frequency

4-602.11 Equipment Food-Contact Surfaces and Utensils.*

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned:

(1) Except as specified in ¶ (B) of this section, before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY;

(2) Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS;

(3) Between uses with raw fruits and vegetables and with POTENTIALLY HAZARDOUS FOOD;

(4) Before using or storing a FOOD TEMPERATURE MEASURING DEVICE; and

(5) At any time during the operation when contamination may have occurred.

(B) *Subparagraph (A)(1) of this section does not apply if the FOOD-CONTACT SURFACE or UTENSIL is in contact with a succession of different raw animal FOODS each requiring a higher cooking temperature as specified under § 3-401.11 than the previous FOOD, such as preparing raw FISH followed by cutting raw poultry on the same cutting board*.

(C) Except as specified in ¶ (D) of this section, if used with POTENTIALLY HAZARDOUS FOOD, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned throughout the day at least every 4 hours.

(D) *Surfaces of UTENSILS and EQUIPMENT contacting POTENTIALLY HAZARDOUS FOOD may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of POTENTIALLY HAZARDOUS FOOD and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) *UTENSILS and EQUIPMENT are used to prepare FOOD in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*

(a) *The UTENSILS and EQUIPMENT are cleaned at the frequency in the following chart that corresponds to the temperature:*

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

; and

(b) *The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the* FOOD ESTABLISHMENT.

(3) *Containers in serving situations such as salad bars, delis, and cafeteria lines hold* READY-TO-EAT POTENTIALLY HAZARDOUS FOOD *that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same* FOOD *that is at the required temperature, and the containers are cleaned at least every 24 hours;*

(4) *T*EMPERATURE MEASURING DEVICES *are maintained in contact with* FOOD, *such as when left in a container of deli* FOOD *or in a roast, held at temperatures specified under Chapter 3;*

(5) *E*QUIPMENT *is used for storage of* PACKAGED *or un*PACKAGED FOOD *such as a reach-in refrigerator and the* EQUIPMENT *is cleaned at a frequency necessary to preclude accumulation of soil residues;*

(6) *The cleaning schedule is* APPROVED *based on consideration of:*

(a) *The type of* FOOD *involved,*

(b) *The amount of* FOOD *residue accumulation, and*

(c) *The amount of* FOOD *residue accumulation, and*

(d) *The temperature at which the* FOOD *is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*

(7) In-use UTENSILS *are intermittently stored in a container of water in which the water is maintained at 60°C (140°F) or more and the* UTENSILS *and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.*

(E) *Except when dry cleaning methods are used as specified under § 4-603.11*, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not POTENTIALLY HAZARDOUS shall be cleaned:**N**

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

4-602.12 Cooking and Baking Equipment.

(A) The FOOD-CONTACT SURFACES of cooking and baking EQUIPMENT shall be cleaned at least every 24 hours. *This section does not apply to hot oil cooking and filtering EQUIPMENT if it is cleaned as specified in Subparagraph 4-602.11(D)(6)*.

(B) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

4-602.13 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

Methods

4-603.11 Dry Cleaning.

(A) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only SURFACES that are soiled with dry FOOD residues that are not POTENTIALLY HAZARDOUS.

(B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 Precleaning.

(A) FOOD debris on EQUIPMENT and UTENSILS shall be scrapped over a waste disposal unit or garbage receptacle or shall be removed in a WAREWASHING machine with a prewash cycle.

(B) If necessary for effective cleaning, UTENSILS and EQUIPMENT shall be preflushed, presoaked, or scrubbed with abrasives.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Soiled items to be cleaned in a WAREWASHING machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(A) Exposes the items to the unobstructed spray from all cycles; and

(B) Allows the items to drain.

4-603.14 Wet Cleaning.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(B) The washing procedures selected shall be based on the type and purpose of the EQUIPMENT or UTENSIL, and on the type of soil to be removed.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

If washing in sink compartments or a WAREWASHING machine is impractical such as when the EQUIPMENT is fixed or the UTENSILS are too large, washing shall be done by using alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) in accordance with the following procedures:

(A) EQUIPMENT shall be disassembled as necessary to allow access of the detergent solution to all parts;

(B) EQUIPMENT components and UTENSILS shall be scrapped or rough cleaned to remove FOOD particle accumulation; and

(C) EQUIPMENT and UTENSILS shall be washed as specified under ¶ 4-603.14(A).

4-603.16 Rinsing Procedures.

Washed UTENSILS and EQUIPMENT shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted

through the use of water or a detergent-SANITIZER solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before SANITIZING if using:

(1) A 3-compartment sink,

(2) Alternative manual WAREWASHING EQUIPMENT equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or

(3) A 3-step washing, rinsing, and SANITIZING procedure in a WAREWASHING system for CIP EQUIPMENT;

(B) Use of a detergent-SANITIZER as specified under § 4-501.115 if using:

(1) Alternative WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) that is APPROVED for use with a detergent-SANITIZER, or

(2) A WAREWASHING system for CIP EQUIPMENT;

(C) Use of a nondistinct water rinse that is integrated in the hot water SANITIZATION immersion step of a 2-compartment sink operation;

(D) If using a WAREWASHING machine that does not recycle the SANITIZING solution as specified under ¶ (E) of this section, or alternative manual WAREWASHING EQUIPMENT such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the SANITIZING solution, and

(2) Wasted immediately after each application; or

(E) If using a WAREWASHING machine that recycles the SANITIZING solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the SANITIZING solution.

4-603.17 Returnables, Cleaning for Refilling.*

(A) Except as specified in ¶¶ (B) and (C) of this section, returned empty containers intended for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.

(B) *A FOOD-specific container for BEVERAGES may be refilled at a FOOD ESTABLISHMENT if:*

(1) *Only a BEVERAGE that is not a POTENTIALLY HAZARDOUS FOOD is used as specified under ¶ 3-304.17(A);*

(2) *The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together, allow effective cleaning at home or in the FOOD ESTABLISHMENT;*

(3) *Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;*

(4) *The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and*

(5) *The container is refilled by:*

(a) *An EMPLOYEE of the FOOD ESTABLISHMENT, or*

(b) *The owner of the container if the BEVERAGE system includes a contamination-free transfer process that can not be bypassed by the container owner.*

(C) *CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.*

4-7 SANITIZATION OF EQUIPMENT AND UTENSILS

Subparts

Objective

4-701.10 Food-Contact Surfaces and Utensils.

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED.

Frequency

4-702.11 Before Use After Cleaning.*

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.

Methods

4-703.11 Hot Water and Chemical.*

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; or

(C) Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114 by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under ¶ 4-501.114(A),

(2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F),

(3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or

(4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B)(79).

4-8 LAUNDERING

Subparts

Objective

4-801.11 Clean Linens.

Clean LINENS shall be free from FOOD residues and other soiling matter.

Frequency

4-802.11 Specifications.

(A) LINENS that do not come in direct contact with FOOD shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal FOOD such as beef, lamb, pork, and FISH.

(C) LINENS and napkins that are used as specified under § 3-304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.
(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of FOOD and clean serving UTENSILS.

Methods

4-803.11 Storage of Soiled Linens.

Soiled LINENS shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of FOOD, clean EQUIPMENT, clean UTENSILS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-803.12 Mechanical Washing.

(A) Except as specified in ¶ (B) of this section, LINENS shall be mechanically washed.

(B) *In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in ¶ 4-301.15(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a WAREWASHING or FOOD preparation sink that is cleaned as specified under § 4-501.14.*

4-803.13 Use of Laundry Facilities.

(A) Except as specified in ¶ (B) of this section, laundry facilities on the PREMISES of a FOOD ESTABLISHMENT shall be used only for the washing and drying of items used in the operation of the establishment.

(B) *Separate laundry facilities located on the PREMISES for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering FOOD ESTABLISHMENT items.*

4-9 PROTECTION OF CLEAN ITEMS

Subparts

Drying

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

After cleaning and SANITIZING, EQUIPMENT and UTENSILS:

(A) Shall be air-dried or used after adequate draining as specified in ¶ (a) of 21 CFR 178.1010 Sanitizing solutions, before contact with FOOD; and

(B) May not be cloth dried *except that UTENSILS that have been air-dried may be polished with cloths that are maintained clean and dry*.

4-901.12 Wiping Cloths, Air-Drying Locations.

Wiping cloths laundered in a FOOD ESTABLISHMENT that does not have a mechanical clothes dryer as specified in ¶ 4-301.15(B) shall be air-dried in a location and in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and the wiping cloths. *This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under § 4-501.114.*

Lubricating and Reassembling

4-902.11 Food-Contact Surfaces.

Lubricants shall be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

4-902.12 Equipment.

EQUIPMENT shall be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

Storing

4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(A) Except as specified in ¶ (D) of this section, cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored:

(1) In a clean, dry location;

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Clean EQUIPMENT and UTENSILS shall be stored as specified under ¶ (A) of this section and shall be stored:

(1) In a self-draining position that allows air drying; and

(2) Covered or inverted.

(C) SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored as specified under ¶ (A) of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(D) *Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under § 4-204.122.*

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *Laundered LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES that are PACKAGED or in a facility such as a cabinet may be stored in a locker room.*

Handling

4-904.11 Kitchenware and Tableware.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES and cleaned and SANITIZED UTENSILS shall be handled, displayed, and dispensed so that contamination of FOOD- and lip-contact surfaces is prevented.

(B) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by EMPLOYEES and by CONSUMERS if CONSUMER self-service is provided.

(C) Except as specified under ¶ (B) of this section, SINGLE-SERVICE ARTICLES that are intended for FOOD- or lip-contact shall be furnished for CONSUMER self-service with the original individual wrapper intact or from an APPROVED dispenser.

4-904.12 Soiled and Clean Tableware.

Soiled TABLEWARE shall be removed from CONSUMER eating and drinking areas and handled so that clean TABLEWARE is not contaminated.

4-904.13 Preset Tableware.

IF TABLEWARE is preset:

(A) It shall be protected from contamination by being wrapped, covered, or inverted;

(B) Exposed, unused settings shall be removed when a CONSUMER is seated; or

(C) Exposed, unused settings shall be cleaned and SANITIZED before further use if the settings are not removed when a CONSUMER is seated.

Chapter

5 Water, Plumbing, and Waste

Parts

5-1 WATER

Subparts

Source

5-101.11 Approved System.*

DRINKING WATER shall be obtained from an APPROVED source that is:

(A) A PUBLIC WATER SYSTEM; or

(B) A nonPUBLIC WATER SYSTEM that is constructed, maintained, and operated according to LAW.

5-101.12 System Flushing and Disinfection.*

A DRINKING WATER system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

5-101.13 Bottled Drinking Water.*

BOTTLED DRINKING WATER used or sold in a FOOD ESTABLISHMENT shall be obtained from APPROVED sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled DRINKING WATER.

Quality

5-102.11 Standards.*

Except as specified under § 5-102.12:

(A) Water from a PUBLIC WATER SYSTEM shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state DRINKING WATER quality standards; and

(B) Water from a nonPUBLIC WATER SYSTEM shall meet state DRINKING WATER quality standards.

5-102.12 Nondrinking Water.*

(A) A nonDRINKING WATER supply shall be used only if its use is APPROVED.

(B) NonDRINKING WATER shall be used only for nonculinary purposes such as air conditioning, nonFOOD EQUIPMENT cooling, fire protection, and irrigation.

5-102.13 Sampling.

Except when used as specified under § 5-102.12, water from a nonPUBLIC WATER SYSTEM shall be sampled and tested at least annually and as required by state water quality regulations.

5-102.14 Sample Report.

The most recent sample report for the nonPUBLIC WATER SYSTEM shall be retained on file in the FOOD ESTABLISHMENT or the report shall be maintained as specified by state water quality regulations.

Quantity and Availability

5-103.11 Capacity.*

(A) The water source and system shall be of sufficient capacity to meet the peak water demands of the FOOD ESTABLISHMENT.

(B) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the FOOD ESTABLISHMENT.

5-103.12 Pressure.

Water under pressure shall be provided to all fixtures, EQUIPMENT, and nonFOOD EQUIPMENT that are required to use water *except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a TEMPORARY FOOD ESTABLISHMENT or in response to a temporary interruption of a water supply need not be under pressure*.

Distribution, Delivery, and Retention

5-104.11 System.

Water shall be received from the source through the use of:

(A) An APPROVED public water main; or

(B) One or more of the following that shall be constructed, maintained, and operated according to LAW:

(1) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,

(2) Water transport vehicles, and

(3) Water containers.

5-104.12 Alternative Water Supply.

Water meeting the requirements specified under Subparts 5-101, 5-102, and 5-103 shall be made available for a mobile facility, for a TEMPORARY FOOD ESTABLISHMENT without a permanent water supply, and for a FOOD ESTABLISHMENT with a temporary interruption of its water supply through:

(A) A supply of containers of commercially BOTTLED DRINKING WATER;

(B) One or more closed portable water containers;

(C) An enclosed vehicular water tank;

(D) An on-PREMISES water storage tank; or

(E) Piping, tubing, or hoses connected to an adjacent APPROVED source.

5-2 PLUMBING SYSTEM

Subparts

Materials

5-201.11 Approved.*

(A) A PLUMBING SYSTEM and hoses conveying water shall be constructed and repaired with APPROVED materials according to LAW.

(B) A water filter shall be made of SAFE MATERIALS.

Design, Construction, and Installation

5-202.11 Approved System and Cleanable Fixtures.*

(A) A PLUMBING SYSTEM shall be designed, constructed, and installed according to LAW.

(B) A PLUMBING FIXTURE such as a handwashing facility, toilet, or urinal shall be EASILY CLEANABLE.[N]

5-202.12 Handwashing Facility, Installation.

(A) A handwashing lavatory shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet.

(B) A steam mixing valve may not be used at a handwashing lavatory.

(C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

(D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

5-202.13 Backflow Prevention, Air Gap.*

An air gap between the water supply inlet and the flood level rim of the PLUMBING FIXTURE, EQUIPMENT, or nonFOOD EQUIPMENT shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch).

5-202.14 Backflow Prevention Device, Design Standard.

A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

5-202.15 Conditioning Device, Design.

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Numbers and Capacities

5-203.11 Handwashing Facilities.*

(A) Except as specified in ¶¶ (B) and (C) of this section, at least 1 handwashing lavatory, a number of handwashing lavatories necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of handwashing lavatories required by LAW shall be provided.

(B) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, automatic handwashing facilities may be substituted for handwashing lavatories in a FOOD ESTABLISHMENT that has at least one handwashing lavatory.*

(C) *If APPROVED, when FOOD exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE LOCATIONS, EMPLOYEES may use chemically treated towelettes for handwashing.*

5-203.12 Toilets and Urinals.*

At least 1 toilet and not fewer than the toilets required by LAW shall be provided. If authorized by LAW and urinals are substituted for toilets, the substitution shall be done as specified in LAW.

5-203.13 Service Sink.

At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

5-203.14 Backflow Prevention Device, When Required.*

A PLUMBING SYSTEM shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the FOOD ESTABLISHMENT, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by LAW, by:

(A) Providing an air gap as specified under § 5-202.13; or

(B) Installing an APPROVED backflow prevention device as specified under § 5-202.14.

5-203.15 Backflow Prevention Device, Carbonator.*

(A) If not provided with an air gap as specified under § 5-203.13, a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.

(B) *A single or double check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under ¶ (A) of this section.*

Location and Placement

5-204.11 Handwashing Facilities.*

A handwashing facility shall be located:

(A) To allow convenient use by EMPLOYEES in FOOD preparation, FOOD dispensing, and WAREWASHING areas; and

(B) In, or immediately adjacent to, toilet rooms.

5-204.12 Backflow Prevention Device, Location.

A backflow prevention device shall be located so that it may be serviced and maintained.

5-204.13 Conditioning Device, Location.

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

Operation and Maintenance

5-205.11 Using a Handwashing Facility.

(A) A handwashing facility shall be maintained so that it is accessible at all times for EMPLOYEE use.

(B) A handwashing facility may not be used for purposes other than handwashing.

(C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

5-205.12 Prohibiting a Cross Connection.*

(A) *Except as specified in 9 CFR 308.3(d) for firefighting*, a PERSON may not create a cross connection by connecting a pipe or conduit between the DRINKING WATER system and a nonDRINKING WATER SYSTEM or a water system of unknown quality.

(B) The piping of a nonDRINKING WATER SYSTEM shall be durably identified so that it is readily distinguishable from piping that carries DRINKING WATER.[N]

5-205.13 Scheduling Inspection and Service for a Water System Device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the PERSON IN CHARGE.

5-205.14 Water Reservoir of Fogging Devices, Cleaning.*

(A) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(1) Maintained in accordance with manufacturer's specifications; and

(2) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under ¶ (B) of this section, whichever is more stringent.

(B) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(1) Draining and complete disassembly of the water and aerosol contact parts;

(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L hypochlorite solution.

5-205.15 System Maintained in Good Repair.*

A PLUMBING SYSTEM shall be:

(A) Repaired according to LAW; and

(B) Maintained in good repair.[S]

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

Subparts

Materials

5-301.11 Approved.

Materials that are used in the construction of a mobile water tank, mobile FOOD ESTABLISHMENT water tank, and appurtenances shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonabsorbent; and

(C) Finished to have a SMOOTH, EASILY CLEANABLE surface.

Design and Construction

5-302.11 Enclosed System, Sloped to Drain.

A mobile water tank shall be:

(A) Enclosed from the filling inlet to the discharge outlet; and

(B) Sloped to an outlet that allows complete drainage of the tank.

5-302.12 Inspection and Cleaning Port, Protected and Secured.

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(A) Flanged upward at least 13 mm (one-half inch); and

(B) Equipped with a port cover assembly that is:

(1) Provided with a gasket and a device for securing the cover in place, and

(2) Flanged to overlap the opening and sloped to drain.

5-302.13 "V" Type Threads, Use Limitation.

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

5-302.14 Tank Vent, Protected.

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(A) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or

(B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

5-302.15 Inlet and Outlet, Sloped to Drain.

(A) A water tank and its inlet and outlet shall be sloped to drain.

(B) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

5-302.16 Hose, Construction and Identification.

A hose used for conveying DRINKING WATER from a water tank shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonaborbent;

(C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

(D) Finished with a SMOOTH interior surface; and

(E) Clearly and durably identified as to its use if not permanently attached.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and DRINKING WATER system when compressed air is used to pressurize the water tank system.

5-303.12 Protective Cover or Device.

A cap and keeper chain, closed cabinet, closed storage tube, or other APPROVED protective cover or device shall be provided for a water inlet, outlet, and hose.

5-303.13 Mobile Food Establishment Tank Inlet.

A mobile FOOD ESTABLISHMENT'S water tank inlet shall be:

(A) 19.1 mm (three-fourths inch) in inner diameter or less; and

(B) Provided with a hose connection of a size or type that will prevent its use for any other service.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.*

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

A PERSON shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under § 5-303.12.

5-304.14 Tank, Pump, and Hoses, Dedication.

(A) Except as specified in ¶ (B) of this section, a water tank, pump, and hoses used for conveying DRINKING WATER shall be used for no other purpose.

(B) *Water tanks, pumps, and hoses APPROVED for liquid FOODS may be used for conveying DRINKING WATER if they are cleaned and SANITIZED before they are used to convey water.*

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

Subparts

Mobile Holding Tank

5-401.11 Capacity and Drainage.

A SEWAGE holding tank in a mobile FOOD ESTABLISHMENT shall be:

(A) Sized 15 percent larger in capacity than the water supply tank; and

(B) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

Retention, Drainage, and Delivery

design, construction, and installation

5-402.10 Establishment Drainage System.

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under ¶ 5-202.11(A).

5-402.11 Backflow Prevention.*

(A) Except as specified in ¶¶ (B) and (C) of this section, a direct connection may not exist between the SEWAGE system and a drain originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILS are placed.

(B) If allowed by LAW, a WAREWASHING machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(C) *If allowed by LAW, a WAREWASHING or culinary sink may have a direct connection.*

location and placement

5-402.12 Grease Trap.

If used, a grease trap shall be located to be easily accessible for cleaning.

operation and maintenance

5-402.13 Conveying Sewage.*

SEWAGE shall be conveyed to the point of disposal through an APPROVED sanitary SEWAGE system or other system, including use of SEWAGE transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to LAW.

5-402.14 Removing Mobile Food Establishment Wastes.

SEWAGE and other liquid wastes shall be removed from a mobile FOOD ESTABLISHMENT at an APPROVED waste SERVICING AREA or by a SEWAGE transport vehicle in such a way that a public health HAZARD or nuisance is not created.

5-402.15 Flushing a Waste Retention Tank.

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

Disposal Facility

5-403.11 Approved Sewage Disposal System.*

design and construction

SEWAGE shall be disposed through an APPROVED facility that is:

(A) A public SEWAGE treatment plant; or

(B) An individual SEWAGE disposal system that is sized, constructed, maintained, and operated according to LAW.

5-403.12 Other Liquid Wastes and Rainwater.

Condensate drainage and other nonSEWAGE liquids and rainwater shall be drained from point of discharge to disposal according to LAW.

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

Subparts

Facilities on the Premises
materials, design, construction, and installation

5-501.10 Indoor Storage Area.

If located within the FOOD ESTABLISHMENT, a storage area for REFUSE, recyclables, and returnables shall meet the requirements specified under §§ 6-101.11, 6-201.11 - 6-201.18, 6-202.15, and 6-202.16.

5-501.11 Outdoor Storage Surface.

An outdoor storage surface for REFUSE, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be SMOOTH, durable, and sloped to drain.

5-501.12 Outdoor Enclosure.

If used, an outdoor enclosure for REFUSE, recyclables, and returnables shall be constructed of durable and cleanable materials.

5-501.13 Receptacles.

(A) Except as specified in ¶ (B) of this section, receptacles and waste handling units for REFUSE, recyclables, and returnables and for use with materials containing FOOD residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

(B) *Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the FOOD ESTABLISHMENT, or within closed outside receptacles.*

5-501.14 Receptacles in Vending Machines.

A REFUSE receptacle may not be located within a VENDING MACHINE, *except that a receptacle for BEVERAGE bottle crown closures may be located within a VENDING MACHINE.*

5-501.15 Outside Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables used with materials containing FOOD residue and used outside the FOOD ESTABLISHMENT shall be designed and constructed to have tight-fitting lids, doors, or covers.

(B) Receptacles and waste handling units for REFUSE and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

numbers and capacities

5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(A) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold REFUSE, recyclables, and returnables that accumulate.

(B) A receptacle shall be provided in each area of the FOOD ESTABLISHMENT or PREMISES where REFUSE is generated or commonly discarded, or where recyclables or returnables are placed.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

5-501.17 Toilet Room Receptacle, Covered.

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

5-501.18 Cleaning Implements and Supplies.

(A) Except as specified in ¶ (B) of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for REFUSE, recyclables, and returnables.

(B) *If APPROVED, off-PREMISES-based cleaning services may be used if on-PREMISES cleaning implements and supplies are not provided.*

location and placement

5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(A) An area designated for REFUSE, recyclables, returnables, and, except as specified in ¶ (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and a public health HAZARD or nuisance is not created.

(B) *A redeeming machine may be located in the PACKAGED FOOD storage area or CONSUMER area of a FOOD ESTABLISHMENT if FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are not subject to contamination from the machines and a public health HAZARD or nuisance is not created.*

(C) The location of receptacles and waste handling units for REFUSE, recyclables, and returnables may not create a public health HAZARD or nuisance or interfere with the cleaning of adjacent space.

operation and maintenance

5-501.110 Storing Refuse, Recyclables, and Returnables.

REFUSE, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

5-501.111 Areas, Enclosures, and Receptacles, Good Repair.

Storage areas, enclosures, and receptacles for REFUSE, recyclables, and returnables shall be maintained in good repair.

5-501.112 Outside Storage Prohibitions.

(A) Except as specified in ¶ (B) of this section, REFUSE receptacles not meeting the requirements specified under ¶ 5-501.13(A) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with FOOD residue may not be stored outside.

(B) *Cardboard or other packaging material that does not contain FOOD residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.*

5-501.113 Covering Receptacles.

Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be kept covered:

(A) Inside the FOOD ESTABLISHMENT if the receptacles and units:

(1) Contain FOOD residue and are not in continuous use; or

(2) After they are filled; and

(B) With tight-fitting lids or doors if kept outside the FOOD ESTABLISHMENT.

5-501.114 Using Drain Plugs.

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

5-501.115 Maintaining Refuse Areas and Enclosures.

A storage area and enclosure for REFUSE, recyclables, or returnables shall be maintained free of unnecessary items, as specified under § 6-501.114, and clean.

5-501.116 Cleaning Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES, and waste water shall be disposed of as specified under § 5-402.14.

(B) Soiled receptacles and waste handling units for REFUSE, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Removal

5-502.11 Frequency.

REFUSE, recyclables, and returnables shall be removed from the PREMISES at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

5-502.12 Receptacles or Vehicles.

REFUSE, recyclables, and returnables shall be removed from the PREMISES by way of:

(A) Portable receptacles that are constructed and maintained according to LAW; or

(B) A transport vehicle that is constructed, maintained, and operated according to LAW.

Facilities for Disposal and Recycling

5-503.11 Community or Individual Facility.

Solid waste not disposed of through the SEWAGE system such as through grinders and pulpers shall be recycled or disposed of in an APPROVED public or private community recycling or REFUSE facility; or solid waste shall be disposed of in an individual REFUSE facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to LAW.

Chapter

6 Physical Facilities

Parts

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Indoor Areas

6-101.11 Surface Characteristics.

(A) Except as specified in ¶ (B) of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(1) SMOOTH, durable, and EASILY CLEANABLE for areas where FOOD ESTABLISHMENT operations are conducted;

(2) Closely woven and EASILY CLEANABLE carpet for carpeted areas; and

(3) Nonabsorbent for areas subject to moisture such as FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet rooms, mobile FOOD ESTABLISHMENT SERVICING AREAS, and areas subject to flushing or spray cleaning methods.

(B) *In a TEMPORARY FOOD ESTABLISHMENT:*

(1) *If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable APPROVED materials that are effectively treated to control dust and mud; and*

(2) *Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.*

Outdoor Areas **6-102.11 Surface Characteristics.**

(A) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(B) Exterior surfaces of buildings and mobile FOOD ESTABLISHMENTS shall be of weather-resistant materials and shall comply with LAW.

(C) Outdoor storage areas for REFUSE, recyclables, or returnables shall be of materials specified under §§ 5-501.11 and 5-501.12.

6-2 DESIGN, CONSTRUCTION, AND INSTALLATION

Subparts

6-201 Cleanability
6-202 Functionality

Cleanability **6-201.11 Floors, Walls, and Ceilings.**

Except as specified under § 6-201.14, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE, *except that antislip floor coverings or applications may be used for safety reasons.*

6-201.12 Floors, Walls, and Ceilings, Utility Lines.

(A) Utility service lines and pipes may not be unnecessarily exposed.

(B) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(C) Exposed horizontal utility service lines and pipes may not be installed on the floor.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(A) In FOOD ESTABLISHMENTS in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).

(B) The floors in FOOD ESTABLISHMENTS in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and SEALED.

6-201.14 Floor Carpeting, Restrictions and Installation.

(A) A floor covering such as carpeting or similar material may not be installed as a floor covering in FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, REFUSE storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(B) If carpeting is installed as a floor covering in areas other than those specified under ¶ (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

6-201.15 Floor Covering, Mats and Duckboards.

Mats and duckboards shall be designed to be removable and EASILY CLEANABLE.

6-201.16 Wall and Ceiling Coverings and Coatings.

(A) Wall and ceiling covering materials shall be attached so that they are EASILY CLEANABLE.

(B) *Except in areas used only for dry storage*, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and SEALED to provide a SMOOTH, nonabsorbent, EASILY CLEANABLE surface.

6-201.17 Walls and Ceilings, Attachments.

(A) Except as specified in ¶ (B) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be EASILY CLEANABLE.

(B) *In a CONSUMER area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.*

6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Studs, joists, and rafters may not be exposed in areas subject to moisture. *This requirement does not apply to TEMPORARY FOOD ESTABLISHMENTS*.

Functionality

6-202.11 Light Bulbs, Protective Shielding.

(A) Except as specified in ¶ (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing* FOOD *in unopened packages, if*:

(1) *The integrity of the packages can not be affected by broken glass falling onto them; and*

(2) *The packages are capable of being cleaned of debris from broken bulbs before the packages are opened*.

(C) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of FOOD, FOOD-CONTACT SURFACES, EQUIPMENT, or UTENSILS.

6-202.13 Insect Control Devices, Design and Installation.

(A) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(B) Insect control devices shall be installed so that:

(1) The devices are not located over a FOOD preparation area; and

(2) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

6-202.14 Toilet Rooms, Enclosed.

A toilet room located on the PREMISES shall be completely enclosed and provided with a tight-fitting and self-closing door *except that this requirement does not apply to a toilet room that is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall.*

6-202.15 Outer Openings, Protected.

(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:

(1) Filling or closing holes and other gaps along floors, walls, and ceilings;

(2) Closed, tight-fitting windows; and

(3) Solid, self-closing, tight-fitting doors.

(B) *Paragraph (A) of this section does not apply if a FOOD ESTABLISHMENT opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.*

(C) *Exterior doors used as exits need not be self-closing if they are:*

(1*) Solid and tight-fitting;*

(2) *Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the FOOD ESTABLISHMENT; and*

(3) *Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.*

(D) Except as specified in ¶¶ (B) and (E) of this section, if the windows or doors of a FOOD ESTABLISHMENT, or of a larger structure within which a FOOD ESTABLISHMENT is located, are kept open for

ventilation or other purposes or a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:

(1) 16 mesh to 25.4mm (16 mesh to 1 inch) screens;

(2) Properly designed and installed air curtains to control flying insects; or

(3) Other effective means.

(E) *Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the ESTABLISHMENT, the weather, or other limiting condition.*

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Perimeter walls and roofs of a FOOD ESTABLISHMENT shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

If located outside, a machine used to vend FOOD shall be provided with overhead protection *except that machines vending canned BEVERAGES need not meet this requirement.*

6-202.18 Outdoor Servicing Areas, Overhead Protection.

SERVICING AREAS shall be provided with overhead protection *except that areas used only for the loading of water or the discharge of SEWAGE and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.*

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

Exterior walking and driving surfaces shall be graded to drain.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

Outdoor REFUSE areas shall be constructed in accordance with LAW and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the REFUSE and from cleaning the area and waste receptacles.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting FOOD ESTABLISHMENT operations.

6-202.112 Living or Sleeping Quarters, Separation.

Living or sleeping quarters located on the PREMISES of a FOOD ESTABLISHMENT such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for FOOD ESTABLISHMENT operations by complete partitioning and solid self-closing doors.

6-3 NUMBERS AND CAPACITIES

Subparts

Handwashing Facilities

6-301.10 Minimum Number.

Handwashing facilities shall be provided as specified under § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Each handwashing lavatory or group of 2 adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

6-301.12 Hand Drying Provision.

Each handwashing lavatory or group of adjacent lavatories shall be provided with:

(A) Individual, disposable towels;

(B) A continuous towel system that supplies the user with a clean towel; or

(C) A heated-air hand drying device.

6-301.13 Handwashing Aids and Devices, Use Restrictions.

A sink used for FOOD preparation or UTENSIL washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and

devices required for a handwashing lavatory as specified under §§ 6-301.11 and 6-301.12 and ¶ 5-501.16(C).

6-301.14 Handwashing Signage.

A sign or poster that notifies FOOD EMPLOYEES to wash their hands shall be provided at all handwashing lavatories used by FOOD EMPLOYEES and shall be clearly visible to FOOD EMPLOYEES.

6-301.20 Disposable Towels, Waste Receptacle.

A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified under ¶ 5-501.16(C).

Toilets and Urinals

6-302.10 Minimum Number.

Toilets and urinals shall be provided as specified under § 5-203.12.

6-302.11 Toilet Tissue, Availability.

A supply of toilet tissue shall be available at each toilet.

Lighting

6-303.11 Intensity.

The light intensity shall be:

(A) At least 110 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and in other areas and rooms during periods of cleaning;

(B) At least 220 lux (20 foot candles):

(1) At a surface where FOOD is provided for CONSUMER self-service such as buffets and salad bars or where fresh produce or PACKAGED FOODS are sold or offered for consumption;

(2) Inside EQUIPMENT such as reach-in and under-counter refrigerators;

(3) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and EQUIPMENT and UTENSIL storage, and in toilet rooms; and

(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.

Ventilation

6-304.11 Mechanical.

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

Dressing Areas and Lockers

6-305.11 Designation.

(A) Dressing rooms or dressing areas shall be designated if EMPLOYEES routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of EMPLOYEES' clothing and other possessions.

Service Sinks

6-306.10 Availability.

A service sink or curbed cleaning facility shall be provided as specified under § 5-203.13.

6-4 LOCATION AND PLACEMENT

Subparts

Handwashing Facilities

6-401.10 Conveniently Located.

Handwashing facilities shall be conveniently located as specified under § 5-204.11.

Toilet Rooms

6-402.11 Convenience and Accessibility.

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

Employee Accommodations

6-403.11 Designated Areas.

(A) Areas designated for EMPLOYEES to eat, drink, and use tobacco shall be located so that FOOD, EQUIPMENT, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination.

(B) Lockers or other suitable facilities shall be located in a designated room or area where contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES can not occur.

Distressed Merchandise

6-404.11 Segregation and Location.

Products that are held by the PERMIT HOLDER for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

Refuse, Recyclables, and Returnables

6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.

Units, receptacles, and areas designated for storage of REFUSE and recyclable and returnable containers shall be located as specified under § 5-501.19.

6-5 MAINTENANCE AND OPERATION

Subpart

6-501 Premises, Structures, Attachments, and Fixtures - Methods

Premises, Structures, Attachments, and Fixtures - Methods

6-501.11 Repairing.

The PHYSICAL FACILITIES shall be maintained in good repair.

6-501.12 Cleaning, Frequency and Restrictions.

(A) The PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean.

(B) Cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing. *This requirement does not apply to cleaning that is necessary due to a spill or other accident.*

6-501.13 Cleaning Floors, Dustless Methods.

(A) Except as specified in ¶ (B) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(B) *Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:*

(1) *Without the use of dust-arresting compounds; and*

(2) *In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.*

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(A) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(B) If vented to the outside, ventilation systems may not create a public health HAZARD or nuisance or unLAWful discharge.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

FOOD preparation sinks, handwashing lavatories, and WAREWASHING EQUIPMENT may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

6-501.16 Drying Mops.

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, EQUIPMENT, or supplies.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Except as specified in ¶ 6-501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 Maintaining and Using Handwashing Facilities.

Handwashing facilities shall be kept clean, and maintained and used as specified under § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors as specified under § 6-202.14 shall be kept closed *except during cleaning and maintenance operations*.

6-501.110 Using Dressing Rooms and Lockers.

(A) Dressing rooms shall be used by EMPLOYEES if the EMPLOYEES regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing and other possessions.

6-501.111 Controlling Pests.*

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the PREMISES by:

(A) Routinely inspecting incoming shipments of FOOD and supplies;[N]

(B) Routinely inspecting the PREMISES for evidence of pests;[N]

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under §§ 7-202.12, 7-206.12, and 7-206.13; and

(D) Eliminating harborage conditions.[N]

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

6-501.113 Storing Maintenance Tools.

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The PREMISES shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

(B) Litter.

6-501.115 Prohibiting Animals.*

(A) Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the PREMISES of a FOOD ESTABLISHMENT.

(B) *Live animals may be allowed in the following situations if the contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result:*

(1) *Edible FISH or decorative FISH in aquariums, SHELLFISH or crustacea on ice or under refrigeration, and SHELLFISH and crustacea in display tank systems;*

(2) *Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;*

(3) *In areas that are not used for FOOD preparation and that are usually open for customers, such as dining and sales areas, SERVICE ANIMALS that are controlled by the disabled EMPLOYEE or PERSON, if a health or safety HAZARD will not result from the presence or activities of the SERVICE ANIMAL;*

(4) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(a) *Effective partitioning and self-closing doors separate the common dining areas from FOOD storage or FOOD preparation areas,*

(b) Condiments, EQUIPMENT, and UTENSILS are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

(c) *Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and*

(5) *In areas that are not used for FOOD preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.*

(C) *Live or dead FISH bait may be stored if contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result.*

Chapter

7 Poisonous or Toxic Materials

Parts

7-1 LABELING AND IDENTIFICATION

Subparts

Original Containers

7-101.11 Identifying Information, Prominence.*

Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label.

Working Containers

7-102.11 Common Name.*

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS taken from bulk supplies shall be clearly and individually identified with the common name of the material.

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

Subparts

Storage

7-201.11 Separation.*

POISONOUS OR TOXIC MATERIALS shall be stored so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[S] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.*

Presence and Use

7-202.11 Restriction.*

(A) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a FOOD ESTABLISHMENT, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a FOOD ESTABLISHMENT.[S]

(B) *¶ (A) of this section does not apply to PACKAGED POISONOUS OR TOXIC MATERIALS that are for retail sale.*

7-202.12 Conditions of Use.*

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT,

(3) The conditions of certification, if certification is required, for use of the pest control materials, and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and for a RESTRICTED USE PESTICIDE, this is achieved by:

(a) Removing the items,

(b) Covering the items with impermeable covers, or

(c) Taking other appropriate preventive actions, and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application.

(C) A RESTRICTED USE PESTICIDE shall be applied only by an applicator certified as defined in 7 USC 136(e) Certified Applicator, of the Federal Insecticide, Fungicide and

Rodenticide Act, or a PERSON under the direct supervision of a certified applicator.

Container Prohibitions

7-203.11 Poisonous or Toxic Material Containers.*

A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense FOOD.

Chemicals

7-204.11 Sanitizers, Criteria.*

Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall meet the requirements specified in 21 CFR 178.1010 sanitizing solutions.

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

Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

7-204.13 Boiler Water Additives, Criteria.*

Chemicals used as boiler water ADDITIVES shall meet the requirements specified in 21 CFR 173.310 Boiler Water Additives.

7-204.14 Drying Agents, Criteria.*

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in FOOD as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,

(3) APPROVED for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients,

(4) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 175-178, or

(5) APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; and

(B) When SANITIZATION is with chemicals, the approval required under Subparagraph (A)(3) or (A)(5) of this section or the regulation as an indirect FOOD ADDITIVE required under Subparagraph (A)(4) of this section, shall be specifically for use with chemical SANITIZING solutions.

Lubricants

7-205.11 Incidental Food Contact, Criteria.*

Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on FOOD-CONTACT SURFACES, on bearings and gears located on or within FOOD-CONTACT SURFACES, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

Pesticides

7-206.11 Restricted Use Pesticides, Criteria.*

RESTRICTED USE PESTICIDES specified under ¶ 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

7-206.12 Rodent Bait Stations.*

Rodent bait shall be contained in a covered, tamper-resistant bait station.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

(A) A tracking powder pesticide may not be used in a FOOD ESTABLISHMENT.

(B) If used, a nontoxic tracking powder such as talcum or flour may not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.[N]

Medicines

7-207.11 Restriction and Storage.*

(A) Only those medicines that are necessary for the health of EMPLOYEES shall be allowed in a FOOD ESTABLISHMENT. *This section does not apply to medicines that are stored or displayed for retail sale.*

(B) Medicines that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be labeled as specified under § 7-101.11 and located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7-207.12 Refrigerated Medicines, Storage.*

Medicines belonging to EMPLOYEES or to children in a day care center that require refrigeration and are stored in a FOOD refrigerator shall be:

(A) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and

(B) Located so they are inaccessible to children.

First Aid Supplies

7-208.11 Storage.*

First aid supplies that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be:

(A) Labeled as specified under § 7-101.11;[S] and

(B) Stored in a kit or a container that is located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, and LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.[s]

Other Personal Care Items

7-209.11 Storage.

Except as specified under §§ 7-207.12 and 7-208.11, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ 6-305.11(B).

7-3 STOCK AND RETAIL SALE

Subpart

7-301 Storage and Display

Storage and Display

7-301.11 Separation.*

POISONOUS OR TOXIC MATERIALS shall be stored and displayed for retail sale so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[s] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES.

Chapter

8 Compliance and Enforcement

Parts

8-1 CODE APPLICABILITY

Subparts

Use for Intended Purpose

8-101.10 Public Health Protection.

(A) The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, unADULTERATED, and honestly presented when offered to the CONSUMER.

(B) In enforcing the provisions of this Code, the REGULATORY AUTHORITY shall assess existing facilities or EQUIPMENT that were in use before the effective date of this Code based on the following considerations:

(1) Whether the facilities or EQUIPMENT are in good repair and capable of being maintained in a sanitary condition;

(2) Whether FOOD-CONTACT SURFACES comply with Subpart 4-101;

(3) Whether the capacities of cooling, heating, and holding EQUIPMENT are sufficient to comply with § 4-301.11; and

(4) The existence of a documented agreement with the PERMIT HOLDER that the facilities or EQUIPMENT will be replaced as specified under ¶ 8-304.11(G) or upgraded or replaced as specified under ¶ 8-304.11(H).

Additional Requirements

8-102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.

(A) If necessary to protect against public health HAZARDS or nuisances, the REGULATORY AUTHORITY may impose specific requirements in addition to the requirements contained in this Code that are authorized by LAW.

(B) The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the PERMIT applicant or PERMIT HOLDER and a copy shall be maintained in the REGULATORY AUTHORITY'S file for the FOOD ESTABLISHMENT.

Variances

8-103.10 Modifications and Waivers.

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

(A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;

(B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and

(C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.

8-103.11 Documentation of Proposed Variance and Justification.

Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

(A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;

(B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and

(C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.

8-103.12 Conformance with Approved Procedures.*

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANs and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring CRITICAL CONTROL POINTS,

(2) Monitoring of the CRITICAL CONTROL POINTS,

(3) Verification of the effectiveness of an operation or process, and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

8-2 PLAN SUBMISSION AND APPROVAL

Subparts

Facility and Operating Plans

8-201.11 When Plans Are Required.

A PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY properly prepared plans and specifications for review and approval before:

(A) The construction of a FOOD ESTABLISHMENT;

(B) The conversion of an existing structure for use as a FOOD ESTABLISHMENT; or

(C) The remodeling of a FOOD ESTABLISHMENT or a change of type of FOOD ESTABLISHMENT or FOOD operation as specified under ¶ 8-302.14(C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this Code.

8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

(A) Intended menu;

(B) Anticipated volume of FOOD to be stored, prepared, and sold or served;

(C) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and

(F) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.

8-201.13 When a HACCP Plan is Required.

(A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP PLAN is required according to LAW;

(2) A VARIANCE is required as specified under § 3-502.11, ¶ 4-204.110(B), or Subparagraph 3-401.11(D)(3); or

(3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of POTENTIALLY HAZARDOUS FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY;

(B) A flow diagram by specific FOOD or category type identifying CRITICAL CONTROL POINTS and providing information on the following:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, and

(2) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved;

(C) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each CRITICAL CONTROL POINT,

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE,

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS,

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; and

(E) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal.

Confidentiality

8-202.10 Trade Secrets.

The REGULATORY AUTHORITY shall treat as confidential in accordance with LAW, information that meets the criteria specified in LAW for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under §§ 8-201.12 and 8-201.14.

Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.

8-3 PERMIT TO OPERATE

Subparts

Requirement

8-301.11 Prerequisite for Operation.

A PERSON may not operate a FOOD ESTABLISHMENT without a valid PERMIT to operate issued by the REGULATORY AUTHORITY.

Application Procedure

8-302.11 Submission 30 Calendar Days Before Proposed Opening.

An applicant shall submit an application for a PERMIT at least 30 calendar days before the date planned for opening a FOOD ESTABLISHMENT or the expiration date of the current PERMIT for an existing facility.

8-302.12 Form of Submission.

A PERSON desiring to operate a FOOD ESTABLISHMENT shall submit to the REGULATORY AUTHORITY a written application for a PERMIT on a form provided by the REGULATORY AUTHORITY.

8-302.13 Qualifications and Responsibilities of Applicants.

To qualify for a PERMIT, an applicant shall:

(A) Be an owner of the FOOD ESTABLISHMENT or an officer of the legal ownership;

(B) Comply with the requirements of this Code;

(C) As specified under § 8-402.11, agree to allow access to the FOOD ESTABLISHMENT and to provide required information; and

(D) Pay the applicable PERMIT fees at the time the application is submitted.

8-302.14 Contents of the Application.

The application shall include:

(A) The name, birth date, mailing address, telephone number, and signature of the PERSON applying for the PERMIT and the name, mailing address, and location of the FOOD ESTABLISHMENT;

(B) Information specifying whether the FOOD ESTABLISHMENT is owned by an association, corporation, individual, partnership, or other legal entity;

(C) A statement specifying whether the FOOD ESTABLISHMENT:

(1) Is mobile or stationary and temporary or permanent, and

(2) Is an operation that includes one or more of the following:

(a) Prepares, offers for sale, or serves POTENTIALLY HAZARDOUS FOOD:

(i) Only to order upon a CONSUMER'S request,

(ii) In advance in quantities based on projected CONSUMER demand and discards FOOD that is not sold or served at an APPROVED frequency, or

(iii) Using time as the public health control as specified under § 3-501.19,

(b) Prepares POTENTIALLY HAZARDOUS FOOD in advance using a FOOD preparation method that involves two or more steps which may include combining POTENTIALLY HAZARDOUS ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,

(c) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for delivery to and consumption at a location off the PREMISES of the FOOD ESTABLISHMENT where it is prepared,

(d) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,

(e) Prepares only FOOD that is not POTENTIALLY HAZARDOUS, or

(f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not POTENTIALLY HAZARDOUS;

(D) The name, title, address, and telephone number of the PERSON directly responsible for the FOOD ESTABLISHMENT;

(E) The name, title, address, and telephone number of the

PERSON who functions as the immediate supervisor of the PERSON specified under ¶ (D) of this section such as the zone, district, or regional supervisor;

(F) The names, titles, and addresses of:

(1) The PERSONS comprising the legal ownership as specified under ¶ (B) of this section including the owners and officers, and

(2) The local resident agent if one is required based on the type of legal ownership;

(G) A statement signed by the applicant that:

(1) Attests to the accuracy of the information provided in the application, and

(2) Affirms that the applicant will:

(a) Comply with this Code, and

(b) Allow the REGULATORY AUTHORITY access to the establishment as specified under § 8-402.11 and to the records specified under §§ 3-203.12 and 5-205.13 and Subparagraph 8-201.14(D)(6); and

(H) Other information required by the REGULATORY AUTHORITY.

Issuance

8-303.10 New, Converted, or Remodeled Establishments.

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § 8-201.11 the REGULATORY AUTHORITY shall issue a PERMIT to the applicant after:

(A) A properly completed application is submitted;

(B) The required fee is submitted;

(C) The required plans, specifications, and information are reviewed and APPROVED; and

(D) A preoperational inspection as specified in § 8-203.10

shows that the establishment is built or remodeled in accordance with the APPROVED plans and specifications and that the establishment is in compliance with this Code.

8-303.20 Existing Establishments, Permit Renewal, and Change of Ownership.

The REGULATORY AUTHORITY may renew a PERMIT for an existing FOOD ESTABLISHMENT or may issue a PERMIT to a new owner of an existing FOOD ESTABLISHMENT after a properly completed application is submitted, reviewed, and APPROVED, the fees are paid, and an inspection shows that the establishment is in compliance with this Code.

8-303.30 Denial of Application for Permit, Notice.

If an application for a PERMIT to operate is denied, the REGULATORY AUTHORITY shall provide the applicant with a notice that includes:

(A) The specific reasons and Code citations for the PERMIT denial;

(B) The actions, if any, that the applicant must take to qualify for a PERMIT; and

(C) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in LAW.

Conditions of Retention

8-304.10 Responsibilities of the Regulatory Authority.

(A) At the time a PERMIT is first issued, the REGULATORY AUTHORITY shall provide to the PERMIT HOLDER a copy of this Code 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.

(B) *Failure to provide the information specified in ¶ (A) of this section does not prevent the REGULATORY AUTHORITY from taking authorized action or seeking remedies if the PERMIT HOLDER fails to comply with this Code or an order, warning, or directive of the REGULATORY AUTHORITY.*

8-304.11 Responsibilities of the Permit Holder.

Upon acceptance of the PERMIT issued by the REGULATORY AUTHORITY, the PERMIT HOLDER in order to retain the PERMIT shall:

(A) Post the PERMIT in a location in the FOOD ESTABLISHMENT that is conspicuous to CONSUMERS;

(B) Comply with the provisions of this Code including the conditions of a granted VARIANCE as specified under § 8-103.12, and APPROVED plans as specified under § 8-201.12;

(C) If a FOOD ESTABLISHMENT is required under § 8-201.13 to operate under a HACCP PLAN, comply with the plan as specified under § 8-103.12;

(D) Immediately contact the REGULATORY AUTHORITY to report an illness of a FOOD EMPLOYEE as specified under § 2-201.15;

(E) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist as specified under § 8-404.11;

(F) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;

(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;

(H) Upgrade or replace refrigeration EQUIPMENT as specified under ¶ 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;

(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;

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

(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.

8-304.20 Permits Not Transferable.

A PERMIT may not be transferred from one PERSON to another PERSON, from one FOOD ESTABLISHMENT to another, or from one type of operation to another if the FOOD operation changes from the type of operation specified in the application as specified under ¶ 8-302.14(C) and the change in operation is not APPROVED.

8-4 INSPECTION AND CORRECTION OF VIOLATIONS

Subparts

Frequency

8-401.10 Establishing Inspection Interval.

(A) Except as specified in ¶¶ (B) and (C) of this section, the REGULATORY AUTHORITY shall inspect a FOOD ESTABLISHMENT at least once every 6 months.

(B) *The REGULATORY AUTHORITY may increase the interval between inspections beyond 6 months if:*

(1) *The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(A) and (B);*

(2) *The FOOD ESTABLISHMENT is assigned a less frequent inspection frequency 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; or*

(3) *The establishment's operation involves only coffee service and other unPACKAGED or prePACKAGED FOOD that is not POTENTIALLY HAZARDOUS such as carbonated BEVERAGES and snack FOOD such as chips, nuts, popcorn, and pretzels.*

(C) The REGULATORY AUTHORITY shall periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves unPACKAGED POTENTIALLY HAZARDOUS FOOD and that:

(1) Has improvised rather than permanent facilities or EQUIPMENT for accomplishing functions such as handwashing, FOOD preparation and protection, FOOD temperature control, WAREWASHING, providing DRINKING WATER, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

8-401.20 Performance- and Risk-Based.

Within the parameters specified in § 8-401.10, the REGULATORY AUTHORITY shall prioritize, and conduct more frequent inspections based upon its assessment of a FOOD ESTABLISHMENT'S history of compliance with this Code and the establishment's potential as a

vector of foodborne illness by evaluating:

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

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

(C) Past performance, for complaints investigated and found to be valid;

(D) The HAZARDS associated with the particular FOODS that are prepared, stored, or served;

(E) The type of operation including the methods and extent of FOOD storage, preparation, and service;

(F) The number of people served; and

(G) Whether the population served is a HIGHLY SUSCEPTIBLE POPULATION.

Access

8-402.11 Allowed at Reasonable Times after Due Notice.

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

8-402.20 Refusal, Notification of Right to Access, and Final Request for Access.

If a PERSON denies access to the REGULATORY AUTHORITY, the REGULATORY AUTHORITY shall:

(A) Inform the PERSON that:

(1) The PERMIT HOLDER is required to allow access to the

REGULATORY AUTHORITY as specified under § 8-402.11 of this Code,

(2) Access is a condition of the acceptance and retention of a FOOD ESTABLISHMENT PERMIT to operate as specified under ¶ 8-304.11(F), and

(3) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to LAW; and

(B) Make a final request for access.

8-402.30 Refusal, Reporting.

If after the REGULATORY AUTHORITY presents credentials and provides notice as specified under § 8-402.11, explains the authority upon which access is requested, and makes a final request for access as specified in § 8-402.20, the PERSON IN CHARGE continues to REFUSE access, the REGULATORY AUTHORITY shall provide details of the denial of access on an inspection report form.

8-402.40 Inspection Order to Gain Access.

If denied access to a FOOD ESTABLISHMENT for an authorized purpose and after complying with § 8-402.20, the REGULATORY AUTHORITY may issue, or apply for the issuance of, an inspection order to gain access as provided in LAW.

Report of Findings

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(A) Administrative information about the FOOD ESTABLISHMENT'S legal identity, street and mailing addresses, type of establishment and operation as specified under ¶ 8-302.14(C), inspection date, and other information such as type of water supply and SEWAGE disposal, status of the PERMIT, and personnel certificates that may be required; and

(B) Specific factual observations of violative conditions or other

deviations from this Code that require correction by the PERMIT HOLDER including:

(1) Failure of the PERSON IN CHARGE to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code specified under § 2-102.11,

(2) Failure of FOOD EMPLOYEES and the PERSON IN CHARGE to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under §§ 2-201.14 and 2-201.15,

(3) Nonconformance with CRITICAL ITEMS of this Code,

(4) Failure of the appropriate FOOD EMPLOYEES to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the REGULATORY AUTHORITY as specified under § 8-103.12,

(5) Failure of the PERSON IN CHARGE to provide records required by the REGULATORY AUTHORITY for determining conformance with a HACCP PLAN as specified under Subparagraph 8-201.14(D)(6), and

(6) Nonconformance with CRITICAL LIMITS of a HACCP PLAN.

8-403.20 Specifying Time Frame for Corrections.

The REGULATORY AUTHORITY shall specify on the inspection report form the time frame for correction of the violations as specified under §§ 8-404.11, 8-405.11, and 8-406.11.

8-403.30 Issuing Report and Obtaining Acknowledgment of Receipt.

At the conclusion of the inspection and according to LAW, the REGULATORY AUTHORITY shall provide a copy of the completed inspection report and the notice to correct violations to the PERMIT HOLDER or to the PERSON IN CHARGE, and request a signed acknowledgment of receipt.

8-403.40 Refusal to Sign Acknowledgment.

The REGULATORY AUTHORITY shall:

(A) Inform a PERSON who declines to sign an acknowledgment of receipt of inspectional findings as specified in § 8-403.30 that:

(1) An acknowledgment of receipt is not an agreement with findings,

(2) Refusal to sign an acknowledgment of receipt will not affect the PERMIT HOLDER'S obligation to correct the violations noted in the inspection report within the time frames specified, and

(3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the REGULATORY AUTHORITY'S historical record for the FOOD ESTABLISHMENT; and

(B) Make a final request that the PERSON IN CHARGE sign an acknowledgment receipt of inspectional findings.

8-403.50 Public Information.

Except as specified in § 8-202.10, the REGULATORY AUTHORITY shall treat the inspection report as a public document and shall make it available for disclosure to a PERSON who requests it as provided in LAW.

Imminent Health Hazard

8-404.11 Ceasing Operations and Reporting.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

(B) *A PERMIT HOLDER need not discontinue operations in an area*

of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.

8-404.12 Resumption of Operations.

If operations are discontinued as specified under § 8-404.11 or otherwise according to LAW, the PERMIT HOLDER shall obtain approval from the REGULATORY AUTHORITY before resuming operations.

Critical Violation

8-405.11 Timely Correction.

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

(B) *Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, the REGULATORY AUTHORITY may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the PERMIT HOLDER to correct critical Code violations or HACCP PLAN deviations.*

8-405.20 Verification and Documentation of Correction.

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

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a critical violation 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.

Noncritical Violation

8-406.11 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER

shall correct noncritical violations by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.

(B) *The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under ¶ (A) of this section if a written schedule of compliance is submitted by the PERMIT HOLDER and no health HAZARD exists or will result from allowing an extended schedule for compliance.*

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

Subpart

8-501 Investigation and Control

Investigation and Control

8-501.10 Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD EMPLOYEE has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through FOOD; may be a carrier of infectious agents that cause a disease that is transmissible through FOOD; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(A) Securing a confidential medical history of the EMPLOYEE suspected of transmitting disease or making other investigations as deemed appropriate; and

(B) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected EMPLOYEE and other EMPLOYEES.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a FOOD EMPLOYEE who is suspected of being infected or diseased, the REGULATORY AUTHORITY may issue an order to the suspected FOOD EMPLOYEE or PERMIT HOLDER instituting one or more of the following control measures:

(A) RESTRICTING the FOOD EMPLOYEE;

(B) EXCLUDING the FOOD EMPLOYEE; or

(C) Closing the FOOD ESTABLISHMENT by summarily suspending a PERMIT to operate in accordance with LAW.

8-501.30 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order.

Based on the findings of the investigation as specified in § 8-501.10 and to control disease transmission, the REGULATORY AUTHORITY may issue an order of RESTRICTION or EXCLUSION to a suspected FOOD EMPLOYEE or the PERMIT HOLDER without prior warning, notice of a hearing, or a hearing if the order:

(A) States the reasons for the RESTRICTION or EXCLUSION that is ordered;

(B) States the evidence that the FOOD EMPLOYEE or PERMIT HOLDER shall provide in order to demonstrate that the reasons for the RESTRICTION or EXCLUSION are eliminated;

(C) States that the suspected FOOD EMPLOYEE or the PERMIT HOLDER may request an appeal hearing by submitting a timely request as provided in LAW; and

(D) Provides the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-501.40 Release of Food Employee from Restriction or Exclusion.

The REGULATORY AUTHORITY shall release a FOOD EMPLOYEE from RESTRICTION or EXCLUSION according to LAW and the following conditions:

(A) A FOOD EMPLOYEE who was infected with ***Salmonella*** **Typhi** if the FOOD EMPLOYEE'S stools are negative for ***S***. **Typhi** based on testing of at least 3 consecutive stool specimen cultures that are taken:

(1) Not earlier than 1 month after onset,

(2) At least 48 hours after discontinuance of antibiotics, and

(3) At least 24 hours apart; and

(B) If one of the cultures taken as specified in ¶ (A) of this section is positive, repeat cultures are taken at intervals of 1 month until at least 3 consecutive negative stool specimen cultures are obtained.

(C) A FOOD EMPLOYEE who was infected with ***Shigella*** spp. or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI*** if the EMPLOYEE'S stools are negative for ***Shigella*** spp. or SHIGA TOXIN-PRODUCING ***ESCHERICHIA COLI*** based on testing of 2 consecutive stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics; and

(2) At least 24 hours apart.

(D) A FOOD EMPLOYEE who was infected with hepatitis A virus if:

(1) Symptoms cease; or

(2) At least 2 blood tests show falling liver enzymes.

Annex

1 *Compliance and Enforcement*

1. PURPOSE

The purpose of this Annex is to set forth provisions, in codified form, that provide a full array of enforcement mechanisms while recognizing the diverse statutes and regulations that currently govern the operations of the thousands of state and local regulatory agencies.

2. EXPLANATION

State or local statutes, regulations, and ordinances vary in their design, specificity, and degree of comprehensiveness in that they may:

(A) Contain authorities that provide the basis for certain post-inspection compliance strategies but remain silent with respect to other enforcement mechanisms;

(B) Include specific requirements that are different from those provided in this Annex; and

(C) Be structured so that provisions such as administrative procedures are embodied in sections of the law that transcend and are separate from those governing food establishments.

Consequently, in this document a deliberate attempt is made to extract those provisions that could conceptually be adopted as an extension of Chapter 8 if they were compatible with existing, governing state and local statutes. The extracted provisions are numbered to sequentially follow Chapter 8 but are placed in this Annex so that regulatory agencies can revise them to be consistent with their statutes and their needs as discussed in the Recommendation, below.

It is anticipated that adoption of this Code will be facilitated by the fact that:

(A) The compliance provisions of Chapter 8 that should be an integral part of state or local food regulations are part of the text of the Code; and

(B) The administrative and judicial enforcement provisions that are critical to the framework of a food regulatory program, but that may be repetitive or discrepant when compared to state or local statutes, are separated in this Annex.

3. PRINCIPLE

Although the situations necessitating escalated enforcement actions comprise a small percentage of those encountered by the regulator, a full spectrum of enforcement tools must be available where immediate hazards exist, or where compliance is not obtained voluntarily. Thus, a jurisdiction must have in place both the necessary statutory framework that includes a broad-based, well-defined enforcement component and regulations that specify the requirements within those legal authorities. It is imperative that there be clearly stated and legally sound rules that include the criteria for compliance and enforcement, the responsibilities of all parties, sanctions for noncompliance, and due process guarantees.

4. RECOMMENDATION

FDA recommends that agencies assess their statutory provisions that pertain to food establishments in light of this Annex and consider proposing changes to their statutes and regulations where they determine that provisions contained within this Annex will strengthen their programs. Such an assessment may involve reviewing problems encountered in attempts to prosecute under existing state or local provisions; considering comments received by the regulatory authority about its enforcement process; consulting with staff and legal counsel to identify gaps or weaknesses in the provisions; comparing provisions with sister agencies for comprehensiveness, equity, and uniformity; and seeking input from outside sources that have experience in taking, or being the subject of, enforcement actions.

Appropriate wording and cross referencing changes to the provisions in this Annex may be necessary, based on whether they are adopted as statutes or regulations. Modifications to the adoption forms (Forms #2-A and #2-B in Annex 7) may also be necessary based on that decision.

Parts

8-6 CONSTITUTIONAL PROTECTION

Subparts

Procedural Safeguards

8-601.10 Preservation of Rights.

The REGULATORY AUTHORITY shall justly apply the remedies according to LAW and this Code, to preserve the rights to equal protection and due process of a PERSON to whom the remedies are applied.

Judicial Review

8-602.10 Rights of Recipients of Orders or Decisions.

A recipient of a REGULATORY AUTHORITY order or decision may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies are exhausted.

8-7 NOTICES

Subpart

8-701 Service of Notice

Service of Notice

8-701.10 Proper Methods.

(Note: Adoption of this section provides the basis for serving notice of inspectional findings as specified in § 8-403.30 and would be cited there.)

A notice issued in accordance with this Code shall be considered to be properly served if it is served by one of the following methods:

(A) The notice is personally served by the REGULATORY AUTHORITY, a LAW enforcement officer, or a PERSON authorized to serve a civil process to the PERMIT HOLDER, the PERSON IN CHARGE, or PERSON operating a FOOD ESTABLISHMENT without a PERMIT;

(B) The notice is sent by the REGULATORY AUTHORITY to the last known address of the PERMIT HOLDER or the PERSON operating a FOOD ESTABLISHMENT without a PERMIT, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired; or

(C) The notice is provided by the REGULATORY AUTHORITY in accordance with another manner of service authorized in LAW.

8-701.20 Restriction or Exclusion Order, Hold Order or Summary Suspension.

An EMPLOYEE RESTRICTION or EXCLUSION order, an order to hold and not distribute FOOD, such as a hold, detention, embargo, or seizure order which is hereinafter referred to as a hold order, or a summary suspension order shall be:

(A) Served as specified in ¶ 8-701.10(A); or

(B) Clearly posted by the REGULATORY AUTHORITY at a public entrance to the FOOD ESTABLISHMENT and a copy of the notice sent by first class mail to the PERMIT HOLDER or to the owner or custodian of the FOOD, as appropriate.

8-701.30 When Notice is Effective.

Service is effective at the time of the notice's receipt or if service is made as specified in ¶ 8-701.20(B), at the time of the notice's posting.

8-701.40 Proof of Proper Service.

Proof of proper service may be made by affidavit of the PERSON making service or by admission of the receipt signed by the PERMIT HOLDER, the PERSON operating a FOOD ESTABLISHMENT without a PERMIT to operate, or an authorized agent.

8-8 REMEDIES

Subparts

Criteria for Seeking Remedies

8-801.10 Conditions Warranting Remedy.

The REGULATORY AUTHORITY may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a PERSON operating a FOOD ESTABLISHMENT or EMPLOYEE:

(A) Fails to have a valid PERMIT to operate a FOOD ESTABLISHMENT as specified under § 8-301.11;

(B) Violates any term or condition of a PERMIT as specified under § 8-304.11;

(C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction APPROVED, directed, or ordered by the REGULATORY AUTHORITY under ¶¶ 8-405.11(A) and (B), and ¶¶ 8-406.11(A) and (B);

(D) Fails to comply with a REGULATORY AUTHORITY order issued as specified in § 8-501.20 concerning an EMPLOYEE suspected of having a disease transmissible through FOOD by infected PERSONS;

(E) Fails to comply with a hold order as specified in §§ 8-701.20 and 8-803.10;

(F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in §§ 8-806.30 or 8-806.40; or

(G) Fails to comply with a summary suspension order issued by the REGULATORY AUTHORITY as specified in §§ 8-701.20 and 8-804.10.

Administrative Inspection Orders

8-802.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may order access for one or more of the following purposes, subject to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-802.20 Contents of Inspection Order.

The REGULATORY AUTHORITY'S inspection order shall:

(A) Stipulate that access be allowed on or to the described PREMISES, FOOD, or records under the order's provisions;

(B) Provide a description that specifies the PREMISES, FOOD, or records subject to the order; and

(C) Specify areas to be accessed and activities to be performed.

Holding, Examination, and Destruction of Food

8-803.10 Hold Order, Justifying Conditions and Removal of Food.

(Note: Adoption of this section provides the basis for ¶ 3-202.18(B) and would be cited there.)

(A) According to time limits imposed by LAW, the REGULATORY AUTHORITY may place a hold order on a FOOD that:

(1) Originated from an unAPPROVED source;

(2) May be unsafe, ADULTERATED, or not honestly presented;

(3) Is not labeled according to LAW, or, if raw MOLLUSCAN SHELLFISH, is not tagged or labeled according to LAW; or

(4) Is otherwise not in compliance with this Code.

(B) If the REGULATORY AUTHORITY has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the REGULATORY AUTHORITY may remove the FOOD that is subject to the order to a place of safekeeping.

8-803.20 Hold Order, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified in § 8-701.20, without prior warning, notice of a hearing, or a hearing on the hold order.

8-803.30 Hold Order, Contents.

The hold order notice shall:

(A) State that FOOD subject to the order may not be used, sold, moved from the FOOD ESTABLISHMENT, or destroyed without a written release of the order from the REGULATORY AUTHORITY;

(B) State the specific reasons for placing the FOOD under the hold order with reference to the applicable provisions of this Code and the HAZARD or adverse effect created by the observed condition;

(C) Completely identify the FOOD subject to the hold order by the common name, the label information, a container description, the quantity, REGULATORY AUTHORITY'S tag or identification information, and location;

(D) State that the PERMIT HOLDER has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20;

(E) State that the REGULATORY AUTHORITY may order the destruction of the FOOD if a timely request for an appeal hearing is not received; and

(F) Provide the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-803.40 Hold Order, Official Tagging of Food.

(A) The REGULATORY AUTHORITY shall securely place an official tag or label on the FOOD or containers or otherwise conspicuously identify FOOD subject to the hold order.

(B) The tag or other method used to identify a FOOD that is the subject of a hold order shall include a summary of the provisions specified in § 8-803.10 and shall be signed and dated by the REGULATORY AUTHORITY.

8-803.51 Hold Order, Food May Not Be Used or Moved.

(A) Except as specified in ¶ (B) of this section, a FOOD placed under a hold order may not be used, sold, served, or moved from the establishment by any PERSON.

(B) *The REGULATORY AUTHORITY may allow the PERMIT HOLDER the opportunity to store the FOOD in an area of the FOOD ESTABLISHMENT if the FOOD is protected from subsequent deterioration and the storage does not restrict operations of the establishment.*

8-803.60 Examining, Sampling, and Testing Food.

The REGULATORY AUTHORITY may examine, sample, and test FOOD in order to determine its compliance with this Code.

8-803.70 Hold Order, Removing the Official Tag.

Only the REGULATORY AUTHORITY may remove hold order tags, labels, or other identification from FOOD subject to a hold order.

8-803.80 Destroying or Denaturing Food.

If a hold order is sustained upon appeal or if a timely request for an appeal hearing is not filed, the REGULATORY AUTHORITY may order the PERMIT HOLDER or other PERSON who owns or has custody of the FOOD to bring the FOOD into compliance with this Code or to destroy or denature the FOOD under the REGULATORY AUTHORITY'S supervision.

8-803.90 Releasing Food from Hold Order.

The REGULATORY AUTHORITY shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the FOOD if the hold order is vacated.

Summary Permit Suspension

8-804.10 Conditions Warranting Action.

The REGULATORY AUTHORITY may summarily suspend a PERMIT to operate a FOOD ESTABLISHMENT if it determines through inspection, or examination of EMPLOYEES, FOOD, records, or other means as specified in this Code, that an IMMINENT HEALTH HAZARD exists.

8-804.20 Summary Suspension, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may summarily suspend a PERSON'S PERMIT as specified in § 8-804.10 by providing written notice as specified in § 8-701.20 of the summary suspension to the PERMIT HOLDER or PERSON IN CHARGE, without prior warning, notice of a hearing, or a hearing.

8-804.30 Contents of the Notice.

A summary suspension notice shall state:

(A) That the FOOD ESTABLISHMENT PERMIT is immediately suspended and that all FOOD operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this Code that are in violation;

(C) The name and address of the REGULATORY AUTHORITY representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and

(D) That the PERMIT HOLDER may request an appeal hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20.

8-804.40 Time Frame for Reinspection.

After receiving a written request from the PERMIT HOLDER stating that the conditions cited in the summary suspension order no longer exist, the REGULATORY AUTHORITY shall conduct a reinspection of the FOOD ESTABLISHMENT for which the PERMIT was summarily suspended within 2 business days, which means 2 days during which the REGULATORY AUTHORITY'S office is open to the public.

8-804.50 Term of Suspension, Reinstatement of Permit.

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the REGULATORY AUTHORITY through reinspection and other means as appropriate.

(B) The suspended PERMIT shall be reinstated immediately if the REGULATORY AUTHORITY determines that the public health HAZARD or nuisance no longer exists. A notice of reinstatement shall be provided to the PERMIT HOLDER or PERSON IN CHARGE.

Hearings Administration

8-805.10 Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

(Note: Adoption of this section provides the basis for ¶¶ 8-303.30(C) and 8-501.30(C). ¶¶ 8-805.10(C) and (D) would be cited there.)

(A) A PERSON who receives a notice of hearing for an administrative remedy as specified in Part 8-7, § 8-801.10, or ¶ 8-805.30(A) and elects to respond to the notice shall file a response to notice as specified in § 8-805.20 within 7 calendar days after service.

(B) A PERMIT applicant may request a hearing regarding the disposition of an application for a new or revised PERMIT if the REGULATORY AUTHORITY does not issue or deny the PERMIT within the time frame specified in LAW.

(C) A PERMIT HOLDER may request a hearing to address concerns about the REGULATORY AUTHORITY'S denial of application for a PERMIT or request for a VARIANCE, or compliance actions, except that a hearing request does not stay the REGULATORY AUTHORITY'S restriction or exclusion of EMPLOYEES specified in §§ 8-501.10 -

8-501.40, a hold order specified in § 8-803.10, or the imposition of a summary suspension specified in § 8-804.10.

(D) A PERSON desiring a hearing in response to a denial of an application for PERMIT or an adverse administrative determination shall submit a hearing request to the REGULATORY AUTHORITY within 10 calendar days of the date of the denial, inspection, or compliance action, unless the REGULATORY AUTHORITY specifies in certain situations that the request shall be submitted within a shorter period of time.

8-805.20 Response to a Notice of Hearing or Request for Hearing, Required Form and Contents.

A response to a hearing notice or a request for hearing as specified in § 8-805.10 shall be in written form and contain the following:

(A) If a response to notice of hearing,

(1) An admission or denial of each allegation of fact;

(2) A statement as to whether the respondent waives the right to a hearing; and may also contain

(3) A statement of defense, mitigation, or explanation concerning any allegation of fact; and

(4) A request to the REGULATORY AUTHORITY for a settlement of the proceeding by consent agreement, if the REGULATORY AUTHORITY will provide this opportunity.

(B) If a request for hearing,

(1) A statement of the issue of fact specified in ¶ 8-805.30(B) for which the hearing is requested; and

(2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact.

(C) If either a response to notice of hearing or a request for a hearing,

(1) A statement indicating whether the presence of witnesses for the REGULATORY AUTHORITY is required; and

(2) The name and address of the respondent's or requester's legal counsel, if any.

8-805.30 Provided Upon Request.

The REGULATORY AUTHORITY shall hold hearings according to LAW and the provisions of this Code:

(A) As determined necessary by LAW or the REGULATORY AUTHORITY to accomplish the purpose and intent of this Code specified in § 8-101.10; and

(B) As requested by a PERMIT applicant or a PERMIT HOLDER if:

(1) Requested as specified in § 8-805.10, and

(2) The request demonstrates that there is a genuine and material issue of fact that justifies that a hearing be held.

8-805.40 Provided in Accordance with Law.

Hearings shall be conducted according to LAW, administrative procedures, and this Code.

8-805.50 Timeliness, Appeal Proceeding Within 5 Business Days, Other Proceeding Within 30 Calendar Days.

(A) The REGULATORY AUTHORITY shall afford a hearing:

(1) Except as provided in ¶ (B) of this section, within 5 business days after receiving a written request for an appeal hearing from:

(a) A PERSON who is EXCLUDED by the REGULATORY AUTHORITY from working in a FOOD ESTABLISHMENT as specified in §§ 8-501.10 - 8-501.40,

(b) A PERMIT HOLDER or PERSON whose FOOD is subject to a hold order as specified in Subpart 8-803, or

(c) A PERMIT HOLDER whose PERMIT is summarily suspended as specified in Subpart 8-804; and

(2) Within 30 calendar days but no earlier than 7 calendar days after the service of a hearing notice to consider administrative remedies for other matters as specified in ¶ 8-805.10(C) or for matters as determined necessary by the REGULATORY AUTHORITY.

(B) A PERMIT HOLDER or PERSON who submits a request for a hearing as specified in Subparagraphs (A)(1)(a)-(c) of this section may waive the prompt hearing in the written request to the REGULATORY AUTHORITY.

8-805.60 Notice, Contents.

A notice of hearing shall contain the following information:

(A) Time, date, and place of the hearing;

(B) Purpose of the hearing;

(C) Facts that constitute the basis or reason for the hearing including specific details of violations or allegations;

(D) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in § 8-807.10;

(E) At the REGULATORY AUTHORITY'S discretion, the procedure for the respondent to request an offer from the REGULATORY AUTHORITY to settle the matter;

(F) The consequences of failing to appear at the hearing;

(G) The maximum sanctions or penalties as specified in ¶¶ 8-806.40(B)-(D) that may result from the hearing if the hearing concerns a proposed administrative remedy and if the facts are found to be as alleged;

(H) If the hearing concerns a proposed administrative remedy, a statement specifying the form and time frame for response as specified in § 8-805.10;

(I) Notification that the written response shall include the information specified in § 8-805.20; and

(J) The name and address of the PERSON to whom such written response shall be addressed.

8-805.70 Proceeding Commences Upon Notification.

A hearing proceeding commences at the time the REGULATORY AUTHORITY notifies the respondent of the hearing proceeding.

8-805.80 Procedure, Expeditious and Impartial.

Hearings shall be conducted in an expeditious and impartial manner.

8-805.90 Confidential.

(A) Hearings or portions of hearings may be closed to the public:

(1) If compelling circumstances, such as the need to discuss in the hearing a PERSON'S medical condition or a FOOD ESTABLISHMENT'S trade secrets, indicate that it would be prudent; and

(2) According to LAW, such as an open meetings LAW.

(B) A party to a hearing shall maintain confidentiality of discussions that warrant closing the hearing to the public.

8-805.100 Record of Proceeding.

A complete record of a hearing shall be prepared under the direction of the PERSON conducting the hearing and maintained as part of the REGULATORY AUTHORITY'S records for the FOOD ESTABLISHMENT. *Except as required by LAW, a verbatim transcript of the hearing need not be prepared*.

Hearing Officer, Purpose Qualifications, Appointment, and Powers

8-806.10 Appointment by Regulatory Authority and Purpose.

The REGULATORY AUTHORITY may appoint a PERSON such as an adjudicator, administrative LAW judge, or examiner, hereinafter referred to as a hearing officer, who presides over a proceeding initiated by the REGULATORY AUTHORITY or by a PERSON contesting an action of the REGULATORY AUTHORITY, to perform one or more of the following:

(A) Hear the facts presented by an applicant or a PERMIT HOLDER;

(B) Make a decision or recommendation concerning administrative remedies to achieve compliance with this Code; or

(C) Address other concerns or allegations appropriately raised according to LAW, in the matter before the hearing officer.

8-806.20 Qualifications.

A hearing officer shall be knowledgeable of the provisions of this chapter and the LAW as they relate to hearings, and be:

(A) A REGULATORY AUTHORITY representative other than the PERSON who inspects the FOOD ESTABLISHMENT or who has any other role in making the decision that is being contested; or

(B) An individual who is not employed by the REGULATORY AUTHORITY.

8-806.30 Powers, Administration of Hearings.

(A) A hearing officer shall have the following powers in a hearing in which the hearing officer presides:

(1) Setting and conducting the course of a hearing requested in accordance with or authorized by this Code,

(2) Issuing subpoenas in the name of the REGULATORY AUTHORITY at the request of a party to a hearing, administering oaths and affirmations, examining witnesses, receiving evidence,

(3) Approving a consent agreement on the issues involved in the hearing entered into by the REGULATORY AUTHORITY and the respondent after the respondent receives a hearing notice,

(4) Sustaining, modifying, rescinding, or vacating an order or directive of the REGULATORY AUTHORITY in an appeal hearing proceeding, and if the order or directive is sustained, ordering appropriate measures to execute the REGULATORY AUTHORITY'S order or directive; and

(B) *Unless a party appeals to the head of the REGULATORY AUTHORITY within 15 days of the hearing or a lesser number of days specified by the hearing officer:*

(1) Rendering a binding decision and final order in a proceeding after conducting a hearing, if the respondent has not waived the right to a hearing, and

(2) Then notifying the respondent of the decision and the order which contains the findings and conclusions of LAW.

8-806.40 Powers, Administrative Remedies.

The hearing officer shall have the following powers in a hearing proceeding concerning an administrative remedy specified in §§ 8-801.10 and 8-805.30:

(A) Issuing orders to abate or correct violations of this Code and establishing a schedule for the abatement or correction of violations;

(B) Making a finding of fact regarding the occurrence of each violation and assessing, levying, and ordering a reasonable civil penalty, according to LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(C) Suspending, revoking, modifying, or imposing reasonable restrictions or conditions on a PERMIT to operate a FOOD ESTABLISHMENT, or ordering the closure of a FOOD ESTABLISHMENT that is operated without a valid PERMIT as required under § 8-301.11 of this Code;

(D) Making a finding of fact regarding the occurrence of each violation of the REGULATORY AUTHORITY'S or hearing officer's LAWful order issued in accordance with this Code and assessing, levying, and ordering a reasonable civil penalty, in accordance with LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(E) Deferring or suspending the imposition of a decision or execution of an order, and imposing a probationary period, upon the condition that the respondent comply with the hearing officer's reasonable terms and conditions;

(F) Dismissing the appeal if the matter is settled between the REGULATORY AUTHORITY and the respondent after a hearing notice is served;

(G) Ordering reinspection of a FOOD ESTABLISHMENT to determine compliance with a hearing officer's order;

(H) Suspending or ordering the payment of a fee established by the REGULATORY AUTHORITY for a reinspection that is required to determine compliance and for the reinstatement of a PERMIT after suspension;

(I) Retaining and exercising jurisdiction for a specific period of time not to exceed 90 calendar days after the hearing officer's decision and final order is issued, over a respondent who receives a hearing notice; and

(J) Modifying or setting aside an order by rehearing upon the hearing officer's own motion, the motion of the REGULATORY AUTHORITY, or the motion of the respondent.

Rights of Parties and Evidence

8-807.10 Rights of Parties.

Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

8-807.20 Evidence to be Presented by the Regulatory Authority.

The REGULATORY AUTHORITY shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

8-807.30 Evidence to be Excluded.

Evidence shall be EXCLUDED:

(A) If it is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized by the state's courts; or

(B) Otherwise according to LAW.

8-807.40 Testimony under Oath.

Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

8-807.50 Written Evidence.

Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

8-807.60 Documentary Evidence.

Documentary evidence may be received in the form of a copy or excerpt.

Settlement

8-808.10 Authorization.

The REGULATORY AUTHORITY may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

8-808.20 Respondent Acceptance of Consent Agreement Is Waiver of Right to Appeal.

Respondents accepting a consent agreement waive their right to a hearing on the matter.

Judicial

8-809.10 Gaining Access to Premises and Records.

Inspection Orders

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may seek access for one or more of the following purposes, according to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-809.20 Contents of Court Petition.

In the absence of a specific set of requirements established by LAW, in its petition to the court to compel access the REGULATORY AUTHORITY shall:

(A) Describe in detail the PREMISES, FOOD, or records on or to which access was denied;

(B) Detail the legal authority to regulate and to have access for a specific purpose on or to the PREMISES, FOOD, or records where access was denied; and

(C) Provide information that the FOOD ESTABLISHMENT possesses a valid PERMIT from the REGULATORY AUTHORITY and that it applies to the PREMISES where access was denied; or

(D) Provide information that a PERSON is known to be or suspected of operating a FOOD ESTABLISHMENT without possessing a valid PERMIT as specified in LAW and under this

Code.

8-809.30 Sworn Statement of Denied Access.

The REGULATORY AUTHORITY shall demonstrate to the court by affidavit, sworn testimony, or both that:

(A) Access on or to the PREMISES, FOOD, or records was denied after the REGULATORY AUTHORITY acted as specified in §§ 8-402.20 and 8-402.30; or

(B) There is reason to believe that a FOOD ESTABLISHMENT is being operated on the PREMISES and that access was denied or is sought under a REGULATORY AUTHORITY'S reasonable administrative plan to enforce the provisions of this Code.

8-809.40 Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may issue an inspection order that:

(A) Includes the information specified in ¶¶ 8-802.20(A)-(C); and

(B) Orders or authorizes any other identified agencies and persons including LAW enforcement agencies to execute, or assist with the execution of, the order.

8-809.50 Optional Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may further issue an inspection order that:

(A) Provides a maximum time limit for the order's execution;

(B) Authorizes LAW enforcement officers who assist in the order's execution to use necessary force against PERSONS or property to execute the order; and

(C) Requires that the agencies or PERSONS ordered or authorized to execute the order shall report to the court the date and time of the order's execution and the findings reached by the inspection, examination, or sampling conducted under the

order.

Means of Instituting Judicial Enforcement Proceedings

8-810.10 Institution of Proceedings.

(A) Proceedings to enforce this Code may be instituted by the REGULATORY AUTHORITY according to LAW by issuing a citation or summons, by filing a misdemeanor complaint affidavit and request for a warrant of arrest with the court of competent jurisdiction, or by referring the complaint to a grand jury for indictment, as appropriate.

(B) The REGULATORY AUTHORITY may designate a representative to issue summons or citations or sign warrants on behalf of the agency.

Criminal Proceedings

8-811.10 Authorities, Methods, Fines, and Sentences.

(A) The REGULATORY AUTHORITY may seek to enforce the provisions of this Code and its orders by instituting criminal proceedings as provided in LAW against the PERMIT HOLDER or other PERSONS who violate its provisions.

(B) A PERSON who violates a provision of this Code shall be guilty of a misdemeanor, punishable by:

(1) A fine of not more than (designate amount) dollars, or by imprisonment not exceeding 1 year, or both the fine and imprisonment; or

(2) If the PERSON has been convicted once of violating this Code or if there is an intent to defraud or mislead, a fine not exceeding (designate amount) or imprisonment not exceeding (designate time) year(s) or both.

(C) Each day on which a violation occurs is a separate violation under this section.

Injunctive Proceeding

8-812.10 Petitions for Injunction.

The REGULATORY AUTHORITY may, according to LAW, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of this Code or its orders.

Civil Proceedings

8-813.10 Petitions, Penalties, and Continuing Violations.

(A) The REGULATORY AUTHORITY may petition a court of competent jurisdiction to enforce the provisions of this Code or its administrative orders and according to LAW collect penalties and fees for violations.

(B) In addition to any criminal fines and sentences imposed as specified in § 8-811.10, or to being enjoined as specified in § 8-812.10, a PERSON who violates a provision of this Code, any rule or regulation adopted in accordance with LAW related to FOOD ESTABLISHMENTS within the scope of this Code, or to any term, condition, or limitation of a PERMIT issued as specified in §§ 8-303.10 and 8-303.20 is subject to a civil penalty not exceeding (designate amount).

(C) Each day on which a violation occurs is a separate violation under this section.

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) Government Depository Library

The USC and CFR are widely available for reference and viewing in some 1400 "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:

Library Programs Service, SL
U.S. Government Printing Office
North Capitol & H Streets, NW
Washington, DC 20401
(202) 512-1114, FAX (202) 512-1432

(2) Internet World Wide Web Information System

The CFR 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

(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 7:30 a.m. to 5:00 p.m. eastern time, Monday-Friday (except holidays. Orders may be charged to Discover/Novus, MasterCard or Visa.

(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

(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; or

(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 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or

contains (*i*) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; 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 and 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 a 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 (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, United States Code.

(As amended by 104th Congress, Fall, 1996.)

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Chapter 1 Purpose and Definitions

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Chapter 4 Equipment, Utensils, and Linens

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Chapter 5 Water, Plumbing, and Waste

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3. FDA SUPPORTING DOCUMENTS

FDA has developed and issued the following guidance documents. A brief summary for each document is provided.

A. (Draft) Recommended National Retail Food Regulatory Program Standards
B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
C. (Draft) Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level
D. Food Establishment Plan Review Guidelines
E. Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors

A. (Draft) Recommended National Retail Food Regulatory Program Standards

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/ret-toc.html 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. Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found at the web site http://vm.cfsan.fda.gov/~ear/rfi-toc.html. 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. (Draft) Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/hret-toc.html. 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 Chapter 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. Food Establishment Plan Review Guidelines

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/previntr.html. 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.

E. Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors

This document can be found at the web site http://vm.cfsan.fda.gov/~dms/retrsk.html. The 1996 report "Reinventing Food Regulations" [National Performance Review] concluded that *foodborne illness caused by harmful bacteria and other pathogenic microorganisms in meat, poultry, seafood, dairy products, and a host of other foods is a significant public health problem in the United States*. For years regulatory and industry food safety programs have been designed to minimize the occurrence of foodborne illness. There is, however, a lack of a national baseline on the occurrence of foodborne disease risk factors.

This project is designed to establish a national baseline on the occurrence of foodborne disease risk factors within the retail segment of the food industry. This report presents the methodology used to establish a baseline and reports the results of the data collected. The report is provided to regulators and industry with the expectation that it will be used to focus greater attention and increased resources on the control of foodborne illness risk factors.

Annex

3 Public Health Reasons/ Administrative Guidelines

Chapter 1 Purpose and Definitions

Applicability and *Terms Defined* **1-201.10 Statement of Application and Listing of Terms.**

(B)(1) Accredited Program.

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an accrediting agency based upon the certifying organization's meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food

Protection, 1085 Denio Avenue, Gilroy, CA 95020-9206. Also included are the National Commission for Certifying Agencies' *Standards for Accreditation of National Certification Organizations* available through the National Organization for Competency Assurance, 1200 19th Street, NW, Suite 300, Washington, DC 20036-2422.

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Chapter 2 Management and Personnel

Responsibility 2-101.11 Assignment.*

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

Knowledge 2-102.11 Demonstration.*

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since it requires no bare hand contact with ready-to-eat food.

Status of "Universal Acceptance" of Food Protection Manager Certificates

Presently there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups and "third-party" organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others - especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary significantly in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

Needed is a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration.

Considerable progress has been made by the Conference for Food Protection toward providing the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. The Conference is simultaneously working on two separate aspects of the program accreditation process.

The first aspect addresses the important matter of ensuring that examinations are reliable, valid, and legally defensible. The Conference has developed a process for the independent evaluation and recognition of food protection manager certification examinations that meet the standards for test development and test administration. Information regarding this CFP Food Protection Manager Certification Examination recognition process can be obtained by accessing the Conference for Food Protection web site at http://www.foodprotect.org.

The second aspect addresses the equally important organizational and operational policies and procedures of a certification program that help ensure honesty and fairness for all stakeholders and protect against conflict of interests. The Conference is working closely with national organizations that have considerable experience with the accreditation of certification programs, and is endeavoring to develop a comparable process for evaluating these aspects of a certification program. It is anticipated that this comparable accreditation process will be submitted for deliberation at the 2002 Conference meeting.

Once the Conference completes its work on these two program components, program accreditation may become the needed mechanism for promoting the universal acceptance of certificates issued by accredited certifiers.

Duties **2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

Subparagraph (L) "EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Disease or Medical Condition **2-201.11 Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants.***

A wide range of communicable diseases and infections may be transmitted by infected food employees to consumers through food or food utensils. Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of both consumers and employees, information concerning the health status of applicants and food employees must be disclosed to the person in charge.

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

Furthermore, an applicant to whom an employment offer is conditionally made or a food employee who meets the Code conditions that require restriction from certain duties or exclusion must be accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not pose an undue hardship and that will prevent the

transmission of the disease(s) of concern through food, such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be made. It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in the References Annex that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease which can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report specific high-risk conditions, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, the Centers for Disease Control and Prevention (CDC) published in the Federal Register on September 27, 2000, (Volume 65, Number 188) a list of infectious and communicable diseases that are transmitted through food. CDC updates the list annually. The list is divided into two parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle food.

The Lists below summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below. The Lists below include all Shiga toxin-producing ***E. coli*** likely to occur in foods in the United States.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons.

	D	**F**	**V**	**J**	**S**
1. Caliciviruses (Norwalk and Norwalk-like viruses)	D	F	V		
2. Hepatitis A virus	-	F	-	J	-
3. ***Salmonella* Typhi**	-	F	-	-	-
4. ***Shigella*** species	D	F	V	-	-
5. ***Staphylococcus aureus***	D	-	V	-	-
6. ***Streptococcus pyogenes***	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons

	D	F	V	J	S
1. ***Campylobacter jejuni***	D	F	V	-	-
2. ***Cryptosporidium parvum***	D	-	-	-	-
3. ***Entamoeba histolytica***	D	F	-	-	-
4. Enterohemorrhagic ***Escherichia coli***	D	-	-	-	-
5. Enterotoxigenic ***Escherichia coli***	D	-	V	-	-
6. ***Giardia lamblia***	D	-	-	-	-
7. Non-typhoidal ***Salmonella***	D	F	V	-	-
8. ***Taenia solium***	-	-	-	-	-
9. ***Vibrio cholerae*** 01	D	-	V	-	-
10. ***Yersinia enterocolitica***	D	F	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever
F = Fever J = Jaundice

The Food Code definition of Shiga toxin-producing ***Escherichia coli*** (STEC) covers all STEC identified in clinical laboratories by O157 and H7 serological tests, or by Shiga toxin tests.

The definition includes all STEC, including those that are not specifically implicated in hemorrhagic colitis (i.e., bloody diarrhea). Only a subset of STEC (>100 STEC strains cause the vast majority of human STEC diarrhea) are traditionally classified as “enterohemorrhagic”, and those serotypes that are considered “enterohemorrhagic”, including ***E. coli*** O157:H7, do not actually cause a hemorrhagic form of colitis in a substantial percentage of cases. Virtually all O157:H7 strains produce Shiga toxin, so are pathogens. Many O157:NM or O157:H- also produce Shiga toxin, but some don't, so testing for shiga toxin is needed to be sure that they are STEC.

The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. An employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The high-risk conditions that require reporting are designed to be used with the symptoms listed to identify employees who may be suffering from an illness due to the following pathogens: ***Salmonella* Typhi**, ***Shigella*** spp., Shiga toxin-producing ***Escherichia coli***, and hepatitis A virus. The specific conditions requiring reporting were identified by CDC as significant contributing factors to the incidence of foodborne illness.

The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based on the number of confirmed cases reported that involved food

employees infected with one of these organisms and the severity of the medical consequences to those who become ill.

The following information, taken from Control of Communicable Diseases Manual, is provided regarding the period of communicability for the four pathogens of concern and the application of that information to employees likely to be shedding certain pathogens:

***Salmonella* Typhi** – As long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter (commonly 1-2 weeks for paratyphoid). About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers; considerable fewer persons affected with paratyphoid organisms may become permanent gallbladder carriers.

Shigella spp. – During acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer. Appropriate antimicrobial treatment usually reduces duration of carriage to a few days.

Shiga toxin-producing serotypes of ***Escherichia coli***, including ***E. coli*** O157:H7 – The duration of excretion of the pathogen, which is typically for a week or less in adults but 3 weeks in one third of children. Prolonged carriage is uncommon.

Hepatitis A – Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice, although prolonged viral excretion (up to 6 months) has been documented in infants born prematurely. The infectious agent is found in feces, reaching peak levels the week or two before onset of symptoms, and diminishing rapidly after liver dysfunction or symptoms appear, which is concurrent with the appearance of circulating antibodies to HAV.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing ***Staphylococcus aureus*** into food.

If an employee has an infected cut and bandages it, plus puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

2-201.12 Exclusions and Restrictions.*

Restriction or exclusion of food employees suffering from a disease or medical symptom listed in the Code is necessary due to the increased risk that the food being prepared will be contaminated with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or medical conditions listed may be suffering from a disease transmissible through food.

Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe disease) of ***Salmonella* Typhi**, ***Shigella*** spp., Shiga toxin-producing ***Escherichia coli***, and hepatitis A virus, a food employee diagnosed with an active case of illness caused by any of these four pathogens must be excluded from food establishments. The exclusion is based on the severe medical consequences to individuals infected with these organisms, i.e., hospitalization and even death.

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella* Enteritidis**. Over 70% of the deaths attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

The Food Code does not require restriction of a food employee with an unprotected, uninfected cut, or a food employee with a covered, protected infected cut/lesion/boil since it requires no bare hand contact with ready-to-eat food.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or exclusion. The employee must also suffer from one of the symptoms listed.

The use of high-risk conditions alone as the sole basis for restricting or excluding food employees is difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of the 4 organisms listed, hepatitis A presents a different twist to this rationale. Food employees who meet a high-risk condition involving hepatitis A may shed the virus before becoming symptomatic. In fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a food employee solely because of a high-risk condition involving hepatitis A is not justified.

The following summarize the rationale for not restricting or excluding an asymptomatic food employee simply because the employee meets a high-risk condition involving hepatitis A:

1. Because hepatitis A virus infection can occur without clinical illness (i.e., without symptoms), or because a person may shed hepatitis A virus in the stool for up to a week before becoming symptomatic, it is possible that a person unknowingly may have been exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the incubation stage. No restriction/exclusion routinely occurs under these -- presumably much more common -- circumstances.

2. Even though the asymptomatic food employee may be infected with hepatitis A virus and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is unlikely if the employee practices good personal hygiene, such as washing hands after going to the bathroom.

3. Exclusions from work for prolonged periods of time may involve economic hardship for the food employee excluded.

Based on the information presented, exclusion or restriction solely on a high-risk condition would be potentially controversial and of questionable merit.

Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle employees and applicants who meet a high-risk condition involving hepatitis A on a case-by-case basis. With this approach in mind, the following criteria are offered as a guide. First, the following information should be collected and analyzed:

1. Clarify the type of contact the individual had with another person diagnosed with hepatitis A virus infection. Keep in mind that the closer the contact (i.e., living in the same household as the infected person), the more likely it is that a susceptible person may become infected.

2. What job does the food employee perform at the food establishment, e.g., is the employee involved in food preparation?

3. When did the employee begin work at the establishment?

4. What level of personal hygiene does the individual exhibit? For example, does the individual adhere to the handwashing requirements specified in the Code?

5. Has the individual suffered from hepatitis A in the past? If the answer to this question is yes, was blood testing done? If the individual did have hepatitis A in the past, the individual is immune from re-infection.

6. In terms of the current high-risk condition, has the individual received immune globin (IG)? When?

In addition, upon being notified of the high-risk condition, the person in charge should immediately:

1. Discuss the traditional modes of transmission of hepatitis A virus infection with the food employee involved.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that are caused by hepatitis A infection.

4. Remind the employee of the employee's responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. In light of the high infectivity of hepatitis A, ensure that the employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

If after consideration of all the information gathered, the person in charge feels that the employee in question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be considered.

A restricted food employee may work in an area of the food establishment where there is wrapped food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term “restricted.” A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer or the same as any other member of the general public.

An excluded individual may not work as a food employee on the premises of any food establishment. In a facility that has different departments, such as a department store, school, or health care facility, the regulatory authority, in concert with other infection control authorities, may consider allowing an excluded food employee to work in an area or department that is separate and segregated from the food preparation, service, and storage areas, and the food equipment and utensil areas, such as the soiled linen/laundry area or exterior maintenance. An excluded person may enter the food establishment as a customer or the same as any member of the general public.

2-201.13 Removal of Exclusions and Restrictions.

Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to highly susceptible populations, and the need to provide extra protection to those high-risk populations.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through laboratory analysis of their stools to have any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The duties that an asymptomatic shedder performs in a food establishment are restricted if the establishment serves a general population or, if a highly susceptible population is involved, the shedder is excluded. Several considerations factor into the need to preclude asymptomatic shedders from food establishment functions that may result in the transmission of foodborne disease.

- Outbreaks of foodborne illness involving ***Salmonella* Typhi** have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness.

- There is some epidemiological evidence of transmission of food via food employees infected with ***Shigella*** spp.

- Healthy consumers are at risk due to a low infectious dose of ***Shigella*** spp.

- Despite lacking epidemiological evidence of transmission of food via food employees infected with Shiga toxin-producing ***Escherichia coli***, the documented ease of transmitting it from person-to-person in a day care setting, suggests a low infectious dose and the potential for the organism to be transmitted through food.

- The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome (HUS), associated with Shiga toxin-producing ***Escherichia coli*** warrant the institution of disease interventions.

- Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population.

The risk that a communicable disease will be transmitted by food employees who are asymptomatic shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases in Man."

The Code requires medical clearance, based on criteria designed to detect the shedder state, before a person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious agents is allowed to resume the duties from which that person was restricted or, in the case of an establishment that serves a highly susceptible population, before the person may return to work.

With respect to a food employee in an establishment that serves an immunocompromised population, the Code provisions are more stringent in that exclusion is required in 3 situations in which it is not required for food employees in other food establishments. Those 3 situations involve an employee who:

(A) Meets a high-risk condition specified in ¶ 2-201.11(D) and has a symptom of acute gastrointestinal illness;

(B) Is diagnosed as an asymptomatic shedder of ***S*. Typhi**, ***Shigella*** spp. or Shiga toxin-producing ***Escherichia coli***; or

(C) Had a recent illness caused by ***S*. Typhi, *Shigella*** spp., or Shiga toxin-producing ***Escherichia coli***. The exclusion is in effect until a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, provides the medical clearance specifically outlined in § 8-501.40 of the Code, indicating that the infectious agent is not detected.

2-201.14 Responsibility of a Food Employee or an Applicant to Report to the Person in Charge.*

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in this Code may transmit disease through the food being prepared. The person in charge must first be aware that an employee or prospective employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

Some of the symptoms that must be reported may be observed by the person in charge. However, food employees and applicants share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or medical diagnoses listed in the Code and food employees must comply with restrictions or exclusions imposed upon them.

2-201.15 Reporting by the Person in Charge.*

Notification of the regulatory authority by the person in charge that an employee is suffering illness caused by ***Salmonella* Typhi, Shigella** spp., Shiga toxin-producing ***Escherichia coli***, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness. The person in charge should be aware of the confidentiality provisions of the Americans with Disabilities Act (ADA). For information about the ADA, call 800-669-EEOC or for telecommunications device for the deaf (TDD) 800-800-3302.

Hands and Arms **2-301.11 Clean Condition.***

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.*

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to ready-to-eat food as well as other pathogens that can be transmitted via cross contamination from raw foods to ready-to-eat foods. Many employees fail to wash their hands as often as necessary and even those who do may use flawed technique.

In the case of a food worker with one hand or a hand-like prosthesis, the EEOC has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement without sacrificing public health concerns.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface, do not survive nor multiply, and a moderate number of organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin, and are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands, and when an antimicrobial soap is used, a minimum of 15 seconds is required.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands.

Handwashing done properly can result in a 2-3 logarithmic reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e. > 10^4 microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13 Special Handwash Procedures.*

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.*

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing facilities are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Sanitizers.

This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

<u>As a Drug Product</u>

There are three means by which a hand sanitizer is considered to be safe and effective when applied to human skin:

1. A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication **Approved Drug Products with Therapeutic Equivalence Evaluations**. Also known as the “Orange Book,” this document provides “product-specifiic” listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand sanitizing products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand sanitizers and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing,

packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more extensive FDA review process for a new drug application (NDA) is required before marketing.

However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not presently objecting to the use of "instant hand sanitizers" based on ethyl alcohol or isopropyl alcohol, or certain chlorine "hand sanitizing dips" since these compounds are included in the OTC Drug Review. The ultimate status of these products will not be known until the final monograph publishes.

Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a specific product has been accepted and included in the proposed monograph may be obtained from the manufacturer. You may also refer to ***Federal Register*** (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.

Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855-2737. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the components of a hand-care product must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the components of a product are reasonably expected to become a component of food based upon the product's intended use, there are three means by which they are considered by FDA to be safe:

1. A substance may be exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles. A review by FDA's Center for Food Safety and Applied Nutrition is required for such an exemption to be issued. The Center's Indirect Additives

Team has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed in the federal food additive regulations. Therefore, there is no food additive prohibition against using these substances as components of an instant hand sanitizer.

2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed thereunder with conditions of safe use. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.

3. A substance may be "generally recognized as safe (GRAS)" for the intended use in contact with food within the meaning of the Federal Food, Drug, and Cosmetic Act § 201(s). Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe. The law also provides for independent GRAS determinations.

   The Indirect Additives Team does not certify or provide approvals for specific products. However, if the use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt from the requirement of a food additive listing regulation. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

   Questions regarding the regulatory status of hand sanitizer components as food additives may be directed to the Indirect Additives Team, HFS-215, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204. It may be helpful or necessary to provide label/promotional information when inquiring about a specific component.

Fingernails **2-302.11 Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11 Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term “jewelry” generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. In the case of a food worker who wears a medical information or medical alert bracelet, the EEOC has agreed that this requirement can be met through reasonable accommodation in accordance with the Americans with Disabilities Act by the person in charge and the employee working out acceptable alternatives to the bracelet worn at the wrist. An example would be wearing the bracelet high on the arm or secured in a manner that does not pose a risk to the food but provides emergency medical information if it is needed.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11 Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11 Eating, Drinking, or Using Tobacco.***

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.*

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints **2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals **2-403.11 Handling Prohibition.***

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Chapter 3 Food

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.***
Sources **3-201.11 Compliance with Food Law.***

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act.

Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices. At the time of publication of the 1999 Food Code, rulemaking had not been finalized regarding a mandatory Hazard Analysis Critical Control Point (HACCP) program for juice products.

Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations. Untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods must bear a warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Additional information is available in the document, "Guidance for Industry. Warning and Notice Statement: Labeling of Juice Products, Small Entity Compliance Guide" which can be found on the FDA Web Page http://www.cfsan.fda.gov/~dms/juicguid.html or obtained from the FDA Office of Food Labeling.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling for Raw Shell Eggs

The Food and Drug Administration is revising its food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy ***Salmonellae*** organisms. The labeling regulation becomes effective September 4, 2001.

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

3-201.12 Food in a Hermetically Sealed Container.*

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.*

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.*

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scrombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and

throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

3-201.15 Molluscan Shellfish.*

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of

molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.*

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom identification expert" and enforcing the Food Code provisions associated with it. In 1998, the Conference for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that was charged with determining what constitutes a wild mushroom expert. However, the committee was unable to provide this information in a practical, useful manner for State and local regulators within the constraints of the Food Code. The 2000 CFP recommended and FDA accepted the committee's alternative solution that a brochure be developed that will provide information on what constitutes a wild mushroom expert, and to replace "identification by a wild mushroom expert" with "written buyer specifications."

The CFP's recommendation attempts to provide the necessary information in a practical, useful manner for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee suggested that written buyer specifications place more responsibility on the food establishment to ensure that wild mushrooms are obtained from a safe source, and also provides state and local regulators a template to use in ensuring wild mushrooms sold at retail are obtained from a safe source.

However, the recommendation for written buyer specifications will not replace Food Code paragraph 3-201.16(A) until the brochure is developed and accepted by the CFP and FDA. In the interim, the following guidance is provided regarding the identification of wild mushrooms:

A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer specification that requires identification of:

(1) The Latin binomial name, the author of the name, and the common name of the mushroom species,
(2) That the mushroom was identified while in the fresh state,
(3) The name of the person who identified the mushroom,
(4) A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.

Additional information can be found on the California Poison Control web site: http://www.calpoison.org/public/mushrooms.html.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.*

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving **3-202.11 Temperature.***

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.*

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

3-202.13 Shell Eggs.*

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

(i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

Amended federal regulations 21 CFR Part 16, Administrative practice and procedure; 21 CFR Part 101 Labeling, Nutrition, Reporting and Recordkeeping requirements; and 21 CFR Part 115 Eggs, Refrigeration issued on December 5, 2000. These regulations require that shell egg cartons bear safe handling instructions and further requires that eggs be placed under refrigeration at 45ºF or lower upon delivery at retail establishments. See Federal Register: (Volume 65, Number 234), Pages 76091-76114. The labeling rule is effective September 4, 2001, and the refrigeration rule is effective June 4, 2001. This rule is one part of the larger Egg Safety Action Plan, a farm-to-table approach for ensuring the safety of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of ***Salmonella*** **Enteritidis**, illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated ***Salmonella*** **Enteritidis** illnesses by 2010.

3-202.14 Eggs and Milk Products, Pasteurized.*

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.*

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.
Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.*

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.*

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

3-203.12 Shellstock, Maintaining Identification.*

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

Preventing Contamination by Employees **3-301.11 Preventing Contamination from Hands.***

In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers, as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers. When the FDA reviewed and analyzed epidemiological data on foodborne illness outbreaks caused by fecal-oral pathogens, 93% of the foodborne illnesses reported were caused by ill food workers preparing food. This finding illustrates the problem caused by ill food workers who continue to prepare food. This is a problem which is exacerbated by an increasing global market place, a tight labor market and lack of knowledge and understanding of food safety among food workers, and the economic need for food workers to work even when ill.

Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3-logs.

Food workers infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for *Giardia* and *Cryptosporidium* is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with hepatitis A. The infective dose for Norwalk virus is also believed to be very small.

The CDC now estimates that Norwalk-like viruses are the leading cause of foodborne illness in the United States. The CDC has also reported that hands are the most important means by which enteric viruses are transmitted. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these

factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.13.
Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Clarification of ¶ 3-301.11(B) of the FDA Food Code with Respect to the Phrase "*Except...when otherwise APPROVED*"...

Background:

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.[1] Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

[1] Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks - United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Objective:

The objective of this guidance is to provide clarification to ¶ 3-301.11(B) of the Food Code regarding the statement "except when otherwise approved." This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of no bare-hand contact through alternative practices and procedures. In this guidance, “hazard” means infected food workers spreading pathogens to food via the hands.

Guidance:

I. **Requirements prerequisite** to consideration of alternatives include compliance with all Food Code provisions, particularly those related to:

(A) **Demonstration of Knowledge** - specifically ¶¶ 2-102.11(A), (B), (C), and (H);

(B) **Duties of the Person in Charge** - specifically ¶ 2-103.11(D);

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions**, and

(2) **Exclusions and restrictions**, i.e., that food employees (including applicants to whom a conditional offer of employment has been made) report their health status as specified in Section 2-201.11; ill food employees are restricted or excluded as specified in Section 2-201.12; and the exclusions and restrictions are removed as specified in Section 2-201.13;

(D) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in Section 2-301.14 - including after using the toilet and between tasks that may recontaminate the hands; and

(E) **Hygienic Practices** as specified in Part 2-4.

II. FDA recommends that the **acceptability of an alternative** to no bare-hand contact **should be based on** evidence that at least the following are addressed:

(A) **Why the operator of the food establishment is unable to comply** with the Code requirement in ¶ 3-301.11(B);

(B) **How the alternative practices and procedures will control the hazard through an active managerial control program**. Such a program includes monitoring and verifying the institution of the prerequisite requirements described in Part I above and satisfies the following:

(1) **The public health hazard** associated with bare-hand contact specific to the food establishment operation **is identified and understood**. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both **procedures and practices** are in place so that **food employees wash their hands** before returning to their work station and **cross-contamination** from touching raw and ready-to-eat food **is precluded**.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an **effective training program for food employees** which emphasizes **not working when ill** with any of the symptoms of foodborne illness, and explains **good hygienic practices, proper handwashing** procedures, and **safe food preparation** procedures. This should include a documented training plan that specifies how **management responsibility for training** has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(C) The alternative should clearly include **monitoring, documentation, and verification** to ensure that the practices and procedures are followed. **Corrective actions need to be predetermined** for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

III. **Documentation of the practices, procedures, and corrective actions** related to an alternative to no bare-hand contact with ready-to-eat food needs to be maintained and readily available at the food establishment at all times for use by the person-in-charge and for review by the regulatory authority.

IV. The regulatory authority should also consider industry's *elective* use, managerial control, and monitoring and verification of additional preventive measures used in tandem with the aforementioned interventions which could include one or more of the following:

(A) Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;

(B) Double handwashing;

(C) Use of nail brushes;

(D) Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles; and

(E) Motivation for food employees not to work when they are ill.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Protection Separation, Packaging, and Segregation.*

Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella*** **Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.*

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document which addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” is available from FDA’s Food Safety Initiative staff and also on the Internet at http://www.fda.gov.

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 140^{o}F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

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3-304.13 Linens and Napkins, Use Limitation.

Refer to the public health reason for § 3-304.11.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Refer to the public health reason for § 3-304.11.
Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Natural Latex Rubber (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NLR gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at http://www.cdc.gov/niosh/latexalt.html.

- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement

discouraging the routine use of NRL gloves by food handlers. (1997) http://allergy.mcg.edu/physicians/joint.html

The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/public/fastfacts/latex.stm

The ACAAI provides information on latex allergies on the web at http://allergy.mcg.edu/physicians/ltxhome.html

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412.html

OSHA addresses gloves in the following federal regulation, which can be found at http://www.osha-slc.gov/OshStd_data/1910_0138.html:

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.
SubPart Number: I
SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

For further information on the OSHA requirements, see [59 FR 16362, April 6, 1994].

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Refer to the public health reason for § 3-304.11.

Preventing Contamination from the Premises

3-305.11 Food Storage.

3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Potentially Hazardous Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.*

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Reservice or Sale.*

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	**3-401.11**	**Raw Animal Foods.***
	3-401.12	**Microwave Cooking.***
	3-401.13	**Plant Food Cooking for Hot Holding.**

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). The microbial lethality using these criteria will provide a 6.5-$\log_{10}$ reduction of Salmonella.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This Part includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63^{o}C(145^{o}F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time

parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork and lamb, are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145^{o}F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145^{o}F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145^{o}F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145^{o}F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68^{o}C (155^{o}F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68^{o}C (155^{o}F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157^{o}F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158^{o}F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158^{o}F for less than one second is an adequate cook based on the following:

> 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetable enteric pathogens;
>
> 2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
>
> 3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74^{o}C(165^{o}F) or above for 15 seconds yield greater than a 7D reduction.

3-401.12 Microwave Cooking.*

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74^{o}C (165^{o}F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food

temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 60°C (140°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

Freezing **3-402.11 Parasite Destruction.***

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw.

3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

Reheating **3-403.11 Reheating for Hot Holding.***

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for § 3-401.12.

3-404.11 Treating Juice.

Refer to public health reason for § 3-801.11.

Temperature and Time Control **3-501.11 Frozen Food.**

3-501.12 Potentially Hazardous Food, Slacking.

3-501.13 Thawing.

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

3-501.14 Cooling.*

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, potentially hazardous foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 52°C (70°F - 125°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella*** **Enteritidis**, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella*** **Enteritidis** will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially hazardous food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a potentially hazardous food after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

Salmonella **Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms. Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

Amended federal regulations 21 CFR Part 16, Administrative practice and procedure; 21 CFR

Part 101 Labeling, Nutrition, Reporting and Recordkeeping requirements; and 21 CFR Part 115 Eggs, Refrigeration issued on December 5, 2000. These regulations require that shell egg cartons bear safe handling instructions and further requires that eggs be placed under refrigeration at 45ºF or lower upon delivery at retail establishments. See Federal Register: (Volume 65, Number 234), Pages 76091-76114. The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. This rule is one part of the larger Egg Safety Action Plan, a farm-to-table approach for ensuring the safety of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of ***Salmonella* Enteritidis** illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated ***Salmonella Enteritidis*** illnesses by 2010.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible

for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram. In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens*** per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 *C. perfringens* per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (Federal Register 64: (3): 732-749)

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F_Appendix%20B.htm, is that product must be cooled from 130ºF to 80°F in 1.5 hours and from 80ºF to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120ºF to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120ºF, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120ºF and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline **for meat and poultry products containing 100 ppm added nitrite** is 130ºF to 80°F in 5 hours and from 80ºF to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the

performance standard for controlling the growth of ***C. perfringens***, and should take corrective action. However, the **presence of nitrite** should ensure compliance with the performance standard for ***C. botulinum***.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 140ºF to 70°F in 2 hours and from 140ºF to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on safe cooling times for cooked, potentially hazardous foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130ºF to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130ºF to 45°F in 15 hours permitted about 1 log growth of ***C. perfringens***.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of ***C. botulinum***.

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other potentially hazardous foods.

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 5°C to 60°C (41°F to 140°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Except for raw shell eggs, control of the growth of ***Listeria monocytogenes*** is the basis for the list of cold holding temperature and time combinations. The list addresses time, in addition to temperature, as a control for the growth of ***Listeria monocytogenes*** in refrigerated, ready-to-eat, potentially hazardous food. The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of ***Listeria monocytogenes***, and do not set an acceptable number of Lm in food. Neither do they imply that ***Listeria monocytogenes*** is in the product. However, the cold holding temperature and time combinations will be vetted through the public comment process on the ***Listeria monocytogenes*** Risk Assessment and Risk Management Plan, reviewed, and if necessary, amended. This public comment period is planned during 2001, after publication of the 2001 Food Code.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon ***Listeria monocytogenes*** begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of Lm in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41ºF for 7 days and 45ºF for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow no more than 1 log of

growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of Lm remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella*** **Enteritidis** to occur. The agency reviewed research indicating that Salmonella Enteritidis multiplies at temperatures of 10ºC (50ºF) and above but can be inhibited at lower temperatures, e.g., 8ºC (46ºF), 7.2ºC (45ºF) and 4ºC (39ºF). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7.2ºC (45ºF) for eggs stored and displayed at retail establishments. Amended federal regulations 21 CFR Part 115, Eggs, Refrigeration issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

3-501.17	**Ready-to-Eat, Potentially Hazardous Food, Date Marking.***
3-501.18	**Ready-to-Eat, Potentially Hazardous Food, Disposition.***

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of ***Listeria monocytogenes*** at 5°C (41°F) and 7°C (45°F). Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, potentially hazardous food may be kept at 5°C (41°F) a total of 7 days or at 7°C (45°F) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 5°C (41°F) but capable of maintaining it at 7°C (45°F) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa and capocolla.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (not potentially hazardous) sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS, and, if applied, would not supercede or replace date marking requirements established by the Food Code or by state/local authorities, that apply after the food is opened in a retail establishment.

Manufacturer’s use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer’s information as good guidance to follow to maintain the quality (taste, smell and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer’s date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time Alone as a Public Health Control.*

The 2000 Conference for Food Protection (CFP) recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, Section 3-501.19.

In response to the CFP recommendation, FDA, in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows potentially hazardous food (PHF) that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed. The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food with Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, ***Listeria monocytogenes*** is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of ***L. monocytogenes*** warrants concern for potentially hazardous RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly. Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including ***Clostridium perfringens*** and ***Bacillus cereus***. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of ***C. perfringens*** or ***B. cereus*** and may actually serve as a heat shock that activates the spores. ***B. cereus*** is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. ***C. perfringens*** is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, ***C. perfringens*** cases are estimated to be more numerous than ***B. cereus*** cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both ***C. perfringens*** and ***B. cereus*** produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a

small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either ***C. perfringens*** or ***B. cereus***. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

FDA intends to do research regarding food products that may have spores in the center of the product, and further evaluate if there are potential hazards that may be associated with them while held without temperature control for 4 hours.

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella*** **Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods **3-502.11 Variance Requirement.***

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in Section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request.

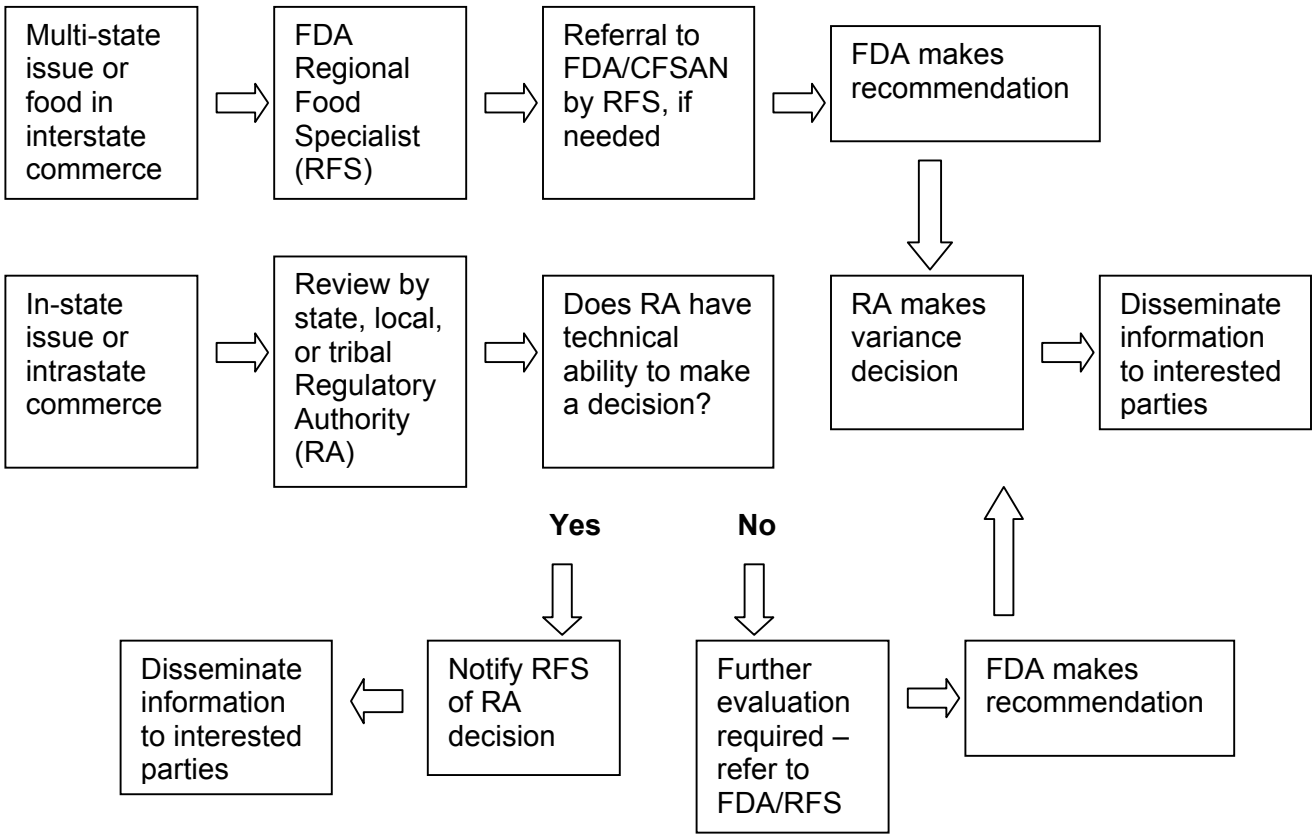
From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code Sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

1) Designate an agency team and assign a leader to address variance requests.

2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.

3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.

   a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists.

Regulators are encouraged to be consistent with national policies, guidelines, or opinions.

b) For variances that address intrastate issues, regulators are also encouraged to determine if other state or national guidance exists, and to stay consistent with it.

4) Make the agency's decision. Inform the applicant.

a) If the variance request is approved, determine the starting date, and document all special provisions with which the applicant must comply.
b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.

5) Inform other interested parties, including the FDA Regional Food Specialist.

a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.

b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.

6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.

7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.

8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.

9) Establish written procedures for withdrawing approval of the variance if it is not successful.

3-502.12 Reduced Oxygen Packaging, Criteria.*

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when using reduced oxygen packaging (ROP) processing procedures. A reduced oxygen packaged food that has at least two barriers to the growth and toxin production of ***C. botulinum*** may be packaged in accordance with the provisions of a HACCP plan. The FDA recommends two barriers be used to ensure the safety of foods when ***C. botulinum*** is a known hazard in the final packaged form.

An ROP food that has only one barrier to the growth and toxin production of ***C. botulinum*** may be produced only if the food establishment obtains a variance and produces the food in accordance with the provisions of a HACCP plan. An example of a single barrier would be a food with a natural pH of 4.6 or less. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate refrigeration. Variance requests related to packaging food using reduced levels of oxygen and having only one barrier to control the growth of ***C. botulinum*** must be considered with particular caution and scrutiny.

This section does not apply to low acid canned foods produced under 21 CFR Part 108 (Emergency Permit Control) and 21 CFR Part 113 (Thermally Processed Low-Acid Foods) or 21 CFR Part 114 (Acidified Foods) because ***C. botulinum*** is not a hazard in the final packaged form.

FDA strongly recommends that garlic garlic-in-oil mixtures that are produced in a food establishment have two barriers in place. It is not possible to acidify the oil although the crushed cloves can be acidified. An example of two effective barriers is acidification of crushed garlic cloves and refrigeration of the garlic-in-oil mixture. Acidification means a finished equilibrium pH of 4.6 or less. Garlic-in-water mixtures can be acidified and refrigerated, using a HACCP plan without the necessity of a variance.

Unfrozen raw fish is specifically excluded from ROP because of this product's natural association with ***Clostridium botulinum***, Type E, which grows at or above 3^{o}C (38^{o}F). To be adequate, a HACCP plan must identify critical control points that are to be monitored to minimize microbial growth during product packaging and storage.

Earlier FDA guidance regarding the reduced oxygen packaging of cured meat products specified a combination of nitrites, nitrates, and salt that at the time of processing consisted of a concentration of at least 120 mg/L of sodium nitrite and a minimum brine concentration of 3.50%. The Code reflects the fact that various substances, combinations of substances, and resultant concentrations are allowed in CFR administered by USDA. The Code provision also includes the requirement for cured poultry products to meet the CFR.

Shelf life must be limited because some pathogens, including ***Listeria monocytogenes***, may be a hazard at refrigeration temperatures. Fourteen days is considered a safe refrigerated shelf life (as opposed to the maximum 7 days allowed under paragraph 3-501.16(A)(2)(a)) because there are two barriers to growth incorporated in this section's requirements. Food that remains frozen from the time that it is packaged until the time it is prepared for service is considered adequately protected.

Accurate	**3-601.11**	**Standards of Identity.**
Representation	**3-601.12**	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from Shiga toxin-producing ***Escherichia coli*** have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in Subparagraph 3-602.11(B)(5) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish, and when those fish are placed into a bulk container for shipment, the bulk container must bear a label declaring the presence of canthaxanthin. That same label information must be displayed at retail when those fish are offered for sale.

The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 101.100(a)(2). For additional information, see the Federal Register announcement Vol. 63, No. 59, March 27, 1998, pages 14814 – 14817.

Consumer Advisory	**3-603.11**	**Consumption of Raw or Undercooked Animal Foods.***

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 CFP meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for **"disclosure"** of what consumers view as "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a **"reminder"** that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in the insert page with § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"... Otherwise Processed to Eliminate Pathogens...":

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus***." Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving mollluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words “meat” rather than “beef, lamb, and pork” and “seafood” rather than “fish” are used. Categorical terms like “meat” are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, “milk” is not mentioned in the actual on-site advisory language. The sale or service of unpasteurized milk is not allowed in interstate commerce and its consumption is not recommended by FDA. Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a state that allows the in-state sale or service of unpasteurized milk, or in the case where a state allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to reminder, options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition **3-701.11** **Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.***

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards **3-801.11** **Pasteurized Foods, Prohibited Reservice, and Prohibited Food.***

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as ***Cryptosporidium***, Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Vibrio cholera***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of ***Salmonella*** **Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to

stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. For further information, see the FDA Talk Paper entitled, “Interim Advisory on Alfalfa Sprouts” issued on August 31, 1998 and available on the FDA web site (www.fda.gov). Since this issue continues to be under investigation, FDA recommends that interested persons check the FDA web site periodically for more recent, updated information.

Although the Code’s allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operational plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(E)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

Chapter 4 Equipment, Utensils, and Linens

Multiuse 4-101.11 Characteristics.*

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials

can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in Section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

4-101.13 Lead in Ceramic, China, and Crystal Utensils, Use Limitation.

Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they’re the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters

often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

4-101.14 Copper, Use Limitation.*

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2½ hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.*

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Lead in Pewter Alloys, Use Limitation.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

4-101.18 Lead in Solder and Flux, Use Limitation.

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys. As mentioned in the public health reasons for §§4-101.12 and 4-101.13, lead has been linked to many health problems especially among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

4-101.19 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.110 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched

by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.111 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Single-Service and Single-Use

4-102.11 Characteristics.*

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength

4-201.11 Equipment and Utensils.

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12 Food Temperature Measuring Devices.*

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability **4-202.11 Food-Contact Surfaces.***

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12 CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy **4-203.11 Temperature Measuring Devices, Food.**

The Metric Conversion Act of 1975 (amended 1988) requires that all federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988) which requires the use of metric values. The $\pm$ 1.5^{o}C requirement is more stringent than the 3^{o}F previously required since $\pm$ 1.5^{o}C is equivalent to $\pm$ 2.7^{o}F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3^{o}F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

Functionality 4-204.11 Ventilation Hood Systems, Drip Prevention.

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the

equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern.
If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated.
Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.*

Failure to store potentially hazardous food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control", provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77^{o}C (170^{o}F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for Section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar

device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.
4-204.120 Equipment Compartments, Drainage.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Moveability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11 Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain potentially hazardous foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and

condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.063 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners

and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

Location 4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation 4-402.11 Fixed Equipment, Spacing or Sealing.

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

4-402.12 Fixed Equipment, Elevation or Sealing.

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment **4-501.11 Good Repair and Proper Adjustment.**

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

With respect to chemical sanitization, Subparagraph 4-501.114 addresses the proper make-up of the sanitizing SOLUTION, i.e., chemical concentration, pH, and temperature at the required MINIMUM levels specified when considered together (and, with respect to quats, the MAXIMUM hardness level). If these minimums (maximum hardness) are not as specified, then this provision is violated.

By contrast, Paragraph 4-703.11(C) addresses exposure TIME in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.

Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is APPROVED and listed for that use under 21 CFR 178.1010. If the chemical used is not thus listed, this section is violated.

The second consideration under this Section is whether the product, if approved and listed, is being used in accordance with the "conditions of use" provided for that product under its 21 CFR 178.1010 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 21 CFR 178.1010(b)(16) lists a quaternary ammonium compound as approved, adding, "In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places." Then look at the related 21 CFR178.1010(c)(11) that limits the concentration of that approved product in solution to 200 ppm. If a sanitarian determined that a solution of this quat was at 600 ppm, Section 7-204.11 would be violated.

To summarize, a too weak sanitizing solution would be a violation of Subparagraph 4-501.114. A too strong solution would be a violation of Section 7-204.11. Section 7-202.12 would not be violated due to the existence of 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110^{o}F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of the hot water delivered to the warewasher manifold must be maintained according to the equipment manufacturer's specification to ensure that the surfaces of utensils or tableware accumulate and build up enough heat to destroy pathogens that may be present on such surfaces. The surface temperature should reach at least 71°C (160°F) as measured by an irreversible registering temperature indicator.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

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4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells do not meet the Code requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

Refer also to the public health reason for § 4-502.13.

Objective **4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.***

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency **4-602.11 Equipment Food-Contact Surfaces and Utensils.***

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in Subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that

may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4-603.17 Returnables, Cleaning for Refilling.*

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11 Before Use After Cleaning.***

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11 Hot Water and Chemical.***

See explanation in 4-501.114.

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

Objective **4-801.11 Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11 Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11 Storage of Soiled Linens**.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 Mechanical Washing.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 Use of Laundry Facilities.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

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

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 Wiping Cloths, Air-Drying Locations.

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11 Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 Equipment.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 Prohibitions.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Handling	**4-904.11**	**Kitchenware and Tableware.**
	4-904.12	**Soiled and Clean Tableware.**
	4-904.13	**Preset Tableware.**

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

Chapter 5 Water, Plumbing, and Waste

Source **5-101.11 Approved System.***

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.*

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.*

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality **5-102.11 Standards.***

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.*

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability

5-103.11 Capacity.*

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention **5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food- contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials **5-201.11 Approved.***

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Design, Construction, and Installation **5-202.11 Approved System and Cleanable Fixtures.***

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of 40°C $\pm$ 2°C (100 to 107°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.*

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.
Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities **5-203.11 Handwashing Facilities.***

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient facilities must be available to make handwashing not only possible, but likely.

5-203.12 Toilets and Urinals.*

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.*

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.*

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement **5-204.11 Handwashing Facilities.***

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine

operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance

5-205.11 Using a Handwashing Facility.

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.*

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning **5-205.14 Water Reservoir of Fogging Devices, Cleaning.***

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila***. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 System Maintained in Good Repair.*

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials **5-301.11 Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction **5-302.11 Enclosed System, Sloped to Drain.**
5-302.12 Inspection and Cleaning Port, Protected and Secured.

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank

inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.*

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank

5-401.11 Capacity and Drainage.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery

5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.*

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.*
5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

Disposal Facility

5-403.11 Approved Sewage Disposal System.*

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12 Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Facilities	**5-501.10**	**Indoor Storage Area.**
on	**5-501.11**	**Outdoor Storage Surface.**
the Premises	**5-501.12**	**Outdoor Enclosure.**
	5-501.13	**Receptacles.**
	5-501.14	**Receptacles in Vending Machines.**
	5-501.15	**Outside Receptacles.**
	5-501.16	**Storage Areas, Rooms, and Receptacles, Capacity and Availability.**
	5-501.17	**Toilet Room Receptacle, Covered.**
	5-501.18	**Cleaning Implements and Supplies.**
	5-501.19	**Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.**
	5-501.110	**Storage Refuse, Recyclables, and Returnables**
	5-501.111	**Areas, Enclosures, and Receptacles, Good Repair.**
	5-501.112	**Outside Storage Prohibitions.**
	5-501.113	**Covering Receptacles.**
	5-501.114	**Using Drain Plugs.**
	5-501.115	**Maintaining Refuse Areas and Enclosures.**
	5-501.116	**Cleaning Receptacles.**

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal **5-502.11 Frequency.**
5-502.12 Receptacles or Vehicles.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling **5-503.11 Community or Individual Facility.**

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas **6-101.11 Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas **6-102.11 Surface Characteristics.**

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability **6-201.11 Floors, Walls, and Ceilings.**
6-201.12 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, therebypreventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality **6-202.11 Light Bulbs, Protective Shielding.**

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code®, 1994 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of Subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.
6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Facilities **6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals **6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting **6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11** **Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers **6-305.11** **Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10** **Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Facilities **6-401.10** **Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11** **Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11** **Designated Areas**.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment

and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11 Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments, **and** ***Fixtures, - Methods*** **6-501.11 Repairing.**

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 Cleaning, Frequency and Restrictions.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Maintaining and Using Handwashing Facilities.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.*

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.*

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are

required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for “service animal” is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by “seeing eye dogs”; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in documents such as, “Commonly Asked Questions About Service Animals in Places of Business”; “The Americans with Disabilities Act Questions and Answers”; “A Guide to Disability Rights Laws”; and “Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement.” The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11 Identifying Information, Prominence.***

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11 Common Name.***

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11 Separation.***

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11 Restriction.***

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.*

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

Container Prohibitions **7-203.11 Poisonous or Toxic Material Containers.***

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals **7-204.11 Sanitizers, Criteria.***

See explanation in 4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.*
7-204.13 Boiler Water Additives, Criteria.*
7-204.14 Drying Agents, Criteria.*

If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it **does not specify any maximum level** (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

Lubricants **7-205.11 Incidental Food Contact, Criteria.***

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.12 Rodent Bait Stations.***

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines **7-207.11 Restriction and Storage.***

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage. There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.*

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies **7-208.11 Storage.***

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Personal Care Items **7-209.11 Storage.**

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Storage and Display **7-301.11 Separation.***

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

8-201.12 Contents of the Plans and Specifications.
8-203.10 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this Plan Review Manual has been used in the FDA State Training Team Plan Review courses. It was endorsed by the CFP at the Conference's 1998 meeting and continues to undergo expansion to address temporary food events. It can be accessed through http://www.fda.gov/~dms/prev-toc.html.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operational procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Potentially hazardous food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

See discussion in Annex 3, 2-201.12.

Annex

4 Food Establishment Inspection

1. INTRODUCTION

(A) Purpose

A principal goal to be achieved by a food establishment inspection is to prevent foodborne disease. Inspection is the primary tool a regulatory agency has for detecting procedures and practices which may be hazardous and taking actions to correct deficiencies. Food Code-based laws and ordinances provide inspectors scientifically based rules for food safety.

This Annex provides regulatory agencies with guidance on planning, scheduling, conducting, and evaluating inspections. It also supports programs by providing recommendations for training and equipping the inspection staff, and attempts to enhance the effectiveness of inspections by stressing the importance of communication and information exchange during regulatory visits. Inspections aid the industry by:

(1) Serving as educational sessions on specific Code requirements as they apply to an establishment and its operation;

(2) Conveying new food safety information to establishment management and providing an opportunity for management to ask questions about general food safety matters; and

(3) Providing a written report to the establishment's permit holder or person in charge so that the responsible person can bring the establishment into conformance with the Code.

FDA has issued national standards for regulatory programs that administer retail food safety programs. The guidance document, "FDA's Recommended National Retail Food Regulatory Program Standards" is discussed in Annex 2, 3.

(B) Background and Current Applications of HACCP

Inspections have been a part of food safety regulatory activities since the earliest days of public health. Traditionally, inspections have focused primarily on sanitation. Each inspection is unique in terms of the establishment's management, personnel, menu, recipes, operations, size, population served, and many other considerations.

Changes to the traditional inspection process were first suggested in the 1970's. The terms "traditional" or "routine" inspection have been used to describe periodic inspections conducted as part of an on-going regulatory scheme. A full range of approaches was tried and many were successful in managing a transition to a new inspection philosophy and format. During the 1980's, many progressive jurisdictions started employing the HACCP approach to refocus their inspections. The term "HACCP approach" inspection is used to describe an inspection using the "Hazard Analysis and Critical Control Point" concepts. Food safety is the primary focus of a HACCP approach inspection. One lesson learned was that good communication skills on the part of the person conducting an inspection are essential.

The HACCP Annex to the Code provides a full background on the origin, principles, and applications of HACCP and explains the concepts used during inspections in greater detail than found in this Annex. It should be reviewed in connection with the material found here to better prepare for performing a HACCP approach inspection. The HACCP Annex also provides an extensive list of references.

FDA has taught thousands of state and local inspectors the principles and applications of HACCP since the 1980's. The State Training Team and the FDA Regional Food Specialists have provided 2-day to week-long courses comprising the scientific principles on which HACCP is based, practical application of these principles including field exercises, and review of case studies. States and local jurisdictions have also offered many training opportunities for HACCP.

A review of state and local retail food protection agencies shows that HACCP is being applied in the following ways:

(1) *Formal Studies* - Inspector is trained in HACCP and is using the concepts to study food hazards in establishments. These studies actually follow foods from delivery to service and involve the write-up of data obtained (flow charts, cooling curves, etc.).

(2) *Routine Use* - State has personnel trained in HACCP and is using the hazard analysis concepts to more effectively discover hazards during routine inspections.

(3) *Consultation* - HACCP-trained personnel are consulting with industry and assisting them in designing and implementing internal HACCP systems and plans.

(4) *Alternative Use* - Jurisdiction used HACCP to change inspection forms or regulations.

(5) *Risk-Based* - Jurisdiction prioritized inventory of establishments and set inspection frequency using a hazard assessment.

(6) *Training* - Jurisdiction is in the active process of training inspectors in the HACCP concepts.

2. PROGRAM PLANNING

(A) Resources

The primary resource available to a jurisdiction is the number of hours to perform inspections and related administrative activities. Total hours required will vary somewhat depending on such things as the type of establishments and geographical distribution.

As a suggested target, it is recommended that approximately 8 to 10 hours be allocated per establishment per year. This includes time for inspection, follow-up inspections, complaint investigations, and administrative work, such as plan review, enforcement documentation preparation, hearings, and court actions. The suggested time is based on a typical mix of establishments and average travel times. Simpler food operations in establishments or smaller areas will mean that fewer hours are needed, whereas more complex operations and larger areas will add additional time requirements.

Other factors which affect the use of planned resources are:

(1) *Inspection frequency for each category of establishment (refer to Section **2.** (C));*

(2) Establishment operations' variation over time; and

(3) Training provided to the inspection staff (refer to Section **3.**).

Establishment variation results from turnover of management and employees or changes in menu and procedures. Initial and continuing staff development are important activities which support quality regulatory programs and should be factored into the overall allocation of available time.

(B) Equipment

Inspectors must be properly equipped to perform the inspections in their assigned territory. Recommended equipment and supplies include:

(1) Necessary forms and administrative materials;

(2) Lab coat or equivalent protection to cover street clothes;

(3) Head cover: baseball cap, hair net, or equivalent;

(4) Alcohol swabs;

(5) Thermocouple or thermistor temperature measuring device for food and ambient air;

(6) Maximum registering thermometer or temperature-sensitive tapes for verifying hot water warewasher final rinse temperature, 73^{o}C (160^{o}F);

(7) Pressure gauge for determining in-line pressure of hot water at injection point of warewasher (15-25 psi) - (inspector should have access to a gauge);

(8) Chemical test kits for different chemical sanitizer types;

(9) Flashlight;

(10) Light meter;

(11) Measuring device for measuring distances;

(12) Time/temperature data logger (optional);

(13) pH meter (optional);

(14) Water activity meter (optional);

(15) Camera (optional); and

(16) Electronic Inspection System (recommended).

If the establishment is performing complex operations, the inspector must also have pH meters, water activity (a_w) meters, and time-temperature data loggers.

Programs require a fully equipped kit for investigating foodborne illness complaints. Kits should include necessary forms, sterile collection utensils and sample containers, indelible marking pens, labels, sealing tape, and an insulated sample shipping case. Sterile containers are also needed for collection of appropriate specimens from victims. Current recommendations from the laboratory for maintaining food samples and patient specimens should be maintained with the kit.

Personal computers are very useful for managing inspection and program data both in the office and the field. If equipped with modems, they also enable the program to keep current with the latest in food safety technical information through the FDA CFSAN Home Page (http://www.cfsan.fda.gov) Internet service. Computer software packages are also useful for modeling the growth of pathogenic bacteria, calculating refrigeration requirements, and investigating foodborne illness reports.

(C) Risk Categorization of Food Establishments

(Refer to Subpart 8-401, Food Code)

Studies have shown that the types of food served, the preparation steps these foods require, the volume of food, the population served, and previous compliance history can have a bearing on the opportunity for the occurrence of foodborne illness.

The rational allocation of inspection resources to target the highest risk establishments with more inspection time and the lowest risk establishments with the least is a HACCP approach concept. Risk categorization allows establishments to be ranked by considering risk factors and creating a variable inspection frequency for each category. An example of risk categorization and frequency of inspection is shown in Table 1.

Table 1. Risk Categorization of Food Establishments

RISK TYPE	RISK TYPE CATEGORY DESCRIPTION	FREQUENCY #/YR
1	Pre-packaged nonpotentially hazardous foods only. Limited preparation of nonpotentially hazardous foods only.	1
2	Limited menu (1 or 2 main items). Pre-packaged raw ingredients are cooked or prepared to order. Retail food operations exclude deli or seafood departments. Raw ingredients require minimal assembly. Most products are cooked/prepared and served immediately. Hot and cold holding of potentially hazardous foods is restricted to single meal service. Preparation processes requiring cooking, cooling, and reheating are limited to 1 or 2 potentially hazardous foods.	2
3	Extensive handling of raw ingredients. Preparation process includes the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous food. Advance preparation for next day-service is limited to 2 or 3 items. Retail food operations include deli and seafood departments. Establishments doing food processing at retail.	3
4	Extensive handling of raw ingredients. Preparation processes include the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous foods. Food processes include advanced preparation for next-day service. Category would also include those facilities whose primary service population is immunocompromised.	4
5	Extensive handling of raw ingredients. Food processing at the retail level, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

Previous compliance history should also be considered when establishing inspection frequency. Non-conformance with critical Code items or HACCP plan requirements may move an establishment up into the next higher frequency range until a record of more consistent compliance is achieved.

There are a wide variety of ways to assign establishments to categories. The simplest method for that jurisdiction is usually the best.

Resources need to be allocated for seasonal and temporary food establishment operations. Frequently, this involves scheduling inspections on weekends and during evening hours. Some jurisdictions have also found it useful to schedule a number of inspections during the evening hours to get a more balanced view of certain food operations.

Some agencies replace one or more of their routine inspections with such alternatives as a full-scale HACCP study, or a staff training session. If a manager certified in food safety is on

duty at all times, some agencies may discontinue routine inspection. Care must be exercised in using these alternatives to maintain sufficient regulatory oversight.

(D) Types of Inspections

The Food Code specifies that access to a retail establishment for inspection is a condition of the acceptance and retention of the food establishment permit. Inspections are generally unannounced to obtain a more accurate assessment of normal operating practices and conditions. Exceptions can be made during construction and preoperational inspections where an appointment is needed to ensure that all parties are available for discussion or where work is intermittent and access to a new establishment is limited; or during follow-up inspections which may require the presence of specific personnel or management from the establishment. Full documentation should be maintained on each inspection as a part of the establishment's official agency record.

Inspections determine the food establishment's compliance with the Food Code. These inspections may be categorized by purpose such as:

(1) Preoperational Inspection
(Refer to Subpart 8-203, Food Code)

The Food Code specifies that a preoperational inspection shall be conducted to ensure that the establishment is built or remodeled in accordance with the approved plans and specifications. It is helpful to have these documents available during the inspection.

(2) Routine Inspection
(Refer to Part 8-4 and Subpart 8-403, Food Code)

Routine inspections should be scheduled on an interval based on risk. These inspections are full reviews of the food establishment operations and facilities and their impact on food safety. They include assessment of food employee and management health, practices, and knowledge of food safety; food flows, source, storage, thawing, preparation (including cooking temperatures and times) and post-preparation processes; equipment and facility construction; cleaning and sanitizing processes; water sources; sewage disposal; and vermin control.

Detailed reports are prepared at the conclusion of each inspection and presented to the person in charge. Items found not to be in compliance are categorized as critical or noncritical. Items found to be repetitive from the previous inspection are also noted. The Code section in violation is included in the report citation section.

(3) Follow-up Inspection
(Refer to Subpart 8-405, Food Code)

The Food Code specifies that the agency shall verify that critical violations have been corrected within 10 days of the initial routine inspection that detected them. Follow-up inspections should be briefer than the routine inspection, since they concentrate on the critical violations previously reported.

Corrections and continued violations should be noted on an inspection report. Continued violations should be used to initiate further compliance actions.

Time available for follow-up inspections will vary between jurisdictions. The compliance strategy is more effective if those follow-ups are mandated in a realistic fashion which takes available resources into account. It is a sign of a weak program when required 10-day follow-ups never occur or are late. It is better to consistently follow-up on the worst 5% than to schedule follow-ups on the worst 25% of the establishments and only perform a few of these. Refer to Section 13., Establishment Scoring, for further information.

(4) HACCP Inspection
(Refer to Subpart 8-403, Food Code)

Establishments operating under a variance requiring a HACCP plan need to be inspected differently. HACCP plans have critical limits which must be routinely monitored and recorded by the establishment, and monitoring and other elements of the plan must be verified by the inspector.

Copies of the firm's approved HACCP plan are useful during these inspections. Additional time may be necessary to fully assess the establishment's compliance with the HACCP plan. Verifying the maintenance of the required records is an important element of the HACCP inspection. Notation in the records of process deviations that occurred and corrective actions taken in response to those deviations should not be cited as adverse findings.

(5) Complaint Inspection
(Refer to Subpart 8-404, Food Code)

Consumer complaints received about a food establishment should be investigated in accordance with the agency's policies. Quick response is required for those related to foodborne illnesses. Speed is essential to preserve both memories of events and possible food or environmental samples. The regulatory agency's medical staff could be used to coordinate, with the complainant's physician or hospital staff, the collection of appropriate specimens.

HACCP principles can be used to supplement traditional procedures for investigation of foodborne illness complaints to help the inspector focus on possible causes and gather better data. Hazard analysis is a useful tool when evaluating implicated menus or foods. It helps focus the investigation on foods which have been epidemiologically linked with illness. Other

foods should not be completely dismissed because as more becomes known about the causes of foodborne illness, foods which may not have been historically linked to illnesses are being implicated.

The charting of food product flows and the designation of critical control points can help delineate potential problems. If a hazard seems evident, the suspect product or process can be recreated with the cooperation of the establishment and the critical limits monitored.

Other consumer complaints about food establishments should be evaluated in terms of public health significance before scheduling inspections. For example, allegations about an establishment purchasing shellfish from an illegal source should receive a higher priority than complaints about a littered parking lot.

3. STAFF TRAINING

Basic staff training is very important to staff development and should be a well-defined process. Initial training is usually provided within the local regulatory agency and more advanced training is available through a state agency's program. National training is available from FDA's State Training Team and from the Centers for Disease Control and Prevention's Distance Learning Program. These programs range from basic to advanced subject-specific seminars offered regionally, to homestudy courses including video, slide, or textbook-based programs, and finally to direct satellite broadcast seminars and courses as a part of the Public Health Training Network. An FDA regional food specialist may be requested to work with a trainee who is employed by a state or large local regulatory program, early in the trainee's career.

(A) Basic Training

The training process can be divided into three phases. The first provides an orientation to the program. This initial phase includes a review of program history, structure, and relationships to other food programs. Specific emphasis should be on the program's goals and objectives. A structured approach is beneficial to familiarize the inspector with the FDA Food Code, as well as state and local food protection codes. This phase can also include interim quizzes to assess knowledge retention and reveal areas which need further work. Development of good communication skills should also be emphasized.

The study of epidemiology of foodborne illness, including the organisms, foods, and contributing factors and case studies, is an important part of the early technical training. Basic food microbiology, including the effects of temperature, pH, water activity, and other hurdles and barriers to the survival and growth of foodborne pathogens, are appropriate subjects. Scientific journal articles in the fields of food microbiology, food technology, and HACCP should be provided. A review of access procedures to on-line databases such as the FDA CFSAN Home Page (http://www.cfsan.fda.gov) is also important.

(B) Field Training

The next phase of training moves the new inspector into the field with the training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, and measuring conditions such as temperatures and sanitizer strength. Time should be spent practicing completion of the inspection forms to conform to the regulatory agency's standard of description of the violation. If the FDA Electronic Inspection System is used by the agency, training in its use could be included in this phase.

The field orientation should also include at least one full HACCP inspection to acquaint the inspector with food operations and flows in establishments. The pre-HACCP review discussions should be guided by the new inspector and include a review of the establishment's menu, operations, and the recipes and standard operating procedures. A full food or operational cycle should be included in this HACCP training exercise, but is not normally expected to be a part of a routine HACCP-based food protection program.

The inspector should be able to demonstrate proficiency with gathering information about the process, including accurate charting of the food flows and determination of the critical control points and their critical limits. The HACCP training exercise should include defining the practical monitoring alternatives for the critical limits, reasonable record maintenance, and a review of acceptable options when critical limits are not met. All of these steps should be conducted in conjunction with the management of the establishment. Observations and measurements should be recorded in an unobtrusive manner during the entire food cycle or operation.

The trainee should prepare a comprehensive report on the HACCP field exercise and the training officer should critique the report. In assessing the success of this important part of the training program, the training officer should include a review of the thoroughness of the information gathering and the observation phases of the exercise.

Evaluation of HACCP skills such as selection of appropriate critical control points should be performed. The training officer should comment on the proficiency of the trainee's communication skills and plans should be made for working on any areas found to need improvement.

(C) Standardization and Certification

The following describes a model for applying the concept of standardizing regulatory personnel and confirming that they are standardized in the understanding, interpretation, and application of the Food Code. The first paragraph addresses the training period during which the person becomes standardized and the second paragraph addresses a formal verification process leading to certification of the standardized person. FDA is in the process of seeking comment regarding a revised, Interim Procedure for the process of certifying retail food regulatory personnel. As those Procedures are finalized, this description will be modified in future editions of the Code.

The future regulatory responsibilities of the trainee should be emphasized during the next phase of field training. This part of the orientation begins as the trainee observes the training officer making inspections, where there is extensive discussion of the inspection process. The points of violation are fully discussed and differentiated from similar conditions which are not violations. The time involved in this phase of training depends on the capabilities of the trainee to grasp and apply the important concepts of translating the words to regulatory actions including the differentiation of the relative significance of the violations. At the end of this phase, the trainee should be proficient in the application of the Food Code and state/local food protection regulations.

The next period should proceed with the reversal of roles in which the trainee determines the violations, explains the reasons, and cites the proper regulation section. The training officer should be standardized by the appropriate FDA retail food specialist. The testing phase should follow the FDA-recommended protocol for certification. Independent simultaneous inspections are made of the establishment, and violations are recorded on inspection reports. After 8 inspections, there should be agreement between the trainee and the training officer on at least 90% of the violations recorded by the training officer that relate to foodborne illness risk factors. If this is not accomplished, remedial training should be given and the certification procedure repeated.

(D) Continuing Education

The final phase of training is never finished. The standardization procedure should be repeated with the training officer on an annual basis. The agency should establish continuing education programs to keep the staff current with the changing food safety concerns and the latest information. Five regional FDA seminars are held each year by the regional food specialists to acquaint state and local agency personnel with new information concerning important changes in the interpretation and application of the Food Code.

Professional association meetings and state agency-sponsored courses also can serve to keep staff development progressing. FDA and other federal agencies offer a series of training opportunities and a lending library of training materials to assist the state and local food regulatory programs. The FDA Web Page http://www.fda.gov/ora/training/course_ora.html) regularly includes listing of these sessions and materials.

Industry-sponsored training sessions should not be overlooked as an educational resource. In addition to providing technical materials, they can foster a better understanding of the concerns of regulators and the industry. The food manager certification training and testing programs offer excellent opportunities for acquiring basic food safety knowledge. Testing inspectors in training may prove helpful in evaluating their knowledge of the material.

4. CONDUCTING THE INSPECTION

The HACCP approach inspection examines an operation as a total process by identifying "critical control points" in an attempt to prevent food safety hazards from occurring (i.e., conditions at the establishment which could lead to foodborne illness).

Individual differences in programs, personnel, establishments, and jurisdictions need to be taken into account in establishing agency procedures for assigning establishments and preparing for and executing inspections. The following discussion is provided as a guideline for developing those procedures.

(A) Assignment

There is no single best way to assign inspections. Regulatory agencies frequently use geographical location, trying to balance hours required to inspect the total number of establishments within each territory. Many times other environmental health functions are also performed in addition to the food protection program, and these functions are accounted for in the work planning. Often agencies periodically rotate areas among inspectors or redivide the areas based on changes in the establishment inspection inventory.

Other agencies may choose to specifically or categorically assign establishments to the inspectors. Institutional-type food operations may be in the inventory of one inspector while those establishments doing food processing at retail under HACCP plans may be under another's. Specialization sometimes has advantages with the more complex types of inspections.

Under certain circumstances, some agencies find it more efficient to maintain all plan review, preoperational, and remodeling inspections under an inspector who specializes in those functions. Others may have all follow-up and other compliance inspections performed by one group of inspectors.

(B) Preparing for the Inspection

The establishment file should be reviewed before the inspection is conducted. This is particularly important if the last inspection was conducted by a different inspector. Notation of previous violations should be made to ensure that these violations will be reviewed.

Inspections of establishments operating under variances and HACCP plans should include a review of specifics of the plan. Pertinent parts of the plan and the establishment's monitoring procedure may need to be copied and taken on the inspection to confirm that the plan is being followed.

The regulatory agencies using the FDA Electronic Inspection System's Field Module will automatically have the previous inspections and the HACCP plan elements loaded onto the notebook computer for reference in the field. Previous violations or HACCP plans may be retrieved during the inspection.

(C) Entering the Establishment

(Refer to Subpart 8-402, Food Code)

Inspectors should enter the establishment during the hours of operation or at other reasonable times. The inspector must provide the permit holder or person in charge with a notice of the purpose of, and intent to conduct, the inspection. According to agency policy, this may be a verbal or a written notice at the time of inspection.

Procedures outlined in the Food Code and in the agency procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

(D) Introductions

The tone of the inspection is often set during the first few minutes of the inspection. The professional but personable approach is the balance which should be maintained. Genuine interest in the establishment and the staff translates into good relations which may be helpful in conveying the agency's goal of promoting public health.

Near the outset, particularly if the visit is a follow-up inspection, questions should be directed to corrections made since the last inspection. This is also the time to explain the nature of the visit, such as an investigation of a complaint or a follow-up.

A preliminary walk-through may be beneficial in acquainting the inspector with the layout and facilities.

(E) Menu/Operations Review

The inspection should start with discussions of the menu and food preparation operations being performed in the establishment. It may be more helpful to involve the chef or departmental supervisor in discussions than rely on the memory of the permit holder. Even though the inspector may be knowledgeable about an operation or establishment, conditions change. A few minutes spent early in the inspection may reveal some faulty assumptions or items of public health significance.

Questions should be phrased to elicit the actual process rather than the answer the establishment employee thinks the inspector wants to hear. For example, "What happens to the gumbo next?" may work better than "Please tell me how you rapidly cool that 50 gallons of gumbo." Brief notes taken at this point, with later verification, keep the process of information gathering moving forward.

Full food flow cycles should be reviewed even though only a portion of them will be taking place during the inspection.

(F) Set the Example

The inspector can begin teaching food safety by the example set when entering the food areas of the establishment. Clothing, including shoes, should be clean. Some jurisdictions provide laboratory coats to their staff to set a more professional image. The inspector should also wear a proper hair restraint to comply with the jurisdiction's requirements for food employees.

Handwashing is the important first step when entering a food area. Not only is a good example set by the inspector but a more accurate assessment of the adequacy of the handwashing facility can be determined. The handwashing procedures of accompanying management can also be observed at this time while discussions are continued about its importance.

(G) Initial Observations

A few minutes should be spent getting the larger view of the operation from a corner of the food area. After the layout and general areas of concern have been determined, the inspector should start on a route through the facility which will include the points determined to be significant during the pre-inspection discussions.

(H) Focus During the Inspection

The primary focus of the inspection should be the food employees and the food. The inspector should observe the sources, storage practices, preparation steps, and post-preparation operations as foodborne illness is primarily attributed to these areas of an operation. The specifics of conditions which are violations should be noted during the inspection.

Information regarding known risks associated with certain food preparation practices and menu items should guide the allocation of time and focus during the inspection. Concentration should be on the complex food processes which involve multiple ingredients being assembled or mixed, cooking of potentially hazardous food, foods which are prepared and held for several hours before service, foods which must be cooled, and steps involving reheating. Foods that have been more frequently implicated in foodborne illness should receive higher priority. Foods prepared in large volumes are definite indicators of a process which should be checked. Foods requiring manual assembly prior to service should also be closely watched during inspections.

(I) Questions About the Establishment's Operations

General questions about food flow and operations are covered in the opening discussions with the permit holder or person in charge. Specific questions about particular parts of the operation are best addressed to the employee performing the operation. Some establishments may have a strict policy about individual employees talking to regulatory

personnel which needs to be respected and accommodated. Questions should be asked in an open-ended format and in a nonthreatening manner.

(J) Inspectional Observations
(Refer to Subpart 8-403, Food Code)

Accurate measurements of conditions in the establishment are integral to a thorough inspection. The Food Code or the establishment's accepted HACCP plan provides the critical limits for operations being conducted. Some of the critical limits to be measured may include food product temperatures, pH, water activity (a_w), food additive concentrations, and sanitizer concentrations. The following sections of this Annex provide discussion on specific measurement considerations.

(1) Food Product Temperature Measurements
(Refer to Subpart 2-103, Food Code)

Food cooking temperatures and times and holding temperatures should be routinely monitored by the food establishment management and by the inspector during each inspection. The temperature measuring device and technique are essential in accurately determining the temperatures of potentially hazardous foods.

The geometric center of a product is often chosen as the point of measurement of product temperature, particularly in measuring critical limits of cooking, cooling, and cold holding processes. Hot holding critical limits may need additional measurements taken at points farthest from the heat source, e.g., near the product surface on steam tables.

Ambient temperature monitoring devices should be used as indicators of where further temperature investigations are warranted. Questionable practices such as improper product cooling methods are other indicators. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, also indicate the need for further examination. However, the temperature of a potentially hazardous food itself, rather than the temperature between packages, is necessary for regulatory citations.

(a) Cooking Temperature Measurements
(Refer to Part 3-4, Food Code)

The three dimensions of bacterial load, temperature, and time need to be considered when inspecting the cooking process. Poultry and leftovers are examples of foods that require higher terminal temperatures than beef products.

Critical limits for cooking potentially hazardous foods in the Food Code include specifications that all parts of the food be heated to a certain temperature. Temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food.

The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 54°C (130°F) is required to be held at this temperature for 112 minutes to ensure destruction of pathogens. Notation should be made of cooking times as well as temperature.

(b) Cooling and Holding Temperature Measurements
(Refer to Part 3-5, Food Code)

Cold and hot holding temperatures should be thoroughly checked during the inspection. This includes the temperature of potentially hazardous food during transport, e.g., hot holding carts being taken to patient areas in an institution or cold food being taken to an off-premise event by a caterer.

Product cooling temperatures and times need to be closely evaluated during inspection. Temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Improper cooling practices, such as tightly packing hot pans together, shrouding rolling racks, or closing the doors on rolling cabinets are factors that warrant further temperature and time investigation.

The time dimension is also important in citing holding temperatures. For example, a casserole which was cooked before noon and measured at 43°C (110°F) at 4:30 PM is far more hazardous than a hamburger properly cooked at 3:30 PM being found at 43°C (110°F) at 4:30 PM. The violation citation should note time when citing the casserole temperatures.

(c) Methods for Temperature Measurements

The temperature measurement is only as accurate as the device used. Regular calibration of the device is an important practice and a provision of the Food Code. Thermometers should have calibration instructions from the manufacturer and suggested calibration intervals. The regulatory agency should maintain a log identifying each piece of its inspection equipment that requires calibration. It is also helpful for the agency to have a person assigned the duty of monitoring calibration maintenance cycles. Certificates of calibration may be useful in legal proceedings when the accuracy of instrumentation is questioned.

Modern thermometers which measure temperature electrically, rather than the older bimetal types which rely on thermal expansion of two different metals, are recommended. In these instruments, a sensor is used to detect the temperature and the signal is amplified and processed electronically. This device generally yields a faster response and provides greater overall accuracy because it does not drift out of calibration and is less likely to give variable readings.

A number of different sensor technologies are available, most of which are satisfactory for the temperature range needed in food temperatures. However, there are considerations other than temperature range which should be taken into account when selecting the best and most appropriate device for the specific application.

Refer to item **8. TEMPERATURE MEASURING DEVICES,** which summarizes the different types of temperature measurement equipment, and item **9. CALIBRATION PROCEDURES**, which discusses procedures that could be used.

(d) Cleaning and Sanitizing the Temperature Probe

Before internal food temperatures are taken, the probe must be cleaned and sanitized. When taking a series of temperatures, it is particularly important to thoroughly clean and sanitize the probe between uses to prevent cross contamination. Boiling water, sanitizers, or alcohol swabs can be used to destroy any remaining pathogens on the probe before it is used.

(e) Monitoring Procedures for Temperature Measurements
(Refer to Subpart 4-502, Food Code)

Some of the most important critical limits in a food operation involve the temperatures and times at which pathogen growth is limited or pathogens are destroyed. Establishments should monitor critical control points at a frequency which ensures that they are under control. Inspections should verify that monitoring is occurring by involving the person in charge of these activities during the regulatory inspection. The presence of required thermometers and their proper use can be assessed.

Comparisons should also be made between a calibrated instrument from the inspecting agency and those used by the establishment. Notation of deviations should be made on the inspection report.

(2) pH Measurements

The pH measurement becomes important in determining if a food is potentially hazardous. The determination can be done in a regulatory agency's laboratory or can be assessed in the field with a portable pH meter. The closer the food approaches the critical pH limit of 4.6, the more precise the measurement should be. If pH adjustment is being used by the food establishment as a part of its HACCP plan for protecting certain food products, regular monitoring of pH should be a requirement. The agency should carefully verify that the instrumentation is suitable, calibration procedures are regularly and properly performed, and sampling procedure and analysis meet scientific standards. The establishment HACCP plan should show the above procedures and the HACCP records should include the results from the calibration and sample measurements. Refer to item **9. CALIBRATION PROCEDURES** for a discussion on the calibration of equipment.

When measuring the pH of a food, the measurement must be representative of the whole. Care must be exercised in the selection of collection containers and procedures to eliminate their influence on the sample's pH. It is recommended that multiple samples of the food product be checked to increase the reliability of the measurement.

The pH measurement checks the hydrogen ion concentration of the food. A pH measurement instrument consists of a meter and a suitable electrode probe. The probe may

be of a flat type which can directly measure the pH of the sample or a regular pH probe used in laboratories. The latter may be used if the food is made into a slurry with recently boiled and cooled distilled water with a pH of 7.0. Boiling removes any CO_2 residual in the water. Care must be taken to maintain the electrode in a clean condition. It should be thoroughly rinsed with distilled water between measurements. Oils from foods can frequently contaminate the sensitive electrodes and cause erroneous measurements. If oily foods are checked, extra cleaning is required.

(3) Water Activity Measurements

Water activity (a_w) is another factor in determining if a food is considered potentially hazardous under the Food Code. The relative humidity of the food influences the ability of bacteria to grow and multiply. Water activity is the ratio of water vapor pressure in a food to the vapor pressure of pure water at the same temperature. Most potentially hazardous foods have an a_w of >0.95 with all pathogenic bacterial growth stopped at an a_w of 0.85.

A laboratory or a field water activity meter may be used to determine the food sample's a_w. Because the measurement is somewhat temperature-dependent, temperature control cabinets are usually used in the laboratory. The time it takes for a final reading to be achieved varies. Older models often take up to several hours after the sample is placed in a sealed sample cavity. Newer models can give a reading within minutes. Multiple samples of the same food product will provide more reliable information on the actual value of the a_w. Refer to item 9. for a discussion on the calibration of equipment.

(4) Food Additives Concentrations
(Refer to Subpart 3-302, Food Code)

If food additives such as sodium nitrite are added as a part of a food processing operation at retail, the regulatory agency should be prepared to analyze food product samples to verify that the additive is being added at the appropriate concentration. Samples usually are collected and returned to a laboratory for the analysis. Recognized methods for sample collection and testing such as those published in the most recent edition of the Association of Official Analytical Chemists (AOAC) Official Methods of Analysis should be used.

Portable analysis systems are sometimes available to conduct the measurement in the field. These systems should be cross checked with the acceptable laboratory methods to verify their accuracy before regulatory reliance is placed on them. They should be maintained with proper field calibration and the replacement of reagents as required in the manufacturer's instructions.

Food establishments using additives as a part of their accepted HACCP plan should regularly monitor the resulting levels. The sampling plan should be readily maintained in the processing area and the results logged in the appropriate records being available by the establishment.

(5) Warewashing Process Evaluation
(Refer to Subpart 4-501, Food Code)

Because proper cleaning of food-contact surfaces is an important safeguard of public health, the wash, rinse, and sanitizing processes must be verified to ensure that they meet Food Code provisions. This is more effective than attempting to recover organisms from food-contact surfaces.

Mechanical warewashers are required to have data plates which indicate acceptable parameters for temperatures and cycle times for that model of machine. The operational parameters, in conjunction with the Food Code provisions, should be used as the basis for the machine's evaluation.

(a) Wash/Rinse/Heat Sanitization Measurement

The devices used for measuring food product temperatures can also be used for determining the critical limits of washing, rinsing, and sanitizing. Manual operations are easier to assess, but this should not deter the inspector from verifying mechanical warewashers.

Both the three-compartment sink and many mechanical warewashers have vats for wash and sometimes rinse water that can be checked with a probe-type thermometer and compared to the installed thermometer readings. The machine must be briefly turned off before these measurements are taken. Hot water sanitizing warewashers require indirect measurement of the sanitizing rinse temperature. This can be done by exposing a securely tied remote probe of a thermocouple or the sensor of a well-shielded maximum registering thermometer to the spray. The temperature should be noted after the sanitizing rinse phase of the cycle is triggered. A temperature exceeding 71^{o}C (160^{o}F) in the spray pattern verifies that the temperature in the manifold is at least 82^{o}C (180^{o}F).

Maximum registering temperature indicators can also be attached to a clean utensil and sent through the machine's cycle. The effect of the wash and rinse temperatures on the indicator need to be considered. If these temperatures approach 71^{o}C (160^{o}F), they may trigger the response of the maximum registering temperature indicator so that the sanitizing rinse can not be accurately determined. The heating elements in these compartments may need to be turned off temporarily in order to verify the sanitizing rinse temperature.

(b) Sanitizer Concentration

The chemical sanitizer concentrations in both manual and mechanical warewashing operations need to be monitored. The Food Code specifies that the establishment shall have a device to measure the sanitizer concentration for the type of sanitizer being used. This device may be used during the inspection, but the inspector should have an independent means of verifying concentrations.

Sanitizer test kits commonly use colorimetric comparisons of a color chart to a strip of treated paper which is immersed in the sanitizing solution. The chart provides approximate solution

strength in mg/L (ppm) for the various colors shown. The kits are sanitizer-specific; therefore it is important to use the one designed for the sanitizer in question.

The sensitivity of the test strips may be affected by age, heat, and humidity. Manufacturer's instructions should be followed with regard to their proper storage, use, and replacement. It is helpful to conspicuously date these sanitizer kits when they are received or opened to ensure that they are replaced when expired.

Test kits require various procedures for immersion into sanitizer solutions and subsequent readings. Some types require a quick immersion; others require holding in the solution for a period of time. The time required for color comparison also varies.

Mechanical warewashing machines using a chemical sanitizing cycle may require slightly different verification that the proper concentration has been applied. When supplied, manufacturer's instructions for measurement should be followed. A reliable indication can be found in the residual sanitizer on the utensil surface.

(c) Pressure Measurements

The hot water sanitizing rinse pressure of mechanical warewashing machines is an important factor. The Food Code specifies that the water supply line shall have a 6.4 mm (1/4 inch) Iron Pipe Size (IPS) valve installed immediately upstream from the automatic sanitizing rinse control valve. To measure the line pressure, it is prudent to request that establishment personnel connect the pressure gauge.

Use of a standard gauge made for measuring the pressure of liquids is recommended. It should read in a range of 100 to 350 kilopascals (15 psi to 50 psi) to accommodate the minimum required pressure and 100% overage of the maximum acceptable pressure. This high upper limit helps protect the proper functioning of the gauge in cases in which extremely high pressure is encountered.

(d) Time Measurements

Time, as well as temperature and concentration, is significant in the evaluation of warewashing operations. A watch with a second readout or hand is needed to make sure that immersion times or cycle segments meet Food Code provisions.

The conveyor speed for mechanical warewashing machines is important in achieving an adequate wash, rinse, and sanitizing cycle. The machine's data plate is required to state the maximum speed for the conveyor. The actual speed is usually adjustable and should be measured during the inspection. This may be done by measuring the length of the machine and dividing this figure by the time that a utensil takes to travel this distance.

(6) Light Distribution
(Refer to Subpart 6-303, Food Code)

Portable light meters reading in the desired range are necessary to measure the level of illumination in food areas of an establishment. The instrument should be routinely calibrated against a standard. Care should be taken that the meter is correctly used by avoiding shadows and reflecting surfaces which will bias measurements.

Measurements should be taken systematically to be representative of the actual light levels. These measurements should be taken 76 cm (30 inches) above the floor. Although it is an impractical and unnecessary method of measurement for the purposes of most inspections, the most accurate measurement of illumination in a given area involves dividing the area into 0.6 m (2 foot) squares and taking readings in each of these squares, recording the readings, and averaging them.

(7) Insect and Rodent Infestation
(Refer to Subpart 6-501, Food Code)

Physical evidence of insect and rodent infestation is usually easy to discover. Live and dead vermin, droppings, nesting, gnawings, grease marks on the walls, and other signs are often readily apparent. A bright flashlight, a magnifying lens, and an ultraviolet light to detect rodent urine stains can be used to reveal these infestations.

5. INSPECTION DOCUMENTATION

Accurate notes of the inspector's observations and recordings are essential. These can be as informal as the inspector's "scratch notes" and may contain liberal use of abbreviations. These notes are usually maintained in the inspector's daily log and are not usually provided as a part of the inspection report. Such notes may serve to refresh the inspector's memory should the violations noted in the inspection report result in administrative or judicial proceedings.

(A) HACCP Inspection Data Form

The HACCP Inspection Data form contained in Annex 7 is one suggested format for recording the observations and measurements collected during an inspection. It consists of an administrative section, a food flow section, a section for recording temperatures which are spot-checked, and categorical sections to record other data. Refer to item **10. HACCP INSPECTION DATA FORM** for a discussion on the use of the form.

(B) Corrections During Inspection
(Refer to Subpart 8-405, Food Code)

Many items found during the inspection can be corrected immediately, if the permit holder or person in charge is accompanying the inspector. Such responsiveness should be

encouraged, particularly for critical violations, because immediate actions best protect public health.

Detailed notes should be kept on the HACCP Inspection Data form for these violations and corrections. Immediate correction does not negate the original violation, but should be recognized as a part of the documentation of the inspection. Violations and corrections should be noted on the official inspection report.

Information on the original occurrence of the violation becomes significant if it recurs. During subsequent inspections, recurrence becomes a repeat violation which has additional compliance consequences.

6. INSPECTION REPORT

(Refer to Subpart 8-403, Food Code)

(A) Purpose

The inspection report is the official agency document regarding compliance of the food establishment with agency requirements.

The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. Such a report should be completed for routine, follow-up, and investigative inspections.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports are to be made available for public inspection in accordance with the agency's Freedom of Information policies, while every precaution is taken to protect trade secrets. *(Refer to Subpart 8-202, Food Code)*

(B) Preparation/Completion of the Inspection Report

The inspection report can be prepared by using either the:

(1) Food Establishment Inspection Report (refer to item 11 for discussion and to Annex 7 for the form); or

(2) FDA Electronic Inspection System (refer to item 12 for discussion).

The inspection report is usually completed at the end of the inspection by reviewing the field notes recorded on the HACCP Inspection Data form (refer to Annex 7). This transfer of information usually provides a more legible and complete report than one completed while each violation is being observed.

Not every item recorded on the HACCP Inspection Data form will be included in the inspection report. The HACCP Inspection Data form may contain some information such as documentation of acceptable holding temperatures that are not necessary for the final report. Inspection findings are recorded on the Food Establishment Inspection Report form to detail the violations found in the establishment. FDA's studies of programs which have the most effective compliance programs found a relationship between the completeness of data provided and the success of the compliance program. The form is designed to maximize the opportunity for capturing relevant information about the violations found at the time of the inspection.

(C) Establishment Scoring

(Refer to Subpart 8-403, Food Code)

Establishment scoring provides an indication of how well an establishment is complying with the food safety rules of the agency. It is also a method for designating those establishments which require follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. These establishments represent a potential public health problem for the community. The specific purpose of the follow-up inspection is to determine if critical violations detected during the initial inspection have been corrected. It may also be the basis for further compliance actions if the remedial actions by the permit holder are not effective.

Some agencies use a system of compliance tools as provided in Chapter 8 of the Food Code to protect public health. The inspection score may serve as the basis for triggering these penalties. Violations which are classified as imminent health hazards in the Food Code warrant immediate actions such as a permit suspension.

Compliance with the provisions of the Code is the basis for retaining the food establishment's permit. The establishment should be in jeopardy of losing its permit if it has a history of noncompliance at a level predetermined by the jurisdiction or if the number of critical items violated warrants a regulatory action based on the jurisdiction's enforcement protocol (refer to item **13. ESTABLISHMENT SCORING**). A history of noncompliance at a level set by the jurisdiction or a single inspection's score of critical items in the highest category of noncompliance would signal the need for strong regulatory response to protect public health. Item **13. ESTABLISHMENT SCORING** provides information on critical and noncritical violation scores.

(D) Closing Conference

The closing conference requires a high level of effective communication. During the conference, the inspector clearly and firmly conveys the compliance status of the establishment. The public health reasons for citing the violations and preventing future occurrences are covered. Acceptable alternatives and time frames for compliance are established during this conference.

The person in charge at the time of the inspection should be the principal establishment representative at the closing conference. It may be beneficial to include other members of the supervisory team in the presentation of findings and subsequent discussions. Ideally, this conference should be held in a quiet location conducive to concentration on the findings and discussion. The length is dependent on a number of factors, but should be kept as brief as possible.

(E) Report Review

The written report is the focus of the closing conference, since it is the record of findings. The listing of the results with the critical violations listed first helps focus the closing conference on the violations which could directly lead to foodborne illness. The notations of repeated violations highlight the areas which may lead to further compliance actions. The organization of violations in the report by operational areas within the establishment often clarifies the information for the review.

The written report includes a notice to correct the identified violations. The permit holder or person in charge must be requested to acknowledge receipt of the report with the required signature. Appropriate procedures are specified in the Code should a signature be refused. Discussion of the results promotes public health compliance in the establishment by giving the permit holder or person in charge an opportunity to ask questions and provide additional information about the establishment's operation. The inspector needs to be well versed in the Food Code and its public health reasons, and have knowledge of the industry in order to competently discuss the concerns of the establishment.

Discussions should focus on the critical violations found during the inspection. The time allocated during the closing conference should be on a risk-to-public-health basis. Noncritical items found to be in violation of the Food Code and actions needed to bring them into compliance should be addressed, but their discussion should not overshadow the significance of the critical violations.

Pamphlets or other educational materials may be useful in reinforcing an understanding of the public health issues involved. Questions which need further research and follow-up response may arise during the inspection, so notes should be taken and follow-up information provided.

Disputes of facts should be resolved in a courteous and professional manner. The permit holder or person in charge should be informed of the responsibilities and rights under the Food Code and of the agency's administrative and judicial procedures.

(F) Compliance Plans

(Refer to Subparts 8-405 and 8-406, Food Code)

The closing conference must include a detailed discussion of the establishment's plans for correcting violations found during the inspection. The violation facts and the alternatives

available for compliance should be emphasized but no recommendations should be made about a particular product or service.

Corrections observed during the inspection must be noted, and reinforcing such responsiveness with encouraging remarks may be to everyone's benefit. However, these violations did occur and therefore they do count as an item of noncompliance.

The compliance plan should address changes in establishment procedures which will prevent the recurrence of noted violations. The best alternatives for compliance usually come from the permit holder or person in charge. One jurisdiction terms this the "table top HACCP" phase of the inspection. The violative process or condition is diagramed and alternatives for correction are explored. For example, the best solution for cooling the gumbo may be to avoid the need for cooling at all by making daily batches.

The establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements.

(G) Notice of Corrections Completed

(Refer to Subpart 8-405, Food Code)

Timely follow-ups are mandated under the Food Code. These follow-ups verify that the critical items cited during the original inspection have been corrected or determine the course for further compliance actions.

Some jurisdictions use procedures which require establishments to return a notice to the agency that violations cited during the inspection have been corrected. These may be form letters or postcards that are preprinted with the agency's mailing address. Such notifications may be helpful, but they do not substitute for an official follow-up inspection. Consistent follow-up on violations is the agency's commitment to public health protection and equitable enforcement.

7. ADMINISTRATIVE PROCEDURES BY THE STATE/LOCAL AUTHORITIES

Administrative organization is a key to effective program management. It must encompass the proper office procedures for establishing administrative files and maintaining the inspection reports and other data pertinent to the establishment.

A comprehensive and detailed record maintenance system supports the program and tracks potential compliance actions. The records maintained usually include documents including ledgers regarding plan review submissions and approvals; permits; inspections; training; complaints; foodborne illness investigations; laboratory sample analyses; and compliance actions, including legal proceedings.

Computerization of the administrative and inspection procedures of the agency has been developing at a rapid rate across the country. The FDA Electronic Inspection System provides a comprehensive basis for the inspection and complaint investigation procedures. Other software may be integrated with it to maintain other aspects of agency records.

(A) Files

The following documents should be included in the active files: records related to initial plan review, permit application and issuance, inspection reports, complaints, investigations, management training and certification, correspondence, and compliance actions. Variance requests including complete HACCP plans and agency actions on the request must be maintained in the establishment's file.

Files must be retained in accordance with the agency's policies, but for those agencies without an established policy, 3 or 4 years in the active file should be sufficient. Closed establishments should be purged from active files, but the files should not be discarded, since these establishments often reopen under different management. The old records may be helpful in advising new, or prospective new, owners about the establishment. Documents related to administrative matters should be kept in an orderly manner to assist in program management. This includes local and state procedures, correspondence and policies, FDA recommendations, references, and source listings such as the Interstate Milk Shippers List and Interstate Certified Shellfish Shippers List.

(B) Follow-up Letters

As an intermediate measure between follow-up inspections and administrative hearings, regulatory agencies often send letters concerning inspection results to the establishments which have continuing problems. These letters to the permit holder specify instances in which deviations from the Food Code were identified during the previous inspection. Letters can cover single establishments or several establishments under the control of the permit holder. Such letters may further strengthen an agency's position in subsequent compliance proceedings.

Follow-up letters can be easily compiled and generated by the FDA Electronic Inspection System. The establishment's records can be quickly reviewed for significant non-compliance. Descriptions of specific violations can be prepared for export to a computer file in word processing software. These data can be quickly merged with the permit holder's name and address and a letter produced. Statewide chain reports can be generated in a similar manner to bring corporate compliance problems to the attention of top management.

(C) Management Reports

Agency managers should constantly review program performance to ensure that it is sufficient for the public health needs of the community. The timeliness of the program's accomplishment of initial, follow-up, and complaint inspections should be reviewed. Violation statistics should be examined for inconsistencies in the inspections. Statistics on the

performance of various sectors of the industry can better focus inspection and educational efforts. Recent foodborne illness data from the community or state should be used to target program resources.

Computerized systems, such as the FDA Electronic Inspection System, should be used for record keeping and reporting to expedite the generation of management reports. These reports keep agency management informed of program performance. Community and political support for food protection programs are engendered through routine and special focus reports on program activities.

(D) Quality Assurance Programs

Continuous program improvement efforts maintain program priorities focused on protecting public health. Regular assessments of the program and individual elements of the program's status determine the direction of program movement.

One of the basics of quality assurance is the design of meaningful and measurable goals. A few well-chosen indicators such as the reduction of overdue follow-ups is desirable. Too many goals make the monitoring system too complex.

Program management is also responsible for ensuring quality inspections through a quality improvement program. Some jurisdictions have members of a quality team or supervisors who monitor a small percentage of inspections through an announced program of reinspection soon after the initial inspection is completed. Conditions will vary somewhat, but general trends can be determined.

From the information gathered, continuing staff education efforts can be directed to needed areas, or program policies can be clarified. Inconsistencies between inspections and application of the rules are a constant complaint of the industry that can be reduced through on-going quality improvement programs.

Retail food protection program evaluations are available from the state-level food regulatory agencies. FDA program evaluations of general program or particular program elements may be requested through the FDA regional retail food specialist and are recommended every 3 years. The program elements are evaluated according to FDA-suggested protocol. A statistically significant random selection of establishments is inspected by FDA-certified inspection or evaluation officers to determine the sanitation level in the state program's jurisdiction. State programs have comparable evaluation services for local programs.

8. TEMPERATURE MEASURING DEVICES

(A) Sensor-Type Temperature Measuring Devices

(1) Bimetal Bayonet Style

A bimetal bayonet style thermometer with a dial face scale with a range of -18 to 105°C (0 to 220°F) may be used for certain applications in food temperature measurement. The scale must be in 1°C (2°F) increments. The dial face should be a minimum of about 1 inch in diameter and is usually available in larger sizes. The stem length should be a minimum of 127 mm (5 inches) and may need to be much longer to measure thicker foods.

Specific measurement instructions from the manufacturer of the instrument should be followed. The temperature measured is an approximate average of the temperature between the immersion point, which is approximately 2 inches up the stem, and the stem tip.
The bimetal bayonet style thermometer can accurately measure the temperature of relatively thick or deep foods such as beef roasts and stock pots. However, this instrument does not accurately measure the temperature of food less than 2 inches thick. The thermistor and the thermocouple discussed below do not have these limitations. The recent foodborne illness outbreaks associated with inadequate cooking of eggs and hamburger patties have shown that it is very important to be able to accurately determine the temperatures associated with these products as well.

(2) Thermistor

This device uses the temperature sensitivity of a semiconductor junction as the sensor. Advantages are high output and fast response at a very low cost. Disadvantages include nonlinearity and a limited upper temperature range, typically 300°C (572°F). The accuracy and response time of a thermistor lend themselves very well to food temperature measurement.

(3) Thermocouple

This device relies on the voltage generated by the junction of two dissimilar metals. The voltage output is proportional to the temperature of the junction. The advantages are a relatively rugged construction and a wide temperature range. Disadvantages include higher cost, lower sensitivity, and non-linear output, which requires a built-in reference. This technology has been used in food preparation for a number of years and has performed very well.

(4) Infrared Thermometers

The infrared thermometer quickly registers surface temperatures which facilitates general food safety system surveillance by allowing the scanning of numerous food temperatures over a short period of time. It operates much like a radar gun and requires the user only to aim at the target food, pull the trigger, and read the displayed temperature. ***This type of***

thermometer is intended only for measuring surface temperatures of food products and should not be used to measure and verify critical internal temperatures such as cooking temperatures.

Infrared thermometers are usually constructed of a high-strength, solvent-resistant plastic and measure invisible infrared energy being emitted from a target object. All objects emit infrared energy. The hotter the object is, the more active its molecules are and the more infrared energy it emits. An infrared thermometer houses optics that collect the radiant infrared energy from the object and focus it onto a detector. The detector converts the energy into an electrical signal which is amplified and displayed as a temperature reading.

(B) Performance - Thermocouples, Thermistors, and Infrared Thermometers

The major applicable sensor types for thermocouples and thermistors have an appropriate temperature range for food product measurement. In addition, response time is more than adequate (<1 second) for all the sensors. A bare sensor, however, is not recommended for food use because of fragility and difficulty of cleaning.

Sensors used for food temperature measurement should be encased in a metal sheath. Unfortunately, the disadvantage of a sheath is that it increases response time. As the thickness and length of the probe increase, response time increases dramatically. A food probe with a maximum diameter of 4 mm (0.150 inch) is the best compromise.

Smaller diameters show similar response times for a wide variety of probe materials, including stainless steel. A usable response time for food measurement should be less than 6 seconds TC (time constant). Probes thicker than 4 mm (0.150 inch) show a response TC of 8 to 10 seconds and should be used only for hot grease and surface measurements.

The TC of any sensor is defined as the time required for that sensor to respond to 63.2% of its total output signal when subject to steep change, for example, rapid immersion into a stirred hot oil bath. The step changes can be either an increase or a decrease in the parameter being measured. Five constants are required for a sensor to reach 99% of its total change.

A second factor in response time is placement of the sensor within the probe. The actual sensor element should be placed no more than 1 mm (0.04 inch) ($\pm$10%) from the tip of the sheath. If the sensor is not firmly against the end of the probe, response time increases dramatically. As an example, if the sensor is placed 1 mm (0.5 inch) from the tip, the response time can be as high as 20 seconds.

The sensor should be held in place by thermally conductive epoxy with a thermal coefficient of at least 7.0. Standard epoxies can act as a heat barrier and should be used in stationary applications only where temperature is relatively constant over a long period of time.

Most types of electrical-based thermometers are capable of effectively measuring the internal temperature of thin foods. Depending on construction, basically all are capable of at least $\pm 0.5^{o}C$ ($\pm 2^{o}F$) accuracy over the required temperature range. The limiting factor for effective temperature measurement is the physical characteristics of the probe that is inserted into the food. Thick metal walls and improper placement of the sensor can lead to erroneous readings. The bimetal bayonet-style thermometer may be suitable for measuring internal temperatures of thick foods.

As stated earlier, infrared thermometers do not measure internal temperature, but register surface temperature only, from a variety of distances based on their field of view. Typical applications are at a salad bar where surface temperatures will likely be higher than internal product temperatures or a hot buffet line where surface temperatures will likely be cooler than internal product temperatures. ***Because it only measures surface temperatures, use of an infrared thermometer should be followed by a closer analysis using an internal temperature measuring device that measures internal food temperature, such as a thermocouple, if problems are suspected.***

(C) Dataloggers

Dataloggers are devices which record temperature over time. The measurements may be stored on a circular chart, printed out, or stored electronically for later reporting or downloading to a computer. These devices are primarily used for ambient or product-specific cold holding or cooling, but may also be used for cooking or smoking operations, hot holding, or special applications such as CIP systems.

Some dataloggers allow multiple sensors to simultaneously report data to the recorder. The frequency of recording may be adjustable from continuous to once every 24 hours depending on the application. Portable dataloggers can be useful in HACCP verification work.

The instrument may be either an analog or digital type. The remote sensing probes are subject to the same parameters discussed in connection with other temperature measuring devices. Proper calibration procedures should also be followed.

The records generated from these devices should indicate date, time, and source of reading and should be signed by the individual responsible for the device at that time.

(D) Time/Temperature Integrators/Indicators

Time/Temperature Indicators or Integrators (TTI) are simple label-like devices that continuously monitor cumulative time and temperature of food products. Some of these devices are threshold-sensitive or change in appearance when a certain threshold for temperature or time is reached. The appearance changes only if the threshold has been breached.

Other devices will record the full history of the temperature and time profile. Some are coupled with bar code-like readers which download information to computers. These devices

and the computer software are calibrated to mimic actual changes in the product over the range of temperatures and times encountered.

TTIs are not widely used now, but industry and public health officials agree that there are widespread potential benefits. Applications would include Reduced Oxygen Packaging (ROP) products such as sous vide or vacuum-packaged foods and some fresh products which are temperature-sensitive, such as milk and seafood.

9. CALIBRATION PROCEDURES

(A) Calibration of Sensor Thermometers

(Refer to Subpart 4-502, Food Code)

Thermometers used for regulatory inspections should be calibrated initially, and then regularly thereafter, to ensure that accuracy of measurement is maintained. This calibration should be in the range of normal regulatory concern, 5°C (41°F) to 74°C (165°F). Calibrations should include both the instrument and any interchangeable probes used with that instrument. Each piece should be separately identified in the calibration records with serial numbers or agency equipment numbers.

The thermometer should be calibrated against a thermometer which has been certified by the National Institute of Standards and Technology (NIST). Standard laboratory calibration protocol such as American Public Health Association (APHA) Standards for the Examination of Dairy Products should be followed. Proper calibration documentation is essential.

A wet ice and boiling water procedure may be used for field checks of the thermometer and sensor. The ice should be broken into very small pieces, packed into an insulated container, and stirred with cold water into a very thick slurry. The sensor should be placed at the very center of the container to a depth of at least 50 mm (2 inches) and should be frequently agitated. The temperature should be noted when the temperature has stabilized after 3 minutes and should be $\pm$0.5°C from 0°C when calibrating a Celsius thermometer or $\pm$2°F from 32°F when calibrating a Fahrenheit thermometer.

The field check for higher temperatures may be conducted with boiling water. Consideration should be given to altitude above sea level in using this method. A 25 cm (>10 inch) deep container of water should be brought to a rolling boil on a stove or other source of constant heat. The probe should be carefully inserted in the boiling water until the sensor is located in the approximate center of the container with at least 76 mm (3 inches) of water below it. The temperature should be noted when the temperature has stabilized after 3 minutes and should be $\pm$0.5°C from 100°C when calibrating a Celsius thermometer or $\pm$2°F from 212°F when calibrating a Fahrenheit thermometer.

Adjustments to some of the instruments are possible to bring them back into calibration. Others should be returned to the manufacturer since field adjustments are not possible. Some instruments are not adjustable and should be replaced.

(B) Calibration of pH Meters

The manufacturer's calibration instructions should be followed for both laboratory and portable pH meters. The calibration procedure must take into consideration the expected pH range of food. This factor is extremely important if a pH of 4.6 is used as a critical limit. A 2-point calibration using standard buffers of 4.0 and 7.0 is most common for working with potentially hazardous foods. Calibrations are usually performed immediately before the pH of the food samples is measured. Compensation for the temperature of the sample is required if the pH meter does not automatically address this variable.

(C) Calibration of Water Activity Equipment

The manufacturer's calibration instructions should be followed for both laboratory and portable a_w instruments. The expected food moisture should be taken into consideration during the calibration procedure. The critical limit of 0.85 is the crucial point at which the instrument should be calibrated if the question is whether or not the food is potentially hazardous.

10. HACCP INSPECTION DATA FORM

(A) Purpose

(Refer to Subpart 8-403, Food Code)

The HACCP Inspection Data form in Annex 7 is one suggested format for recording the observations and measurements collected during an inspection. It consists of an administrative section, a food flow section, a section for recording other temperatures which are spot-checked, and categorical sections to record other data.

(B) Form Completion

(1) Administrative Section

This section contains the minimum information to link the form to the particular establishment. It identifies the date and time of the inspection. This information may be important later to substantiate findings in relation to a particular food preparation process.

(2) Food Flow Section

This section allows for space for the inspector to record detailed information about as many as four food items identified as having the most potential for presenting problems. Additional sheets can be used if more than four foods are tracked. The foods are listed horizontally across the top, and steps from source to reheating are included down the left side of the form.

Under each food listed, space is provided for recording information observed such as times and temperatures for each of the steps. A shaded column is provided for each of the foods to identify the critical limit, if any, for each of the steps. As an example, if the baking of chickens is being observed, the internal temperature and cooking time would be noted in the observation (unshaded) column, e.g., indicating that the food was baked to a temperature of 63 - 86°C (145 - 187°F) for 2 minutes. The critical limits column at this step would specify 74°C (165°F) for 15 seconds unless the establishment is preparing chickens under a variance regarding time and temperature, in which case the time and temperature conditions of the variance would be listed in this column.

The entire preparation and service cycle may not occur during the inspection. It should be clearly delineated on the form at which point the observations began and ended. The additional parts of the process can be discussed with the permit holder or person in charge to determine any potential problem areas where critical limits may not have been met.

(3) Food Temperature Recording

This section allows for the recording of food temperatures which are not being tracked above. The index letters indicating the food steps above can be used in conjunction with the recording of these measurements. Both acceptable and violative temperatures may be recorded here, but only the violative temperatures are later cited on the inspection report.

(4) Other Data

This section is located on the back of the form and can be used to record observations and measurements related to other areas of the operation. These include the following areas: management/personnel; other food; equipment, utensils, and linens; water, plumbing, and waste; physical facilities; and poisonous or toxic materials. Notes can be recorded under each of these categories. Additional forms can be used for the same establishment, if needed.

11. FOOD ESTABLISHMENT INSPECTION REPORT

(A) Introduction

(Refer to Subpart 8-403, Food Code)

When using the manual method of preparing the Food Establishment Inspection Report, enter the data on the report form (refer to Annex 7 for the form) in the appropriate field. Use continuation pages to give a full description of the conditions found in the establishment.

(B) Administrative Data

Enter the administrative data to clearly identify the food establishment and update the information when necessary. Use abbreviations where they do not interfere with reliable identification of the establishment.

Use the Inspection Type (**Insp. Type**) when recording the reason for the inspection. Use the Time blank for recording the time the establishment inspection takes or the time of day the inspection was made. Each agency should develop models for standardizing the way this form is completed.

(C) Debiting Methodology

It is critical to standardize the inspection process within the agency. Standardization using state-level and federal-level standardization procedures and certified inspection personnel is important for a program. The standardization procedure is explained in more detail in the staff training section.

The following process delineates the specifics of what constitutes a violation of the Food Code. It limits the possible shades of gray but does not totally eliminate them.

Items are marked as violations on the inspection report when they clearly exist in the food establishment. A violation represents a deviation from a Food Code provision. Slight violations, such as one dirty utensil among thousands of clean ones, does not indicate that the establishment is significantly deviating from the requirement to use clean utensils.

Each violation of a Food Code provision is reported as a separate item on the inspection report. This does not mean, however, that each instance should be considered a distinctly separate reportable violation. Some discretion is warranted when preparing the inspection report, but this discretion should have a firm basis within the standardization process.

For example, a cooler with mechanical problems may result in a dozen or more potentially hazardous food items being at a violative temperature. It may categorically be considered a malfunctioning refrigeration device under § 4-301.11, Cooling, Heating, and Holding Capacities, because repairs are needed to bring the unit into compliance. The food temperature violation is also cited only one time under ¶ 3-501.16(A)(2), Potentially Hazardous Food, Hot and Cold Holding. Additionally, if the time the food is out of temperature warrants, each of the violative foods should be discarded by the permit holder or person in charge and disposition noted on the report.

Alternatively, the unit may be properly functioning, but improper cooling practices were used, resulting in the high temperatures being found in the potentially hazardous food. This would be a violation of ¶ 3-501.15(A), Cooling Methods, and ¶ 3-501.16(A), Potentially Hazardous Food, Hot and Cold Holding.

If 12 separate coolers were found with items out of temperature as the result of 12 separate instances of improper practices by employees, each instance should be individually cited as a critical violation. The details included in each citation should clearly delineate the conditions found in each instance.

Failure to clean floors is another example which can be easily visualized. A large meat cutting room may have numerous separate areas requiring cleaning. If there is a build-up of old food debris and other filth on the floor of the room in five separate areas, then one violation would exist. However, if the cleaning problem existed in this room, the produce area, bakery, and two restrooms, one violation of ¶ 6-501.12(A) is cited with each of the incidences listed.

(D) Violation Data

Record inspectional findings on the report form to detail the violations found during the inspection of the establishment. As mentioned elsewhere in this Annex, FDA's studies of programs which have the most effective compliance programs found a relationship between the completeness of data provided and the success of the compliance program. The form is designed to maximize the opportunity for capturing relevant information about the violations found at the time of the inspection. Use as many of the rows of the Violation Description section as are needed to describe the violation.

Indicate critical violations in the first column, **Category,** using an **X**. Always list the critical violations first for emphasis. Leave a blank line between individual violations cited.

Note repeat violations with an **X** in the second column, **Repeat**. Repeat items are those that were in violation on the last inspection. Indicating in this column when the original violation occurred may also be helpful.

Record specific Food Code section references in the third column, **Code References**. The Inspectional Guide (refer to Annex 7) may be used to quickly find the appropriate Code section numbers. The Code reference provides information about the legal basis for the noted violation and helps the person in charge to find the actual Code requirement. It is important to standardize inspectors in accurately citing the Code. Succinctly provide the specifics of the observed violation in the fourth column, **Violation Description/Remarks/ Corrections**. Record any explanations or other data, including the fact that a correction was made during the inspection. Use as many lines as necessary to explain the details of the violation. Legibility is important.

12. FDA ELECTRONIC INSPECTION SYSTEM

(A) Introduction

(Refer to Subpart 8-403, Food Code)

The FDA Electronic Inspection System (FDA EIS) is a powerful tool for regulatory agencies to use in managing important program data. It can provide the regulated establishments with a comprehensive, legible, and understandable report of the agency's evaluation of the establishment.

The FDA EIS software is being provided to state and local regulatory agencies as a part of the Food and Drug Administration's mandate under the Public Health Service Act to assist

these agencies in their important roles of protection of the consumer's food, seafood, and milk supplies. Federal agencies are receiving this support under the Economy Act. A complete package is available at a nominal cost from National Technical Information Service.

FDA EIS may be used to integrate data management between existing agency database management systems and the food protection program. It can also consolidate inspection data collection and reporting between different levels of food protection programs within a state.

There are two components to the integrated FDA EIS software package, the *Office System* and the *Field System*.

(B) Office System

Features of the EIS that expedite and enhance office-based functions include:

(1) *Flexibility* - Agencies can customize definitions to match the way their programs currently operate.

(2) *Easy to Use* - FDA EIS is menu-driven to allow quick implementation of powerful program features.

(3) *Ad Hoc Reports* - Menus are used to easily format and save management reports routinely needed and to generate spontaneous, unique reports for immediate management decisions.

(4) *Complaint Management* - FDA EIS provides integrated input, ledger, assignment, and tracking for routine establishment complaints.

(5) *HACCP Support* - Program provides a risk-based inspection frequency and accommodates thousands of Hazard Analysis Critical Control Point (HACCP) plans allowing an individual establishment's plan to be incorporated into that firm's inspection.

(6) *Reports* - The *Office System* has a wide variety of reporting capabilities, including statistical analysis, graphical portrayal of management data, or incorporation into word processing applications.

(C) Field System

EIS features that support and enhance inspections include:

(1) *Previous Inspections* - Agencies can choose how many previous inspections are automatically loaded on the Field System for ready reference during the current inspection.

(2) *Automatic Repeat* - Possible repeat violations are automatically flagged for inspector concurrence, and the previous violation statement can be automatically repeated and prepared for editing.

(3) *Code Citation* - Definitive Code section citation is possible to provide for clear and defensible inspection reports.

(4) *Violation Look-Up* - Possible violations can be searched by keyword, chapter, or database for easy Code citation.

(5) *Violation Reporting* - Specific description of findings during inspection to increase management understanding of violations and aid in possible enforcement actions.

(6) *Departmental Reporting* - Findings may be allocated to specific operational areas of an establishment, in effect creating sub-reports for departmental managers which cite only violations occurring in their area of responsibility.

(7) *Realistic Results* - Violations are summarized by number of critical and noncritical items to produce establishment score.

(8) *Reference Library* - An FDA reference library including Code interpretations, Milk Shippers and Shellfish Shippers lists, and Food Recall List may be kept up to date by downloading from the FDA CFSAN Web Page at http://www.cfsan.fda.gov/list.html. FDA's *Foodborne Pathogenic Microorganisms and Natural Toxins Reference Book* (aka Bad Bug Book) is also available for inclusion. State and local SOPs and inspection manuals can be easily added by the user.

(9) *System Support and Future Enhancements* - Consistent with available resources FDA will endeavor to provide technical support and system updates and enhancements.

(D) Basic Implementation Level

The FDA EIS provides two approaches for implementation. The basic plan is achievable by those regulatory agencies with access to an IBM-compatible personal computer. The inspection data is entered in a batch process into the office computer, and the full power of the database management and reporting systems can be immediately used.

Inspection Reports can be preprinted with most of the administrative information inserted through a word processor merge file. The permit generation process can be facilitated with the FDA EIS Office System. Complaint and foodborne illness data tracking are enhanced the implementation of the basic plan.

(E) Advanced Implementation Level

Moving up the technological ramp, the full power and benefits of FDA EIS can be used when the Field System is installed on notebook computers. Inspection results are entered at the conclusion of each inspection and the report is generated within the establishment with a portable printer.

Data accuracy will be more ensured with this method. Timeliness will also be enhanced in generating the agency's management reports. The cost savings should quickly justify the purchase of the modest field computer and printer required to run the FDA EIS Field System.

13. ESTABLISHMENT SCORING

(A) Introduction

(Refer to Subpart 8-404, Food Code)

Certain Food Code violations are imminent health hazards and require immediate action or closure of the affected part of the food establishment. Sewage backing up in a food preparation area is an example of an imminent health hazard. Imminent health hazards require immediate intervention and may result in a summary suspension of the permit as specified in the Food Code.

Critical items are Food Code violations which are more likely to contribute to food contamination, illness, or environmental degradation and represent substantial public health hazards. The Food Code delineates critical items by the use of asterisks * after the tag line. All provisions within an asterisked section are critical unless they are otherwise marked by a superscripted ^{N}, which means that the item is noncritical, or a superscripted ^{S}, which means criticality is dependent upon the circumstances.

In previous codes, violations have been always considered critical or noncritical. The Food Code allows the inspector to use professional judgement regarding some of the violations to determine their seriousness based on the likelihood of food contamination, illness, or environmental degradation occurring as a result of the violation.

(B) Scoring Methods

The Food Code is based on citing violations in two categories, critical and noncritical. Each of the violations is expected to be corrected within given time frames. The number of violations is the basis for applying the compliance action provisions of the Food Code. The score, which is the number of items in violation, is significant as an indicator of the overall control of the causes of foodborne illness; however, there is no defined point at which a score translates into a significant health hazard. In fact, it is possible to have only one critical violation which has the potential for causing a foodborne illness outbreak.

Regulatory agencies which have categorized their establishments based on risk, as reviewed earlier, may choose to score their establishments by using these same categories. Others may choose to score their establishments by a simpler method which does not reflect the complexity of relative risk for foodborne illness causation.

A basic premise of the first two methods discussed below is that it is easier for simpler operations to achieve compliance with the Food Code. More complex operations have more opportunity for missing the targets. In no case should a significant level of noncompliance which will affect public health be tolerated.

Each jurisdiction has variations in conditions which need to be considered in establishing the compliance strategies which will work best for it. Some jurisdictions, even within the same state, have significantly higher or lower levels of compliance when measured with a standardized inspection. An establishment's critical violation score that requires a follow-up inspection will be much different between jurisdictions. Guidance regarding the rational allocation of the available regulatory resources is the purpose of the following discussion.

(1) Total Quality Management Method

A total quality management (TQM) methodology employs statistical process control to keep the organization's efforts focused on continuous quality improvement. By using measurable factors, such as the number of critical items in violation, an organization can continually monitor its results and make adjustments in process (follow-up inspections) to derive the most food safety benefits.

This method uses the industry norms to set the levels for precipitating the follow-up inspection. With the TQM method, regulatory resources are always focused on the establishments within a given category that require further regulatory compliance actions. (Refer to item **2. PROGRAM PLANNING**, © *Risk Categorization of Food Establishments,* for information about possible categories.) An industry norm can usually be reliably established for the jurisdiction after the first 50 inspections of establishments in that particular category. This norm is not static and will change with improvement in compliance and other influences. A regulatory agency would be well advised to conduct a semiannual or annual review of the categorical industry norms.

The TQM method uses the simple but effective statistical tool of percentile rank to judge the compliance of an establishment against the range of compliance levels of similar establishments within that category. The establishment percentile rank is expressed as the percentage of the scores, in the collection of scores, below its score.

The raw scores of critical violations are arrayed to show a frequency distribution to derive the percentile rank. Then the level established is compared with this frequency distribution. A point below the selected level of compliance is chosen as the number of critical items to initiate a follow-up inspection.

Table 2 shows an example summary of the frequency information for critical item violations for Type 4 establishments which have extensive menus and prepare large quantities of food that require many preparation steps. Portrayed are the raw scores and the frequency of occurrence of each critical violation. These calculations may be routinely done through manual computation or use of simple software packages. In this hypothetical jurisdiction and within this category, the highest 20% of violators of critical items in the Code has been established as the point at which follow-up inspections will be made. The frequency distribution is counted down from the highest number of violations to determine that for this period of time the establishments with more than eight critical violations would have follow-ups. This is three more critical violations than the average establishment in this category would have for the same period of time.

Table 2.
Example of Percentile Ranking
of Risk Type 4 Establishments

Est. = Establishment Identification
No. = No. of Critical Violations on an Initial Inspection
Sum Critical Violations = 581.00
Mean No. of Critical Violations = 5.81

Est.	No.	Est.	No.	Est.	No.	Est.	No.
1	1	26	8	51	20	76	5
2	2	27	5	52	4	77	7
3	4	28	7	53	5	78	4
4	5	29	6	54	3	79	4
5	6	30	1	55	2	80	3
6	10	31	3	56	4	81	3
7	13	32	6	57	4	82	4
8	2	33	7	58	12	83	5
9	3	34	5	59	11	84	5
10	4	35	4	60	12	85	4
11	2	36	8	61	3	86	3
12	6	37	10	62	4	87	3
13	5	38	12	63	12	88	5
14	4	39	3	64	2	89	15
15	14	40	3	65	3	90	1
16	2	41	5	66	4	91	2
17	3	42	4	67	5	92	4
18	6	43	5	68	5	93	9
19	4	44	5	69	11	94	4
20	3	45	7	70	10	95	3
21	7	46	6	71	3	96	11
22	8	47	2	72	3	97	2
23	4	48	3	73	5	98	14
24	14	49	8	74	6	99	12
25	4	50	12	75	8	100	7

No.	Freq.	%	No.	Follow-ups for highest 20% of category Freq.	%
1	3	3	9	1	1
2	9	9	10	3	3
3	17	17	11	3	3
4	19	19	12	6	6
5	15	15	13	1	1
6	7	7	14	3	3
7	6	6	15	1	1

(2) *Fixed Categorization*

In this method, a fixed number of critical violations as selected for each category of establishment. Table 3 illustrates one application of this method using this type of categorization.

Table 3. Critical Violations

Type	Critical
1	2
2	3
3	5
4	5

The number of violations used may be adjusted to accommodate current levels of resources in the agency and varying levels of compliance in the industry.

(3) *Fixed without Categorization*

The simplest method of establishing follow-up is to set a single level of compliance for all types and complexities of establishments. This figure should accommodate more realistic levels of compliance in the more complex operations, e.g., five critical violations in a full-service cafeteria would be the criterion before a follow-up inspection is triggered. This may mean that few, if any, follow-ups will be conducted in the quick service or simple retail food store operations.

As with the other methods, the number of critical items for causing follow-ups may be altered to conform to resource realities in the agency and changing levels of conformance in the industry.

Annex

5 *HACCP Guidelines*

NOTE: Annex 5 is currently being reviewed and revised to reflect FDA's current thinking. The information contained herein is likely to change when the next Food Code is issued.

1. INTRODUCTION

HACCP (Hazard Analysis and Critical Control Point) is a systematic approach in identifying, evaluating and controlling food safety hazards. Food safety hazards are biological, chemical or physical agents that are reasonably likely to cause illness or injury int he absence of their control. A HACCP system is a preventive system of hazard control rather than a reactive one. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent hazards attributable to a product or a process, determining the necessary steps that will control the identified hazards, and implementing active managerial control practices to ensure that the hazards are eliminated or minimized.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards – biological, chemical, or physical properties – that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are include din the system, again, to ensure that potential hazards are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.

HACCP represents an important food protection tool supported by Standard Operating Procedures, employee training and other prerequisite programs that small independent businesses as well as national companies can implement to achieve active managerial control of hazards associated with foods. Employee training is key to successful

implementation. Employees must learn which control points are critical in an operation and what the critical limits are at these points, for each preparation step they perform. Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

Local jurisdictions can effectively promote the industry's use of HACCP and apply the concepts during inspections. The implementation of HACCP continues to evolve as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. The document entitled, "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level" is discussed in Annex 2, 3. and can be found at the web site http://vm.cfsan.fda.gov/~dms/hret-toc.html. This Guide recognizes that there are differences between using a HACCP plan in food manufacturing plants. 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. The Agency recognizes that this document has areas that need to be further clarified, 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.

FDA has also issued the guidance document, "FDA's Recommended National Retail Food Regulatory Program Standards" as discussed in Annex 2, 3. Program Standard 3 addresses the regulatory program's use of HACCP principles at retail.

(A) Definitions

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

(1) *Acceptable level* means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.

(2) *Control point* means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.

(3) *Critical control point*, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.

(4) *Critical limit,* as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(5) *Deviation* means failure to meet a required critical limit for a critical control point.

(6) *HACCP plan,* as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(7) *Hazard,* as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(8) *Monitoring* means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.

(9) *Preventive measure* means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.

(10) *Risk* means an estimate of the likely occurrence of a hazard.

(11) *Sensitive ingredient* means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.

(12) *Verification* means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

(B) History

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. Application of the system in the early 1960's created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogens, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP replaced end-product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

(C) Advantages of HACCP

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control.

Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for ensuring food safety. Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP-based inspections are becoming increasingly acknowledged by the regulatory community.

Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP is a viable and practical option to improve food safety. FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis.

2. HACCP PRINCIPLES

(A) Background of NACMCF

Established in 1988, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

(B) Development of HACCP Principles

In November 1992, NACMCF defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HCCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. From this committee, HACCP was defined as a systematic approach tot he identification, evaluatin and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the critical control points (CCPs).
Principle 3: Establish critical limits.
Principle 4: Establish monitoring procedures.
Principle 5: Establish corrective actions.
Principle 6: Establish verification procedures.
Principle 7: Establish record-keeping and documentation procedures.

PRINCIPLE #1: HAZARD ANALYSIS

(a) *Purposes*

The hazard analysis process accomplishes three purposes:

(i) Hazards of significance are identified;

(ii) The hazard analysis provides a risk basis for selecting likely hazards;

(iii) Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.

Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching that goal must be clearly defined.

The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe. The analysis of hazards requires the assessment of two factors with respect to any identified hazard, i.e., the likelihood that the hazard will occur and the severity if it does occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involve low risk and that are not likely to occur need not be considered for the purposes of HACCP.

To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.

Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment, such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.

(b) *Flow Diagram*

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a **HACCP** team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Annex.

(c) *Biological Hazards*

Foodborne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported foodborne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross-contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be foodborne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Norwalk viruses are examples of viral hazards associated with ready-to-eat foods.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready-to-eat food. Fishborne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

TABLE 1. Hazardous Microorganisms and Parasites Grouped on the Basis of Risk Severity[a]

Severe Hazards

Clostridium botulinum types A, B, E, and F
Shigella dysenteriae
***Salmonella* Typhi; paratyphi** A, B
Hepatitis A and E
Brucella abortus; ***B. suis***
Vibrio cholerae 01
Vibrio vulnificus
Taenia solium
Trichinella spiralis

Moderate Hazards: Potentially Extensive Spread[b]

Listeria monocytogenes
Salmonella spp.
Shigella spp.
Enterovirulent ***Escherichia coli*** (EEC)
Streptococcus pyogenes
Rotavirus
Norwalk virus group
Entamoeba histolytica
Diphyllobothrium latum
Ascaris lumbricoides
Cryptosporidium parvum

Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Vibrio cholerae, non-01
Vibrio parahaemolyticus
Yersinia enterocolitica
Giardia lamblia
Taenia saginata

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[a] Adapted from International Commission on Microbiological Specifications for Food (ICMSF) (1986). Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

[b] Although classified as moderate hazards, complications and sequelae may be severe in certain susceptible populations.

(d) *Chemical Hazards*

Chemical hazards in foods should be considered during a hazard analysis. Chemical contaminants may be naturally occurring or may be added during the processing of food. Harmful chemicals at very high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

The following table provides some examples of chemical hazards found within the naturally occurring and added chemical categories. The Code of Federal Regulations, Title 21, provides guidance on naturally occurring toxic substances and allowable limits for many of the chemicals added during processing (food additives). The FDA Compliance Policy Guidelines also provide information on other naturally occurring chemicals.

Table 2. Types of Chemical Hazards and Examples[a]

Naturally Occurring Chemicals

Mycotoxins (e.g., aflatoxin) from mold
Scombrotoxin (histamine) from protein decomposition
Ciguatoxin from marine dinoflagellates
Toxic mushroom species
Shellfish toxins (from marine dinoflagellates)
  Paralytic shellfish poisoning (PSP)
  Diarrhetic shellfish poisoning (DSP)
Neurotoxic shellfish poisoning (NSP)
  Amnesic shellfish poisoning (ASP)
Plant toxins
Pyrrolizidine alkaloids
Phytohemagglutinin

Added Chemicals

Agricultural chemicals:
  Pesticides, fungicides, fertilizers, insecticides,
  antibiotics and growth hormones
Polychlorinated biphenyls (PCBs)
Industrial chemicals
Prohibited substances (21 CFR 189)
  Direct
  Indirect
Toxic elements and compounds:
  Lead, zinc, arsenic, mercury, and cyanide

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[a] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY and adapted.

Food additives:
  Direct - allowable limits under GMPs
    Preservatives (nitrite and sulfiting agents)
    Flavor enhancers (monosodium glutamate)
    Nutritional additives (niacin)
    Color additives
  Secondary direct and indirect
    Chemicals used in establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, coatings, and paints)
Poisonous or toxic chemicals intentionally added (sabotage)

(e) *Food Allergens*

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen-specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's website, www.cfsan.fda.gov/~lrd/allerg7.html.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.

Peanuts
Soybeans
Milk
Eggs
Fish
Crustacea
Tree nuts
Wheat

Current FDA policy, as reflected in FDA Compliance Policy Guide (CPG) 555.250 with regard to direct addition as ingredients or sub-ingredients, is:

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i)(2); 21 U.S.C. 343(i)(2); 21 C.F.R.101.4) unless a labeling exemption applies.

FDA's Regulations (21 CFR 101.100(a)(3)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens used as processing aids qualify for this exemption. FDA, however, does not consider food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4.

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances can be insanitary conditions that may render the food injurious to health and adulterate the product under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

(f) *Physical Hazards*

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment.

As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 3. Main Materials of Concern as Physical Hazards and Common Sources[a,b]

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, fields, wire, employees

[a] Adapted from Corlett (1991).

[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

(f) *Determining Level of Risk*

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe. There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan.

The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

(g) *Hazard Analysis Process*

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

(i) *Ingredients*

• Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., ***Salmonella***, ***Staphylococcus***

aureus), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

(ii) *Intrinsic factors of food*

Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.

- Which intrinsic factors of the food must be controlled in order to ensure food safety?

- Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?

- Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

- Are there other similar products in the market place? What has been the safety record for these products?

(iii) *Procedures used for preparation/processing*

- Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.

- Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

(iv) *Microbial Content of the Food*

- Is the food commercially sterile (i.e., low acid canned food)?

- Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

- What is the normal microbial content of the food stored under proper conditions?

- Does the microbial population change during the time the food is stored before consumption?

- Does that change in microbial population alter the safety of the food?

(v) *Facility design*

- Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

- Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

(vi) *Equipment design*

- Will the equipment provide the time/temperature control that is necessary for safe food?

- Is the equipment properly sized for the volume of food that will be prepared?

- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

- Is the equipment reliable or is it prone to frequent breakdowns?

- Is the equipment designed so that it can be cleaned and sanitized?

- Is there a chance for product contamination with hazardous substances, e.g., glass?

- What product safety devices such as time/temperature integrators are used to enhance consumer safety?

(vii) *Packaging*

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

- Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

- Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

• Does the package include instructions for the safe handling and preparation of the food by the consumer?

• Are tamper-evident packaging features used?

• Is each package legibly and accurately coded to indicate production lot?

• Does each package contain the proper label?

(viii) *Sanitation*

• Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?

• Can the facility be cleaned and sanitized to permit the safe handling of food?

• Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

(ix) *Employee health, hygiene, and education*

• Can employee health or personal hygiene practices impact the safety of the food being prepared?

• Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

• Will the employees inform management of a problem which could impact food safety?

(x) *Conditions of storage between packaging and the consumer*

• What is the likelihood that the food will be improperly stored at the wrong temperature?

• Would storage at improper temperatures lead to a microbiologically unsafe food?

(xi) *Intended use*

• Will the food be heated by the consumer?

• Will there likely be leftovers?

(xii) *Intended consumer*

- Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill.

- Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immunocompromised individuals)?

(h) *Developing Preventive Measures*

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure, would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	Identified Hazard	Preventive Measures
Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens

PRINCIPLE #2: IDENTIFY THE CRITICAL CONTROL POINTS (CCP) IN FOOD PREPARATION

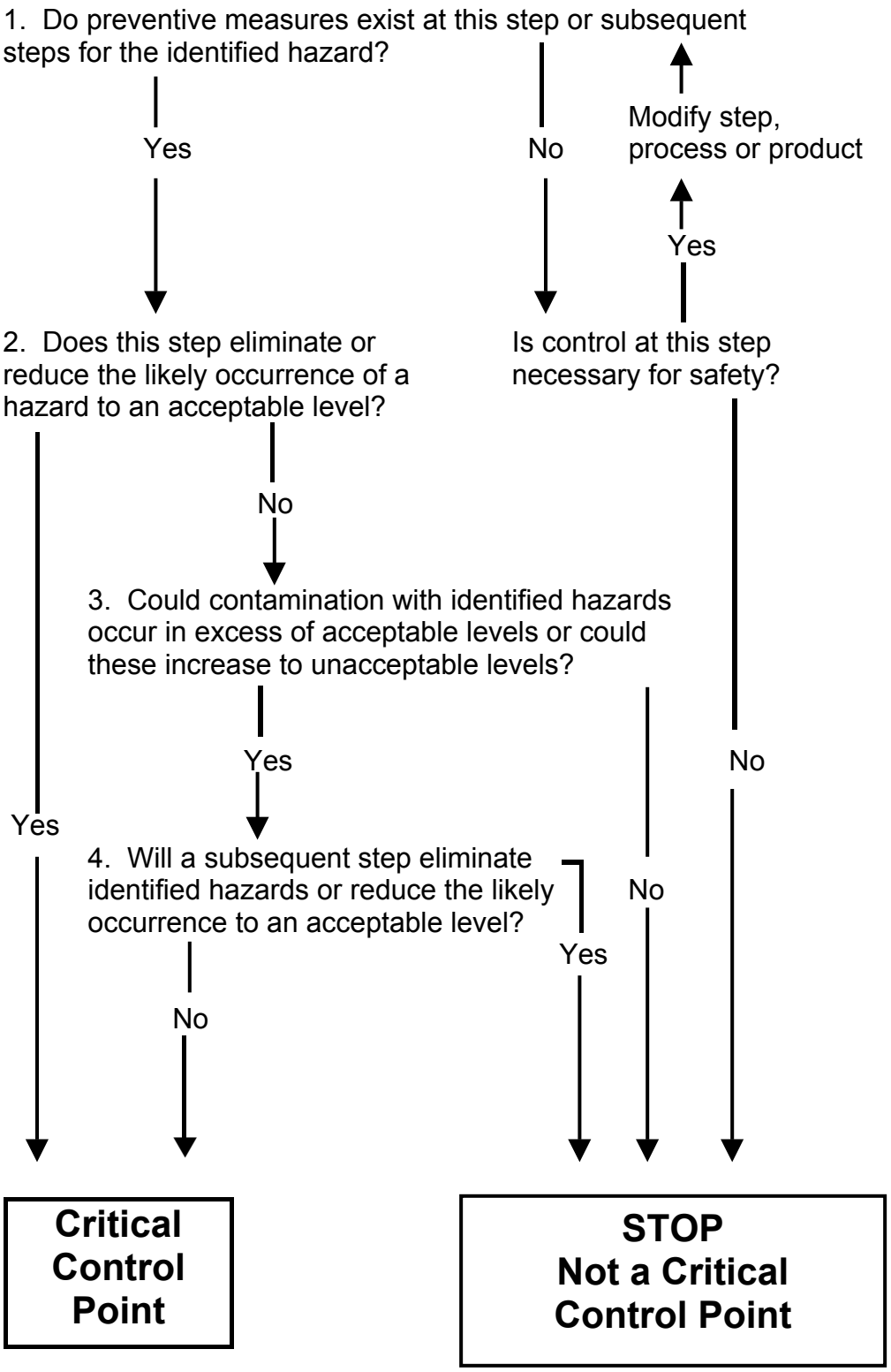
A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration or the adjustment of a food's pH to a level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

CCP Decision Tree Table



Decision Tree adapted from NACMCF.

PRINCIPLE #3: ESTABLISH CRITICAL LIMITS FOR PREVENTIVE MEASURES

Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, a_w, pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits

Time
Temperature
Humidity
a_w
pH
Titratable acidity
Preservatives
Salt concentration
Available chlorine
Viscosity

(a) *Critical Limit*

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) *Target Level*

In some cases, variables involved in food preparation may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71 ±3°C (160±°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

(c) *Application Example*

An example for Principle 3 is the cooking of beef patties. The process should be designed to eliminate the most heat-resistant vegetative pathogen which could reasonably be expected to be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance. The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	CCP	Critical Limits
Cooking	YES	Minimum internal temperature of patty: 68°C / 155°F Broiler temperature: _____°C / _____°F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min ___ Patty thickness: _____ cm / ____in Patty composition: e.g., % Fat, % Filler Oven humidity: _____% RH

PRINCIPLE #4: ESTABLISH PROCEDURES TO MONITOR CCPS

(a) *Observations and Measurements*

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

(i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;

(ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and

(iii) It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring

Visual observations
Temperature
Time
pH
a_w

(b) *Continuous Monitoring*

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

(c) *Monitoring Procedures*

When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits must not occur. For example, when a temperature of $68^{O}C$ ($155^{O}F$) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs, preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and ensure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing that focuses on isolating the source of a problem).

PRINCIPLE #5: ESTABLISH THE CORRECTIVE ACTION TO BE TAKEN WHEN MONITORING SHOWS THAT A CRITICAL LIMIT HAD BEEN EXCEEDED

(a) *Purpose of Corrective Action Plan*

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

(i) Determine the disposition of any food that was produced when a deviation was occurring;

(ii) Correct the cause of the deviation and ensure that the critical control point is under control; and

(iii) Maintain records of corrective actions.

(b) *Aspects of Corrective Action Plan*

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf-life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to ensure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to ensure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date or expected shelf life of the product.

PRINCIPLE #6: ESTABLISH PROCEDURES TO VERIFY THAT *THE HACCP SYSTEM IS WORKING*

(a) *Establishing Verification Procedures*

(i) The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.

(ii) The second phase of verification ensures that the facility's HACCP plan is functioning effectively. A functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end-product sampling, food establishments must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

(iii) The third phase consists of documented periodic revalidations, independent of audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.

(iv) The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily.

(b) *The following are some examples of HACCP plan verification activities which should be used as a part of a HACCP program:*

(i) Verification procedures may include:

- Establishment of appropriate verification inspection schedules;
- Review of the HACCP plan;
- Review of CCP records;
- Review of deviations and their resolution, including the disposition of food;
- Visual inspections of operations to observe if CCPs are under control;
- Random sample collection and analysis;
- Review of critical limits to verify that they are adequate to control hazards;
- Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;
- Validation of HACCP plan, including on-site review and verification of flow diagrams and CCPs; and
- Review of modifications of the HACCP plan.

(ii) *Verification inspections should be conducted:*

- Routinely or on an unannounced basis, to ensure that selected CCPs are under control;

- When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;

- When foods prepared at the establishment have been implicated as a vehicle of foodborne disease;

- When requested on a consultative basis and resources allow accommodating the request;

- When established criteria have not been met; and

- To verify that changes have been implemented correctly after a HACCP plan has been modified.

(iii) *Verification reports should include information about:*

- Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;

- The status of records associated with CCP monitoring;

- Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;

- Deviations and corrective actions;

- Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;

- Modifications to the HACCP plan; and

- Training and knowledge of individuals responsible for monitoring CCPs.

(c) *Training and Knowledge*

(i) *Focus and Objective*

Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper handwashing and use of utensils or gloves for working with ready-to-eat food should be stressed. The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

(ii) *Reinforcement*

Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

- A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Foodborne Illness: It's Your Business;

- Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and

- Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

HACCP PRINCIPLE #7: ESTABLISH EFFECTIVE RECORD KEEPING SYSTEMS THAT DOCUMENT THE HACCP SYSTEM

(a) *Written HACCP Plan*

This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

(b) *Record Keeping*

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a

limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

(c) *Contents of the Plan and Records*

The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

(i) Listing of the HACCP team and assigned responsibilities;
(ii) Description of the product and its intended use;
(iii) Flow diagram food preparation indicating CCPs;
(iv) Hazards associated with each CCP and preventive measures;
(v) Critical limits;
(vi) Monitoring system;
(vii) Corrective action plans for deviations from critical limits;
(viii) Record keeping procedures; and
(ix) Procedures for verification of HACCP system.

(d) *Format for HACCP Information*

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated as follows:

Process Step	CCP	Chemical Physical Biological Hazards	Critical Limit	Monitoring Procedures Frequency Person(s) Responsible	Corrective Action(s) Person(s) Responsible	HACCP Records	Verification Procedures/ Person(s) Responsible

The following chart is an example of a HACCP plan documentation for a product cooling step in a retail level food establishment.

PROCESS STEP	COOLING
CCP	**Critical Control Point #8**
Criteria or Critical Limit	Cool Foods Rapidly in Small Quantities to $5^{o}C(41^{o}F)$
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor The Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/ Discard
HACCP Records	Deli Cooking/Cooling Log
HACCP System Verification	Deli Safety Audit by Store Manager

(e) *Examples of Records obtained during the operation of the plan:*

(i) *Ingredients*

- Supplier certification documenting compliance with establishment's specifications.
- Establishment audit records verifying supplier compliance.
- Storage temperature record for temperature-sensitive ingredients.
- Storage time records of limited shelf-life ingredients.

(ii) *Preparation*

- Records from all monitored CCPs.
- Records verifying the continued adequacy of the food preparation procedures.

(iii) *Packaging*

- Records indicating compliance with specifications of packaging materials.
- Records indicating compliance with sealing specifications.

(iv) *Finished product*

- Sufficient data and records to establish the efficacy of barriers in maintaining product safety.

• Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.

• Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

(v) *Storage and distribution*

• Temperature records.

• Records showing no product shipped after shelf life date on temperature-sensitive products.

(vi) *Deviation and corrective action*

• Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

(vii) *Employee training*

• Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. Refer to the discussion regarding Training and Knowledge under Principle #7.

3. SUMMARY

HACCP is a systematic approach to food safety which will dramatically improve the level of food safety. The NACMCF has developed the seven HACCP principles discussed within this Annex. The FDA recommends the implementation of a HACCP system throughout the food industry using these NACMCF recommendations.

An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. The statistics from foodborne surveillance reveal that retail level food establishments can have a significant impact on the health of consumers.

Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing, and food preparation practices. The education and training of all personnel are critical to the success and effectiveness of any HACCP program. The Food Code stresses the application to HACCP principles and the knowledge and responsibilities of establishment management and employees.

Specific HACCP plans for the products prepared and sold by the retail food establishment should be developed and implemented for optimal food safety management. HACCP systems are recommended for use as a tool for regulatory inspections. The regulatory official should incorporate procedures in the inspection process that ensure record reviews and active monitoring.

Because the retail food establishment industry is composed of large, small, chain, and independent establishments, the level of food safety expertise varies widely and is not necessarily linked to size or affiliation. Regardless of the size and sophistication of the establishment, a HACCP plan for safe food preparation and sales needs to be designed, implemented, and verified.

Studies have shown that a significant level of illness and mortality from foodborne disease in institutional feeding operations such as hospitals, nursing homes, and prisons is related to preventable causes. For populations that may be more vulnerable to foodborne disease, FDA and the NACMCF recommend that HACCP systems be immediately implemented by establishments and institutions preparing foods for these susceptible individuals.

Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under the Food Code are required to develop and implement a HACCP plan for that part of the operation. Additionally, any establishment seeking a variance from the requirements of the Code must submit a HACCP plan. The HACCP Annex can serve to guide these establishments in this process.

Food establishments have the primary responsibility for food safety. The development and implementation of HACCP programs is a reliable and responsible step to help ensure the safety of food offered for consumption.

4. ACKNOWLEDGMENTS

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Some of the charts were provided courtesy of "Overview of Biological, Chemical, and Physical Hazards" in "HACCP Principles and Applications, Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992 p 8-28. Chapman and Hall, New York.

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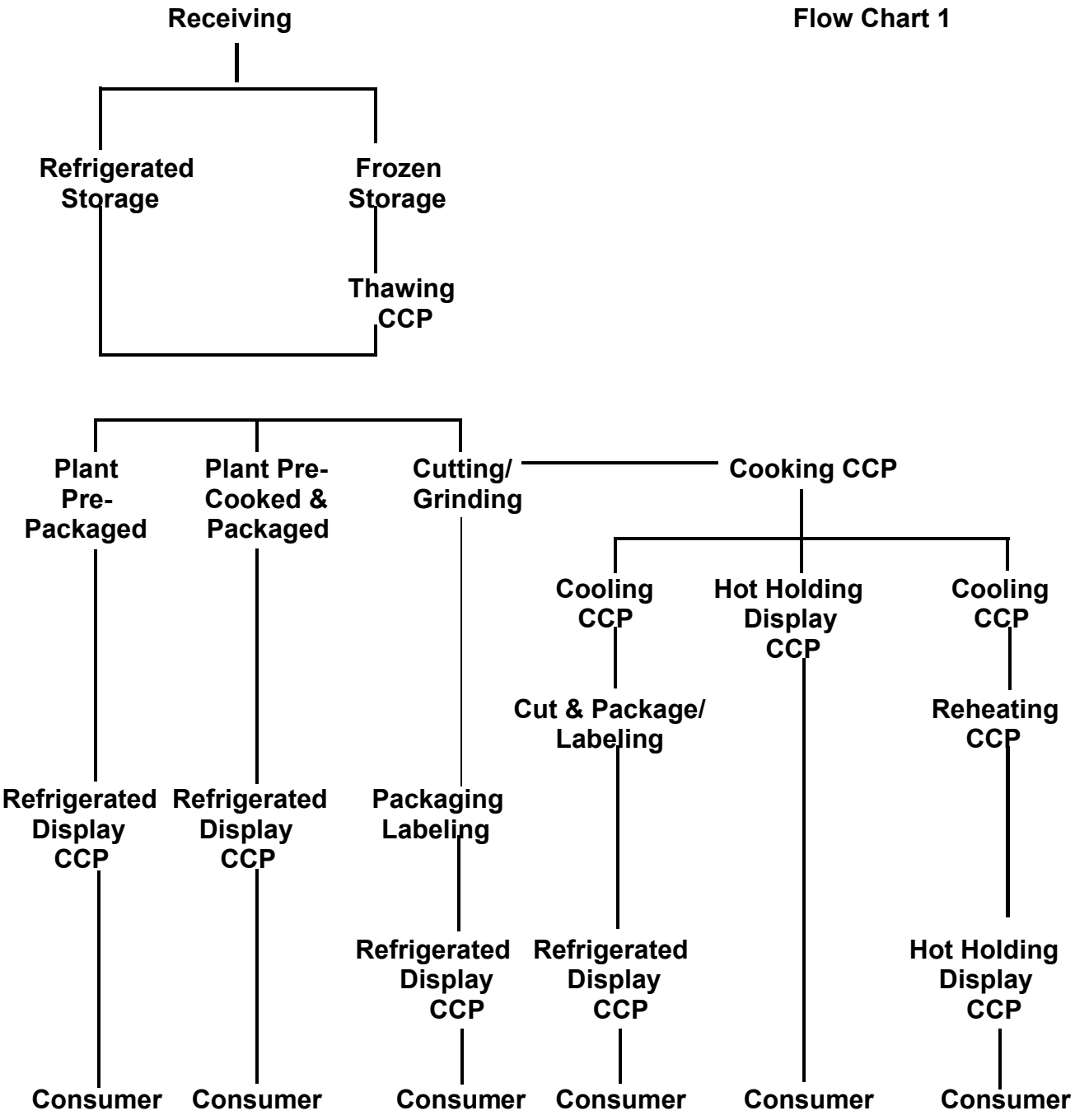
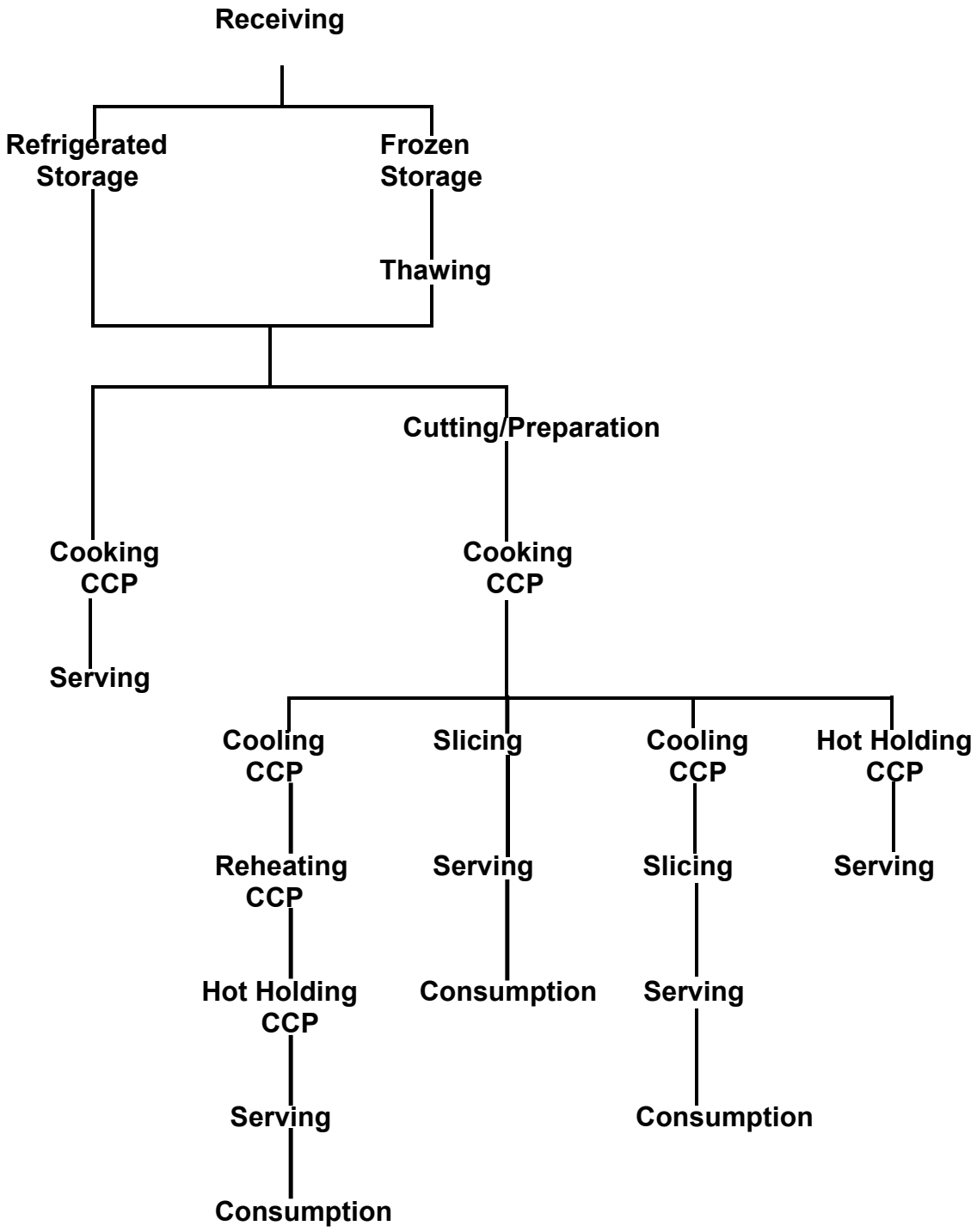
Two Typical Flow Diagrams



Flow Chart 2


Receiving
Refrigerated Storage
Frozen Storage
Thawing
Cutting/Preparation
Cooking CCP
Serving
Cooking CCP
Cooling CCP
Slicing
Cooling CCP
Hot Holding CCP
Reheating CCP
Serving
Slicing
Serving
Hot Holding CCP
Consumption
Serving
Serving
Consumption
Consumption

Annex

6 Food Processing

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

During the past decade, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions *need only be available and acceptable to the regulatory authority at the time of inspection.*

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11 and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations *based on the prior approval of a HACCP plan*.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. The purpose of this Annex is to provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include other packaging options such as:

(1) *Cook-chill* is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

(2) *Controlled Atmosphere Packaging (CAP)* is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

(3) *Modified Atmosphere Packaging (MAP)* is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous

composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.

(4) *Sous Vide* is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

(a) Preparation of the raw materials (this step may include partial cooking of some or all ingredients);

(b) Packaging of the product, application of vacuum, and sealing of the package;

(c)Pasteurization of the product for a specified and monitored time/temperature;

(d) Rapid and monitored cooling of the product at or below 3^{o}C(38^{o}F) or frozen; and

(e) Reheating of the packages to a specified temperature before opening and service.

(5) *Vacuum Packaging* reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram negative bacteria such as Pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf-life for foods in the distribution chain, providing additional time to reach new geographic markets or longer display at retail. Providing an extended shelf-life for ready-to-eat convenience foods and advertising foods as "Fresh-Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless potentially hazardous foods are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assume that during distribution of foods or while they are held by retailers or consumers, refrigerated temperatures may not be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier need to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth, is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

An anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens. Some of these are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology.

(1) *Refrigerated Holding Requirements for Foods in ROP*

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of potentially hazardous foods to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-processing contamination occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5^{o}-12^{o}C (41^{o}-53^{o}F), at any stage during storage or distribution, foodborne pathogens, including ***Bacillus cereus***, ***Salmonella*** spp., ***Staphylococcus aureus***, and ***Vibrio parahaemolyticus*** can grow slowly.

Marginal refrigeration that does not facilitate growth may still allow ***Salmonella*** spp., ***Campylobacter*** spp., and ***Brucella*** spp. to survive for long periods of time.

Recent published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used. Additionally, some commercial equipment is incapable of maintaining foods below 7.2°C (45°F) because of refrigeration capacity, insufficient refrigerating medium, or poor maintenance.

Most warehouses and transport vehicles in U.S. distribution chains maintain temperatures in the 0°-3.3°C (32°-38°F) range. It must be assumed, however, for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods. At retail, further temperature abuse must also be assumed. For instance, retail display cases can be as high as 13.3°C (56°F) for short periods and some refrigerated foods are provided no refrigeration for short periods of time. These realities point to the need for establishments to implement controls, such as buyer specifications, over refrigerated distribution systems so that better temperature control can be ensured.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

Recently, there has been an increased interest in vacuum packaging or MAP at retail using conventional refrigeration for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case but primarily the latter, germination of ***Clostridium botulinum*** spores must be inhibited because spores are not destroyed by a heating step. Sanitary safeguards must be employed to prevent reintroduction of pathogens. Chief among these is ***Listeria monocytogenes***.

Clostridum botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C. botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3°C (38°F). Other strains of ***C. botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at

temperatures slightly above 10°C (50°F). If present, ***C. botulinum*** could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for botulism toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide, processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments in combination with ROP may actually select for ***C. botulinum*** by killing off its competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration to prevent spoilage and ensure product safety. For this reason, sous vide products are frequently flash frozen in liquid nitrogen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place.

Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf-life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature. Any one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations should be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process. Special labeling of these products is necessary to ensure adequate warning to consumers that these foods must be refrigerated at 5°C (41°F) and consumed by the date required by the Code for that particular product.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) recently commented on the microbial safety of refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf-life and are ready-to-eat or prepared with little or no additional heat treatment. The

Committee recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf-life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process, microbiological studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf-life may be a problem. A recent study on fresh vegetables inoculated with ***L. monocytogenes*** was conducted to determine the effect of CAP on shelf life. The study found that CAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigeration Temperatures*

Extended shelf-life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often can not, or do not, maintain adequate refrigeration of potentially hazardous foods at home. Foods in ROP that are taken home may not be eaten until enough time/temperature abuse has occurred to allow any pathogens present to increase to levels which can increase the chance of illness. Under the best of circumstances home refrigerators can be expected to range between 5° and 10°C (41°-50°F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C (50°F). Another study reported more than 1 of 4 home refrigerators are above 7.2°C (45°F) and almost 1 of 10 are above 10°C (50°F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of ***C. botulinum*** spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the

past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished through written certification from the product manufacturer. Independent laboratory analysis using methodology approved by the regulatory authority can also be used to verify incoming product and should be used to verify the barriers in a product that is packaged within the establishment by an ROP method. It should be noted that the Association of Food and Drug Officials (AFDO) guidelines recommend that laboratory analysis be conducted by official methods of the Association of Official Analytical Chemists (AOAC).

The multiple barrier or hurdle efficacy should be validated by inoculated pack or challenge studies. A product should be tested under abuse temperatures to demonstrate product safety during the food's shelf life.

Any changes in product formulation or processing procedures are cause for notification of the regulatory authority and a required approval of the revised ROP process. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in poultry products are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of Section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under Section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) *Employee Training*

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex and the potential hazards associated with these foods. At the discretion of the regulatory authority, a description of the training and course content provided to the employees must either be available for review or have prior approval by the regulatory authority.

(2) *Refrigeration Requirements*

Foods in ROP that have only one barrier, i.e., refrigeration, to ***C. botulinum***, must be refrigerated to 5°C (41°F) or below and marked with a use-by date within either the manufacturer's labeled use-by date or 14 days after preparation at retail, whichever comes first. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier. Any extension of shelf life past 14 days will require a further variance that considers lower refrigeration temperatures. Foods that are intended for refrigerated storage beyond 14 days must be maintained at or below 3°C (38°F).

(3) *Labeling - Refrigeration Statements*

All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 5°C (41°F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods held under ROP which have lower refrigeration requirements as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale if the temperature and time specified in the variance are exceeded.

(4) *Labeling - "Use-by date"*

Each container of food in ROP must bear a "use-by" date. This date cannot exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority. The date assigned by a repacker cannot extend beyond the manufacturer's recommended "pull date" for the food. The "use-by" date must be listed on the principal display panel in bold type on a contrasting background. Any label must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within 14 days of retail packaging or repackaging, as an acceptable alternative to a 14 day "use-by" date, i.e., for product packaged on November 1, 1999 - "Sell by November 10, 1999" - use within 4 days of sell-by date. Foods that are frozen before or immediately after packaging and remain frozen until use should bear a "Keep frozen, use within 4 days after thawing" statement.

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Processed fish and smoked fish may not be packed by ROP unless establishments are approved for the activity and inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law. Caviar may be packed on the premises by ROP if the establishment is approved by the regulatory authority and has an approved scheduled process established by a processing authority acceptable to the regulatory authority.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese and other ingredients such as vegetables, meat, or fish at retail must be approved for ROP and inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations the plan must include:

(1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;

(2) A list of equipment and food-contact packaging supplies used, including compliance standards required by the regulatory authority, i.e., USDA or a recognized third party equipment by the evaluation organization such as NSF International;

(3) A description of the lot identification system acceptable to the regulatory authority;

(4) A description of the employee training program acceptable to the regulatory authority;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) Precautions Against Contamination at Retail

Only unopened packages of food products obtained from sources that comply with the applicable laws relating to food safety can be used to package at retail in a reduced oxygen atmosphere. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product must be diverted for another use in the retail establishment.

(K) Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

(L) Dedicated Area/Restricted Access

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. There shall be an effective separation to prevent cross contamination between raw and cooked foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method. Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

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3. SMOKING AND CURING

(A) Introduction

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled. A number of proprietary mixtures which are uniform in composition are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 318 and 381. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich

spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminution. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods are slow to diffuse curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49^{o}C (>120^{o}F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel. As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

(E) Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because ***Staphylococcus aureus*** can be introduced. ***Staphylococcus aureus*** produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy ***Trichinella spirilla***. At retail, products which contain raw pork and which are not subsequently cooked must be produced from trichina-free certified pork or treated to destroy trichina. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

(i) Purchase of prepared cure mixes; or

(ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

(iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.

(b) *Raw Material Handling*

(i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.

(ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.

(c) Formulating, Preparation and Curing

(i) A formulation and preparation procedure must be documented.

(ii) All equipment and utensils must be cleaned and sanitized.

(iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.

(iv) Calibrated scales must be used to weigh ingredients.

(v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.

(vi) Methods and procedures must be strictly controlled to ensure uniform cure.

(vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.

(viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.

(ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 35° and 45°F. The lower temperature is set for the purpose of ensuring cure penetration and the upper temperature is set to limit microbial growth. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >120°F as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even air flow and moisture should be recorded in operational records of the smokehouse for these various loads. Procedures should be documented for opening and closing combinations of vents and drains which are required during each specific smokehouse operation.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the Food Code must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 165°F should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the Food Code or under a variance. USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v)Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *Dedicated Area/Restricted Access*

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

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Annex

7 Model Forms, Guides, and Other Aids

1) Employee health information

- **a) Form 1-A APPLICANT AND FOOD EMPLOYEE INTERVIEW**
- **b) Form 1-B FOOD EMPLOYEE REPORTING AGREEMENT**
- **c) Form 1-C APPLICANT AND FOOD EMPLOYEE MEDICAL REFERRAL**
- **d) Guide 1-D EXCLUSIONS AND RESTRICTIONS**
- **e) Guide 1-E REMOVAL OF EXCLUSIONS AND RESTRICTIONS**
- **f) List 1-F WORLDWIDE STATUS OF *SALMONELLA* TYPHI, *SHIGELLA* SPP., SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*, AND HEPATITIS A VIRUS BY GEOGRAPHICAL AREA**

2) Adoption information

- **a) Form 2-A ADOPTION BY REFERENCE**
- **b) Form 2-B ADOPTION BY SECTION-BY-SECTION REFERENCE**

3) Inspection information

- **a) Form 3-A HACCP INSPECTION DATA**
- **b) Form 3-B FOOD ESTABLISHMENT INSPECTION REPORT**
- **c) Guide 3-C INSPECTIONAL GUIDE**

4) Summary information

- **a) Chart 4-A SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3**
- **b) Chart 4-B SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING**
- **c) Chart 4-C SUMMARY CHART - DATE MARKING AND DISPOSING READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD**
- **d) Chart 4-D FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX**
- **e) Summary of Changes**

The documents provided in this Annex are intended to facilitate adoption of the Food Code and the application of its provisions as they relate to applicants' and food employees' health and to food establishment inspections.

Forms 1-A –1-C, Guides 1-D and 1-E, and List 1-F are designed to assist those responsible for preventing foodborne disease. The Food Code specifies that the **permit holder is responsible** for requiring applicants and food employees to report certain symptoms, diagnoses, past illnesses, high-risk conditions, and foreign travel as they relate to diseases transmitted through food by infected workers. The **food employee is personally responsible** for reporting this information to the person in charge.

Forms 2-A and 2-B can be used for the Code adoption process and Forms 3-A and 3-B are provided for use in recording HACCP information and inspectional observations. Guide 3-C is a compressed outline of the Code to use as a tool in locating and citing Code provisions.

FORM 1-A

Applicant and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on illness due to ***Salmonella* Typhi, *Shigella*** spp., Shiga toxin-producing ***Escherichia coli*** , and Hepatitis A Virus

The purpose of this form is to ensure that Applicants to whom a conditional offer of employment has been made and Food Employees advise the Person in Charge of past and current conditions described so that the Person in Charge can take appropriate steps to preclude the transmission of foodborne illness.

Applicant or Employee name (print) _____
Address _____
_____

Telephone *Daytime:*_____ *Evening:*_____

TODAY:

Are you suffering from any of the following:

1. Symptoms

Diarrhea?	**YES/NO**
Fever?	**YES/NO**
Vomiting?	**YES/NO**
Jaundice?	**YES/NO**
Sore throat with fever?	**YES/NO**

2. Lesions containing pus on the hand, wrist or an exposed body part?
(*such as boils and infected wounds, however small)* **YES/NO**

PAST:

Have you ever been diagnosed as being ill with typhoid fever (*Salmonella* Typhi), shigellosis *(Shigella* spp.), Shiga toxin-producing ***Escherichia coli* infection (*E. coli* O157:H7),** or **hepatitis A** (hepatitis A virus)?
YES/NO
If you have, what was the date of the diagnosis? _____

HIGH-RISK CONDITIONS

1. Have you been exposed to or suspected of causing a confirmed outbreak of typhoid fever, shigellosis, Shiga toxin-producing ***Escherichia coli* infection, or hepatitis A? YES/NO**
2. Do you live in the same household as a person diagnosed with typhoid fever, shigellosis, hepatitis A, or illness due to Shiga toxin-producing ***Escherichia coli*? YES/NO**
3. Do you have a household member attending or working in a setting where there is a confirmed outbreak of typhoid fever, shigellosis, Shiga toxin-producing ***Escherichia coli* infection, or hepatitis A? YES/NO**

Name, Address, and Telephone Number of your Doctor:
Name_____
Address _____
_____

Telephone *- Daytime* _____ *Evening* _____

Signature of Applicant or Food Employee _____ **Date** _____

Signature of Permit Holder's Representative _____ **Date** _____

FORM 1-B

Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on illness due to ***Salmonella* Typhi, *Shigella*** spp.***,*** Shiga toxin-producing ***Escherichia coli***, and Hepatitis A Virus

The purpose of this agreement is to ensure that Food Employees notify the Person in Charge when they experience any of the conditions listed so that the Person in Charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

FUTURE SYMPTOMS and PUSTULAR LESIONS:

1. **Diarrhea**
2. **Fever**
3. **Vomiting**
4. **Jaundice**
5. **Sore throat with fever**
6. **Lesions containing pus on the hand, wrist, or an exposed body part**
   (*such as boils and infected wounds, however small)*

FUTURE MEDICAL DIAGNOSIS:

Whenever diagnosed as being ill with typhoid fever (***Salmonella* Typhi**), **shigellosis** (***Shigella*** spp.), Shiga toxin-producing ***Escherichia coli* infection (*Escherichia coli* O157:H7), or hepatitis A** (hepatitis A virus)

FUTURE HIGH-RISK CONDITIONS:

1. Exposure to or suspicion of causing any confirmed outbreak of typhoid fever, shigellosis, Shiga toxin-producing *Escherichia coli* **infection, or hepatitis A**
2. A household member diagnosed with typhoid fever, shigellosis, illness due to Shiga toxin-producing *Escherichia coli*, **or hepatitis A**
3. A household member attending or working in a setting experiencing a confirmed outbreak of typhoid fever, shigellosis, Shiga toxin-producing *Escherichia coli* **infection, or hepatitis A**

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and high-risk conditions specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Applicant or Food Employee Name (please print) _____

Signature of Applicant or Food Employee _____ **Date** _____

Signature of Permit Holder's Representative _____ **Date** _____

FORM 1-C

Applicant and Food Employee Medical Referral

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on Illness due to ***Salmonella* Typhi, *Shigella*** spp.***,*** Shiga toxin-producing ***Escherichia coli***, and Hepatitis A Virus

The Food Code specifies, under ***Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition,*** that Applicants to whom a conditional offer of employment has been made and Food Employees obtain medical clearance from a physician licensed to practice medicine whenever the individual:

1. Is chronically suffering from a symptom such as **diarrhea;** *or*
2. Meets one of the high-risk conditions specified under Paragraph 2-201.11(D) and is suffering from any symptom specified under Subparagraph 2-201.11(B)(1).
3. Has a **current illness** involving ***Salmonella* Typhi** (typhoid fever), ***Shigella*** spp. (shigellosis), Shiga toxin-producing ***Escherichia coli*** (Shiga toxin-producing ***Escherichia coli*** infection), or hepatitis A virus (hepatitis A), *or*
4. Reports ***past illness*** involving ***S.* Typhi** (typhoid fever), ***Shigella*** spp. (shigellosis), Shiga toxin-producing ***Escherichia coli***, or hepatitis A virus (hepatitis A), if the establishment is a facility serving a highly susceptible population such as preschool age children, immunocompromised persons, or older adults.

Applicant or Food Employee being referred:(_____ (Name, please print)_____)
Serving a highly susceptible population YES ☐ NO ☐

REASON FOR MEDICAL REFERRAL: The reason for this referral is checked below:

☐ Chronic diarrhea or other chronic symptom _____(specify)_____ .
☐ Meets a high-risk condition specified under Paragraph 2-201.11(D) _____(specify)_____ and suffers from a symptom specified under Subparagraph 2-201.11(B)(1). _____(specify)_____ .
☐ Diagnosed or suspected typhoid fever, shigellosis, Shiga toxin-producing ***Escherichia coli*** infection, or hepatitis A.
☐ Reported past illness from typhoid fever, shigellosis, Shiga toxin-producing ***Escherichia coli*** infection, or hepatitis A.
☐ Other medical condition of concern per the following description:_____

PHYSICIAN'S CONCLUSION:

☐ Applicant or food employee is free of ***S.* Typhi*, Shigella*** spp., Shiga toxin-producing ***Escherichia coli***, or hepatitis A virus and may work as a food employee without restrictions.
☐ Applicant or food employee is an asymptomatic shedder of ___(pathogen)__ and is restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in establishments that do not serve highly susceptible populations.
☐ Applicant or food employee is not ill but continues as an asymptomatic shedder of ___(pathogen)__ and should be excluded from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in food establishments that serve highly susceptible populations such as those who are preschool age, immunocompromised, or older adults and in a facility that provides preschool custodial care, health care, or assisted living.
☐ Applicant or food employee is suffering from typhoid fever, Shigellosis, Shiga toxin-producing ***Escherichia coli*** infection, or hepatitis A and should be excluded from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

COMMENTS: (In accordance with Title I of the Americans with Disabilities Act (ADA) and to provide only the information necessary to assist the food establishment operator in preventing foodborne disease transmission, please confine comments to explaining your conclusion and estimating when the employee may be reinstated.)

_____

Signature of Physician_____ **Date**____

_____

Paraphrased from the FDA Food Code for Physician's Reference

From §2-201.11(A) Organisms of Concern:

Any foodborne pathogen, with special emphasis on these 4 organisms:
S.* Typhi** ***Shigella spp. Shiga toxin-producing ***Escherichia coli*** **Hepatitis A** virus

From §2-201.11(B)(1) Symptoms:

Symptoms associated with an acute gastrointestinal illness such as:
Diarrhea **Fever** **Vomiting** **Jaundice** **Sore throat with fever**

From §2-201.11(D) High-Risk Conditions Related to a Person's Activities:

(1) Suspected of causing a foodborne outbreak or being exposed to an outbreak caused by 1 of the 4 organisms above, at an event such as a family meal, church supper, or festival because the person:
Prepared or consumed an implicated food; or
Consumed food prepared by a person who is infected or ill with the organism that caused the outbreak or who is suspected of being a carrier;
(2) Lives with, and has knowledge about, a person who is diagnosed with illness caused by 1 of the 4 organisms; or
(3) Lives with, and has knowledge about, a person who works where there is an outbreak caused by 1 of the 4 organisms.

From §2-201.12 Exclusion and Restriction:

Decisions to exclude or restrict a food employee are made considering the available evidence about the person's role in actual or potential foodborne illness transmission. Evidence includes:
Symptoms **Diagnosis** **High-risk conditions** **Past illnesses** **Stool/blood tests**

- In facilities serving highly susceptible populations such as day care centers and health care facilities, a person for whom there is evidence of foodborne illness is almost always excluded from the food establishment.
- In other establishments that offer food to typically healthy consumers, a person might only be restricted from certain duties, based on the evidence of foodborne illness.
- Exclusion from any food establishment is required when the person is:
  Diagnosed with illness caused by 1 of the 4 organisms of concern; or
  Jaundiced within the last 7 days.

From §8-501.40 Release of Employee from Exclusion or Restriction:

In addition to local law, these requirements must be met in the situations specified:
- For infection with ***S.* Typhi**, the person's stools must be negative for 3 consecutive cultures taken at least 1 month after onset, no earlier than 48 hours after antibiotics are discontinued, and at least 24 hours apart.
- For ***Shigella*** spp. or Shiga toxin-producing ***Escherichia coli*** infections, the person's stools must be negative for 2 consecutive cultures taken no earlier than 48 hours after antibiotics are discontinued and at least 24 hours apart.
- For hepatitis A virus infection, the symptoms must cease or at least 2 blood tests must show falling liver enzymes.

GUIDE 1-D

Exclusions and Restrictions for Food Employees and Applicants

Health Status	Facilities Serving Highly Susceptible Population	Facilities Not Serving Highly Susceptible Population
1. Diagnosed with illness due to ***Salmonella* Typhi*,* *Shigella*** spp.*,* Shiga toxin-producing ***Escherichia coli***, or hepatitis A virus	Exclude 2-201.12(A)	Exclude 2-201.12(A)
2. Experiencing a symptom listed in 2-201.11(B)	Restrict 2-201.12(B)	Restrict 2-201.12(B)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition* of 2-201.11(D)(1)-(3)	Exclude 2-201.12(C)(1)*	Restrict 2-201.12(B)(1)
4. Asymptomatic but stools positive for ***S.* Typhi**, ***Shigella*** spp., or Shiga toxin-producing ***Escherichia coli***	Exclude 2-201.12(C)(2)	Restrict 2-201.12(B)(2)
5. Past illness from ***Salmonella* Typhi** within the last 3 months	Exclude 2-201.12(C)(3)	No Restrictions
6. Past illness from ***Shigella*** spp. or Shiga toxin-producing ***Escherichia coli*** within the last month	Exclude 2-201.12(C)(4)	No Restrictions
7. Onset of jaundice within the last 7 days	Exclude 2-201.12(D)(1)	Exclude 2-201.12(D)(1)

***** High-risk conditions apply only to exclusions under this Subparagraph.

GUIDE

1-E Removal of Exclusions & Restrictions for Food Employees and Applicants

HEALTH STATUS 2-201.11 and .12	FACILITIES SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13	FACILITIES NOT SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13
1. Diagnosed with illness due to ***Salmonella* Typhi, *Shigella*** spp., Shiga toxin-producing ***Escherichia coli***, or hepatitis A virus 2-201.11(A)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(1)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(2)
2. Experiencing a symptom listed in 2-201.11(B)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition 2-201.11(D)(1)-(3) 2-201.12(C)(1)	Doctor*: 1. Stools or blood free or 2. No jaundice per .13(D) 3..12 (C)(1) Noninfectious condition (C)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
4. Asymptomatic but stools positive for ***S.* Typhi**, ***Shigella*** spp., or Shiga toxin-producing ***Escherichia coli*** 2-201.12(B)(2) & (C)(2)	Doctor* - stools free (C)	Doctor* - stools free (B)(2)
5. Past illness from ***Salmonella* Typhi** within the last 3 months 2-201.11(C)	Doctor* - stools free (C)	NA
6. Past illness from ***Shigella*** spp., or Shiga toxin-producing ***Escherichia coli*** within last month 2-201.11(C)	Doctor* - stools free (C)	NA
7. Onset of jaundice within last 7 days 2-201.12(D)(1)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)
8. Onset of jaundice more than 7 days ago 2-201.12(D)(2)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)

*Where “doctor” is indicated, nurse practitioner or physician assistant, if allowed by law, may provide documentation.

LIST 1-F

Worldwide Status of *Salmonella* Typhi, *Shigella,* *Escherichia coli* O157:H7, and Hepatitis A Virus by Geographical Area.

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on ***Salmonella*** **Typhi**, ***Shigella*** spp.*,* Shiga toxin-producing ***Escherichia coli****, and Hepatitis A Virus*

The following list of countries and regions shows where typhoid fever, hepatitis A, and various diarrheal diseases commonly occur or are epidemic as reported to the Centers for Disease Control and Prevention (CDC) by the World Health Organization (WHO). CDC publishes this information annually in what is referred to as the "Yellow Book," ***Health Information for International Travel****. Statistics cited were adapted from CDC's 1996-97 edition in the section entitled "Geographical Distribution of Potential Health Hazards to Travelers." The list is not comprehensive. Reporting to WHO is voluntary and is based on mortality, not morbidity.* ***Where the Yellow Book refers to nonspecific "diarrheal disease," Shiga toxin-producing Escherichia coli has been denoted as a possible cause in the U.S., Canada, Europe, Japan and Argentina****.*

This list is intended to be used as an aid to increase awareness of the person in charge that travel to some points outside the U.S. may increase the risk for acquiring foodborne illness. The person in charge can use the list to educate food employees about the need to be vigilant in the protection of their health during travel and the importance of informing the person in charge if symptoms occur or if there is a diagnosis of an illness (due to one of the four pathogens listed above) during or following travel.

AFRICA

Northern Africa ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Algeria, Egypt, Libyan Arab Jamahiriya, Morocco, and Tunisia

Sub-Saharan Africa ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Angola, Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte D'Ivoire, Djiouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Niger, Nigeria, Réunion, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, Sudan, Togo, Uganda, United Republic of Tanzania, Zaire, Zambia, and Zimbabwe.

Southern Africa ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Botswana, Lesotho, Namibia, St. Helena, South Africa, and Swaziland.

The Americas

North America ☐ Typhoid | ☐ Shigellosis | ☐ Shiga toxin-producing ***Escherichia coli*** | ☐ Hepatitis A

Bermuda, Canada, Greenland, St. Pierre and Miquelon and the United States of America.

Mainland Middle America ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Belize, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, and Panama.

Caribbean Middle America ☐ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Antigua and Barbuda, Aruba, Bahamas, Barbados, British Virgin Islands, Cayman Islands, Cuba, Dominica, Dominican Republic, Grenada, Guadeloupe, Haiti, Jamaica, Martinique, Montserrat, Netherlands Antilles, Puerto Rico, St. Christopher and Nevis, Saint Lucia, Saint Vincent, and the Grenadines, Trinidad and Tobago, Turks and Caicos Islands, and the Virgin Islands (USA).

Tropical South America ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** ☑ Hepatitis A

Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, and Venezuela.

Temperate South America ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Argentina, Chile, Falkland Islands (Malvinas), and Uruguay.

Asia

East Asia ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

China, the Democratic People's Republic of Korea, Hong Kong, Japan, Macao, Mongolia, and the Republic of Korea.

Eastern South Asia ☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar (formerly Burma), the Philippines, Singapore, Thailand, and Viet Nam.

Middle South Asia

☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Afghanistan, Armenia, Azerbaijan, Bangladesh, Bhutan, India, Islamic Republic of Iran, Kazakhstan, Kyrgyzstan, Maldives, Nepal, Pakistan, Sri Lanka, Tajikistan, Turkmenistan, and Uzbekistan.

Western South Asia

☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☑ Hepatitis A

Bahrain, Cyprus, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syrian Arab Republic, Turkey, the United Arab Emirates, and Yemen.

Europe

Northern Europe

☐ Typhoid | ☐ Shigellosis | ☐ Shiga toxin-producing ***Escherichia coli*** | ☐ Hepatitis A

Belarus, Belgium, Czech Republic, Denmark (with the Faroe Islands), Estonia, Finland, Germany, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Republic of Moldova, Russian Federation, Slovakia, Sweden, Ukraine, and the United Kingdom (with the Channel Islands and the Isle of Man).

Southern Europe

☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☐ Hepatitis A

Albania, Andorra, Austria, Bosnia, and Herzegovina, Bulgaria, Croatia, France, Gibraltar, Greece, Hungary, Italy, Liechtenstein, Malta, Monaco, Portugal (with the Azores and Madeira), Romania, San Marino, Slovenia, Spain (with the Canary Islands), Switzerland, and the former Yugoslav Republic of Macedonia, and Yugoslavia.

OCEANIA

Australia, New Zealand & Antarctic

☐ Typhoid | ☐ Shigellosis | ☐ Shiga toxin-producing ***Escherichia coli*** | ☐ Hepatitis A

Melanesia & Micronesia (Polynesia)

☑ Typhoid | ☑ Shigellosis | ☑ Shiga toxin-producing ***Escherichia coli*** | ☐ Hepatitis A

American Samoa, Cook Islands, Easter Island, Federated States of Micronesia, Fiji, French Polynesia, Guam, Kiribati, Marshall Islands, Nauru, New Caledonia, Niue, Palau, Papua New Guinea, Pitcairn, Samoa, Solomon Islands, Tokelau, Tonga, Trust Territory of the Pacific Islands, Tuvalu, Vanuata, Wake Island (U.S.) and the Wallis and Futuna Islands.

FORM 2-A

Adoption by Reference

This "short form" may be used by governmental bodies adopting the Food Code where authorized by law. Use of the adoption by reference form may substantially reduce the cost of publishing and printing.

The description of the Food Code, below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(**statute/regulation/ordinance**) Number _____

ADOPTING THE 2001 EDITION OF THE "FOOD CODE" REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING, AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **(governing body)** of the **(jurisdiction)** does ordain as follows:

SECTION 1. ADOPTION OF FOOD CODE

That a certain document, three copies of which are on file in the office of the **(jurisdiction's keeper of records)** of the **(type of jurisdiction)** of **(name of jurisdiction)** being marked and designated as the *Food Code, 2001 Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration be, and is hereby adopted as, the Food Code of **(type of jurisdiction)** of **(name of jurisdiction)** in the State of **(state name)**; for regulating the design, construction, management and operation of food establishments, and providing for plans submission and approval and the issuance of permits and collection of fees therefore.

SECTION 2. INSERTIONS AND CHANGES

That the following provisions are hereby revised as follows:

Paragraph 8-811.10(B) Insert **(Dollar Amount)**
Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **(statute/regulation/ordinance)** number **(present code number)** of the **(jurisdiction)** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)** **.**

BY: _____

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Food Manufacturing Violations:

Criminal fines and sentence for violations of up to **$10,000** and **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$5,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Federal law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 2-B

Adoption by Section-by-Section Reference

This "long form" may be used by governmental bodies adopting the Food Code section-by-section.

The description of the "Food Code," below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number _____

ADOPTING A CODE REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **_(governing body)_** of the **_(jurisdiction)_** does ordain as follows:

(REPRINT THE *FOOD CODE, 2001 RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION,* SECTION-BY-SECTION)

SECTION 2. INSERTIONS AND CHANGES

That the following provisions may need to be completed as follows:

Paragraph 8-811.10(B) Insert (**Dollar Amount**)
Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **_(statute/regulation/ordinance)_** number **_(present code number)_** of the **_(jurisdiction)_** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY: _____

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

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Criminal fines and sentence for violations of up to **$10,000** and **one** year imprisonment if there is shown an intent to defraud or mislead, and

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B. For Retail Food Violations:

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Maryland law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Federal law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 3-A

HACCP Inspection Data

The HACCP Inspection Data form is designed to accommodate the recording of observations during an inspection. The design of the form focuses on information related to the flow of potentially hazardous foods being prepared, displayed, sold, and served within the establishment. The form is intended as a worksheet for use in noting food temperatures/times at each step and other pertinent data as they compare to the established critical limits. This juxtaposition of the observations and the critical limits highlights the violative steps. The information then is transferred to the Establishment Inspection Report form.

Refer to Annex 4, Food Establishment Inspection, Sections 5 and 10, for further discussion regarding the use of the form.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

HACCP INSPECTION DATA

EST. NAME: **PERMIT NO.** **INSPECTOR:**
DATE: **TIME IN:** **:AM / PM** **TIME OUT:** **:AM/ PM**

Record all observations below - transfer violations to Inspection Report

FOOD TEMPERATURES / TIMES / OTHER CRITICAL LIMITS

Use Additional Forms If Necessary

FOOD STEP	1.	CRITICAL LIMIT	2	CRITICAL LIMIT	3	CRITICAL LIMIT	4	CRITICAL LIMIT
A. SOURCE								
B. STORAGE								
C. PREP BEFORE COOK								
D. COOK								
E. PREP AFTER COOK								
F. HOT/COLD HOLD								
G. DISPLAY/ SERVICE								
H. COOL								
I. REHEAT								

OTHER FOOD TEMPERATURES OBSERVED **Use steps from above for location**

FOOD	TEMP. $^0C/^0F$	STEP	FOOD	TEMP. $^0C/^0F$	STEP	FOOD	TEMP. $^0C/^0F$	STEP

MANAGEMENT / PERSONNEL OBSERVATIONS	
OTHER FOOD OBSERVATIONS	
EQUIPMENT, UTENSILS, AND LINEN OBSERVATIONS	
WATER, PLUMBING, AND WASTE OBSERVATIONS	
PHYSICAL FACILITIES	
POISONOUS OR TOXIC MATERIALS OBSERVATIONS	

FORM 3-B

Food Establishment Inspection Report

The food establishment inspection report is the official agency document regarding compliance of the establishment with agency requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. The Food Establishment Inspection Report form is provided as a model for use during routine, follow-up, and investigative inspections.

Refer to Annex 4, Food Establishment Inspection, Sections 6, 11, and 12, for further discussion.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

FOOD ESTABLISHMENT INSPECTION REPORT

Violations cited in this report shall be corrected within the time frames specified below, but within a period not to exceed 10 calendar days for critical items (§ 8-405.11) or 90 days for noncritical items (§ 8-406.11).

VIOLATIONS: CRITICAL _____ NONCRITICAL _____

ESTABLISHMENT:		**PERMIT NUMBER:**	**DATE:**
ADDRESS:	**CITY:**	**STATE:**	**ZIP:**
PERSON IN CHARGE / TITLE:			**TELEPHONE:**
INSPECTOR / TITLE:			
INSPECTION TYPE:	**ROUTINE** **FOLLOW-UP** **COMPLAINT** **OTHER:**		**TIME:**

Critical **(X)**	Repeat **(X)**	Code Reference	Violation Description / Remarks / Corrections

FOOD ESTABLISHMENT INSPECTION REPORT

ESTABLISHMENT: **PERMIT NUMBER:** **DATE:**

Critical **(X)**	Repeat **(X)**	Code Reference	Violation Description / Remarks / Corrections

GUIDE
3-C

Inspectional Guide

The major headings from each of the Code chapters have been extracted and condensed in this Guide to key word phrases to assist the person conducting inspections in locating the Code citation that corresponds to a given violation. The Guide is intended to be used during inspections as an aid in referencing Code provisions, ensuring that provisions of the Code are not overlooked during the inspection, and accurately completing the Food Establishment Inspection Report form.

INSPECTIONAL GUIDE

Management and Personnel

SUPERVISION

2-101.11 Assignment of **Responsibility***
2-102.11 Demonstration of **Knowledge***
2-103.11 **Duties** of Person in Charge

EMPLOYEE HEALTH

Disease or Medical Condition

2-201.11 Responsibility of Person in Charge*
2-201.12 Exclusions and Restrictions*
2-201.13 Removal of Exclusions/Restrictions
2-201.14 Reporting by Employee/Applicant*
2-201.15 Reporting by Person In Charge*

PERSONAL CLEANLINESS

Hands and Arms

2-301.11 Clean Condition*
2-301.12 Cleaning Procedure*
2-301.13 Special Handwash Procedures*
2-301.14 When to Wash*
2-301.15 Where to Wash
2-301.16 Hand Sanitizers
2-302.11 **Fingernail** Maintenance
2-303.11 **Jewelry** Prohibitions
2-304.11 **Outer Clothing** Cleanliness

HYGIENIC PRACTICES

2-401.11 Eating, Drinking, or Using Tobacco*
2-401.12 Discharges-Eye, Nose, Mouth*
2-402.11 **Hair Restraint** Effectiveness
2-403.11 **Animal** Handling Prohibition*

Food

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3-101.11 Safe/Unadult/Honestly Presented*

SOURCES/SPECIFICATIONS/ORIGINAL CONTAINER/RECORDS

Sources

3-201.11 Compliance with Food Law*
3-201.12 Hermetically Sealed Food*
3-201.13 Fluid Milk and Milk Products*
3-201.14 Fish*
3-201.15 Molluscan Shellfish*
3-201.16 Wild Mushrooms*
3-201.17 Game Animals*

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3-202.11 Temperature*
3-202.12 Additives*
3-202.13 Shell Eggs*
3-202.14 Pasteurized Eggs and Milk*
3-202.15 Package Integrity*
3-202.16 Ice*
3-202.17 Shucked Shellfish, Packaging/ID
3-202.18 Shellstock Identification*
3-202.19 Shellstock, Condition
3-202.110 Juice Treated

Original Containers and Record of Source

3-203.11 Molluscan Shellfish, Original Container
3-203.12 Shellstock, Maintaining Identification*

PROTECT. FROM CONTAMINATION AFTER RECEIVING

3-301.11 **Contamination from Employees' Hands***
3-301.12 Contamination When Tasting*

Contamination from Other Foods/Ingredients

3-302.11 Separation/Packaging/Segregation*
3-302.12 Containers Identified/Common Name
3-302.13 Pasteurized Eggs, Certain Recipes.*
3-302.14 Protection from Unapproved Additives*
3-302.15 Washing Fruits and Vegetables

Contamination from Ice Used as a Coolant

3-303.11 Exterior Ice Prohibited Ingredient
3-303.12 Food in Contact with Water or Ice

Contamination from Equip./Utensils/Linens

3-304.11 Food Contact with Equip. and Utensils*
3-304.12 In-Use Utensils/Between-Use Storage
3.304.13 Linens and Napkins, Use Limitation
3-304.14 Wiping Cloths, Use Limitation
3-304.15 Gloves, Use Limitation
3-304.16 Clean Tableware for Second Portions
3-304.17 Refilling Returnables

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3-305.11 Food Storage
3-305.12 Food Storage, Prohibited Areas
3-305.13 Vended Food, Original Container
3-305.14 Food Preparation

Contamination from Consumers

3-306.11 Food Display
3-306.12 Condiments, Protection
3-306.13 Consumer Self-Service Operations*
3-306.14 Returned Food and Reservice of Food*

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3-307.11 Miscellaneous Sources

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Cooking

3-401.11 Raw Animal Foods*
3-401.12 Microwave Cooking*
3-401.13 Plant Foods for Hot Hold

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3-402.11 Parasite Destruction*
3-402.12 Records, Creation and Retention

Reheating

3-403.10 Preparation for Immediate Service
3-403.11 Hot Holding*

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3-404.11 Treating Juice

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3-501.12 Slacking
3-501.13 Thawing
3-501.14 Cooling*
3-501.15 Cooling Methods
3-501.16 Hot and Cold Holding*
3-501.17 Ready-to-Eat, Pot. Haz. Food, Dating Marking*
3-501.18 Ready-to-Eat, Pot. Haz. Food, Disposition*
3-501.19 Time as a Public Health Control*

Special Processing Methods

3-502.11 Variance Requirement*
3-502.12 Reduced Oxygen Packaging, Criteria*

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Accurate Representation

3-601.11 Standards of Identity
3-601.12 Honestly Presented

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3-602.11 Food Labels
3-602.12 Other Forms of Information

Consumer Advisory

3-603.11 Consumption of Raw Animal Foods*

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3-701.11 Discarding Contaminated Food*

HIGHLY SUSCEPTIBLE POPULATIONS

3-801.11 Special Requirements*

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Multiuse

4-101.11 Characteristics*
4-101.12 Cast Iron
4-101.13 Lead in Ceramic, China, Crystal Utensils
4-101.14 Copper*
4-101.15 Galvanized Metal*
4-101.16 Sponges
4-101.17 Lead in Pewter
4-101.18 Lead in Solder and Flux
4-101.19 Wood
4-101.110 Nonstick Coatings
4-101,111 Nonfood-Contact Surfaces

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4-102.11 Characteristics*

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Durability and Strength

4-201.11 Equipment and Utensils
4-201.12 Food Temperature Measuring Devices*

Cleanabilty

4-202.11 Food-Contact Surfaces*
4-202.12 CIP Equipment
4-202.13 "V" Threads
4-202.14 Hot Oil Filtering Equipment
4-202.15 Can Openers
4-202.16 Nonfood-Contact Surfaces
4-202.17 Kick Plates, Removable
4-202.18 Ventilation Hood, Filters

Accuracy

4-203.11 Food Temperature Measuring Devices
4-203.12 Ambient Temp. Measuring Devices
4-203.13 Pres. Meas. Dev., Mech. Ware. Equip.

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4-204.11 Ventilation Hoods, Drip Prevention
4-204.12 Equip. Openings, Closures/Deflectors
4-204.13 Dispensing Equipment, Barriers
4-204.14 Vending Machine, Stage Closure
4-204.15 Bearings and Gear Boxes, Leakproof
4-204.16 Beverage Tubing, Separation
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4-204.18 Condenser Unit, Separation
4-204.19 Can Openers on Vending Machines
4-204.110 Molluscan Shellfish Tanks
4-204.111 Vending Machines, Automatic Shutoff*
4-204.112 Temperature Measuring Devices
4-204.113 Warewasher, Data Plate Operat.Spec.
4-204.114 Warewasher, Internal Baffles
4-204.115 Warewasher, Temp. Measuring Devices
4-204.116 Manual Warewashing, Heaters/Baskets
4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers
4-204.118 Warewasher, Flow Pressure Device
4-204.119 Sinks and Drainboards/Self-Draining
4-204.120 Equipment Compartments, Drainage
4-204.121 Vending Mach./Liquid Waste Products
4-204.122 Case Lot Handling Equip/Moveability
4-204.123 Vending Machine Doors and Openings

NUMBERS AND CAPACITIES

Equipment

4-301.11 Cooling/Heating/Holding Capacities
4-301.12 Warewashing, Sink Requirements
4-301.13 Drainboards
4-301.14 Ventilation Hood Systems, Adequacy
4-301.15 Clothes Washers and Dryers

Utensils and Measuring/Testing Devices

4-302.11 Utensils for Consumer Self-Service
4-302.12 Food Temperature Measuring Devices
4-302.13 Wash/San. Temp. Measuring Devices
4-302.14 Sanitizing Solution Testing Devices

LOCATION AND INSTALLATION

4-401.11 Equip. **Location**/Preventing Contam.

Installation

4-402.11 Fixed Equipment, Spacing/Sealing
4-402.12 Fixed Equipment, Elevation/Sealing

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Equipment

4-501.11 Good Repair and Proper Adjustment
4-501.12 Cutting Surfaces
4-501.13 Microwave Ovens
4-501.14 Equipment, Cleaning Frequency
4-501.15 Warewasher, Operating Instructions
4-501.16 Warewashing Sinks, Use Limitation
4-501.17 Warewashing, Cleaning Agents
4-501.18 Warewashing, Clean Solutions
4-501.19 Warewashing, Wash Sol. Temperature
4-501.110 Warewasher, Wash Sol. Temperature
4-501.111 Warewashing, San. Water Temp.*
4-501.112 Warewasher, San. Water Temp.
4-501.113 Warewasher, Sanitization Pressure
4-501.114 Chem.San., Temp./pH/Concentr./Hard.*
4-501.115 Chem.San., Detergent-Sanitizers
4-501.116 Determining Chem.San. Concentration

Utensil/Temperature/Pressure Measuring Device

4-502.11 Good Repair and Calibration
4-502.12 Single-Ser./Use Art., Required Use
4-502.13 Single-Ser./Use Art., Use Limitation
4-502.14 Shells, Use Limitation

CLEANING OF EQUIPMENT AND UTENSILS

Objective

4-601.11 Clean Sight/Touch-No Accum/Encrust.*

Frequency

4-602.11 Food-Contact Surfaces and Utensils*
4-602.12 Cooking and Baking Equipment
4-602.13 Nonfood-Contact Surfaces

Methods

4-603.11 Dry Cleaning
4-603.12 Precleaning
4-603.13 Loading of Soiled Items, Warewasher
4-603.14 Wet Cleaning
4-603.15 Washing, Alternative Manual Equipment
4-603.16 Rinsing Procedures
4-603.17 Returnables, Cleaning for Refilling*

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4-702.11 **Frequency**-Before Use After Cleaning*
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INSPECTIONAL GUIDE

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4-801.11 **Objective**, Clean Linens
4-802.11 **Frequency**, Specifications
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4-803.11 Storage of Soiled Linens
4-803.12 Mechanical Washing
4-803.13 Use of Laundry Facilities
PROTECTION OF CLEAN ITEMS
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4-901.11 Equipment and Utensils, Air-Drying
4-901.12 Wiping Cloths, Air-Drying
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4-902.11 Food-Contact Surfaces
4-902.12 Equipment
Storing
4-903.11 Equip./Uten./Lin./Sing.-Ser/Use Art.
4-903.12 Prohibitions
Handling
4-904.11 Kitchenware and Tableware
4-904.12 Soiled and Clean Tableware
4-904.13 Preset Tableware

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Source
5-101.11 Approved System*
5-101.12 System Flushing and Disinfection*
5-101.13 Bottled Drinking Water.*
Quality
5-102.11 Standards*
5-102.12 Nondrinking Water*
5-102.13 Sampling
5-102.14 Sample Report
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5-104.11 System
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5-201.11 **Materials**, Approved*
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5-202.11 Approved System/Cleanable Fixtures*
5-202.12 Handwashing Facility, Installation
5-202.13 Backflow Prevention, Air Gap*
5-202.14 Backflow Prevention Device, Design
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Numbers and Capacities
5-203.11 Handwashing Facilities*
5-203.12 Toilets and Urinals*
5-203.13 Service Sink
5-203.14 Backflow Prevention Device/Required*
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Location and Placement
5-204.11 Handwashing Facilities*
5-204.12 Backflow Prevention Device/Location
5-204.13 Conditioning Device, Location
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5-205.11 Handwashing Facility
5-205.12 Prohibiting a Cross Connection*
5-205.13 Scheduling Device Inspect./Service
5-205.14 Fogging Device Reservoir/Cleaning*
5-205.15 System Maintained/Repair*
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5-301.11 **Materials**, Approved
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5-302.11 Enclosed System, Sloped to Drain
5-302.12 Inspection Port, Protected/Secured
5-302.13 "V" Type Threads, Use Limitation
5-302.14 Tank Vent, Protected
5-302.15 Inlet and Outlet, Sloped to Drain
5-302.16 Hose, Construction/Identification
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5-303.11 Filter, Compressed Air
5-303.12 Protective Equipment or Device
5-303.13 Mobile Food Est. Water Tank Inlet
Operation and Maintenance
5-304.11 Flushing and Disinfecting System*
5-304.12 Using Pump and Hoses/Backflow Prev.
5-304.13 Protect. Inlet/Outlet/Hose Fitting
5-304.14 Dedicating Tank, Pump, and Hoses

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5-401.11 Capacity and Drainage
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5-402.11 Backflow Prevention*
5-402.12 Grease Trap
5-402.13 Conveying Sewage*
5-402.14 Removing Mobile Food Est. Wastes
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5-403.11 Approved Sewage Disposal System*
5-403.12 Other Liquid Wastes and Rainwater
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5-501.11 Outdoor Storage Surface
5-501.12 Outdoor Enclosure
5-501.13 Receptacles
5-501.14 Receptacles in Vending Machines
5-501.15 Outside Receptacles
5-501.16 Areas-Receptacles, Capacity/Avail.
5-501.17 Toilet Room Receptacle, Covered
5-501.18 Cleaning Implements and Supplies
5-501.19 Storage Areas and Units/Location
5-501.110 Storing Refuse/Recyclables/Return.
5-501.111 Areas/Enclosures/Receptacles, Repair
5-501.112 Outside Storage Prohibitions
5-501.113 Covering Receptacles
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5-501.115 Maintaining Refuse Areas/Enclosures
5-501.116 Cleaning Receptacles
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5-502.11 Frequency
5-502.12 Receptacles or Vehicles
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5-503.11 Community or Individual Facility

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6-101.11 **Indoors**, Surface Characteristics
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6-201.11 Floors, Walls, and Ceilings
6-201.12 Floors/Walls/Ceilings,Utility Lines
6-201.13 Junctures, Coved/Enclosed/Sealed
6-201.14 Carpeting,Restriction/Installation
6-201.15 Floor Covering, Mats and Duckboards
6-201.16 Wall, Ceiling, Coverings/Coatings
6-201.17 Walls and Ceilings, Attachments
6-201.18 Wall, Ceiling, Studs/Joists/Rafters
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6-202.11 Light Bulbs, Protective Shielding
6-202.12 Ventilation System, Exhaust Vents
6-202.13 Insect Contr. Dev., Design/Install.
6-202.14 Toilet Rooms, Enclosed
6-202.15 Outer Openings, Protected
6-202.16 Exterior Walls/Roofs, Barriers
6-202.17 Outdoor Vending Areas, Protection
6-202.18 Outdoor Servicing Areas, Protection
6-202.19 Outdoor Walk/Drive Surfaces, Drained
6-202.110 Outdoor Refuse Areas, Curbed/Drained
6-202.111 Homes/Living/Sleeping Qtrs., Prohib.
6-202.112 Living/Sleeping Quarters, Separation
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6-301.11 Hand Cleanser, Available
6-301.12 Hand Drying Provision
6-301.13 Handwash Aids and Devices, Use Restrictions
6-301.14 Handwashing Signage
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6-302.11 Toilet Tissue, Availability
6-303.11 **Lighting**, Intensity
6-304.11 **Ventilation**, Mechanical
6-305.11 **Dressing Areas/Lockers**, Designation
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6-402.11 **Toilet Rooms**, Convenient/Accessible
6-403.11 **Employee Accommodations**, Designated
6-404.11 **Distressed Merchandise**, Segregated

MAINTENANCE AND OPERATION
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6-501.11 Repairing
6-501.12 Cleaning, Frequency/Restrictions
6-501.13 Cleaning Floors, Dustless Methods
6-501.14 Clean. Vent. Sys., Prev. Discharge
6-501.15 Clean. Maint. Tools, Prev. Contam.*
6-501.16 Drying Mops
6-501.17 Floors - Absorbent Materials
6-501.18 Maintaining/Using Handwashing Facilities
6-501.19 Closing Toilet Room Doors
6-501.110 Using Dressing Rooms and Lockers
6-501.111 Controlling Pests*
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7-101.11 Identifying Information, Prominence*
7-102.11 **Working Containers**, Common Name*
OPERATIONAL SUPPLIES AND APPLICATIONS
7-201.11 **Storage**, Separation*
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7-202.11 Restriction*
7-202.12 Conditions of Use*
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7-203.11 Poisonous/Toxic Material Containers*
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7-204.11 Sanitizers*
7-204.12 Washing Fruits and Vegetables*
7-204.13 Boiler Water Additives*
7-204.14 Drying Agents*
7-205.11 **Lubricants**, Incidental Food Contact*
Pesticides
7-206.11 Restricted-Use, Criteria*
7-206.12 Bait Stations*
7-206.13 Tracking Powders*
Medicines
7-207.11 Restriction and Storage*
7-207.12 Medicines, Refrigerated Storage*
7-208.11 **First Aid Supplies**, Storage*
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7-301.11 **Storage and Display**, Separation*

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8-103.11 Documentation and Justification
8-103.12 Conformance with Procedures*
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8-201.11 When Plans Are Required
8-201.12 Contents of Plans/Specifications
8-201.13 HACCP Plan/When Required
8-201.14 Contents of a HACCP Plan
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8-301.11 **Requirement**, for Operation
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8-302.11 Submit 30 Days Before Opening
8-302.12 Form of Submission
8-302.13 Applicant Qualification/Responsibility
8-302.14 Contents of the Application
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8-304.11 Permit Holder Responsibility
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8-402.11 After Due Notice at Reasonable Time
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8-404.11 Ceasing Operations and Reporting
8-404.21 Resumption of Operations
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8-406.11 Time Frame for Correction

Chart 4-A

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

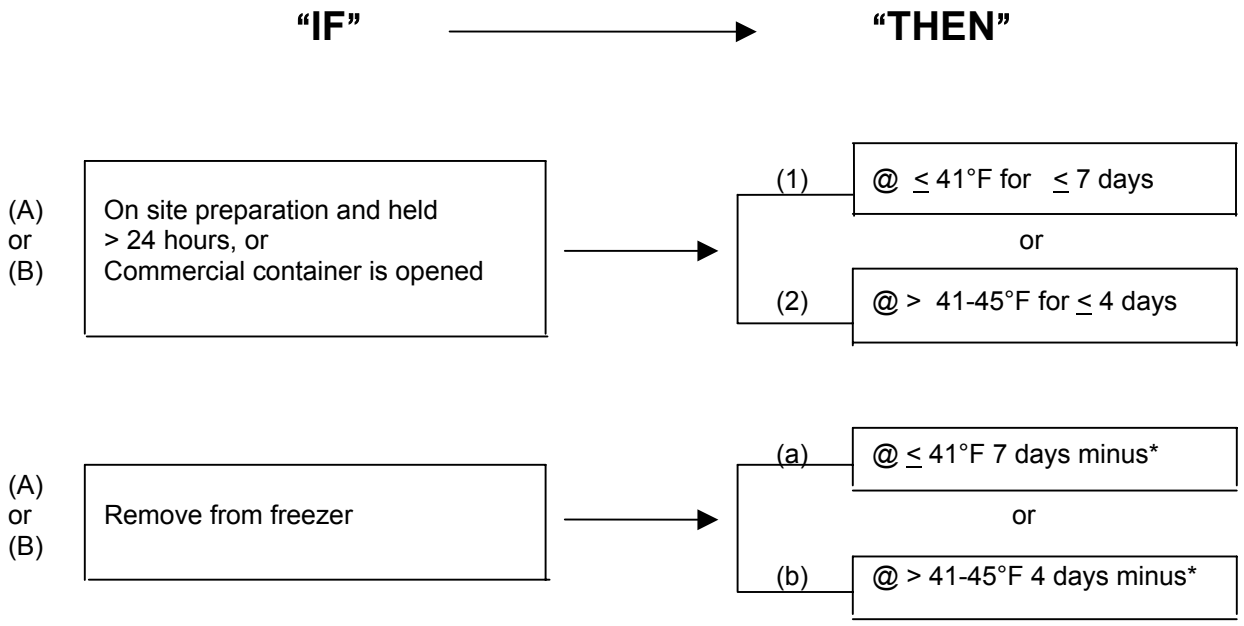
Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Unpasteurized Shell Eggs prepared for immediate service **Commercially Raised Game Animals and Exotic Species of Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Unpasteurized Shell Eggs not prepared for immediate service **Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected 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 **Stuffed Fish; Stuffed Meat;** **Stuffed Pasta;** **Stuffed Poultry** **Stuffing Containing Fish, Meat, or Poultry** **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) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after removing from microwave oven	2 hours
¶ 3-403.11(C) Food that is taken from a commercially processed, hermetically sealed container or intact package	60°C (140°F)	No time specified	2 hours
¶ 3-403.11(E) Unsliced portions of roasts of beef and roasts of pork cooked as specified under Subparagraph 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under Subparagraph 3-401.11(B)		Not applicable
	OR		
	Minimum time and temperature conditions listed in this chart for ¶ 3-403.11(A) or ¶ 3-403.11(B).		

Chart 4-C **Summary Chart**
Ready-to-Eat, Potentially Hazardous Food,
Date Marking § 3-501.17 and Disposition § 3-501.18



*Time from preparation, or opening 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

Chart 4-D

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged potentially hazardous food is served, then requirements listed in the **Potentially Hazardous Menu - *Prepackaged*** column apply. Likewise, if only food that is not potentially hazardous is prepared on board, then requirements listed in the **Not Potentially Hazardous Menu - *Food Preparation*** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged potentially hazardous food and potentially hazardous food prepared on board, then the more stringent requirements of the **Potentially Hazardous Menu - *Food Preparation*** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not potentially hazardous.

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX			
Food Code	***Potentially Hazardous Menu***		***Not Potentially Hazardous Menu***
Areas/Chapter	*Food Preparation*	*Prepackaged*	*Food Preparation*
Personnel	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)
Food	3-101.11 3-201.11-.16 3-202.16; Applicable Sections of Part 3-3; 3-501.16 3-501.18(A) &(C)	3-101.11 3-201.11-.16 3-303.12(A) 3-305.11; 3-305.12 (Applicable to Service Area or Commissary)	3-101.11; 3-201.11 3-202.16; Applicable Sections of Part 3-3
Temperature Requirements	3-202.11; Applicable Sections of Parts 3-4 & 3-5	3-202.11 3-501.16	NONE
Equipment Requirements	Applicable Sections of Parts 4-1- 4-9 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5
Water & Sewage	5-104.12 5-203.11(A) & (B) Part 5-3; 5-401.11 5-402.13-.15	5-203.11(B)	5-104.12 5-203.11(A) & (B) Part 5-3; 5-401.11 5-402.13-.15
Physical Facility	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111	6-101.11 6-102.11(A) & (B) 6-202.15 6-501.111	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111
Toxic Materials	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7
Servicing	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code
Compliance and Enforcement	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1

INDEX

U. S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
2001 Food Code

Errata

2001 Food Code Errata Sheet

August 23, 2002

The spiral bound version of the 2001 Food Code, issued in August 2002, is the most up-to-date printed version. In November 2001, an 8 ½ x 11 paperbound version was printed for the FDA but had limited distribution.

If the spiral bound version is being used, see the corrections listed in Table 1. Errors that were discovered after the printing of the spiral-bound version of the 2001 Food Code, issued in August 2002, appear in Table 1.

If the 8 ½ x 11 paperbound version is being used, see the corrections listed in both Table 1 and Table 2. Errors that were discovered after the printing of the 8 ½ x 11 paperbound version of the 2001 Food Code, issued in November 2001, appear in Table 2.

Table 1 - Corrections to 2001 Food Code - Spiral Bound Version issued August 2002

This corrected language does not appear in either the spiral bound or paperbound versions of the 2001 Food Code. Changes and additions are shown in highlighted text. Deletions are shown in ~~strikethrough~~ text.

If you are using an older web browser, such as Netscape 4 or MSIE 4, and you do not see the ~~strikeouts~~ and highlighting, you may download this document in PDF format.

Food Code Provision		Corrected Language
Front Cover	now reads	~~Washington, DC~~ College Park, MD 20740

Food Code Provision		Corrected Language
1-201.10(B)(38)(a)	now reads	...or other equine in 9 CFR 301 Definitions, as Poultry in 9 CFR 381 Poultry Products Inspection Regulations, or as FISH as defined...
2-201.12(B)(1)	now reads	Suffering from a symptom specified under ¶¶ 2-201.11(B)(1)(a), (b), (c), ~~and~~ or (e) or (B)(2), or
2-301.16(A)(1)(b)	now reads	Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash; ~~or~~ and
3-501.17(C)	is now italicized to read	*A refrigerated,* READY-TO-EAT POTENTIALLY HAZARDOUS FOOD *that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine, may be marked as specified in ¶ (A) or (B) of this section, or by an alternative method acceptable to the* REGULATORY AUTHORITY.
4-502.11	now reads	Good Repair and Calibration A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded. (B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy. (C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use. ~~(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use~~
4-602.11(D)	now reads	*(6) The cleaning schedule is* APPROVED *based on consideration of:* *(a) Characteristics of the EQUIPMENT and its use,* *(b) The type of* FOOD *involved,* *~~(c) The amount of~~* ~~FOOD~~ *~~residue accumulation,~~* *(c) The amount of* FOOD *residue accumulation, and* *(d) The temperature at which the* FOOD *is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*
Annex 2-1-201.10(4)	now reads	... Title 9, Subchapter A Part 301 Definitions

Food Code Provision		Corrected Language
Annex 2-1-201.10(5)	now reads	... Title 9, Subchapter A Part 381 Poultry Products Inspection Regulations
Annex 2-3-201.11(2)	now reads	Code of Federal Regulations, Title 21, Part 16, Regulatory Hearing Before the Food and Drug Administration
Annex 2-3-201.11(3)	now reads	Code of Federal Regulations, Title 21, Part 101, Food Labeling
Annex 2-3-201.11(4)	now reads	Code of Federal Regulations, Title 21, Part 115, Shell Eggs
Annex 2-3-202.11(1)	now reads	... Title 9, Part 590.50, Temperature and Labeling Requirements. ~~(Currently printed in the *Federal Register*, 63 (166): 45663-45675).~~
Annex 6-2(F)	now reads	...substances specified in 9 CFR 424 Preparation and Processing Operations are exempt from...
Annex 6-3(A)	now reads	... specified requirements for added nitrite may be found in USDA regulations, 9 CFR 424. It is important...

Table 2 - Corrections to 2001 Food Code - 8½ x 11 Paperbound Version
(printed for the FDA but had limited distribution)

The following corrected language does appear in the spiral bound version but not in the 8 ½ x 11 paperbound versionof the 2001 Food Code. Changes and additions are shown in highlighted text. Deletions are shown in ~~strikethrough~~ text.

If you are using an older web browser, such as Netscape 4 or MSIE 4, and you do not see the ~~strikeouts~~ and highlighting, you may download this document in PDF format.

Food Code Provision		Corrected Language
1-201.10(B)(66)(a)(ii)	now reads	... Voluntary Poultry Inspection Regulations.
3-201.17(A)(2)	now reads	... 9 CFR 352 Exotic Animals; Voluntary Inspection or rabbits that ... 9 CFR 354 Voluntary Inspection of Rabbits and Edible Products Thereof;
3-403.11(E)	now reads	*Remaining unsliced portions of roasts ~~of beef~~ that ...*
3-501.16(A)(1)	now reads	At *... a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a* *temperature of 54°C (130°F) or above; or*
3-501.16(A)(2)	now reads	At a temperature ~~and time~~ specified in the following:
3-501.16(A)(2)(a)	now reads	~~At~~ 5°C (41°F) or less ~~for a maximum of 7 days~~; or
3-501.16(A)(2)(b)	now reads	~~At~~ 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) ~~for a maximum of 4 days~~ in existing refrigeration ...
3-501.17(A)	now reads	... combinations specified below. The day of...
3-501.17(A)(1)	added to read	5°C (41°F) or less for a maximum of 7 days; or
3-501.17(A)(2)	added to read	7°C (45°F) or between 5°C (41°F) and 7°C (45°C) for a maximum of 4 days in existing refrigeration equipment that is not capable of maintaining the FOOD at 5°C (41°F) or less if:
3-501.17(A)(2)(a)	added to read	The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and
3-501.17(A)(2)(b)	added to read	Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

Food Code Provision		Corrected Language
3-501.17(B)	now reads	Except as specified ... based on the temperature and time combinations specified in ¶ (A) of this section; and
3-501.18(A)(1)	now reads	(A) A FOOD specified in 3-501.17(A) or (B) shall be discarded if it: (1) Exceeds either of the temperature and time combinations specified in ~~¶3-501.16 (A)(2)~~ ¶ 3-501.17(A), except time that the product is frozen;
3-501.18(A)(3)	now reads	Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in ~~¶3-501.16 (A)(2)~~¶ 3-501.17(A).
3-501.18(B)	now reads	(B) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in ~~¶ 3-501.16(A)(2)~~ ¶ 3-501.17(A).
3-502.12(B)(2)(c)	now reads	specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact ...
5-203.15(A)	now reads	... § 5-202.13; or
Annex 2-3-201.11(5)	now reads	Federal Register: (Volume 65, Number 234), Pages 76091-76114.
Annex 2-3-201.11(6)	now reads	Goverd, K.A., F.W. Beech, R.P. Hobbs ...
Annex 2-3-201.11(7)	now reads	Zhao, T., M.P. Doyle and R.E. Besser, 1993...
Annex 2-3-502.12~~(4)~~	now deleted	~~Code of Federal Regulations, Title 9, Part 318.7, ...~~
Annex 2-3-502.12~~(5)~~ (4)	now reads	... Title 9, Part 424.21, Use of food ingredients and sources of radiation.
Annex 2-3-502.12~~(6)~~ (5) through ~~(16)~~ (15)	now renumbered	
Annex 2-3. FDA SUPPORTING DOCUMENTS Pages 237-238,254-257, and 422	now reads	... http://www. ...
Annex 3-2-301.16 (1)	now reads	The Center's Indirect Additives Group ...

Food Code Provision		Corrected Language
Annex 3-2-301.16(3)	now reads	Questions regarding ... Indirect Additives Group, HFS-215, Office of Food Additive Safety, Center for Food ...
Annex 3-3-401.11-13, under Temperature for Comminuted Meat at Less Than 1 Second, the second paragraph	now reads	1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;
Annex 3-3-501.19, Page 313	now reads	**Holding Cold Food Without Temperature Control**
Annex 5-6. OTHER SOURCES OF HACCP INFORMATION Page 454	now reads	FDA CFSAN ... 5100 Paint Branch Parkway, College Park, MD 20740-3835 ~~or E-mail jck@vm.cfsan.fda.gov~~.

August 29, 2003

Supplement to the 2001 FDA Food Code

Mr. Joe Levitt, Center Director for the Center for Food Safety and Applied Nutrition and Ms. Janice Oliver, Deputy Center Director, are pleased to issue FDA's *Supplement to the 2001 FDA Food Code*.

The Food Code is an important part of the strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system. This Supplement, which updates the 2001 Food Code, reflects the current science, emerging food safety issues, and imminent health hazards related to food safety. Some key highlights of the Supplement are:

- A revised criteria for hand sanitizers;
- A revised hot holding temperature requirement for receiving potentially hazardous foods; and
- A revised language prohibiting bare hand contact with ready-to-eat food in facilities serving highly susceptible populations

Another key change is the decision to move to a four-year interval between complete Food Code revisions. The next complete revision of the Food Code will be published in 2005. The Supplement will provide the most current food safety provisions to agencies planning to initiate rule-making activities before 2005. In addition, this Supplement gives other users of the Food Code -- educators, trainers, and the food service, retail food, and vending industries -- up-to-date information on mitigating risk factors that can contribute to foodborne illnesses.

The Department of Health and Human Services (DHHS); USDA; state, local, and other federal and tribal government agencies; as well as the food industry share responsibility for ensuring that our food supply is safe. Therefore, FDA encourages all jurisdictions to use the 2001 Food Code and its Supplement to examine the level of food safety protection and to take the necessary steps to increase their level of safety.

DHHS and USDA, in partnership with numerous others, will continue to strengthen our nation's food safety system and to work toward uniform and effective food safety standards for food service, retail stores, and retail-level establishments nationwide.

Supplement to the 2001 FDA Food Code

U. S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
2001 Food Code

Supplement to the 2001 Food Code

August 29, 2003

IMPORTANT - Save this Supplement. It is intended to keep the 2001 Food Code up to date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2001 Food Code effective upon issuance.

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

For public sale by:

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Introduction

The Food and Drug Administration (FDA) is pleased to issue this Supplement to the 2001 Food Code (hereafter referred to as Supplement). This Supplement updates the 2001 Food Code to address several recommendations made by the 2002 Conference for Food Protection (CFP) with which the FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA) concur. The changes contained in this Supplement reflect the current science and emerging food safety issues, and imminent health hazards related to food safety.

From 1993 through 2001, the complete Food Code has been issued every two years. With the support of the Conference for Food Protection, FDA has decided to move to a four-year interval between complete Food Code revisions. The next complete revision of the Food Code will be published in 2005. Until that time, this Supplement allows several changes upon which there is substantial concurrence among the Federal Agencies and the other stakeholders to be incorporated into the Food Code. The Supplement ensures that the most current food safety provisions are available to agencies planning to initiate rule-making activities prior to 2005. This Supplement provides other users of the Food Code, such as educators, trainers, and the food service, retail food, and vending industries, with up-to-date information of how to best mitigate risk factors that contribute to foodborne illness.

While the recommendations of the 2002 Conference for Food Protection meeting provide the basis for the Food Code changes contained in this Supplement, not all recommendations of the 2002 CFP meeting were incorporated. Some recommendations require further consideration or research by one or more of the Federal agencies. FDA anticipates that most of the 2002 CFP recommendations with which the Federal agencies agree will be addressed in the 2005 Food Code.

The Supplement has been organized to facilitate the adoption of its provisions by Federal, state, local, and tribal authorities. The Supplement is divided into 3 Parts:

Part 1 - Summary of Changes - a "quick view" of the modifications
Part 2 - Amendments, Additions, Deletions to Chapters 1-8 and the Annexes - actual language modifications
Part 3 - New Terms for the Index to the Food Code

For consistency, drafting conventions used in the *Federal Register* for proposed rules are used in the Supplement to the 2001 Food Code. The standard terms to be used to describe a change are:

Amend. "Amend" means that an existing Food Code provision has changed. Because it is an introductory term, it is always used with one of the following specific amendatory terms to precisely describe the change to the Food Code provision.

Amendatory Terms

Add - means a new provision has been inserted in the Food Code.
Redesignate - means to modify a Food Code provision by reformatting the text of the provision into a new structural nomenclature designation.
Remove - means an existing provision is being taken out of the Food Code.
Revise - means an existing Food Code provision is replaced in part, or in its entirety.

For example:

Amend § 4-204.110 to **revise** subparagraph (B)(1) and to **add** subparagraph (B)(3) to read as follows: [text of changed subparagraph and newly added subparagraph]

Modifications are organized by Food Code chapter and are identified by Section number and title, and the paragraph, (e.g., 9-101.11(A)) or subparagraph (e.g., 9-101.00(A)(1)) to which the change is made. The full text of a Section is provided only if necessary to provide the proper context. Using Chapter 3 as an example, a change is introduced as follows:

Chapter 3 Food

Amend § 3-202.11 to revise paragraph (D) to read as follows:

Specifications for Receiving

3-202.11 Temperature.*

[text of changed paragraph]

Using Chapter 4 as an example, a change to the Annexes is introduced as follows:

Annex 3 Public Health Reasons/Administrative Guidelines

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

Amend Public Health Reason for § 4-501.112 to revise to read as follows:

[text of changed paragraph]

We encourage all jurisdictions to examine the level of food safety protection their current rules and implementation strategies provide and take the steps necessary to increase that level in light of the 2001 Food Code and its Supplement. Food Code adoption and implementation in all jurisdictions is an important strategy for achieving uniform national food safety standards and for enhancing the efficiency and effectiveness of our nation's food safety system.

The Department of Health and Human Services (DHHS) and USDA, along with state and local, and other federal and tribalgovernment agencies and the food industry, share responsibility for ensuring that our food supply is safe. DHHS and USDA, in partnership with numerous others, will continue to take progressive steps to strengthen our nation's food safety system. We look forward to achieving uniform and effective standards of food safety for food service, retail stores, and other retail-level establishments nationwide.

IMPORTANT. This entire Supplement to the 2001 Food Code is intended to keep the 2001 Food Code up-to-date. Changes, additions, deletions, and format modifications listed herein constitute revisions to the 2001 Food Code effective upon issuance.

Part 1 Summary of Changes

The amendments to the 2001 Food Code and its Annexes contained in the Supplement are summarized below. If an amendment relates directly to a recommendation of the Conference for Food Protection (CFP), the CFP issue number is provided in parenthesis immediately after the summary entry.

Preface

Item 9(A)
Revised the Food Code revision cycle from 2 years to 4 years (CFP Issue 2002-II-22)

Item 10
Revised the Acknowledgements paragraph to update the text

Chapter 1 Definitions
Added definitions for the terms "disclosure" and "reminder" (CFP Issue 2002-II-20)

Chapter 2

2-102.11(A)
Added language to define what is meant by "complying with this Code" with respect to demonstration of knowledge by the person in charge (CFP Issue 2002-I-28)

2-301.16(A)(2)
Revised the criteria for hand sanitizers to more accurately and concisely identify current federal food additive regulations that relate to hand sanitizer formulations and redesignated (A)(2) as (A)(2)(a)-(d)

Chapter 3

3-202.11(D)
Revised hot holding temperature requirement for receiving potentially hazardous foods from 60°C (140°F) to 57°C (135°F). (CFP Issue 2002-III-14)

3-301.11(B) and (C)
Revised language of paragraph (B), redesignated paragraph (C) as paragraph (D) and added new paragraph (C) prohibiting bare hand contact with ready-to-eat food by food employees in food establishments serving highly susceptible populations (CFP Issue 2002-III-24)

3-304.12(F)
Revised hot holding temperature requirement for storing in-use utensils from 60°C (140°F) to 57°C (135°F). (CFP Issue 2002-III-14)

3-304.14
Added new paragraph (E) to address storage of wiping cloth containers (CFP Issue 2002-I-31)

3-306.13(A)
Revised and redesignated paragraph (A) as subparagraphs (A)(1) and (A)(2) regarding consumer self-service operations (CFP Issue 2002-I-04)

3-401.11(D)
Added language regarding a consumer's selection of raw or under cooked animal foods (CFP Issue 2002-II-21) and a reference to 3-801.11 (C) (1)-(2)

3-401.13

Revised hot holding temperature requirement for plant food cooking and hot holding, from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

3-403.11(C)
Revised hot holding temperature requirement involving reheating for hot holding from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

3-501.14(A)
Revised the initial timed cooling temperature from 60°C (140°F) to 57°C (135°F) and clarified the intent of the cooling parameters (CFP Issue 2002-III-40)

3-501.16 (A)(1)
Revised hot holding temperature requirement for potentially hazardous foods from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

3-502.12(B)(5)
Revised to include "except the time the product is maintained frozen" (CFP Issue 2002-III-38)

3-603.11
Revised to require a disclosure and reminder for satisfactory compliance with the consumer advisory provision (CFP Issue 2002-II-20)

3-801.11
Revised the section title by removing the words, "Prohibited Reservice"

Removed prohibition of the re-service of food in an unopened, original package to highly susceptible populations (CFP Issue 2002-I-01)

Added prohibition of bare hand contact with ready-to-eat food for food employees in food establishments serving highly susceptible populations (CFP Issue 2002-III-24)

Chapter 4

4-204.111(B)(2)
Revised vending machine automatic shutoff requirement for potentially hazardous foods that are held hot from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

4-204.117
Removed the words, "designed and" from the introductory phrase to clarify that the warewashing machine's features prescribed in this section are not necessarily integrated into the machine design by the manufacturer and instead may be added at the time of installation

4-602.11(D)(7)
Revised hot holding requirement for in-use utensils stored in water from 60°C (140°F) to 57°C (135°F) (CFP Issue 2002-III-14)

Chapter 8

8-402
Revised Subpart title to include "competency" (CFP Issue 2002-II-14)

8-402.10
Added new paragraph to address competency of inspectors (CFP Issue 2002-II-14)

Annex 2

3-501.16
2. BIBLIOGRAPHY
Added new references for the hot holding of potentially hazardous food

Annex 3

2-301.16
Expanded the explanation of the applicable federal regulations pertaining to substances that are "generally recognized as safe (GRAS)" and substances that are the subject of a Food Contact Substance Notification in relation to their use in hand sanitizers

3-301.11
Added explanation for prohibiting bare hand contact in establishments serving highly susceptible populations

3-401.11
Added new paragraph to the introductory text regarding a consumer's right to select raw or undercooked animal foods

3-501.14
Revised to include additional information on cooling

3-501.16
Amended the temperature "Danger Zone," by replacing 60°C (140°F) with 57°C (135°F) and added discussion of the temperature criteria for hot holding of potentially hazardous foods

3-502.12
Added new paragraph discussing the use of proper cooling and freezing in reduced oxygen packaged products

3-603.11
Added new paragraphs under, "Satisfactory Compliance" that provides additional information on how to achieve compliance with the disclosure and reminder requirements for consumer advisories

4-501.112
Revised the section to specify the temperature parameters of a warewasher using hot water for sanitizing

4-703.11
Revised the section to discuss the utensil surface temperature that must be reached to ensure sanitization

8-402.10
Added new section to address the competency of inspectors

Annex 4

3. STAFF TRAINING
Revised the introductory text

Part 2 Amendments, Additions, Deletions to Chapters 1-8 and the Annexes

Preface

9. THE CODE REVISION PROCESS

Amend § 9 to revise paragraph (A) to read as follows:

FDA is issuing a new edition of the Food Code every 4 years. During the 4-year span of time between editions, FDA may issue supplements to an existing edition. Each new edition will incorporate the changes made in the supplement as well as any new revisions.

10. ACKNOWLEDGMENTS

Amend § 10 to revise the paragraph to read as follows:

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations. It is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those who contributed to public health and food safety in the development of the Food Code.

Chapter 1 Purpose and Definitions
Ammendments, Additions, and Deletions

***Amend § 1-201.10 to add to paragraph (B) the following defined terms*:**

Applicability and Terms Defined

1-201.10 Statement of Application and Listing of Terms.

Applicability and Terms Defined 1-201.10 **Statement of Application and Listing of Terms.**

(B) Terms Defined.

Disclosure.

"Disclosure" means a written statement that clearly identifies the animal-derived foods which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

Reminder.

"Reminder" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

(Return to Food Code 2001)

Chapter 2 Management and Personnel
Ammendments, Additions, and Deletions

***Amend § 2-102.11 to revise paragraph (A) to read as follows:*:**

2-102.11 Demonstration.*

Based on the RISKS of foodborne illness inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code by having no violations during the current inspection;
(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM; or
(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;
(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;
(3) Describing the symptoms associated with the diseases that are transmissible through FOOD;
(4) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD and the prevention of foodborne illness;
(5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH;
(6) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD including MEAT, POULTRY, EGGS, and FISH;
(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD;
(8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(a) Cross contamination,
(b) Hand contact with READY-TO-EAT FOODS,
(c) Handwashing, and
(d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair;

(9) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:

(a) Sufficient in number and capacity, and
(b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

(10) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;
(11) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
(12) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of

according to LAW;
(13) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;
(14) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the establishment; and
(15) Explaining the responsibilities, rights, and authorities assigned by this Code to the:
(a) FOOD EMPLOYEE,
(b) PERSON IN CHARGE, and
(c) REGULATORY AUTHORITY.

(**Return to Food Code 2001**)

***Amend § 2-301.16 to revise subparagraph (A)(2) and redesignate as (A)(2)(a)-(d) to read as follows*:**

2-301.16 Hand Sanitizers.

(A) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:
(1) Comply with one of the following:
(a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness; or
(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, and
(2) Consist of components that are:
(a) Listed for such use in contact with FOOD in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*; or
(b) Exempt from regulation as FOOD ADDITIVES under 21 CFR 170.39 - *Threshold of regulation for substances used in food-contact articles*; or
(c) Generally recognized as safe (GRAS) for the intended use in contact with FOOD within the meaning of the Federal Food, Drug and Cosmetic Act (FFDCA); or
(d) Permitted for such use by an effective Food Contact Substance Notification as defined by paragraph 409(h) of the FFDCA and listed in FDA's Inventory of Effective Premarket Notifications for Food Contact Substances; and
(3) Be applied only to hands that are cleaned as specified under § 2-301.12.

(**Return to Food Code 2001**)

Chapter 3 Food
Ammendments, Additions, and Deletions

***Amend § 3-202.11 to revise paragraph (D) to read as follows*:**

Specifications for Receiving

3-202.11 Temperature.*

(A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD shall be at a temperature of 5°C (41°F) or below when received.
(B) *If a temperature other than 5°C (41°F) for a* POTENTIALLY HAZARDOUS FOOD *is specified in* LAW *governing its distribution, such as* LAWS *governing milk and* MOLLUSCAN SHELLFISH, *the* FOOD *may be received at the specified temperature.*
(C) Raw shell EGGS shall be received in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.
(D) POTENTIALLY HAZARDOUS FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 57°C (135°F) or above.
(E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.
(F) Upon receipt, POTENTIALLY HAZARDOUS FOOD shall be free of evidence of previous temperature abuse.

(**Return to Food Code 2001**)

Amend § 3-301.11 to revise paragraph (B), redesignate paragraph (C) as paragraph (D), and add a new paragraph (C) to read as follows:

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands*

(A) Food EMPLOYEES shall wash their hands as specified under *§ 2-301.12*.
(B) *Except when washing fruits and vegetables as specified under* § *3-302.15 or as specified in* ¶ *(C) of this section,* FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.
(C) *When otherwise* APPROVED, FOOD EMPLOYEES *not serving a* HIGHLY SUSCEPTIBLE POPULATION *may contact exposed,* READY-TO-EAT FOOD *with their bare hands.*
(D) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.**S**

(**Return to Food Code 2001**)

Amend § 3-304.12 to revise paragraph (F) to read as follows:

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

(A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;
(B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;
(C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;
(E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or
(F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

(**Return to Food Code 2001**)

Amend § 3-304.14 to add new paragraph (E) to read as follows:

3-304.14 Wiping Cloths, Use Limitation.

(E) *Working containers of sanitizing solutions for storage of in-use wiping cloths may be placed above the floor and used in a manner to prevent contamination of food, equipment, utensils, linens, single-service or single-use articles*.

(**Return to Food Code 2001**)

Amend § 3-306.13 to revise and redesignate paragraph (A) as paragraph (A) and subparagraphs (A)(1) and (A)(2) to read as follows:

3-306.13 Consumer Self-Service Operations.*

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. *This paragraph does not apply to:*
(1) CONSUMER *self-service of* READY-TO-EAT FOODS *at buffets or salad bars that serve* FOODS *such as sushi or raw shellfish;*
(2) *ready-to-cook individual portions for immediate cooking and consumption on the* PREMISES *such as* CONSUMER-*cooked* MEATS *or* CONSUMER-*selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster.*

(**Return to Food Code 2001**)

Amend § 3-401.11 to revise paragraph (D) to read as follows:

Cooking

3-401.11 Raw Animal Foods.*

(D) *A raw animal* FOOD *such as raw* EGG, *raw* FISH, *raw-marinated* FISH, *raw* MOLLUSCAN SHELLFISH, *or steak tartare; or a partially cooked* FOOD *such as lightly cooked* FISH, *soft cooked* EGGS, *or rare* MEAT *other than* WHOLE-MUSCLE, INTACT BEEF *steaks as specified in ¶ (C) of this section, may be served or offered for sale upon consumer request or selection in a* READY-TO-EAT *form if:*
(1) *As specified under 3-801.11(C)(1)-(2), the* FOOD ESTABLISHMENT *serves a population that is not a* HIGHLY SUSCEPTIBLE POPULATION, *and*
(2) *The consumer is informed as specified under § 3-603.11 that to ensure its safety, the* FOOD *should be cooked as specified under ¶ (A) or (B) of this section; or*
(3) *The regulatory authority grants a* VARIANCE *from ¶ (A) or (B) of this section as specified*

in § 8-103.10 based on a HACCP PLAN *that:*

(a) *Is submitted by the* PERMIT HOLDER *and* APPROVED *as specified under § 8-103.11,*
(b) *Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe* FOOD*, and*
(c) *Verifies that* EQUIPMENT *and procedures for* FOOD *preparation and training of* FOOD EMPLOYEES *at the* FOOD ESTABLISHMENT *meet the conditions of the* VARIANCE.

(**Return to Food Code 2001**)

Amend § 3-401.13 to revise to read as follows:

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F).

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***Amend § 3-403.11 to revise paragraph (C) to read as follows*:**

3-403.11 Reheating for Hold Holding.*

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.
(B) Except as specified under ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
(C) READY-TO-EAT FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD PROCESSING PLANT that is inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding.
(D) Reheating for hot holding shall be done rapidly and the time the FOOD is between the temperature specified under ¶ 3-501.16(B) and 74°C (165°F) may not exceed 2 hours.
(E) *Remaining unsliced portions of roasts of beef that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

(**Return to Food Code 2001**)

Amend § 3-501.14 to revise paragraph (A) to read as follows:

3-501.14 Cooling.*

(A) Cooked POTENTIALLY HAZARDOUS FOOD shall be cooled:
(1) Within 2 hours, from 57°C (135°F) to 21° C (70°F); and
(2) Within a total of 6 hours, from 57°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).
(B) POTENTIALLY HAZARDOUS FOOD shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

(C) Except as specified in ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).
(D) Raw shell EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

(**Return to Food Code 2001**)

***Amend § 3-501.16 to revise subparagraph (A)(1) to read as follows*:**

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

(A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-501.19,* and except as specified in ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD shall be maintained:
(1) At 57°C (135°F) or above, *except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above*; or
(2) At a temperature specified in the following:
(a) 5°C (41°F) or less; or
(b) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:
(i) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and
(ii) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

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Amend § 3-502.12(B) to revise subparagraph (B)(5) to read as follows:

Clostridium botulinum Controls

3-502.12 Reduced Oxygen Packaging, Criteria.*

(B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:
(5) Limits the refrigerated shelf life to no more than 14 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(**Return to Food Code 2001**)

Amend § 3-603.11 to revise to read as follows:

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not

Otherwise Processed to Eliminate Pathogens.*

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased risk of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in paragraphs (B) and (C) of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order);" or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked MEATS , POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions."

(**Return to Food Code 2001**)

***Amend § 3-801.11 to remove the words, "Prohibited Reservice" from the tag line to revise the title to read as follows*:**

Additional Safeguards

3-801.11 Pasteurized Foods and Prohibited Food.*

(**Return to Food Code 2001**)

Amend § 3-801.11 to remove paragraph (C), redesignate paragraph (D) as paragraph (C), and add new paragraph (D) to read as follows:

Additional Safeguards

3-801.11 Pasteurized Foods and Prohibited Food.*

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, Section 101.17(g) *Food Labeling*, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 - *Hazard Analysis and Critical Control Point (HACCP) Systems*, Subpart B *Pathogen Reduction*, 120.24 *Process controls*.

(B) Pasteurized shell EGGS or pasteurized liquid, frozen, or dry EGGS or EGG products shall be substituted for raw shell EGGS in the preparation of:

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and EGG-fortified BEVERAGES; and

(2) Except as specified in ¶ (E) of this section, recipes in which more than one EGG is broken and the EGGSare combined.

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare;

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw shell EGGS, and meringue; and

(3) Raw seed sprouts.

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOODas specified under §3-301.11(B).

(E) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw* EGGS *are combined immediately before cooking for one* CONSUMER'S *serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled* EGGS*;*

(2) *The raw* EGGS *are combined as an ingredient immediately before baking and the* EGGS *are thoroughly cooked to a* READY-TO-EAT *form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a* HACCP PLAN *that:*

(a) *Identifies the* FOOD *to be prepared,*

(b) *Prohibits contacting* READY-TO-EAT FOOD *with bare hands,*

(c) *Includes specifications and practices that ensure*:

(i) ***Salmonella* Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella* Enteritidis** *is destroyed by cooking the* EGGS *according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of* READY-TO-EAT FOOD *with raw* EGGS*, and*

(ii) *Delineate cleaning and* SANITIZATION *procedures for* FOOD-CONTACT SURFACES, and

(e) *Describes the training program that ensures that the* FOOD EMPLOYEE *responsible for the preparation of the* FOOD *understands the procedures to be used*

(**Return to Food Code 2001**)

Chapter 4 Equipment, Utensils and Linens Ammendments, Additions, and Deletions

Amend § 4-204.111 to revise subparagraph (B)(2) to read as follows:

4-204.111 Vending Machines, Automated Shutoff.*

(A) A machine vending POTENTIALLY HAZARDOUS FOOD shall have an automatic control that prevents the machine from vending FOOD:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain FOOD temperatures as specified under Chapter 3; and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3.

(B) When the automatic shutoff within a machine vending POTENTIALLY HAZARDOUS FOOD is activated:

(1) In a refrigerated VENDING MACHINE, the ambient temperature may not exceed any time/temperature combination as specified under ¶ 3-501.16(A)(2) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or

(2) In a hot holding VENDING MACHINE, the ambient temperature may not be less than 57°C (135°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked

(**Return to Food Code 2001**)

Amend § 4-204.117 to revise the introductory text to read as follows:

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

A WAREWASHING machine that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be equipped to:

(A) Automatically dispense detergents and SANITIZERS; and

(B) Incorporate a visual means to verify that detergents and SANITIZERS are delivered or a visual or audible alarm to signal if the detergents and SANITIZERS are not delivered to the respective washing and SANITIZING cycles.

(**Return to Food Code 2001**)

Amend § 4-602.11(D) to revise subparagraph (D)(7) to read as follows:

4-602.11 Equipment Food-Contact Surfaces and Utensils.*

(D) *Surfaces of* UTENSILS *and* EQUIPMENT *contacting* POTENTIALLY HAZARDOUS FOOD *may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of* POTENTIALLY HAZARDOUS FOOD *and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) UTENSILS *and* EQUIPMENT *are used to prepare* FOOD *in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*

(a) *The* UTENSILS *and* EQUIPMENT *are cleaned at the frequency in the following chart that corresponds to the temperature:*

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

; and

(b) *The cleaning frequency based on the ambient temperature of the refrigerated room or areas is documented in the* FOOD ESTABLISHMENT.

(3) *Containers in serving situations such as salad bars, delis, and cafeteria lines hold* READY-TO-EAT POTENTIALLY HAZARDOUS FOOD *that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same* FOOD *that is at the required temperature, and the containers are cleaned at least every 24 hours;*

(4) TEMPERATURE MEASURING DEVICES *are maintained in contact with* FOOD*, such as when left in a container of deli* FOOD *or in a roast, held at temperatures specified under Chapter 3;*

(5) EQUIPMENT *is used for storage of* PACKAGED *or un*PACKAGED FOOD *such as a reach-in refrigerator and the* EQUIPMENT *is cleaned at a frequency necessary to preclude accumulation of soil residues;*

(6) *The cleaning schedule is* APPROVED *based on consideration of:*

(a) *Characteristics of the* EQUIPMENT *and its use,*

(b) *The type of* FOOD *involved,*

(c) *The amount of* FOOD *residue accumulation, and*

(d) *The temperature at which the* FOOD *is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*

(7) *In-use* UTENSILS *are intermittently stored in a container of water in which the water is maintained at 57°C (135°F) or more and the* UTENSILS *and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.*

(Return to Food Code 2001)

Chapter 8 Compliance and Enforcement Ammendments, Additions, and Deletions

***Amend to revise Subpart title for 8-4 to read as follows*:**

Applicability and Terms Defined

8-402 Competency and Access

(Return to Food Code 2001)

Amend to add § 8-402.10 to read as follows:

Applicability and Terms Defined

8-402.10 Competency of Inspectors.

An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have the knowledge, skills, and ability to adequately perform the required duties.

(Return to Food Code 2001)

Annex 2 References, 2. BIBLIOGRAPHY, Chapter 3 Ammendments, Additions, and Deletions

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Amend References for § 3-501.16 to add new references and redesignate numbering to read as follows:

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8. Collee, J.G., Knolden, J.A. and B.C. Hobbs. 1961. Studies on the growth, sporulation and carriage of ***Clostridium welchii*** with special reference to food poisoning strains. J. Appl. Bacteriol. 24:326-329.
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11. El-Sherbeeny, M.R., M.F. Saddik, H.E-L. Aly, and F.L. Bryan. 1985. Microbiological profile and storage temperatures of Egyptian rice dishes. J. Food Prot. 48: 39-43.
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13. Hall, H.E. and R. Angelotti. 1965. ***Clostridium perfringens*** in meat and meat product. Applied Microbiology. 13: 352-354
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Food Sci. 48: 286-287.
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16. Ladiges, W.C., J.F. Foster and W.M. Ganz. 1974. Incidence and viability of ***Clostridium perfringens*** in ground beef. J.Milk Food Technol. 37(12) 622-623.
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Annex 3 Public Health Reasons/Administrative Guidelines, Chapter 2 Management and Personnel
Ammendments, Additions, and Deletions

2-301.16 Hand Sanitizers.

Amend Public Health Reasons for § 2-301.16 to revise to read as follows:

This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need both to protect workers and to ensure safe food, hand sanitizers must comply with both the human drug and the food safety provisions of the law. -The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are two means by which a hand sanitizer is considered to be safe and effective when applied to human skin:

A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication **Approved Drug Products with Therapeutic Equivalence Evaluations**. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand sanitizing products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand sanitizers and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2003, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized.

Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a specific product has been accepted and included in the proposed monograph may be obtained from the manufacturer. You may also refer to ***Federal Register*** (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.

Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855-2737. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

As a Food Additive

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand sanitizer must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand sanitizer are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

2. A substance may be regulated for the intended use as a food additive under 21 CFR 174 - *Indirect Food Additives - General*, and be listed along with conditions of safe use in 21 CFR 178 - *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers*. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.

3. The intended use of a substance, including substances that contact food such as those in hand sanitizers, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

   For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrates that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at http://www.cfsan.fda.gov/~rdb/opa-gras.html). Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA section 409 (h). Substances that are the subject of an effective food contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Premarket Notifications for Food Contact Substances. This list is available on-line at http://www.cfsan.fda.gov/~dms/opa-fcn.html. A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive.

However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand sanitizers as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

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Annex 3 Public Health Reasons/Administrative Guidelines, Chapter 3: Food Ammendments, Additions, and Deletions

3-301.11 Preventing Contamination from Hands.*

Amend Public Health Reasons for § 3-301.11 to add the following sentence to the end of the second paragraph under," Clarification of ¶ 3-301.11(B) of the FDA Food Code with Respect to the Phrase "Except... when otherwise* APPROVED" *:

Due to the immunocompromised condition of highly susceptible populations, alternatives to the no bare hand contact with ready-to-eat food requirement are prohibited in establishments serving these populations.

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3-401.11 Raw Animal Foods.*

***Amend Public Health Reasons for § 3-401.11 to add the following two paragraphs to the end of the introductory text*:**

The requirements specified under 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to the consumer prior to making their food selections. In a catered situation, such as a wedding reception, each guest is responsible for making his or her own requests or selections.

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3-501.14 Cooling.*

***Amend Public Health Reasons for § 3-501.14 to add the following paragraph after the first paragraph of the introductory text*:**

The Food Code provision for cooling provides for cooling from 135°F to 41°F or 45°F in 6 hours, with cooling from 135°F to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this

cooling process. An example of proper cooling might involve cooling from 135°F to 70°F in 1 hour, in which case 5 hours remain for cooling from 70°F to 41°F or 45°F. Conversely, if cooling from 135°F to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70°F took 3 hours, the food safety hazards may not be adequately controlled.

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3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Amend Public Health Reasons for § 3-501.16 to add the following four paragraphs to the end of the section:

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

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3-502.12 Reduced Oxygen Packaging, Criteria.*

Amend Public Health Reasons for § 3-502.12 to add the following paragraph to the end of the section:

Formation of ***Clostridium botulinum*** toxin may not be a significant hazard in reduced oxygen packaged products which are properly cooled and frozen immediately after processing, maintained frozen, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important: Keep frozen until used. Thaw under refrigeration immediately before use.")

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3-603.11 Consumption of Raw or Undercooked Animal Foods.*

Amend Public Health Reasons for § 3-603.11 to add the following three paragraphs to the end of the existing text under, "Satisfactory Compliance":

The information contained in both the DISCLOSURE and REMINDER should be publicly available and readable so that consumers have benefit of the total message (DISCLOSURE and REMINDER) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code (Section 3-603.11 in the 1999 FDA Model Food Code)*, March 22, 2000 is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available on the FDA/CFSAN web page at http://www.cfsan.fda.gov/~dms/fc99guid.html

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Annex 3 Public Health Reasons/Administrative Guidelines, Chapter 4: Equipment, Utensils, and Linens
Ammendments, Additions, and Deletions

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

Amend Public Health Reasons for § 4-501.112 to revise to read as follows:

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer's specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71°C (160°F) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90°C (194°F) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74°C (165°F) for a stationary rack, single temperature machine, and 82°C (180°F) for other machines are based on the sanitizing rinse contact time required to achieve the 71°C (160°F) utensil surface temperature.

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4-703.11 Hot Water and Chemical.*

Amend Public Health Reasons for § 4-703.11 to revise to read as follows:

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a

parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization.

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71°C (160°F), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

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Annex 3 Public Health Reasons/Administrative Guidelines, Chapter 8: Poisonous or Toxic Materials
Ammendments, Additions, and Deletions

Amend Public Health Reasons to add new § 8-402.10 to read as follows:

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *National Voluntary Retail Food Regulatory Program Standards* to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

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Annex 4 Food Establishment Inspection, 3. STAFF TRAINING
Ammendments, Additions, and Deletions

Amend Public Health Reasons to revise the introductory text to read as follows:

Basic staff training is very important to staff development and should be a well-defined process. Initial training is usually provided within the local regulatory agency and more advanced training is available through a state agency's program. National training is available from the FDA's Division of Human Resource Development (ORA-U) and the State Training Team, and from the Centers for Disease Control and Prevention's Distance Learning Program. These programs range from basic to advanced subject-specific seminars offered regionally, to home study courses including video, slide, or textbook-based programs, and finally to direct satellite broadcast seminars and courses as a part of the Public Health Training Network.

FDA supports the concept of a competency standard for regulatory professionals and encourages

development of education, training and certification criteria consistent with Standard 2 - Trained Regulatory Staff in the draft *National Voluntary Retail Food Regulatory Program Standards.*

There are many components of a valid and credible certification process. Different pre-requisite training and/or testing processes exist for regulators who will be responsible for inspection of foodservice and other retail food establishments. This range of perspectives speaks to the need for criteria that includes consensus support. FDA's draft *National Voluntary Retail Food Program Standard*s were developed based on input from regulatory officials, industry professionals, and academia and consumer groups. Standard 2 - Trained Regulatory Staffincorporates an educational curriculum, field training, *Food Code* standardization, and continuing education as minimum criteria for assessing the competency of regulators.

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Part 3 New Terms for the Index to the Food Code Ammendments, Additions, and Deletions

Under Index term, "Consumer," add
subheading Advisory,
subheading Disclosure,
subheading Reminder
Competency of Inspectors
Wiping cloths - container storage
Disclosure
Reminder

FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by dvd/kwg/cjm April 7, 2004