Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY

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:

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Washington, DC 20401
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(2) Internet World Wide Web Information System

The CFR are available on-line in downloadable form through the Internet World Wide Web information system. Two sources are:

(a) 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-retrieve.html#page1

(b) The U.S. House of Representatives
Internet Law Library
Code of Federal Regulations (Searchable)

http://law.house.gov/cfr.htm

(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)
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(202)512-1800 from 7:30 a.m. to 5:00 p.m. easter 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 (FOOTNOTE 3) (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.
(FOOTNOTE 3) So in original. Probably should be “subparagraph” .
(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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2-401.11 Eating, Drinking, or Using Tobacco.*
2-402.11 Effectiveness. (Hair Restraints)

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Annex

3 Public Health Reasons/ Administrative Guidelines

CHAPTER 2 **MANAGEMENT AND PERSONNEL**
CHAPTER 3 **FOOD**
CHAPTER 4 **EQUIPMENT, UTENSILS, AND LINENS**
CHAPTER 5 **WATER, PLUMBING, AND WASTE**
CHAPTER 6 **PHYSICAL FACILITIES**
CHAPTER 7 **POISONOUS OR TOXIC MATERIALS**

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 effectiveness of the person in charge in protecting the health of the consumer is evidenced by the person's ability to apply the required knowledge to the establishment's operations by designing and implementing procedures that ensure continued compliance with the Code.

Status of "Universally Acceptable" Manager Knowledge Certificate

In 1993 the "job knowledge" and "management responsibilities" recommendations of the Conference for Food Protection (CFP) were incorporated into the Food Code's Management and Personnel Chapter. These provisions appear under "Supervision" as Knowledge/Demonstration and Duties/Person in Charge.

Not included in the Food Code, to date, is a needed mechanism to facilitate universal acceptance of food manager certificates by food regulatory authorities as a means of demonstrating a manager's knowledge. FDA has expressed its desire and intent to add a Food Code provision containing criteria for universal acceptance as soon as the Agency and other stakeholders reach consensus on the criteria.

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 certificate-issuing programs to recognize. A premise that large programs are probably good and small ones are probably not, while perhaps expedient, is neither valid nor fair. FDA and the CFP have identified "third party" accreditation of certifiers based upon specified standards as a practical means for judging acceptability for universal acceptance.

However, at the time of the publication of the 1997 Food Code, although it has worked diligently, the CFP Food Manager Certification Committee/Accreditation Subcommittee has not yet completed its work in gaining consensus on the scope of the needed accreditation

(test vs program), the standards to be applied, and the most appropriate accrediting organization.

Nonetheless, the 1997 Food Code is modified to reflect FDA's intent and to be responsive to our understanding of the long-range intent of the CFP, i.e., to provide a framework for universally accepting certain food managers' certificates. The 1997 Food Code recognizes that framework as one means of meeting the knowledge requirement once remaining decisions about accreditation criteria are made and announced. Refer to the CFP recommendations 90-02-07 "Report on Food Protection Management Certification" and 96-02-04 "Demonstration of Knowledge."

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.

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 (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 "Americans with Disabilities Act of 1990", on August 16, 1992, the Centers for Disease Control and Prevention (CDC) published 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 (List I) and pathogens occasionally transmitted (List II) through food by infected food employees.

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.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Employees.

	D	F	V	J	S
1. Hepatitis A virus	-	F	-	J	-
2. ***Salmonella typhi***	-	F	-	-	-
3. ***Shigella*** species	D	F	V	-	-
4. Norwalk and Norwalk-like viruses	D	F	V	-	-
5. ***Staphylococcus aureus***	D	-	V	-	-
6. ***Streptococcus pyogenes***	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Employees

	D	F	V	J	S
1. ***Campylobacter jejuni***	D	F	V	-	-
2. ***Entamoeba histolytica***	D	F	-	-	-
3. Enterohemorrhagic ***Escherichia coli***	D	-	-	-	-
4. Enterotoxigenic ***Escherichia coli***	D	-	V	-	-
5. ***Giardia lamblia***	D	-	-	-	-
6. Non-typhoidal ***Salmonella***	D	F	V	-	-
7. Rotavirus	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 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., ***Escherichia coli*** O157:H7, 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.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent the most 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.

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., ***Escherichia coli*** O157:H7, 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 symptoms experienced by individuals infected with ***Salmonella typhi, Shigella*** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus are often severe and of sufficient duration that most employees will seek medical assistance. The Code provisions related to individuals who encounter any of the high-risk conditions listed and also suffer from any of the symptoms listed in the Code are designed to identify individuals who are likely to be suffering from an illness caused by 1 of the 4 organisms that requires exclusion.

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 the use of the double handwash technique 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.

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 ***E. coli*** O157:H7, 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 ***E. coli*** O157:H7 warrant the institution of disease interventions.

- Restriction in a food establishment that does not serve a highly susceptible populaiton 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 ***Escherichia coli*** O157:H7; or

(C) Had a recent illness caused by ***S.typhi*, *Shigella*** spp., or ***E. coli*** O157:H7. The exclusion is in effect until a licensed physician 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 of an employee or an applicant suffering illness caused by ***Salmonella typhi, Shigella*** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness.

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.*

Many employees fail to wash their hands as often as necessary and even those who do may use a flawed technique. 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 dirt or soil present.

Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Proper handwashing by employees after defecation establishes a protective barrier against the transmission of pathogens that may be present in the feces.

Pathogens transmissible through food may also be present in other body fluids. Therefore, precautions would be appropriate whenever an employee handles body fluids or body wastes directly or indirectly, because of the increased risk of the presence of disease. Fecal material and other contaminants routinely accumulate under the fingernails; therefore, particular attention must be given to the fingernails, fingertips, and areas between the fingers. Once the material and soil are loosened, they can be washed away in the rinsing step of proper handwashing.

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 lavatory in order to help ensure that food employees effectively clean their hands. Handwashing lavatories 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.

As a Drug Product

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.

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.

The ***List of Proprietary Substances and Nonfood Compounds*** prepared by USDA's Food Safety and Inspection Service is available from the Superintendent of Documents, Government Printing Office.

As a Food Additive

A product's manufacturer can provide documentation about whether its product: 1) is regulated for the intended use as a Food Additive, 2) is generally recognized as safe (GRAS) for the intended use in contact with food, or 3) has been included in a letter exempting the product from the requirements of the federal food additive regulations.

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.

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.***

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 consmers 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 Part I of the National Shellfish Sanitation Program Manual. 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.

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.

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.

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 ***Escherichia coli*** O157:H7, ***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 mollluscan 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 mulluscan 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.

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. 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.

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 Manual of Operations Part II. 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.

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.*

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.

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.

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.***
	3-304.12	**In-Use Utensils, Between-Use Storage.**
	3-304.13	**Linens and Napkins, Use Limitation.**
	3-304.14	**Wiping Cloths, Used for One Purpose.**
	3-304.15	**Gloves, Use Limitation.**
	3-304.16	**Using Clean Tableware for Second Portions and Refills.**
	3-304.17	**Refilling Returnables.**

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.

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.

Soiled wiping cloths and repeatedly used gloves, especially when moist, can become breeding grounds for pathogens that could be transferred to food. If used in this improper condition or stored with articles that contact ready-to-eat food, these items cause food contamination.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

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, 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 121 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 3 minutes after it has reached 63°C (145°F).

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°C(145°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.

The parameters of 68°C (155°F) for 15 seconds specified for pork, ratites, injected meats and comminuted fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program provide a 5D reduction of organisms based on the Goodfellow and Brown study. 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°C (155°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 ***E. coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C(165°F) or above for 15 seconds yield greater than a 7D reduction.

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°C (165°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)

Fresh fruits and vegetables 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.

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 held. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Although it takes as many as 1 million cells to cause foodborne illness, the generation time for ***C. perfringens*** is very short at temperatures just below adequate hot holding. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held below adequate hot holding temperatures, 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 to public health reason for § 3-401.12.

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.*

Proper 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 extended 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 - 49°C (70°F - 120°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*** should be killed or inactivated. However, under poorly monitored conditions, other pathogens such as ***Salmonella*** may be reintroduced. Thus, cooling requirements have been based on growth characteristics of organisms that grow rapidly under temperature abuse conditions.

A separate method for cooling shell eggs is allowed in food establishments because of the cumulative information that has been gathered about the specific dynamics of the particular pathogen of concern in intact shell eggs. Information continues to unfold and FDA and USDA are coordinating efforts to address the transportation and distribution of shell eggs from the processing level to the consumer. The two agencies intend to publish jointly an Advance Notice of Proposed Rulemaking to address a range of food safety issues, including proper cooling to minimize growth of pathogens. As rules are developed, provisions of the Food Code will be adjusted to coincide.

Aside from the recognized need for an integrated approach to the cooling of eggs from farm to table, there are several germane facts that are currently known and that support unique provisions for cooling eggs at retail during this interim period until rules are adopted.

- There is only one type of microorganism, pathogenic to humans, which appears to be passed transovarially, i.e., ***Salmonella enteritidis (S.e.)***.

- ***S.e.*** 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 on the exterior of the yolk membrane, in contact with the bacteriostatic albumen. Growth does not appear to begin until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

- Rapidly cooling eggs after washing by the producer or packer can cause damage to the eggs. The eggs may develop cracks and/or checks because of temperature gradients which could lead to absorption through the shell of microorganisms on the surface.

Based on these facts and current shell egg industry practices including techniques used in cleaning, packing, and transportation, shell eggs are allowed longer than 4 hours to cool to the temperature required under the Code. However, procedures should be encouraged that shorten the time eggs are stored at ideal temperatures for the growth of ***Salmonella*** spp. and that call for expedited delivery to consumers. Food establishment operators should coordinate with their suppliers to hasten egg deliveries and should minimize the amount of time involved in cooling eggs after they are received by arranging flats, cases, and cartons of shell eggs in refrigerated units in a way that maximizes the circulation of cooled air.

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^{o}C to 60^{o}C (41^{o}F to 140^{o}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.

3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*
3-501.18 Ready-to-Eat, Potentially Hazardous Food, Disposition.*
3-501.19 Time as a Public Health Control.*

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 like organisms may increase to hazardous levels 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 or discarded by the expiration date.

Potentially hazardous food may be held without temperature control for short time periods not exceeding four hours because there will be no significant growth or toxin production possible in that limited time.

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.

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 variance is not required when the operation is confined to foods that have secondary barriers to refrigeration such as pH or a_w to prevent the growth of ***Clostridium botulinum***. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate

refrigeration. 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°C (38°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 is revised to reflect the fact that various substances, combinations of substances, and resultant concentrations are allowed in CFR administered by USDA. The Code provision also now includes the requirement for cured poultry products to meet the CFR.

Shelf-life must be determined considering holding temperatures because some pathogens, including ***Listeria monocytogenes***, may be a hazard at refrigeration temperatures. Safe food that remains frozen from the time it is packaged until 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 ***Escherichia coli*** O157:H7 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 become 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.

■ 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:

- Foods packaged in a food establishment if:

    ☐ 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

    ☐ The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

- Low-volume food products if:

    ☐ 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

    ☐ The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

- 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;

- Foods similar to those specified in the perceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

    ☐ Ready-to-eat but not necessarily for immediate consumption,

    ☐ Prepared primarily in the food establishment from which it is sold, and

    ☐ Not offered for sale outside the food establishment;

- Foods of no nutritional significance such as coffee;

- Bulk food for further manufacturing or repacking; and

- Raw fruits, vegetables, and fish.

■ 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.

■ 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.

Consumer Advisory **3-603.11** **Consumption of Raw or Undercooked Animal Foods.***

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.

Beginning with the 1993 Food Code, FDA included a provision for a point-of-purchase consumer advisory. No specific language was recommended. In this Annex, Public Health Reasons, FDA stated:

> "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."

In response to that request and in order to achieve a uniform message for consumers, the Conference for Food Protection (CFP) at its 1996 meeting recommended the following language for the consumer advisory:

> **"Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, pork, poultry or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."**

FDA subjected the CFP-recommended language to representative consumer focus groups in three states. The cumulative information obtained through this process was not supportive of the language nor of the method of communication, i.e., there was resistance to, and skepticism about, menu notices and some misunderstanding of the message. Consequently, the language recommended by the CFP is not included in the 1997 Code.

However, FDA continues to believe that it is the shared responsibility of the industry, regulators, and the medical community to ensure proper information is available so that consumers make knowledgeable food choices. Therefore, when consumers are advised, FDA supports the use of a uniform message and suggests that the CFP-recommended language be used until a more meaningful advisory is developed.

FDA will continue to explore through its educational initiatives and processes and with the CFP and other groups, ways to effectively communicate the risk of foodborne illness associated with certain foods. The Agency will issue further guidance either as an interim interpretation before issuance of the 1999 Food Code or as part of that Code.

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.***

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.

The addition to the Food Code regarding apple cider and juice is based on the epidemiology implicating unpasteurized apple juice in serious foodborne illness. The new provision recognizes that highly susceptible populations may safely consume pasteurized cider/apple juice or commercially sterile shelf-stable product obtained in a hermetically sealed container. Juices, other than apple juice or those containing apple juice, are not being included at this time since the epidemiology is less compelling and the Agency does not yet have benefit of public comment.

FDA is not proposing a regulatory requirement against the on-site juicing of fruits and vegetables at this time (even for a highly susceptible population) since juicing is typically done for an individual serving or in a very small batch for immediate service at mealtime or supplemental feeding time, rather than pooled and held in large volume. We have no information that current on-site mealtime juicing practices have resulted in illness, and these practices probably carry less risk than other typical institutional food service practices.

The principal foodborne illness agents of concern with respect to unpasteurized apple juice are ***Cryptosporidium***, ***Escherichia coli*** O157:H7, and ***Salmonella***.

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.

Cast iron is an alloy of iron and heavy metals which may leach into food if left in contact with acidic foods for extended periods of time. Heavy metal poisoning has resulted from such situations. The temporary or incidental contact that results from using cast iron as a cooking surface and for dispensing utensils used as part of an uninterrupted, short-term process is acceptable because of the brief contact time involved.

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.

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 ± 1.5°C requirement is more stringent than the 3°F previously required since ± 1.5°C is equivalent to ± 2.7°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°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.

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.

4-204.118 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.

Also refer 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.

Also refer 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.

Also refer 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.

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.**

When the weight of the equipment exceeds 14 kg (30 pounds), it is no longer considered by Code definition to be easily movable.

Consequently, 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.

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 75°C (170°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.

If the temperature of the hot water delivered to the warewasher manifold is inadequate to effect sanitization, surviving pathogenic organisms could contaminate equipment and utensils.

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.

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.

Also refer 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.

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.

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.***

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.

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.

5-103.13 Hot Water.

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.

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 Lavatory, Water Temperature and Flow.

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. 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 Lavatory.*

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient lavatories 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.*

This section is reserved.

The text of this section was deleted in response to a 1996 Conference for Food Protection (CFP) Recommendation. FDA intends to further review the information that is available related to alternative methods of protecting the consumer from this potential cause of copper poisoning and to report its findings to the CFP for reconsideration of the matter.

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, for some reason, a negative pressure develops in the water line to the carbonator, some acidic water will be drawn into the water line. If this line is made of copper, carbonic acid will dissolve some of the copper. When pressure is restored, the trapped water containing dissolved copper will return to the carbonator and be mixed into the first few drinks. This may result in copper poisoning.

Location and Placement

5-204.11 Handwashing Lavatory.*

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. Lavatories which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the lavatory unavailable for regular employee use. Nothing must block the approach to a sink thereby discouraging its use, and the sink 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 Lavatory.

Lavatories must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing lavatory 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 lavatories 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 on the Premises	**5-501.10**	**Indoor Storage Area.**
	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	**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, thereby preventing 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.

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 Lavatories **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.

6-301.20 **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 Lavatories **6-401.10** **Conveniently Located.**

Lavatories 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 Lavatories**.

Handwashing lavatories are critical to food protection and must be maintained in operating order at all times so they will be used.

Also refer 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 support 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.

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.***

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.

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.

Annex

4 Food Establishment Inspection

1. INTRODUCTION
2. PROGRAM PLANNING
3. STAFF TRAINING
4. CONDUCTING THE INSPECTION
5. INSPECTION DOCUMENTATION
6. INSPECTION REPORT
7. ADMINISTRATIVE PROCEDURES BY THE STATE/LOCAL AUTHORITIES
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10. HACCP INSPECTION DATA FORM
11. FOOD ESTABLISHMENT INSPECTION REPORT
12. FDA ELECTRONIC INSPECTION SYSTEM
13. ESTABLISHMENT SCORING

1. INTRODUCTION

(A) Purpose

The ultimate 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.*

(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 Branch 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 recent 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 free FDA PRIME CONNECTION on-line data 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 insanitary public restrooms.

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 Branch 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 FDA PRIME CONNECTION 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 10 to 15 inspections, there should be agreement between the trainee and the training officer on at least 80% of the violations recorded by the training officer. 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. Six 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. FDA PRIME CONNECTION regularly includes listings 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 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 always 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. 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 55°C (130°F) is required to be held at this temperature for 120 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 measurement also takes up to several hours after the sample is placed in a sealed sample cavity. 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°C (160°F) in the spray pattern verifies that the temperature in the manifold is at least 82°C (180°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°C (160°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 therfore 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^{o}C (572^{o}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.

(B) Performance - Thermocouples and Thermistors

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) (±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 ±0.5^{o}C (±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.

(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 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 ±0.5°C (±2°F) from 0°C (32°F).

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 ±0.5°C (±2°F) from 100°C (212°F).

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^{o}C (145 - 187^{o}F) for 2 minutes. The critical limits column at this step would specify 74^{o}C (165^{o}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 § 4-501.11, 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(B) or (C), 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(B) or (C), 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. The software and documentation are available without cost through downloading from FDA PRIME CONNECTION. A complete package will be made 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) *Epi-Tracker* - A sophisticated relational database program is included to input foodborne illness complaints, track environmental samples and patient specimens, and look for similarities between previously reported complaints.

(6) *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.

(7) *Data Export* - Reports are formatted by FDA EIS for direct export as a .WK1 file, a .DBF file or as an ASCII file which can be used by a wide variety of other software packages for further 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 is incorporated with the Field System and may be kept up to date through FDA PRIME CONNECTION downloads. FDA's *Foodborne Pathogenic Microorganism and Natural Toxins Reference 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 with 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 (TQM) Method*

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**, (C) *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

			Follow-ups for highest 20% of category		
No.	**Freq.**	**%**	**No.**	**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
8	5	5	20	1	1

(2) *Fixed Categorization*

In this method, a fixed number of critical violations is 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

1. INTRODUCTION
2. HACCP PRINCIPLES
3. SUMMARY
4. ACKNOWLEDGMENTS
5. BIBLIOGRAPHY
6. OTHER SOURCES OF HACCP INFORMATION

1. INTRODUCTION

The acronym HACCP stands for Hazard Analysis and Critical Control Point, which is a prevention-based food safety system. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent risks attributable to a product or a process and then determining the necessary steps that will control the identified risks.

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 included in the system, again, to ensure that potential risks 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. HACCP is not something limited to food franchises or chains. The concept can be applied by small independents as well as national or regional companies and can be integrated into the recipes and standard operating procedures of any size establishment. 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.

As is the case with industry, mastering and applying regulatory aspects of HACCP is not limited to large state programs. Local jurisdictions can effectively promote HACCP and apply the concept during inspections. The implementation of HACCP continues to evolve and to be further refined as new products and procedures are developed and 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.

(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 ensurethat 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

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which developed HACCP principles, was established in 1988 and has as members officials from several federal agencies which include the Food and Drug Administration, the Centers for Disease Control and Prevention, the Food Safety Inspection Service, the Agricultural Research Service, the National Marine Fisheries Service, and the U.S. Army. The NACMCF also has national experts from academia, state government, consumer groups, and the food industry.

(B) Principles

The NACMCF has developed seven widely accepted HACCP principles that explain this process in great detail. To prepare an effective HACCP plan these principles must be followed. Further, a comprehensive review of a HACCP plan must include consideration of these principles. These HACCP principles are discussed below.

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 proces 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 abortis; 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
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)

[a]Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY and adapted.

(e) *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
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

[a] Adapted from Corlett (1991).
[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

(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.

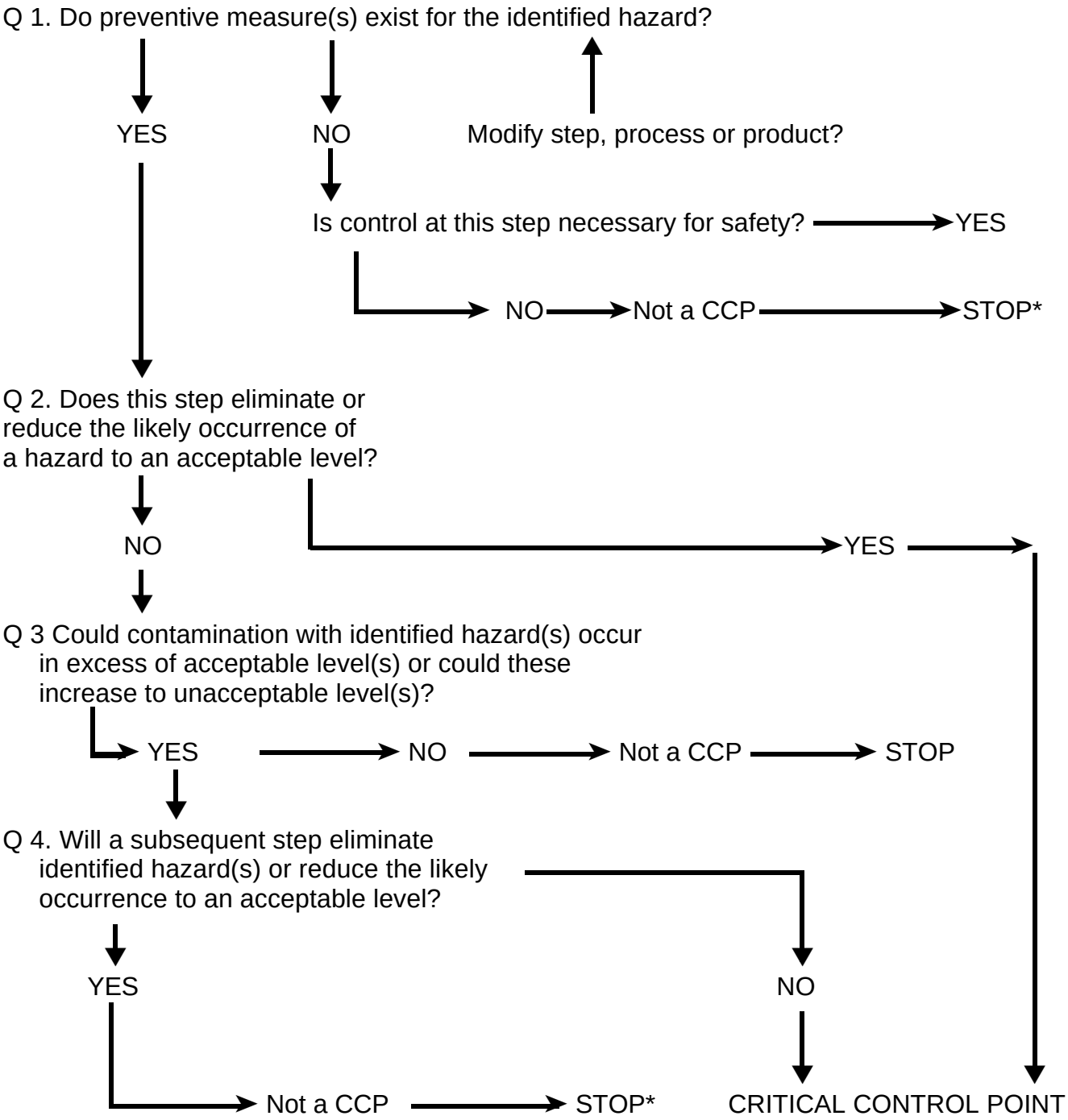
Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control 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.

Critical Control Point Decision Tree

(Apply at each step in food preparation that has an identified hazard)



*PROCEED TO NEXT STEP IN THE DESCRIBED PROCESS

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.

HACCP PRINCIPLE #6: 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.

PRINCIPLE #7: 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.

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

Much of this HACCP Annex material is adapted from National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System, adopted March 20, 1992.

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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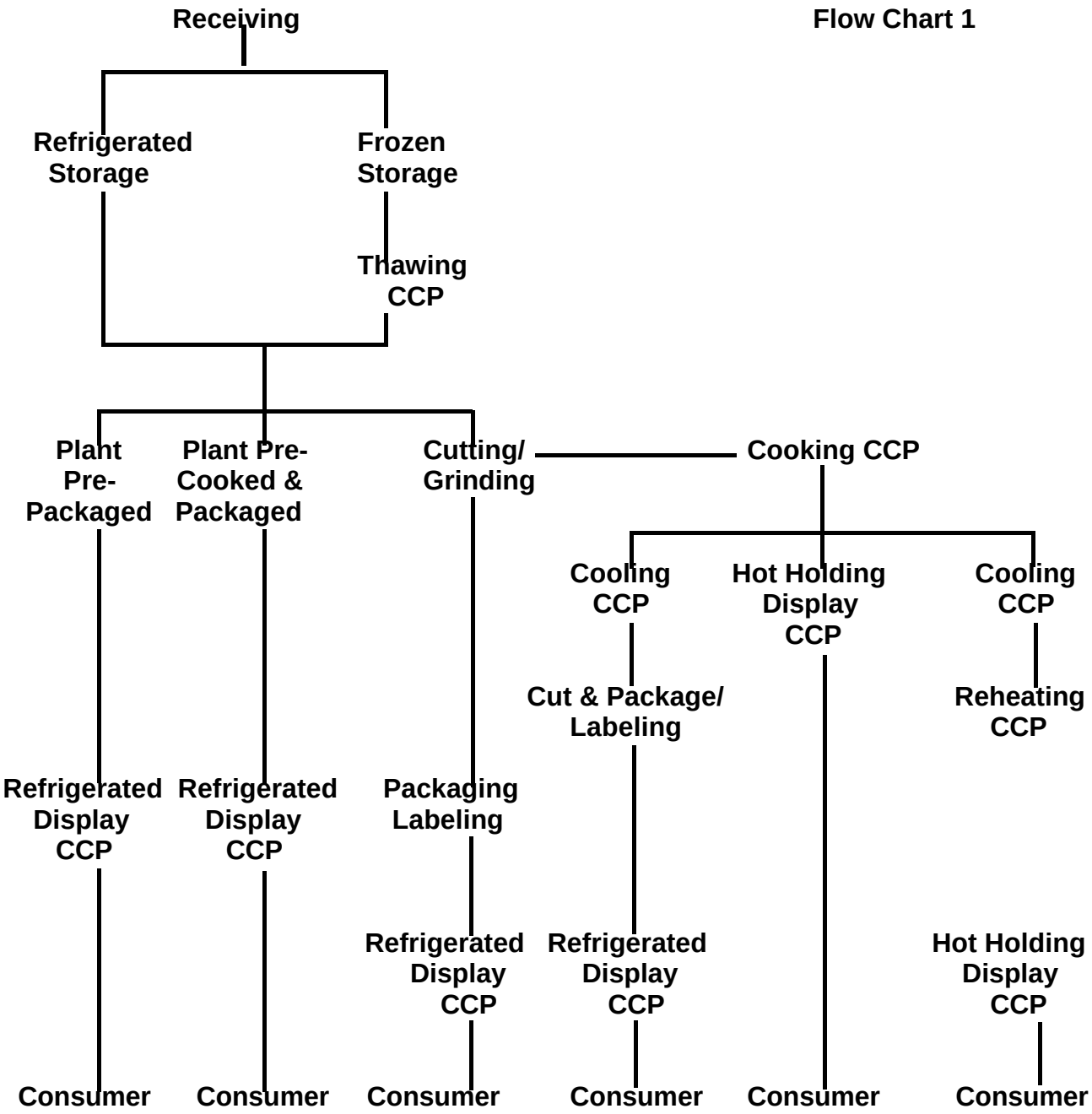
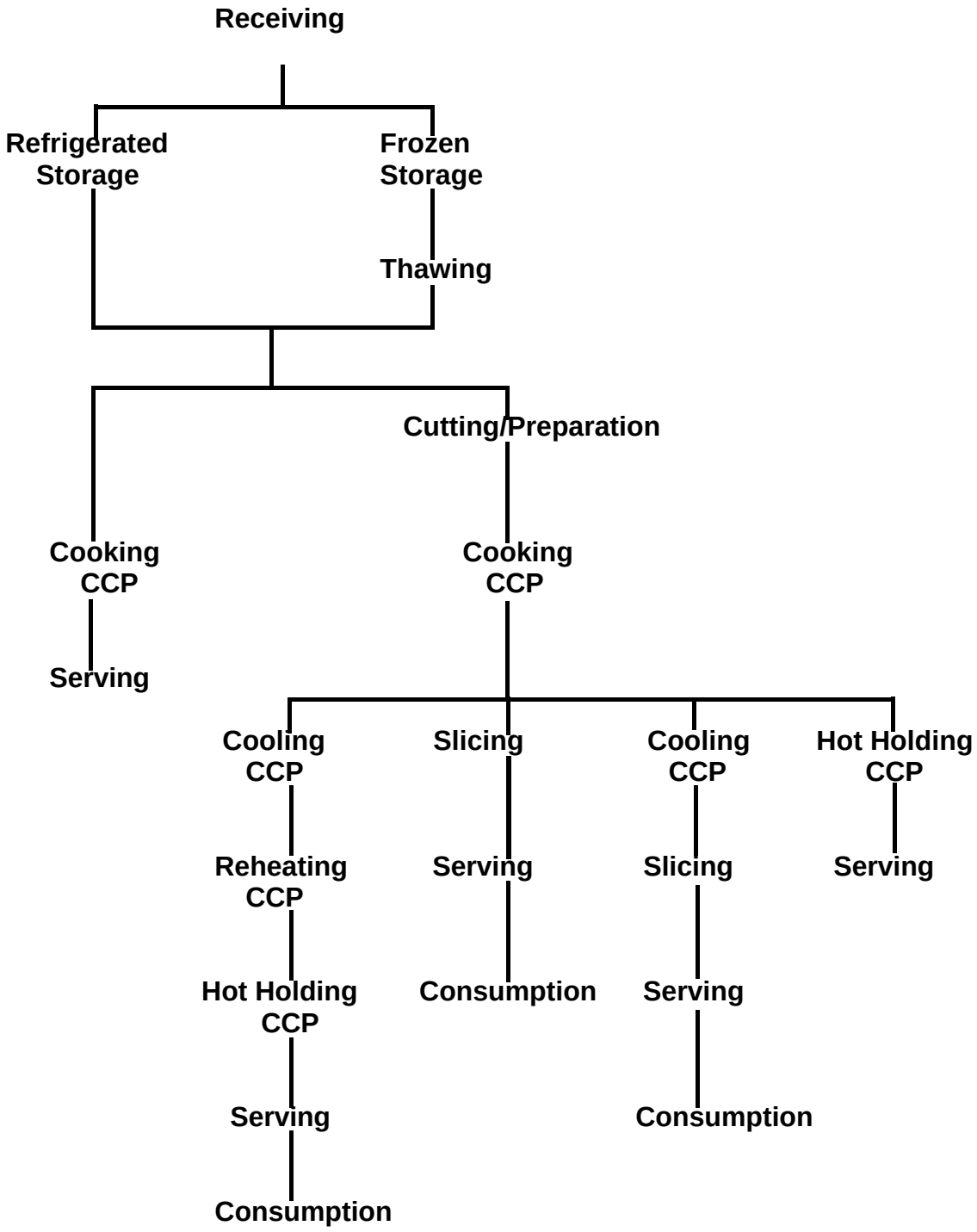
Two Typical Flow Diagrams



Flow Chart 2


Receiving
Refrigerated Storage
Frozen Storage
Thawing
Cutting/Preparation
Cooking CCP
Serving
Cooking CCP
Cooling CCP
Reheating CCP
Hot Holding CCP
Serving
Slicing
Serving
Consumption
Cooling CCP
Slicing
Serving
Hot Holding CCP
Serving
Consumption

Annex

6 Food Processing

1. INTRODUCTION
2. REDUCED OXYGEN PACKAGING
3. SMOKING AND CURING

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°-12°C (41°-53°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). A recent study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C (50°F). Another recent 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 without barriers 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,

1993 - "Sell by November 10, 1993" - 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. Form 1 APPLICANT AND FOOD EMPLOYEE INTERVIEW
2. Form 2 FOOD EMPLOYEE REPORTING AGREEMENT
3. Form 3 APPLICANT AND FOOD EMPLOYEE MEDICAL REFERRAL
4. Form 4 ADOPTION BY REFERENCE
5. Form 5 ADOPTION BY SECTION-BY-SECTION REFERENCE
6. Form 6 HACCP INSPECTION DATA
7. Form 7 FOOD ESTABLISHMENT INSPECTION REPORT
8. Guide 1 EXCLUSIONS AND RESTRICTIONS
9. Guide 2 REMOVAL OF EXCLUSIONS AND RESTRICTIONS
10. Guide 3 INSPECTIONAL GUIDE
11. List WORLDWIDE STATUS OF *SALMONELLA TYPHI*, *SHIGELLA* SPP., *ESCHERICHIA COLI* O157:H7, AND HEPATITIS A VIRUS BY GEOGRAPHICAL AREA
12. Chart 1 SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3
13. Chart 2 SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING
14. Matrix FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX
15. Summary SUMMARY OF CHANGES IN THE FDA FOOD CODE

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 1-3, Guides 1 and 2, and the List 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 4 and 5 can be used for the Code adoption process and Forms 6 and 7 are provided for use in recording HACCP information and inspectional observations. Guide 3 is a compressed outline of the Code to use as a tool in locating and citing Code provisions.

FORM 1

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., ***Escherichia coli*** O157:H7, and Hepatitis A Virus

The purpose of this form is to ensure that Applicants 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.), *Escherichia coli* O157:H7 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, *E. coli* O157:H7 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 *E. coli* O157:H7? 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, *E. coli* O157:H7 infection, or hepatitis A? YES/NO
4. Have you traveled outside the United States or to a U.S. territory within the last 50 days? 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 2

Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on illness due to ***Salmonella typhi, Shigella*** spp.***,*** ***Escherichia coli*** O157:H7, 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.), ***Escherichia coli*** **O157:H7 infection (E. 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, *E. coli* O157:H7 infection, or hepatitis A
2. A household member diagnosed with typhoid fever, shigellosis, illness due to *E. coli* O157:H7, or hepatitis A
3. A household member attending or working in a setting experiencing a confirmed outbreak of typhoid fever, shigellosis, *E. coli* O157:H7 infection, or hepatitis A
4. Travel outside the United States or to a U.S. territory within the last 50 days

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 3

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.**,** ***Escherichia coli*** O157:H7, and Hepatitis A Virus

The Food Code specifies, under ***Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition***, that Applicants 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), ***Escherichia coli*** O157:H7 (***E. coli*** O157:H7 infection), or hepatitis A virus (hepatitis A), *or*
4. Reports ***past illness*** involving ***S. typhi*** (typhoid fever), ***Shigella*** spp. (shigellosis), ***E. coli*** O157:H7, 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, ***E. coli*** O157:H7 infection, or hepatitis A.
☐ Reported past illness from typhoid fever, shigellosis, ***E. coli*** O157:H7 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., ***E. coli*** O157:H7, 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, ***E. coli*** O157:H7 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. ***E. coli*** O157:H7 **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 a person who is diagnosed with illness caused by 1 of the 4 organisms;
(3) Lives with a person who works where there is an outbreak caused by 1 of the 4 organisms; or
(4) Traveled out of the United States or to a U.S. territory in the last 50 days.

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 ***E. coli*** O157:H7 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.

FORM 4

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 1997 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, 1997 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) and (D) 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:

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.

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 5

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, 1997 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:

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.

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 6

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 7

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 1

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., ***Escherichia coli*** O157:H7, 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)-(4)	Exclude 2-201.12(C)(1)*****	Restrict 2-201.12(B)(1)
4. Asymptomatic but stools positive for ***S. typhi***, ***Shigella*** spp., or ***E. coli*** O157:H7	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 ***E. coli*** O157:H7 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)
8. Onset of jaundice more than 7 days ago	Exclude 2-201.12(D)(2)(a)	Restrict 2-201.12(D)(2)(b)

***** High-risk conditions apply only to exclusions under this Subparagraph.

GUIDE 2

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., ***Escherichia coli*** O157:H7, 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)-(4) 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 ***E. coli*** O157:H7 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 ***E. coli*** O157:H7 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)

GUIDE 3

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
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LIST

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., ***Escherichia coli** O157:H7, and Hepatitis A Virus.*

The following list of countries shows where typhoid fever, hepatitis A, and various diarrheal diseases commonly occur or are epidemic or endemic 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 1995 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.*

This list is intended to be used as a guide and rationale for the application of Subparagraph 2-201.11(D)(4) of the Code.

AFRICA

Northern Africa

☑ Typhoid | ☐ ✓ Shigellosis | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ Hepatitis A

Algeria, Egypt, Libyan Arab Jamahiriya, Morocco, and Tunisia

Sub-Saharan Africa

☑ Typhoid | ☑ Shigellosis | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ 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 | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ Hepatitis A

Botswana, Lesotho, Namibia, St. Helena, South Africa, and Swaziland.

The AMERICAS

North America

☐ Typhoid | ☐ Shigellosis | ☐ *E. coli* O157:H7 | ☐ Hepatitis A

Bermuda, Canada, Greenland, St. Pierre and Miquelon and the United States of America.

Mainland Middle America

☑ Typhoid | ☐ ✓ Shigellosis | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ Hepatitis A

Belize, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, and Panama.

Caribbean Middle America

☐ Typhoid | ☑✓ Shigellosis | ☑✓ *E. coli* O157:H7 | ☐ ✓ 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 | ☑ *E. coli* O157:H7 ✓☐ Hepatitis A

Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, and Venezuela.

Temperate South America

☑ Typhoid | ☑✓ Shigellosis | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ Hepatitis A

Argentina, Chile, Falkland Islands (Malvinas), and Uruguay.

ASIA

East Asia

☐ Typhoid | ☑✓ Shigellosis | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ 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 | ☐ ✓ *E. coli* O157:H7 | ☐ ✓ 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	☐ ✓ *E. coli* O157:H7	☐ ✓ 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	☐ ✓ *E. coli* O157:H7	☐ ✓ 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	☐ *E. coli* O157:H7	☐ 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	☐ ✓ *E. coli* O157:H7	☐ 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	☐ *E. coli* O157:H7	☐ Hepatitis A

Melanesia & Micronesia (Polynesia)

☑ Typhoid	☐ ✓ Shigellosis	☐ ✓ *E. coli* O157:H7	☐ 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.

Chart 1

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** **Fish and Meat Not Specified** in Subparagraphs 3-401.11(A)(2) and (3) and ¶ 3-304.11(B)	**63°C (145°F)**	**15 seconds**
Unpasteurized Shell Eggs not prepared for immediate service **Pork** **Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats**	**68°C (155°F)** 66°C (150°F) 63°C (145°F)	**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 2

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(C) Unsliced portions of roasts of beef cooked as specified under Subparagraph 3-401.11(A)(3)	Same oven parameters and minimum time and temperature conditions as specified under Subparagraph 3-401.11(A)(3)		Not applicable
	OR		
	Minimum time and temperature conditions listed in this chart for ¶ 3-403.11(A) or ¶ 3-403.11(B).		

Matrix

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

Summary of Changes in the FDA Food Code

This Summary provides a synopsis of the textual changes from the 1995 FDA Food Code Chapters and Annexes to the 1997 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. This record should not be relied upon as an absolute comparison that identifies each and every change.

General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the '95 Code, to use defined terms consistently and eliminate redundancies, and to standardize the Code's structural premise and its application with respect to the use of certain conventions. Those conventions include italicized language; the use of the numbering system and the words "under" and "in" for purposes of designating debitable violations; and converting to "if"-based requirements, several provisions previously written as exceptions but numbered as debitable items.

- Defined words and terms are in small capital letters throughout the Chapters and Annex 1 to highlight that they have a specific meaning within the context of the Code. Refer to the Preface, Information to Assist the Reader for a discussion of this feature.

- **Section numbers and definition numbers listed refer to the 1995 Code unless otherwise noted. Renumbering occurred in the 1997 edition, based on the changes made.**

Chapter 1:

(11)(b) deleted "formed roast beef"
(12) deleted; §6-501.115 is the only place in the Food Code where the term is used and the terminology is generally understood and does not have a meaning unique to the Code
(19) 40 CFR Part 141 more appropriately stated as 40 CFR 141
(25)(a) corrected "water activity" to "warewashing"
(26) revised "Fish" in context of Seafood Final Rule; establishes consistency with the Seafood HACCP Regulation, 21 CFR 123.3(d); the term "mollusks" includes abalone, sea snails, and land snails (e.g., escargot and other terrestrial gastropods, such as the giant African land snail Achatina fulica); the addition of examples of aquatic life and the mention of mollusks are intended to make clear which species are covered by

the term “fish”; water-dwelling reptiles and amphibians other than alligators, turtles, and frogs have not been specifically listed because they are not significant food sources in the United States; aquatic plants are excluded, consistent with the traditional treatment of these products by FDA; aquatic snakes are also excluded, consistent with their being considered game animals by FDA
(31)(b)(I) "permitted" is a defined term and is now in small caps
(33) Game animal definition revised to coincide with USDA definitions and to be consistent with ¶¶3-201.17(A) and 3-401.11(A)
(41) corrected "require" to "requires"
(60)(a)(iii) "Potentially hazardous food" definition revised ("raw shell eggs") to recognize in-shell pasteurization process; (b) last phrase now describes garlic and oil mixtures that are not acidified or modified to render the mixture not potentially hazardous
(c) (v) The term “variance” was deleted since a variance from Code requirements is unnecessary where there is evidence that a food is not potentially hazardous as defined. Reworded to discuss multiple barriers that in combination inhibit growth; change recognizes that although a food has an elevated pH or a_w, it may not be potentially hazardous as determined by lab evidence and classifying it as a food that is not potentially hazardous does not entail a variance
(c)(vi) added to capture the fact that food that is not potentially hazardous does not mean the food is free of pathogens
(61) "Poultry" definition revised for consistency internally and with USDA definition.
(62) “Premises” (b) The word “organization” was replaced with the word “operation” because the former seemed inappropriate for referring to the broad types of facilities that are listed as examples
"USDA" Definition added

Chapter 2:

2-102.11 amended: the opening portion (CFP 96-02-04); (C) (CFP 96-02-01); and (M)
2-103.11(H) (CFP 96-01-07) added term "ready-to-eat" for clarification of intent
2-201.11(D) (CFP 96-01-21) addressed “U.S.” and its territories, separately and included reference to the CDC document used as the basis for Annex 7 guidance regarding travel out of the country. Deleted "illness" and "infection" after "hepatitis A virus" because the organism, not the illness is being discussed; subparagraph (D)(1)(c) changed "carrier" to "shedder"; language in D(4) and Form 1 made consistent
2-201.12(B) references (D) and in (B)(2) added ***Shigella*** spp. or ***E. coli*** O157:H7 to the end of the sentence so that no known asymptomatic shedders may work unrestricted in a food establishment (CFP 96-03-19)
2-201.13 (A)(2)(b) deleted (CFP 96-03-19) (A)(1) and (2) merged into (A) so that reinstatement of a person excluded due to a diagnosis involves the same medical clearance regardless of whether or not the person works in a facility serving a highly susceptible population

2-201.13 (B) and (C) added Crohn's disease as possible reason for symptom of foodborne illness that actually results from a noninfectious condition
2-201.13 (B)(2) added ***Shigella*** spp., or ***E. coli*** O157:H7 to the end of the sentence to be consistent with change to 2-201.12(B)(2) - i.e., for reinstatement from restriction of an asymptomatic shedder, the stools must be free of whichever is the infectious agent of concern
2-201.13 (C) and (D) revised to set the same standard for reinstatement for exclusion due to diagnosis, jaundice, and symptom plus a high-risk condition
2-201.15 "hepatitis A virus infection" → "hepatitis A virus"
2-301.13 deleted but reserved (FDA response regarding CFP 96-03-08)
2-301.14 (F) moved to the opening statement; (C) cross references 2-403.11(B) and specifically mentions handling of aquatic animals (CFP 96-01-27)
2-301.16 (A) revised in accordance with OTC Drug and Food Additive requirements to provide specific information regarding hand sanitizers
2-304.11 changed (CFP 96-01-41/42)
2-403.11 (B) changed (CFP 96-01-27)

Chapter 3:

Note: Adjustments were made throughout Chapter 3 to accommodate the allowance for storage of potentially hazardous food at 45 F under certain conditions.

3-201.14 changed (CFP 96-03-37) (see also 8-201.13)
3-201.17 (A) recognizes USDA's Inspection Programs for Exotic Animals and for Rabbits; (B) prohibits use of a game animal that is on the list of endangered species for human food
3-202.11 used "such as" to list examples of foods that are not required to be 41 F upon receipt; changed to reflect existing temperatures in PMO for milk (45 F), NSSP Manual for molluscan shellfish (45 F ambient for shellstock and 45 F internal food temperature for shucked shellfish), and shell eggs; (C) changed to reflect addition of 3-401.16; added a ¶(D) to address maintaining frozen food frozen during shipment and upon receipt
3-202.12 added a reference to USDA 9 CFR as it applies to citric acid in cured pork
3-202.14/.15 combined these two provisions since they require pasteurization of certain foods; changed tagline
3-202.18 & .19 restructured and added language to be consistent with recently published 21 CFR 1240.60, Molluscan Shellfish
3-203.12 added new language requiring that tags be kept on the original shellstock container, unless the shellstock are removed and identified as provided in 2-203.12(B). Makes the shellstock tagging requirements consistent with the intent of the NSSP Manual, Part II, which requires that shellstock tags bear a statement that the tag will be attached to the container until empty
3-301.11 changed (FDA response to CFP 96-03-16)
3-302.11 (A)(4) "covered containers, or wrappings"; subparagraph (B)(5) added to recognize that shellstock are not required to be covered

3-302.13 "raw shell eggs" added to acknowledge the use of in-shell pasteurization process; "noncommercial mayonnaise" "mayonnaise" to eliminate ambiguity; ¶ (B) moved to new 3-801.11
3-304 Subpart name changed to reflect insertion of a new 3-304.13
3-304.11(B) cross reference changed to the appropriately debited provision
3-304.13 added a new .13 to insert linens and napkins use limitation portion of 4-101.16
3-304.14 combined two sections on use limitations on gloves into this one section; §3-304.14 addressed the use limitations for single-use gloves, but §4-502.15 addressed the use limitations for slash-resistant gloves; §4-502.15 deleted and the wording moved to ¶¶3-304.14(B) and (C); ¶(D) limitations regarding the use of cloth gloves moved here from ¶4-101.16 (C)
3-304.16(B) cross reference made specific to ¶4-603.17(B)
3-306.15 relocated to §3-801.11
Part 3-3 created a new Subpart 3-307 to provide an "other" category to capture sources of contamination not specifically delineated in 3-301 through 306
3-401.11 restructured and reworded; merged cooking and oven parameter charts into text; made changes to specifically address time/temperature for ratites; clarified the cooking temperature requirement for game animals commercially raised for food and identified these animals as needing the same microbial inactivation as other similar meats and fish; since an in-shell pasteurization process exists, specific reference to raw shell eggs emphasizes the applicability of the requirement to raw eggs only
3-401.11(A)(2) changed to "or the temperature ... that corresponds to the holding time"
3-401.11(A)(3) vs ¶3-401.11(C)

Combined the two sections; relocated the beef cooking temperatures from ¶(C) to Subparagraph (A)(3) to provide better continuity for the raw animal food cooking temperature requirements and located all cooking parameters within Subparagraph (A)(1)

3-401.11(B)(2)(b) "that shows" "showing"
3-401.11(C)(1) changed (CFP 96-01-11)
3-401.12 changed and corrected "cooking" to "holding" time (CFP 96-03-24)
3-401.13 chart (now merged into 3-401.11) modified for clarity to properly convey the research report upon which it is based (ABC Research May 2, 1979 "Fate of ***Salmonella*** inoculated into beef for cooking").

- "Less than or equal to 4.5 kg (10 lbs)" changed to "*Less than 4.5 kg (10 lbs)"*
- "Greater than 4.5 kg (10 lbs)" reads "*4.5 kg (10 lbs) or more"*
- The temperature specified for convection oven cooking of roasts weighing 4.5 kg or more changed from 163 C to 121 C
- Conveys that the temperatures specified for Still Dry and Convection ovens mean that a roast may be cooked safely at **a temperature as low as** those specified (i.e., a minimum)
- The temperatures specified for High Humidity cooking mean the **temperature specified or a lesser temperature** that will deliver the cook/ hold time and temperature

- Corrected the oven temperature requirement for >10 lbs in a convection oven

3-401.15 (3-401.12 in the '97 Code) addressed microwave industry's information/ concerns by specifying 165 F throughout the food

3-401.13 a new section ("Plant Foods") added to address the proper cooking of vegetables & fruits for hot holding; Part 3-4 previously addressed cooking only as it applied to raw animal-derived foods

3-402.11 & .12 changed (CFP 96-01-11)

3-402.11 updated to reflect Seafood HACCP rule which recognizes certain species of tuna do not need to be frozen to prevent parasitic infection if ingested in raw state

3-403.11 (B) changed to read: "... food reheated in a microwave oven for hot holding ..."

3-403.11 changed ¶(D) to only require the rapid (2 Hour) reheat between the required refrigeration temperature and 165 F

3-403.12 §3-403.10

3-501.12 - .14 updated to recognize existing equipment per revised ¶3-501.16 (C) (CFP 96-03-21)

3-501.14(D) added to specify that shell eggs placed upon receipt in a refrigerated unit that is capable of maintaining food at the required temperature constitutes satisfactory compliance

3-501.16 (C) **& .18** (A) revised cold holding provisions relating to existing equipment but did not include a consume-by date for the food which was part of the proposed language (CFP 96-03-21 and AFDO); ¶(A) cross references the allowance in ¶3-403.11(E) for reheating roasts using the roast cooking chart

3-501.17 and .18 revised and restructured to: clarify when date marking is to be done; address the use of foods that require date marking and that are frozen at some point in between preparation and the number of days at which they must be consumed; indicate the number of days allowed at 41 F and 45 F; and specify the situations under which marked or unmarked food is to be discarded

3-501.19 (A) revised for clarity; (B) revised to read "... cooked and served, served if ready-to-eat, or discarded." Changed to add clarification to the methods of marking and disposition of the food at the end of 4 hours

3-502.11 modified to include adding components (in addition to "food additives") for either food preservation or as a means of making a food not potentially hazardous; clarified that variance applies to ROP foods where a ***C. bot***. barrier in addition to refrigeration exists

3-502.12 (A)(2)(c) revised to recognize alternatives for curing meat and poultry in USDA CFR

3-601.11 updated to encompass all standards of identity

3-602.11 expanded for clarity and to provide more detailed information regarding labeling requirements

3-602.11 and 3-602.12 rewritten so that certain findings will not rationally be judged as violating either or both of these sections

3-603.11 Inserted page explaining current status of consumer advisory

3-801.11 created new part, subpart, section to combine food restrictions for highly susceptible populations in one provision; added requirement for the use of

pasteurized (or commercially sterile, shelf-stable) apple cider, apple juice, and other beverages containing apple juice; requires substituting pasteurized eggs for "raw shell eggs" to recognize in-shell pasteurization process; ¶(D) refers to "raw-marinated" fish (CFP 96-01-11)

Chapter 4:

Note: Adjustments were made in Chapter 4 to accommodate the allowance for storage of potentially hazardous food at 45 F under certain conditions.

4-101.13 "lead" included in the tagline; 1.1 was not addressed in the 1995 Code (chart revised)
4-101.14 added a ¶(B) regarding brewing alcoholic beverages to address the level of copper that is toxic to yeast versus the level of copper that is toxic to humans
4-101.15 redrafted the provision in conformance with Agency policy
4-101.16 (A) and (B) moved to new 3-304.13; (C) moved to ¶3-304.14(D)
4-101.17 changed tagline and provision to address pewter alloys (CFP 96-01-46) Lead is excluded from modern pewter. ASTM B 560-79 standard is the basis for the cited lead level
4.101.18 added the word "lead" in the tagline
Subpart 4-101 added 4-101.110 to address the use of perfluorocarbon resin which is used to provide a "nonstick finish" or "nonstick coating"; it is a noncorrosive plastic material that has been approved for food-contact surfaces since 1960; it has been determined that even the flakes cause no health hazard if ingested; the maintenance of the surfaces is covered under ¶4-502.11(A)
4-202.11(E)(3) changed to keep the Code consistent with recent NSF Joint Committee deliberations and decisions about what constitutes easy disassembly, i.e., NSF definition of "simple tools" = handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.
4-203.11 & .12 changed accuracy for the use range (CFP 96-01-47)
4-203.13 addressed the accuracy of the warewashing machine flow pressure measuring device, i.e., plus or minus 14 kilopascals (2 psi). Flow pressure is a very important factor in sanitization efficacy as recognized in NSF Standard #3, Section 5.1.12.2.
4-204.112 expanded ¶(E) to address temperature measuring devices (TMDs) for warewashers, the use range, and to be consistent with NSF Standard #3, 5.1.7.2.
4-204.117 added requirement for low sanitizer alarm (portion of CFP 96-03-33)
4-204.118

- added a requirement for a pressure measuring device such as a gauge or electronic transducer
- eliminated the requirement for a 1/4 inch IPS valve except where the pressure measuring device is installed on the line pressure side of the solenoid valve (see NSF #3, 5.1.12.2)

4-205.10 added new subpart and section to address equipment that is certified or classified by ANSI-accredited certifying organizations (CFP 92-01-02/94-01-03)

4-301.12 (D)(2)(d) added to address hot water sanitization in a 2-compartment sink
4-401.11 deleted one inappropriate cross reference
4-501.110 (A)(1) use of “single tank” redundant and deleted; see NSF #3; order rearranged to keep similar types of machines together
4-501.112 restructured and clarified to alleviate misinterpretation regarding the intent of the maximum temperature component (90 C/194 F) of this provision; it does not apply to wand-type hand-held high pressure (high temperature) now widely used for cleaning/sanitizing equipment such as meat saws, etc. In (A), “single tank” was redundant and was deleted; see NSF Standard #3, Table one
4-501.113 changed to "immediately downstream or" to be consistent with §4-204.117
4-501.114 (C)(3) changed to a maximum of 500 ppm hardness or not to exceed the hardness level specified by the manufacturer
4-502.11 (A) changed to address repair of water and ambient TMDs (Food TMDs are included under the definition of "utensil") and Pressure Measuring Devices
4-502.13 included interpretation in the Code regarding dispensing tube on bulk milk machines; cut on diagonal leaving no longer than one inch protruding from chilled dispensing head
4-502.15 deleted entire section; combined with §3-304.14
4-602.11 expanded to address cleaning of equipment such as reach-in refrigerators, surfaces contacting food that is not potentially hazardous, and food storage equipment used for food that is not potentially hazardous, e.g., iced tea and soft drink dispensers and coffee bean grinders
4-701.11 changed 4-701.10 and added an asterisk to §4-702.11
4-703.11 (C) recognized 7 seconds contact time for chlorine solution of 50 mg/L based on NSF study (CFP Executive Board discussion re FDA response to CFP 96-03-33)

Chapter 5:

5-102.12(A) reworded for clarity
5-202.14 corrected "Engineers" to "Engineering"
5-203.12 revised for clarity and to accommodate local plumbing provisions regarding the substitution of urinals for toilets
5-203.15 deleted but reserved (CFP 96-03-01)
5-302.16 changed (CFP 96-03-41)
5-303.12 "equipment" "cover"
5-402.11 → 5-402.10 and "sized" changed to "designed"
5-501.13 and .15 "equipment" "waste handling unit"
5-501.18 "equipment" "implement" and "waste handling unit"
5-501.19 "equipment" "waste handling unit" and "public health HAZARD or nuisance"
5-501.110 "equipment" "waste handling unit"
5-501.113/ .114/ .116 "equipment" "waste handling unit"

Chapter 6:

6-201.11 added cross reference to §6-201.14
6-201.14(A) added to the end of the sentence: "... or other areas where the floor is subject to moisture, flushing, or spray cleaning methods"; ¶(B), specified what "other areas" means in context of ¶(A)
6-201.18 cross reference replaced with "(areas) subject to moisture"
6-202.12 "food preparation surfaces" → "FOOD-CONTACT SURFACES"
6-202.13 (A)&(B) Electrocution Devices rewritten to clarify that the electronic device in ¶(A) is the same type as the electronic device in ¶(B)
6-202.15 rewritten because it could be interpreted in different ways; rewritten and restructured for clarity and to address in the context of food courts in malls, cafeterias in office buildings, and airport food establishments
6-301.11(B) deleted (CFP 96-03-08)
6-301.11 & .12 changed for consistency “have available” versus “be provided with”
6-303.11 ¶(B) addressed lighting in a reach-in refrigerator, under-counter refrigerators and consumer self-service areas, and clarified the point at which the measurement of intensity is appropriate for determining compliance
6-405.10 "equipment" "waste handling units" and tagline changed
6-5 subpart name changed
6-501.14 "public health HAZARD or nuisance"
6-501.111(B)(3) changed “extermination” to “other means of pest control” and revised to eliminate repetition of definition of “premises” in 1995 edition in Subparagraphs (A)(1) and (2)
6-501.113 "equipment" "tools"/ "items" and ¶(B) reworded

Chapter 7:

7-201.11 and 7-301.11 "may not" "can not"
7-207.12 day care centers want them on top shelf so children cannot reach them. ¶(B) amended to reflect APHA Guidelines that state "inaccessible to children" and the word "employees'" deleted since medicines may also belong to children in a day care setting
7-206.11 revised to accurately reference the CFR
7-209.11 added related cross references

Chapter 8:

8-101.10 (B)(4) added cross reference to new ¶ 8-304.11(H) the effect of which is to require a documented agreement of the permit holder to upgrade or replace existing refrigeration equipment as specified under ¶ 3-501.16(C) within 5 years of Code adoption unless one of the reasons for upgrading or replacing the unit specified under ¶8-304.11(G) occurs first
8-102.10, 8-103.10, and 8-103.11 "public health HAZARD (or/and) nuisance"

8-201.13 (A)(2) deleted reference to Subparagraph 3-201.14(A)(2)(b) since variance provision regarding recreationally caught fish is replaced with approval by the Regulatory Authority (CFP 96-03-37)
8-304.11 (G) "public health HAZARD"→"public health HAZARD or nuisance"; Added a new (H) which makes the permit holder responsible for upgrading or replacing existing refrigeration equipment as specified under ¶3-501.16(C) within 5 years of Code adoption unless one of the reasons for upgrading or replacing the unit specified under ¶8-304.11(G) occurs first; ¶¶(H), (I), & (J) relettered to (I), (J), and (K)
8-401.10 changed the tag line from "Establishing" to "Establishing Inspection Interval"

Annex 1:
8-803.10 (A) broken into (1) - (4), updated in accordance with Seafood HACCP rules, 21 CFR 1240.60(d), and annotated to show this addition as the basis for Code provisions related to potential seizure of untagged, unlabeled, mistagged, or mislabeled molluscan shellfish
Annex 2:
Definition of Adulteration as amended in 1996 included (CFP 96-01-12)
References - updated and corrected as appropriate
Annex 3:
Changed title of Annex to include Administrative Guidance
Reasons updated to correlate to the changes in Code provisions
Annexes 4 & 5:
Minor changes; term "risk assessment" modified in several places
Annex 6:
Minor changes for clarification and to coincide with changes in Chapter 3 with respect to when reduced oxygen packaging requires a variance and alternatives in the CFR administered by USDA for curing meat and poultry products
Annex 7:
Forms and Guides updated to reflect changes in Chapter 2
Inspectional Guide updated to show changes in Code provision structure and titles
Summary Charts for cooking and reheating times and temperatures added
Matrix for mobile units added (CFP 94-01-01(A))
Final version of this Summary provided

Initials:
AFDO = Association of Food and Drug Officials
APHA = American Public Health Association
ASTM = American Society of Testing Materials
CDC = Centers for Disease Control and Prevention
CFP = Conference for Food Protection
CFR = Code of Federal Regulations
HACCP = Hazard Analysis Critical Control Point
NSF = NSF International
NSSP = National Shellfish Sanitation Program
OTC = Over the Counter
PMO = Pasteurized Milk Ordinance
ROP = Reduced Oxygen Packaging

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