

3 *Public Health Reasons/ Administrative Guidelines*

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Chapter 1 Purpose and Definitions

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(B)(1) Accredited Program.

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an accrediting agency based upon the certifying organization's meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of*

Food Protection Manager Certification Programs available from the Conference for Food Protection, 1085 Denio Avenue, Gilroy, CA 95020-9206. Also included are the **National Commission for Certifying Agencies' Standards for Accreditation of National Certification Organizations** available through the National Organization for Competency Assurance, 1200 19th Street, NW, Suite 300, Washington, DC 20036-2422.

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Chapter 2 Management and Personnel

Responsibility 2-101.11 Assignment.*

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

Knowledge 2-102.11 Demonstration.*

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since it requires no bare hand contact with ready-to-eat food.

Status of "Universal Acceptance" of Food Protection Manager Certificates

Presently there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups and "third-party" organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others - especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary significantly in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

Needed is a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration.

Considerable progress has been made by the Conference for Food Protection toward providing the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. The Conference is simultaneously working on two separate aspects of the program accreditation process.

The first aspect addresses the important matter of ensuring that examinations are reliable, valid, and legally defensible. The Conference has developed a process for the independent evaluation and recognition of food protection manager certification examinations that meet the standards for test development and test administration. Information regarding this CFP Food Protection Manager Certification Examination recognition process can be obtained by accessing the Conference for Food Protection web site at <http://www.foodprotect.org>.

The second aspect addresses the equally important organizational and operational policies and procedures of a certification program that help ensure honesty and fairness for all stakeholders and protect against conflict of interests. The Conference is working closely with national organizations that have considerable experience with the accreditation of certification programs, and is endeavoring to develop a comparable process for evaluating these aspects of a certification program. It is anticipated that this comparable accreditation process will be submitted for deliberation at the 2002 Conference meeting.

Furthermore, an applicant to whom an employment offer is conditionally made or a food employee who meets the Code conditions that require restriction from certain duties or exclusion must be accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not pose an undue hardship and that will prevent the transmission of the disease(s) of concern through food, such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be made. It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in the References Annex that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease which can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness.

Applicants, to whom a conditional offer of employment is extended, and food employees are required to report specific high-risk conditions, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, the Centers for Disease Control and Prevention (CDC) published in the Federal Register on September 27, 2000, (Volume 65, Number 188) a list of infectious and communicable diseases that are transmitted through food. CDC updates the list annually. The list is divided into two parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle food.

The Lists below summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below. The Lists below include all Shiga toxin-producing *E. coli* likely to occur in foods in the United States.

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

	D	F	V	J	S
1. Caliciviruses (Norwalk and Norwalk-like viruses)	D	F	V		
2. Hepatitis A virus	-	F	-	J	-
3. <i>Salmonella</i> Typhi	-	F	-	-	-
4. <i>Shigella</i> species	D	F	V	-	-
5. <i>Staphylococcus aureus</i>	D	-	V	-	-

6. *Streptococcus pyogenes*

- F - - S

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

	D	F	V	J	S
1. <i>Campylobacter jejuni</i>	D	F	V	-	-
2. <i>Cryptosporidium parvum</i>	D	-	-	-	-
3. <i>Entamoeba histolytica</i>	D	F	-	-	-
4. Enterohemorrhagic <i>Escherichia coli</i>	D	-	-	-	-
5. Enterotoxigenic <i>Escherichia coli</i>	D	-	V	-	-
6. <i>Giardia lamblia</i>	D	-	-	-	-
7. Non-typhoidal <i>Salmonella</i>	D	F	V	-	-
8. <i>Taenia solium</i>	-	-	-	-	-
9. <i>Vibrio cholerae</i> 01	D	-	V	-	-
10. <i>Yersinia enterocolitica</i>	D	F	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever
 F = Fever J = Jaundice

The Food Code definition of Shiga toxin-producing *Escherichia coli* (STEC) covers all STEC identified in clinical laboratories by O157 and H7 serological tests, or by Shiga toxin tests.

The definition includes all STEC, including those that are not specifically implicated in hemorrhagic colitis (i.e., bloody diarrhea). Only a subset of STEC (>100 STEC strains cause the vast majority of human STEC diarrhea) are traditionally classified as “enterohemorrhagic”, and those serotypes that are considered “enterohemorrhagic”, including *E. coli* O157:H7, do not actually cause a hemorrhagic form of colitis in a substantial percentage of cases. Virtually all O157:H7 strains produce Shiga toxin, so are pathogens. Many O157:NM or O157:H- also produce Shiga toxin, but some don't, so testing for shiga toxin is needed to be sure that they are STEC.

The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. An employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The high-risk conditions that require reporting are designed to be used with the symptoms listed to identify employees who may be suffering from an illness due to the following pathogens: *Salmonella* Typhi, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, and hepatitis A virus. The specific conditions requiring reporting were identified by CDC as significant contributing factors to the incidence of foodborne illness.

The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and the severity of the medical consequences to those who become ill.

The following information, taken from Control of Communicable Diseases Manual, is provided regarding the period of communicability for the four pathogens of concern and the application of that information to employees likely to be shedding certain pathogens:

Salmonella Typhi – As long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter (commonly 1-2 weeks for paratyphoid). About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers; considerable fewer persons affected with paratyphoid organisms may become permanent gallbladder carriers.

Shigella spp. – During acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer. Appropriate antimicrobial treatment usually reduces duration of carriage to a few days.

Shiga toxin-producing serotypes of *Escherichia coli*, including *E. coli* O157:H7 – The duration of excretion of the pathogen, which is typically for a week or less in adults but 3 weeks in one third of children. Prolonged carriage is uncommon.

Hepatitis A – Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice, although prolonged viral excretion (up to 6 months) has been documented in infants born prematurely. The infectious agent is found in feces, reaching peak levels the week or two before onset of symptoms, and diminishing rapidly after liver dysfunction or symptoms appear, which is concurrent with the appearance of circulating antibodies to HAV.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing *Staphylococcus aureus* into food.

If an employee has an infected cut and bandages it, plus puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

2-201.12

Exclusions and Restrictions.*

Restriction or exclusion of food employees suffering from a disease or medical symptom listed in the Code is necessary due to the increased risk that the food being prepared will be contaminated with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or medical conditions listed may be suffering from a disease transmissible through food.

Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe disease) of *Salmonella* Typhi, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, and hepatitis A virus, a food employee diagnosed with an active case of illness caused by any of these four pathogens must be excluded from food establishments. The exclusion is based on the severe medical consequences to individuals infected with these organisms, i.e., hospitalization and even death.

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by *Salmonella* Enteritidis. Over 70% of the deaths attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

The Food Code does not require restriction of a food employee with an unprotected, uninfected cut, or a food employee with a covered, protected infected cut/lesion/boil since it requires no bare hand contact with ready-to-eat food.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or exclusion. The employee must also suffer from one of the symptoms listed.

The use of high-risk conditions alone as the sole basis for restricting or excluding food employees is difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of the 4 organisms listed, hepatitis A presents a different twist to this rationale. Food employees who meet a high-risk condition involving hepatitis A may shed the virus before becoming symptomatic. In fact, the

infected employee could be shedding hepatitis A virus for up to a week before experiencing symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a food employee solely because of a high-risk condition involving hepatitis A is not justified.

The following summarize the rationale for not restricting or excluding an asymptomatic food employee simply because the employee meets a high-risk condition involving hepatitis A:

- 1. Because hepatitis A virus infection can occur without clinical illness (i.e., without symptoms), or because a person may shed hepatitis A virus in the stool for up to a week before becoming symptomatic, it is possible that a person unknowingly may have been exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the incubation stage. No restriction/exclusion routinely occurs under these -- presumably much more common -- circumstances.**
- 2. Even though the asymptomatic food employee may be infected with hepatitis A virus and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is unlikely if the employee practices good personal hygiene, such as washing hands after going to the bathroom.**
- 3. Exclusions from work for prolonged periods of time may involve economic hardship for the food employee excluded.**

Based on the information presented, exclusion or restriction solely on a high-risk condition would be potentially controversial and of questionable merit.

Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle employees and applicants who meet a high-risk condition involving hepatitis A on a case-by-case basis. With this approach in mind, the following criteria are offered as a guide. First, the following information should be collected and analyzed:

- 1. Clarify the type of contact the individual had with another person diagnosed with hepatitis A virus infection. Keep in mind that the closer the contact (i.e., living in the same household as the infected person), the more likely it is that a susceptible person may become infected.**
- 2. What job does the food employee perform at the food establishment, e.g., is the employee involved in food preparation?**
- 3. When did the employee begin work at the establishment?**
- 4. What level of personal hygiene does the individual exhibit? For example, does the individual adhere to the handwashing requirements specified in the Code?**

5. **Has the individual suffered from hepatitis A in the past? If the answer to this question is yes, was blood testing done? If the individual did have hepatitis A in the past, the individual is immune from re-infection.**
6. **In terms of the current high-risk condition, has the individual received immune globulin (IG)? When?**

In addition, upon being notified of the high-risk condition, the person in charge should immediately:

1. **Discuss the traditional modes of transmission of hepatitis A virus infection with the food employee involved.**
2. **Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.**
3. **Review the symptoms listed in the Code that are caused by hepatitis A infection.**
4. **Remind the employee of the employee's responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.**
5. **In light of the high infectivity of hepatitis A, ensure that the employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.**

If after consideration of all the information gathered, the person in charge feels that the employee in question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be considered.

A restricted food employee may work in an area of the food establishment where there is wrapped food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term "restricted." A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer or the same as any other member of the general public.

An excluded individual may not work as a food employee on the premises of any food establishment. In a facility that has different departments, such as a department store, school, or health care facility, the regulatory authority, in concert with other infection

control authorities, may consider allowing an excluded food employee to work in an area or department that is separate and segregated from the food preparation, service, and storage areas, and the food equipment and utensil areas, such as the soiled linen/laundry area or exterior maintenance. An excluded person may enter the food establishment as a customer or the same as any member of the general public.

2-201.13 Removal of Exclusions and Restrictions.

Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to highly susceptible populations, and the need to provide extra protection to those high-risk populations.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through laboratory analysis of their stools to have any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The duties that an asymptomatic shedder performs in a food establishment are restricted if the establishment serves a general population or, if a highly susceptible population is involved, the shedder is excluded. Several considerations factor into the need to preclude asymptomatic shedders from food establishment functions that may result in the transmission of foodborne disease.

- \$ Outbreaks of foodborne illness involving *Salmonella* Typhi have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness.
- \$ There is some epidemiological evidence of transmission of food via food employees infected with *Shigella* spp.
- \$ Healthy consumers are at risk due to a low infectious dose of *Shigella* spp.
- \$ Despite lacking epidemiological evidence of transmission of food via food employees infected with Shiga toxin-producing *Escherichia coli*, the documented ease of transmitting it from person-to-person in a day care setting, suggests a low infectious dose and the potential for the organism to be transmitted through food.
- \$ The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome (HUS), associated with Shiga toxin-producing *Escherichia coli* warrant the institution of disease interventions.
- \$ Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population.

The risk that a communicable disease will be transmitted by food employees who are asymptomatic shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases in Man."

The Code requires medical clearance, based on criteria designed to detect the shedder state, before a person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious agents is allowed to resume the duties from which that person was restricted or, in the case of an establishment that serves a highly susceptible population, before the person may return to work.

With respect to a food employee in an establishment that serves an immunocompromised population, the Code provisions are more stringent in that exclusion is required in 3 situations in which it is not required for food employees in other food establishments. Those 3 situations involve an employee who:

(A) Meets a high-risk condition specified in & 2-201.11(D) and has a symptom of acute gastrointestinal illness;

(B) Is diagnosed as an asymptomatic shedder of *S. Typhi*, *Shigella* spp. or Shiga toxin-producing *Escherichia coli*; or

(A) Had a recent illness caused by *S. Typhi*, *Shigella* spp., or Shiga toxin-producing *Escherichia coli*. The exclusion is in effect until a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, provides the medical clearance specifically outlined in ' 8-501.40 of the Code, indicating that the infectious agent is not detected.

2-201.14

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

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in this Code may transmit disease through the food being prepared. The person in charge must first be aware that an employee or prospective employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

Some of the symptoms that must be reported may be observed by the person in charge. However, food employees and applicants share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or medical diagnoses listed in the Code and food employees must comply with restrictions or exclusions imposed upon them.

2-201.15 Reporting by the Person in Charge.*

Notification of the regulatory authority by the person in charge that an employee is suffering illness caused by *Salmonella* Typhi, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness. The person in charge should be aware of the confidentiality provisions of the Americans with Disabilities Act (ADA). For information about the ADA, call 800-669-EEOC or for telecommunications device for the deaf (TDD) 800-800-3302.

Hands and Arms 2-301.11 Clean Condition.*

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.*

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to ready-to-eat food as well as other pathogens that can be transmitted via cross contamination from raw foods to ready-to-eat foods. Many employees fail to wash their hands as often as necessary and even those who do may use flawed technique.

In the case of a food worker with one hand or a hand-like prosthesis, the EEOC has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement without sacrificing public health concerns.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungual space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to

decontaminate.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface, do not survive nor multiply, and a moderate number of organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin, and are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands, and when an antimicrobial soap is used, a minimum of 15 seconds is required.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands.

Handwashing done properly can result in a 2-3 logarithmic reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e. $> 10^4$ microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13

Special Handwash Procedures.*

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15**Where to Wash.**

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing facilities are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16**Hand Sanitizers.**

This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. The prohibition against bare hand contact contained in & 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are three means by which a hand sanitizer is considered to be safe and effective when applied to human skin:

1. A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication Approved Drug Products with Therapeutic Equivalence Evaluations. Also known as the AOrange Book,@ this document provides Aproduct-specific@ listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical

Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand sanitizing products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act ' 201(g). As drugs, hand sanitizers and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more extensive FDA review process for a new drug application (NDA) is required before marketing.

However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not presently objecting to the use of Ainstant hand sanitizers@ based on ethyl alcohol or isopropyl alcohol, or certain chlorine Ahand sanitizing dips@ since these compounds are included in the OTC Drug Review. The ultimate status of these products will not be known until the final monograph publishes.

Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a specific product has been accepted and included in the proposed monograph may be obtained from the manufacturer. You may also refer to *Federal Register* (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.

Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855-2737. Specific product label/promotional information and the formulation are required for determining a product=s regulatory status.

As a Food Additive

To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the components of a hand-care product must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the components of a product are reasonably expected to become a component of food based upon the product's intended use, there are three means by which they are considered by FDA to be safe:

1. A substance may be exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles. A review by FDA's Center for Food Safety and Applied Nutrition is required for such an exemption to be issued. The Center's Indirect Additive Group has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed in the federal food additive regulations. Therefore, there is no food additive prohibition against using these substances as components of an instant hand sanitizer.
2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed thereunder with conditions of safe use. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.
3. A substance may be Generally recognized as safe (GRAS) for the intended use in contact with food within the meaning of the Federal Food, Drug, and Cosmetic Act ' 201(s). Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe. The law also provides for independent GRAS determinations.

The Indirect Additive Group does not certify or provide approvals for specific products. However, if the use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt from the requirement of a food additive listing regulation. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of hand sanitizer components as food additives may be directed to the Indirect Additive Group, HFS-215, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204.

It may be helpful or necessary to provide label/promotional information when inquiring about a specific component.

Fingernails 2-302.11 Maintenance.

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry 2-303.11 Prohibition.

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term “jewelry” generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. In the case of a food worker who wears a medical information or medical alert bracelet, the EEOC has agreed that this requirement can be met through reasonable accommodation in accordance with the Americans with Disabilities Act by the person in charge and the employee working out acceptable alternatives to the bracelet worn at the wrist. An example would be wearing the bracelet high on the arm or secured in a manner that does not pose a risk to the food but provides emergency medical information if it is needed.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing 2-304.11 Clean Condition.

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

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

Prevention

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

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

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints 2-402.11 Effectiveness.

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals 2-403.11 Handling Prohibition.*

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Chapter 3 Food

Condition 3-101.11 Safe, Unadulterated, and Honestly Presented.*
Sources 3-201.11 Compliance with Food Law.*

Refer to the public health reason for ' 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of ' 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices. At the time of publication of the 1999 Food Code, rulemaking had not been finalized regarding a mandatory Hazard Analysis Critical Control Point (HACCP) program for juice products.

Refer to Chapter 1 for the definition of juice. It is important to note that the definition of Juice includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations. Untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods must bear a warning statement as specified in 21 CFR Section 101.17(g). That statement is: **AWARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems. Additional information is available in the document, **Guidance for Industry. Warning and Notice Statement: Labeling of Juice Products, Small Entity Compliance Guide** which can be found on the FDA Web Page <http://www.cfsan.fda.gov/~dms/juicguid.html> or obtained from the FDA Office of Food Labeling.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and pre-labeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling for Raw Shell Eggs

The Food and Drug Administration is revising its food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonellae* organisms. The labeling regulation becomes effective September 4, 2001.

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

3-201.12

Food in a Hermetically Sealed Container.*

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for " 3-101.11 and 3-201.11.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

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.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Listeria monocytogenes* that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant

occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16

Wild Mushrooms.*

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Regulatory authorities have expressed their difficulty in determining what constitutes a “wild mushroom identification expert” and enforcing the Food Code provisions associated with it. In 1998, the Conference for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that was charged with determining what constitutes a wild mushroom expert. However, the committee was unable to provide this information in a practical, useful manner for State and local regulators within the constraints of the Food Code. The 2000 CFP recommended and FDA accepted the committee’s alternative solution that a brochure be developed that will provide information on what constitutes a wild mushroom expert, and to replace “identification by a wild mushroom expert” with “written buyer specifications.”

The CFP’s recommendation attempts to provide the necessary information in a practical, useful manner for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee suggested that written buyer specifications place more responsibility on the food establishment to ensure that wild mushrooms are obtained from a safe source, and also provides state and local regulators a template to use in ensuring wild mushrooms sold at retail are obtained from a safe source.

However, the recommendation for written buyer specifications will not replace Food Code paragraph 3-201.16(A) until the brochure is developed and accepted by the CFP and FDA. In the interim, the following guidance is provided regarding the identification of wild mushrooms:

A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer specification that requires identification of:

- (1) The Latin binomial name, the author of the name, and the common name of the mushroom species,**
- (2) That the mushroom was identified while in the fresh state,**
- (3) The name of the person who identified the mushroom,**
- (4) A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.**

Additional information can be found on the California Poison Control web site:
<http://www.calpoison.org/public/mushrooms.html>.

Refer also to the public health reason for " 3-101.11 and 3-201.11.

3-201.17 Game Animals.*

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the

human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving 3-202.11 Temperature.*

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2°C (45°F).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of *Staphylococcus aureus*). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.*

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

3-202.13 Shell Eggs.*

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

- (i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

- (ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.
- (iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.
- (iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).
- (v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.
- (vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

Amended federal regulations 21 CFR Part 16, Administrative practice and procedure; 21 CFR Part 101 Labeling, Nutrition, Reporting and Recordkeeping requirements; and 21 CFR Part 115 Eggs, Refrigeration issued on December 5, 2000. These regulations require that shell egg cartons bear safe handling instructions and further requires that eggs be placed under refrigeration at 45°F or lower upon delivery at retail establishments. See Federal Register: (Volume 65, Number 234), Pages 76091-76114. The labeling rule is effective September 4, 2001, and the refrigeration rule is effective June 4, 2001. This rule is one part of the larger Egg Safety Action Plan, a farm-to-table approach for ensuring the safety of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of *Salmonella* Enteritidis, illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated *Salmonella* Enteritidis illnesses by 2010.

3-202.14

Eggs and Milk Products, Pasteurized.*

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.*

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed. Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.*

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.*

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

Original Containers and Records **3-203.11 Molluscan Shellfish, Original Container.**

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

3-203.12 Shellstock, Maintaining Identification.*

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product.....	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
<u>Epidemiological investigation.....</u>	<u>10 days</u>
Total.....	90 days

In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods (NACMCF), concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers, as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers. When the FDA reviewed and analyzed epidemiological data on foodborne illness outbreaks caused by fecal-oral pathogens, 93% of the foodborne illnesses reported were caused by ill food workers preparing food. This finding illustrates the problem caused by ill food workers who continue to prepare food. This is a problem which is exacerbated by an increasing global market place, a tight labor market and lack of knowledge and understanding of food safety among food workers, and the economic need for food workers to work even when ill.

Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3-logs.

Food workers infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for *Giardia* and *Cryptosporidium* is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with hepatitis A. The infective dose for Norwalk virus is also believed to be very small.

The CDC now estimates that Norwalk-like viruses are the leading cause of foodborne illness in the United States. The CDC has also reported that hands are the most important means by which enteric viruses are transmitted. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungual space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of

ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled.

Refer to the public health reasons for " 2-301.11, 2-301.12, and 2-301.13. Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Clarification of § 3-301.11(B) of the FDA Food Code with Respect to the Phrase "*Except...when otherwise APPROVED*"...

Background:

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.¹ Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

¹Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks - United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Objective:

The objective of this guidance is to provide clarification to & 3-301.11(B) of the Food Code regarding the statement "except when otherwise approved." This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of no bare-hand contact through alternative practices and procedures. In this guidance, Ahazard@ means infected food workers spreading pathogens to food via the hands.

Guidance:

I. Requirements prerequisite to consideration of alternatives include compliance with all Food Code provisions, particularly those related to:

(A) Demonstration of Knowledge - specifically && 2-102.11(A), (B), (C), and (H);

(B) Duties of the Person in Charge - specifically & 2-103.11(D);

(C) Employee Health regarding:

(1) Reporting of diseases and medical conditions, and

(2) Exclusions and restrictions, i.e., that food employees (including applicants to whom a conditional offer of employment has been made) report their health status as specified in Section 2-201.11; ill food employees are restricted or excluded as specified in Section 2-201.12; and the exclusions and restrictions are removed as specified in Section 2-201.13;

(D) Personal Cleanliness, i.e., handwashing procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in Section 2-301.14 - including after using the toilet and between tasks that may recontaminate the hands; and

(E) Hygienic Practices as specified in Part 2-4.

II. FDA recommends that the acceptability of an alternative to no bare-hand contact should be based on evidence that at least the following are addressed:

(A) Why the operator of the food establishment is unable to comply with the Code requirement in & 3-301.11(B);

(B) How the alternative practices and procedures will control the hazard through an active managerial control program. Such a program includes monitoring and verifying the

institution of the prerequisite requirements described in Part I above and satisfies the following:

(1) The public health hazard associated with bare-hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees which emphasizes not working when ill with any of the symptoms of foodborne illness, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(C) The alternative should clearly include monitoring, documentation, and verification to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

III. Documentation of the practices, procedures, and corrective actions related to an alternative to no bare-hand contact with ready-to-eat food needs to be maintained and readily available at the food establishment at all times for use by the person-in-charge and for review by the regulatory authority.

IV. The regulatory authority should also consider industry's elective use, managerial control, and monitoring and verification of additional preventive measures used in tandem with the aforementioned interventions which could include one or more of the following:

(A) Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;

(B) Double handwashing;

(C) Use of nail brushes;

(D) Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles; and

(E) Motivation for food employees not to work when they are ill.

Preventing Food and Ingredient Contamination 3-302.11 Packaged and Unpackaged Food - Protection Separation, Packaging, and Segregation.*

Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps.

Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

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

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

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

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism *Salmonella* Enteritidis may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.*

Refer to the public health reason for ' 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document which addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The AGuide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables@ is

available from FDA's Food Safety Initiative staff and also on the Internet at <http://www.fda.gov>.

Preventing Contamination from Ice Used as a Coolant 3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

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

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens 3-304.11 Food Contact with Equipment and Utensils.*

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or

product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

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

Refer to the public health reason for ' 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 140°F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

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3-304.13 Linens and Napkins, Use Limitation.

Refer to the public health reason for ' 3-304.11.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Refer to the public health reason for ' 3-304.11.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration

should be ensured by checking the solution periodically with an appropriate chemical test kit.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for ' 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

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

Natural Latex Rubber (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NLR gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components.

FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at <http://www.cdc.gov/niosh/latexalt.html>.
- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) <http://allergy.mcg.edu/physicians/joint.html>

The AAAAI provides information on latex allergies on the web at <http://www.aaaai.org/public/fastfacts/latex.stm>

The ACAAI provides information on latex allergies on the web at <http://allergy.mcg.edu/physicians/ltxhome.html>

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) <http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412.html>

OSHA addresses gloves in the following federal regulation, which can be found at http://www.osha-slc.gov/OshStd_data/1910_0138.html:

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.
SubPart Number: I
SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

For further information on the OSHA requirements, see [59 FR 16362, April 6, 1994].

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

Refer to the public health reason for ' 3-304.11.

3-304.17 Refilling Returnables.

Refer to the public health reason for ' 3-304.11.

Preventing 3-305.11 Food Storage.
Contamination 3-305.12 Food Storage, Prohibited Areas.
from the
Premises

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 from overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

*Preventing
Contamination
by Consumers*

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.*

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Reservice or Sale.*

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources 3-307.11 Miscellaneous Sources of Contamination.

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking 3-401.11 Raw Animal Foods.*
 3-401.12 Microwave Cooking.*
 3-401.13 Plant Food Cooking for Hot Holding.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). The microbial lethality using these criteria will provide a 6.5- \log_{10} reduction of Salmonella.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This Part includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°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.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, AFor the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork and lamb, are not included.@

NACMCF comments included, ADue to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.@

As reflected in the definition of Awhole-muscle, intact beef steak,@ marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, *Trichinella spiralis*, *Toxoplasma gondii*, and *Taenia solium*, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°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 Shiga toxin-producing *Escherichia coli*. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the AReport of the Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods= (NACMCF) Review of the Meat Patty Proposal@ (undated), it is stated on page 7, in Option (A), that:

ABased on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement.@

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

- 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetable enteric pathogens;**

2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

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

3-401.12 Microwave Cooking.*

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°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: Hedderson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 60°C (140°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

Freezing

3-402.11

Parasite Destruction.*

Refer to the public health reason for ' 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw.

3-402.12

Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

Reheating

3-403.11

Reheating for Hot Holding.*

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of *Clostridium perfringens* that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of *C. perfringens* can cause foodborne illness when they grow to high numbers. Highly resistant *C. perfringens* spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by *Staphylococcus aureus*, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for ' 3-401.12.

3-404.11 Treating Juice.

Refer to public health reason for ' 3-801.11.

Temperature and Time Control 3-501.11 Frozen Food.

3-501.12 Potentially Hazardous Food, Slacking.

3-501.13 Thawing.

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

3-501.14 Cooling.*

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, potentially hazardous foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 52°C (70°F - 125°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as *Clostridium perfringens* or *Bacillus cereus* should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as *Salmonella* or *Listeria monocytogenes* may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs.

However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for *Salmonella* Enteritidis, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that *Salmonella* Enteritidis will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially hazardous food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a potentially hazardous food after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

Salmonella Enteritidis has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

Amended federal regulations 21 CFR Part 16, Administrative practice and procedure; 21 CFR Part 101 Labeling, Nutrition, Reporting and Recordkeeping requirements; and 21 CFR Part 115 Eggs, Refrigeration issued on December 5, 2000. These regulations require that shell egg cartons bear safe handling instructions and further requires that eggs be placed under refrigeration at 45°F or lower upon delivery at retail establishments. See Federal Register: (Volume 65, Number 234), Pages 76091-76114. The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. This rule is one part of the larger Egg Safety Action Plan, a farm-to-table approach for ensuring the safety of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of *Salmonella* Enteritidis illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated *Salmonella* Enteritidis illnesses by 2010.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the

overall time that eggs are stored at temperatures that allow the growth of *Salmonella* spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of *Clostridium botulinum* and *Clostridium perfringens* and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of *C. botulinum* or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of *C. botulinum* and no more than 1 log growth of *C. perfringens*. The performance standard of no more than 1 log growth of *C. perfringens* was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of *C. perfringens* per gram as one of the criteria for incriminating *C. perfringens* as a causative agent of foodborne illness in finished product. However, foods responsible for *C. perfringens* outbreaks were found usually to contain 10^6 vegetative *C. perfringens* cells per gram. In FSIS microbiological raw product surveys, samples were found to contain more than 1000 *C. perfringens* per gram. There is some probability that greater than 10^4 *C. perfringens* per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of *C. perfringens* in the raw product are spores.
2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 *C. perfringens* (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative *C. perfringens* per gram in the product if it is improperly cooled after cooking.
3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 log₁₀ growth of *C. perfringens* would

be appropriate to ensure that there would be no more than 10^5 *C. perfringens* per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of *C. perfringens* to no more than 1 \log_{10} would be reasonable and somewhat conservative with respect to product safety. (Federal Register 64: (3): 732-749)

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F_Appendix%20B.htm, is that product must be cooled from 130°F to 80°F in 1.5 hours and from 80°F to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120°F to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120°F, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120°F and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline for meat and poultry products containing 100 ppm added nitrite is 130°F to 80°F in 5 hours and from 80°F to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the performance standard for controlling the growth of *C. perfringens*, and should take corrective action. However, the presence of nitrite should ensure compliance with the performance standard for *C. botulinum*.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 140°F to 70°F in 2 hours and from 140°F to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods

(NACMCF) to review the data on safe cooling times for cooked, potentially hazardous foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130°F to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130°F to 45°F in 15 hours permitted about 1 log growth of *C. perfringens*.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of *C. botulinum*.
2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.
3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other potentially hazardous foods.

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

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

Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 5°C to 60°C (41°F to 140°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Except for raw shell eggs, control of the growth of *Listeria monocytogenes* is the basis for the list of cold holding temperature and time combinations in 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Listeria monocytogenes* in refrigerated, ready-to-eat, potentially hazardous food. The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Listeria monocytogenes*, and do not set an acceptable number of Lm in food. Neither do they imply that *Listeria monocytogenes* is in the product. However, the cold holding temperature and time combinations will be vetted through the public comment process on the *Listeria monocytogenes* Risk Assessment and Risk Management Plan, reviewed, and if necessary, amended. This public comment period is planned during 2001, after publication of the 2001 Food Code.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon *Listeria monocytogenes* begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of Lm in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41°F for 7 days and 45°F for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of Lm remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient

temperature not to exceed 7.2°C (45°F). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of **Salmonella Enteritidis** to occur. The agency reviewed research indicating that Salmonella Enteritidis multiplies at temperatures of 10°C (50°F) and above but can be inhibited at lower temperatures, e.g., 8°C (46°F), 7.2°C (45°F) and 4°C (39°F). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7.2°C (45°F) for eggs stored and displayed at retail establishments. Amended federal regulations 21 CFR Part 115, Eggs, Refrigeration issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

3-501.17	Ready-to-Eat, Potentially Hazardous Food, Date Marking.*
3-501.18	Ready-to-Eat, Potentially Hazardous Food, Disposition.*

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as *Listeria monocytogenes*, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of *Listeria monocytogenes* at 5°C (41°F) and 7°C (45°F). Based on a predictive growth curve modeling program for *Listeria monocytogenes*, ready-to-eat, potentially hazardous food may be kept at 5°C (41°F) a total of 7 days or at 7°C (45°F) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 5°C (41°F) but capable of maintaining it at 7°C (45°F) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for *Listeria monocytogenes* to multiply,

before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled "Keep Refrigerated." For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label "Keep Refrigerated." To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa and capocola.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label "Keep Refrigerated." Examples of these products are cooked bologna, cooked salami and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (not potentially hazardous) sausages, the intact casing provides a barrier to

contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7

days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS, and, if applied, would not supercede or replace date marking requirements established by the Food Code or by state/local authorities, that apply after the food is opened in a retail establishment.

Manufacturer's use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer's information as good guidance to follow to maintain the quality (taste, smell and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer's date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time Alone as a Public Health Control.*

The 2000 Conference for Food Protection (CFP) recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, Section 3-501.19. In response to the CFP recommendation, FDA, in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows potentially hazardous food (PHF) that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed. The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of *L. monocytogenes* warrants concern for potentially hazardous RTE foods. Although the FDA and USDA have a zero tolerance for *L. monocytogenes* in RTE food, conditions are permitted in the Food Code that would allow *L. monocytogenes* cells 1 log of growth (3.3 generations). *Salmonella* is also a concern especially with products containing eggs. However *L. monocytogenes* grows more rapidly than *Salmonella* at refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41°F or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of *L. monocytogenes* remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for *L. monocytogenes* in food were not found, however published values at 68°F and 70°F in egg and milk products confirmed slow *L. monocytogenes* growth at room temperatures. Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, *L. monocytogenes* would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food

products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly. Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including *Clostridium perfringens* and *Bacillus cereus*. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B. cereus* and may actually serve as a heat shock that activates the spores. *B. cereus* is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, *C. perfringens* cases are estimated to be more numerous than *B. cereus* cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both *C. perfringens* and *B. cereus* produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either *C. perfringens* or *B. cereus*. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

FDA intends to do research regarding food products that may have spores in the center of the product, and further evaluate if there are potential hazards that may be associated with them while held without temperature control for 4 hours.

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with *Salmonella* Enteritidis, that the use of time as a public health control in institutional settings is not allowed.

<i>Specialized Processing Methods</i>	3-502.11	Variance Requirement.*
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Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in Section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific

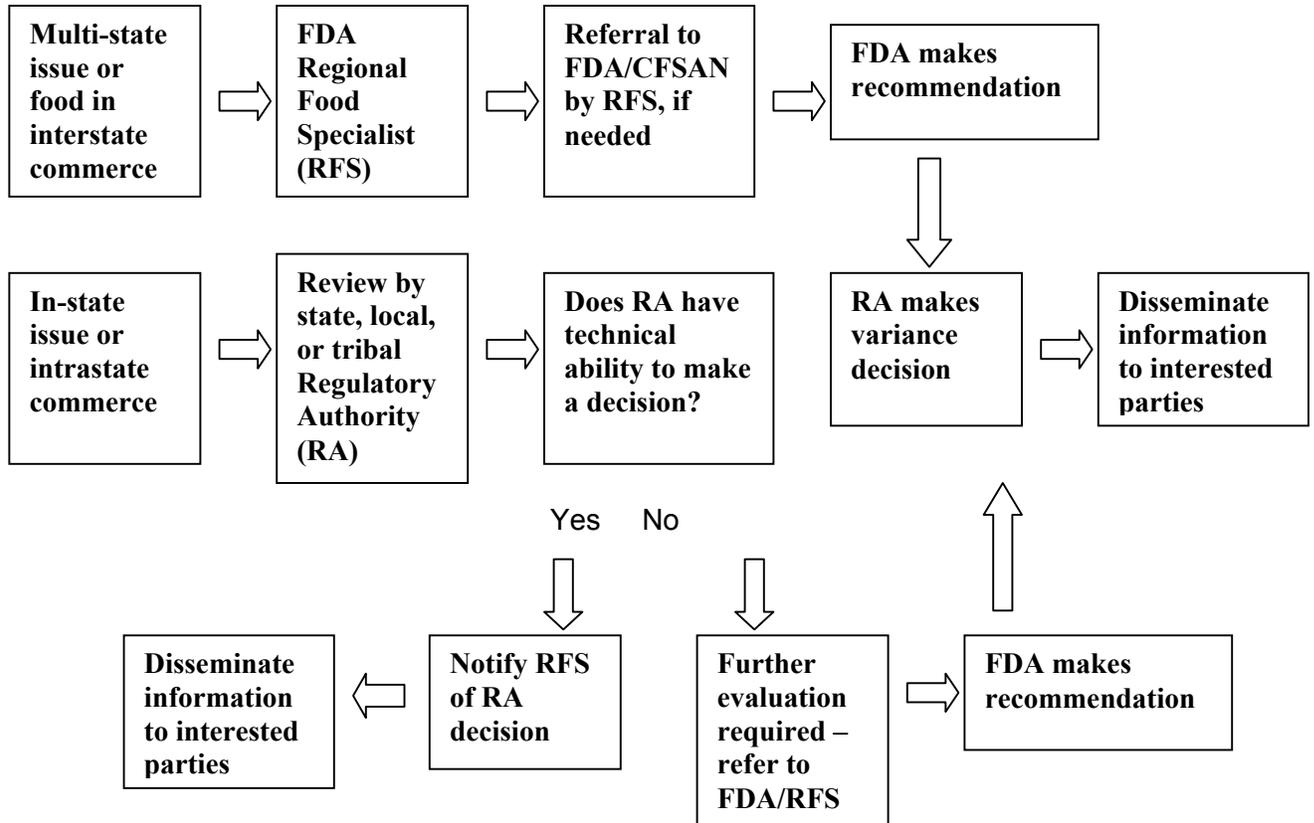
competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code Sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

- 1) Designate an agency team and assign a leader to address variance requests.
- 2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.
- 3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.
 - a) **For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the**

issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.

- b) For variances that address intrastate issues, regulators are also encouraged to determine if other state or national guidance exists, and to stay consistent with it.
- 4) Make the agency's decision. Inform the applicant.
- a) If the variance request is approved, determine the starting date, and document all special provisions with which the applicant must comply.
 - b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.
- 5) Inform other interested parties, including the FDA Regional Food Specialist.**
- a) **For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.**
 - b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.
- 6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.
- 7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.
- 8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.
- 9) Establish written procedures for withdrawing approval of the variance if it is not successful.**

3-502.12

Reduced Oxygen Packaging, Criteria.*

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when using reduced oxygen packaging (ROP) processing procedures. A reduced oxygen packaged food that has at least two barriers to the growth and toxin production of *C. botulinum* may be packaged in accordance with the provisions of a HACCP plan. The FDA recommends two barriers be used to ensure the safety of foods when *C. botulinum* is a known hazard in the final packaged form.

An ROP food that has only one barrier to the growth and toxin production of *C. botulinum* may be produced only if the food establishment obtains a variance and produces the food in accordance with the provisions of a HACCP plan. An example of a single barrier would be a food with a natural pH of 4.6 or less. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate refrigeration. Variance requests related to packaging food using reduced levels of oxygen and having only one barrier to control the growth of *C. botulinum* must be considered with particular caution and scrutiny.

This section does not apply to low acid canned foods produced under 21 CFR Part 108 (Emergency Permit Control) and 21 CFR Part 113 (Thermally Processed Low-Acid Foods) or 21 CFR Part 114 (Acidified Foods) because *C. botulinum* is not a hazard in the final packaged form.

FDA strongly recommends that garlic-in-oil mixtures that are produced in a food establishment have two barriers in place. It is not possible to acidify the oil although the crushed cloves can be acidified. An example of two effective barriers is acidification of crushed garlic cloves and refrigeration of the garlic-in-oil mixture. Acidification means a finished equilibrium pH of 4.6 or less. Garlic-in-water mixtures can be acidified and refrigerated, using a HACCP plan without the necessity of a variance.

Unfrozen raw fish is specifically excluded from ROP because of this product's natural association with *Clostridium botulinum*, Type E, which grows at or above 3°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 reflects the fact that various substances, combinations of substances, and resultant concentrations are allowed in CFR administered by USDA. The Code provision also includes the requirement for cured poultry products to meet the CFR.

Shelf life must be limited because some pathogens, including *Listeria monocytogenes*, may be a hazard at refrigeration temperatures. Fourteen days is considered a safe refrigerated shelf life (as opposed to the maximum 7 days allowed under paragraph 3-501.17(A)) because there are two barriers to growth incorporated in this section's requirements. Food that remains frozen from the time that it is packaged until the time it is prepared for service is considered adequately protected.

Accurate	3-601.11	Standards of Identity.
<i>Representation</i>	3-601.12	Honestly Presented.
<i>Labeling</i>	3-602.11	Food Labels.
	3-602.12	Other Forms of Information.

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from Shiga toxin-producing *Escherichia coli* have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in Subparagraph 3-602.11(B)(5) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than \$500,000 (or no more than \$50,000 in food sales alone), and

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

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Food Labeling by a small business with less than 100 full-time equivalent employees, or

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

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

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

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in ' 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish, and when those fish are placed into a bulk container for shipment, the bulk container must bear a label declaring the presence of canthaxanthin. That same label information must be displayed at retail when those fish are offered for sale.

The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 101.100(a)(2). For additional

establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided, as described in the insert page with ' 3-603.11 of the Code. Disclosure is achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. The reminder is a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to ' 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the

information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

A... Otherwise Processed to Eliminate Pathogens...@:

This phrase is included in ' 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by ' 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in && 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing *Vibrio vulnificus* in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, *Apasteurized to reduce Vibrio vulnificus@* or *Atemperature treated to reduce Vibrio vulnificus.@* Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not,

however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, ' 3-603.11. In the insert page for ' 3-603.11, the Reminder options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words Ameat@ rather than Abeef, lamb, and pork@ and Aseafood@ rather than Afish@ are used. Categorical terms like Ameat@ are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, Amilk@ is not mentioned in the actual on-site advisory language. The sale or service of unpasteurized milk is not allowed in interstate commerce and its consumption is not recommended by FDA. Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by ' 3-603.11 of this Code operates in conjunction with a dairy farm in a state that allows the in-state sale or service of unpasteurized milk, or in the case where a state allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to reminder, options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from *Vibrio* infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

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

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

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

Refer to the public health reason for ' 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of Juice@ includes puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of *Salmonella* Enteritidis traced to stuffed pasta made with raw eggs and labeled Fully cooked.@ Eggs remain a major source of these infections,

causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a *Salmonella* Enteritidis control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of *Salmonella* Enteritidis in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to *Salmonella* Enteritidis.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. For further information, see the FDA Talk Paper entitled, *Interim Advisory on Alfalfa Sprouts* issued on August 31, 1998 and available on the FDA web site (www.fda.gov). Since this issue continues to be under investigation, FDA recommends that interested persons check the FDA web site periodically for more recent, updated information.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to " 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operational plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(E)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of *Salmonella* Enteritidis.

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.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in Section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs

and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

4-101.14 Copper, Use Limitation.*

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 22 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.

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.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and

Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.117 Warewashing Machines, Automatic Dispensing
of Detergents and Sanitizers.

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for Section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

- 4-204.119 Warewashing Sinks and Drainboards, Self-Draining.
4-204.120 Equipment Compartments, Drainage.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

- 4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

- 4-204.122 Case Lot Handling Equipment, Moveability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

- 4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability 4-205.10 Food Equipment, Certification and Classification.

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment 4-301.11 Cooling, Heating, and Holding Capacities.

The ability of equipment to cool, heat, and maintain potentially hazardous foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

- 1. Application of cleaners and the removal of soil;**
- 2. Removal of any abrasive and removal or dilution of cleaning chemicals; and**
- 3. Sanitization.**

Refer also to the public health reason for ' 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for ' 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for ' 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices 4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.063 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

- 1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and**
- 2. Too much sanitizer in the final rinse water could be toxic.**

Location 4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation 4-402.11 Fixed Equipment, Spacing or Sealing.

This section is designed to ensure that fixed equipment is installed in a way that:

- 1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;**
- 2. Ensures that equipment that is subject to moisture is sealed;**
- 3. Prevents the harborage of insects and rodents; and**
- 4. Provides accessibility for the monitoring of pests.**

4-402.12 Fixed Equipment, Elevation or Sealing.

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment 4-501.11 Good Repair and Proper Adjustment.

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

With respect to chemical sanitization, Subparagraph 4-501.114 addresses the proper make-up of the sanitizing SOLUTION, i.e., chemical concentration, pH, and temperature at the required MINIMUM levels specified when considered together (and, with respect to quats, the MAXIMUM hardness level). If these minimums (maximum hardness) are not as specified, then this provision is violated.

By contrast, Paragraph 4-703.11(C) addresses exposure TIME in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.

Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is APPROVED and listed for that use under 21 CFR 178.1010. If the chemical used is not thus listed, this section is violated.

The second consideration under this Section is whether the product, if approved and listed, is being used in accordance with the "conditions of use" provided for that product under its 21 CFR 178.1010 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 21 CFR 178.1010(b)(16) lists a quaternary ammonium compound as approved, adding, "In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places." Then look at the related 21 CFR 178.1010(c)(11) that limits the concentration of that approved product in solution to 200 ppm. If a sanitarian determined that a solution of this quat was at 600 ppm, Section 7-204.11 would be violated.

To summarize, a too weak sanitizing solution would be a violation of Subparagraph 4-501.114. A too strong solution would be a violation of Section 7-204.11. Section 7-202.12 would not be violated due to the existence of 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of the hot water delivered to the warewasher manifold must be maintained according to the equipment manufacturer's specification to ensure that the surfaces of utensils or tableware accumulate and build up enough heat to destroy pathogens that may be present on such surfaces. The surface temperature should reach at least 71°C (160°F) as measured by an irreversible registering temperature indicator.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

With respect to chemical sanitization, Subparagraph 4-501.114 addresses the proper make-up of the sanitizing SOLUTION, i.e., chemical concentration, pH, and temperature at the required MINIMUM levels specified when considered together (and, with respect

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To summarize, a too weak sanitizing solution would be a violation of Subparagraph 4-501.114. A too strong solution would be a violation of Section 7-204.11. Section 7-202.12 would not be violated due to the existence of Section 7-204.11 that specifically addresses the use chemical sanitizers.

4-501.115 Manual Warewashing Equipment, Chemical
Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical
Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices 4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells do not meet the Code requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

Refer also to the public health reason for ' 4-502.13.

Objective 4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.*

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in Subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in ' 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods 4-603.11 Dry Cleaning.

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4-603.17 Returnables, Cleaning for Refilling.*

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Objective 4-701.10 Food-Contact Surfaces and Utensils.

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency 4-702.11 Before Use After Cleaning.*

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods 4-703.11 Hot Water and Chemical.*

See explanation in 4-501.114.

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

Objective 4-801.11 Clean Linens.

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency 4-802.11 Specifications.

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods 4-803.11 Storage of Soiled Linens.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 Mechanical Washing.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 Use of Laundry Facilities.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

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

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 Wiping Cloths, Air-Drying Locations.

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling 4-902.11 Food-Contact Surfaces.

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 Equipment.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing 4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 Prohibitions.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Handling 4-904.11 Kitchenware and Tableware.
 4-904.12 Soiled and Clean Tableware.
 4-904.13 Preset Tableware.

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

Chapter 5 Water, Plumbing, and Waste

Source 5-101.11 Approved System.*

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.*

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.*

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality 5-102.11 Standards.*

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.*

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability 5-103.11 Capacity.*

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention 5-104.11 System.

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials 5-201.11 Approved.*

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

*Design,
Construction,
and Installation*

5-202.11

Approved System and Cleanable Fixtures.*

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12

Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (100 to 107°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13

Backflow Prevention, Air Gap.*

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14

Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.

Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities 5-203.11 Handwashing Facilities.*

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient facilities must be available to make handwashing not only possible, but likely.

5-203.12 Toilets and Urinals.*

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.*

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.*

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement 5-204.11 Handwashing Facilities.*

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance 5-205.11 Using a Handwashing Facility.

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.*

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning 5-205.14 Water Reservoir of Fogging Devices, Cleaning.*

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as *Legionella pneumophila*. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 System Maintained in Good Repair.*

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials 5-301.11 Approved.

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction 5-302.11 Enclosed System, Sloped to Drain.
5-302.12 Inspection and Cleaning Port, Protected and Secured.

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities 5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance 5-304.11 System Flushing and Disinfection.*

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system.

Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank 5-401.11 Capacity and Drainage.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery 5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.*

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.*

5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

*Disposal
Facility*

5-403.11 Approved Sewage Disposal System.*

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12 Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

<i>Facilities on the Premises</i>	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.

In the National Fire Protection Association's NFPA 101, Life Safety Code⁷, 1994 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways

are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of Subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in & 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

- 6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.
- 6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Facilities 6-301.10 Minimum Number.

Refer to the public health reason for ' 5-203.11.

- 6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

- 6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

- 6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

- 6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals 6-302.10 Minimum Number.

Refer to the public health reason for ' 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting 6-303.11 Intensity.

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation 6-304.11 Mechanical.

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers 6-305.11 Designation.

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks 6-306.10 Availability.

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Facilities 6-401.10 Conveniently Located.

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms 6-402.11 Convenience and Accessibility.

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations 6-403.11 Designated Areas.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise 6-404.11 Segregation and Location.

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables 6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments, and Fixtures, - Methods 6-501.11 Repairing.

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 Cleaning, Frequency and Restrictions.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Maintaining and Using Handwashing Facilities.

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

Refer also to the public health reason for ' 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.*

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.*

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required under ' 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for A service animal@ is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by A seeing eye dogs@; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in documents such as, [A Commonly Asked Questions About Service Animals in Places of Business](#); [The Americans with Disabilities Act Questions and Answers](#); [A Guide to Disability Rights Laws](#); and [Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement](#). The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is <http://www.usdoj.gov/crt/ada/adahom1.htm>.

Chapter 7 Poisonous or Toxic Materials
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<i>Original Containers</i>	7-101.11	Identifying Information, Prominence.*
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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.

<i>Working Containers</i>	7-102.11	Common Name.*
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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.

<i>Storage</i>	7-201.11	Separation.*
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Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

*Presence
and Use* 7-202.11 Restriction.*

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.*

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

*Container
Prohibitions* 7-203.11 Poisonous or Toxic Material Containers.*

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals 7-204.11 Sanitizers, Criteria.*

See explanation in 4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

7-204.12	Chemicals for Washing Fruits and Vegetables, Criteria.*
7-204.13	Boiler Water Additives, Criteria.*
7-204.14	Drying Agents, Criteria.*

If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it does not specify any maximum level (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

<i>Lubricants</i>	7-205.11	Incidental Food Contact, Criteria.*
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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.

<i>Pesticides</i>	7-206.12	Rodent Bait Stations.*
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Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines 7-207.11 Restriction and Storage.*

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.*

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

*First Aid
Supplies* 7-208.11 Storage.*

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

*Personal
Care Items* 7-209.11 Storage.

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

*Storage and
Display* 7-301.11 Separation.*

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

8-201.12	Contents of the Plans and Specifications.
8-203.10	Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this Plan Review Manual has been used in the FDA State Training Team Plan Review courses. It was endorsed by the CFP at the Conference's 1998 meeting and continues to undergo expansion to address temporary food events. It can be accessed through <http://www.fda.gov/~dms/prev-toc.html>.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operational procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

- (1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,
- (2) Food is received from approved sources as specified under ' 3-201.11,
- (3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,
- (4) Potentially hazardous food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under " 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with & 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-501.20 Restriction or Exclusion of Food Employee, or
Summary Suspension of Permit.

See discussion in Annex 3, 2-201.12.

5

HACCP Guidelines

NOTE: Annex 5 is currently being reviewed and revised to reflect FDA's current thinking. The information contained herein is likely to change when the next Food Code is issued.

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

1. INTRODUCTION

HACCP (Hazard Analysis and Critical Control Point) is a systematic approach in identifying, evaluating and controlling food safety hazards. Food safety hazards are biological, chemical or physical agents that are reasonably likely to cause illness or injury in the absence of their control. A HACCP system is a preventive system of hazard control rather than a reactive one. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent hazards attributable to a product or a process, determining the necessary steps that will control the identified hazards, and implementing active managerial control practices to ensure that the hazards are eliminated or minimized.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards – biological, chemical, or physical properties – that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential hazards are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.

HACCP represents an important food protection tool supported by Standard Operating Procedures, employee training and other prerequisite programs that small independent businesses as well as national companies can implement to achieve active managerial control of hazards associated with foods. Employee training is key to successful implementation. Employees must learn which control points are critical in an operation and what the critical limits are at these points, for each preparation step they perform. Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

Local jurisdictions can effectively promote the industry's use of HACCP and apply the concepts during inspections. The implementation of HACCP continues to evolve as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. The document entitled, "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level" is discussed in Annex 2, 3. and can be found at the web site <http://www.cfsan.fda.gov/~dms/hret-toc.html>. This Guide recognizes that there are differences between using a HACCP plan in food manufacturing plants. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system. The Agency recognizes that this document has areas that need to be further clarified, developed with broader input, and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

FDA has also issued the guidance document, "FDA's Recommended National Retail Food Regulatory Program Standards" as discussed in Annex 2, 3. Program Standard 3 addresses the regulatory program's use of HACCP principles at retail.

(A) *Definitions*

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

- (1) ***Acceptable level*** means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.
- (2) ***Control point*** means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
- (3) ***Critical control point***, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.
- (4) ***Critical limit***, as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.
- (5) ***Deviation*** means failure to meet a required critical limit for a critical control point.
- (6) ***HACCP plan***, as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.
- (7) ***Hazard***, as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
- (8) ***Monitoring*** means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.
- (9) ***Preventive measure*** means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
- (10) ***Risk*** means an estimate of the likely occurrence of a hazard.
- (11) ***Sensitive ingredient*** means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.
- (12) ***Verification*** means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

(B) *History*

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. Application of the system in the early 1960's created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogens, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP replaced end-product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

(C) *Advantages of HACCP*

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control.

Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for ensuring food safety.

Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP-based inspections are becoming increasingly acknowledged by the regulatory community.

Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP is a viable and practical option to improve food safety. FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis.

2. HACCP PRINCIPLES

(A) *Background of NACMCF*

Established in 1988, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

(B) *Development of HACCP Principles*

In November 1992, NACMCF defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HCCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the critical control points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

PRINCIPLE #1: HAZARD ANALYSIS

(a) *Purposes*

The hazard analysis process accomplishes three purposes:

- (i) Hazards of significance are identified;**
- (ii) The hazard analysis provides a risk basis for selecting likely hazards;**
- (iii) Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.**

Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching that goal must be clearly defined.

The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe. The analysis of hazards requires the assessment of two factors with respect to any identified hazard, i.e., the likelihood that the hazard will occur and the severity if it does occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involve low risk and that are not likely to occur need not be considered for the purposes of HACCP.

To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.

Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment, such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.

(b) *Flow Diagram*

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a HACCP team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Annex.

(c) *Biological Hazards*

Foodborne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported foodborne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross-contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be foodborne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Norwalk viruses are examples of viral hazards associated with ready-to-eat foods.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready-to-eat food. Fishborne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

TABLE 1. Hazardous Microorganisms and Parasites
Grouped on the Basis of Risk Severity^a

Severe Hazards

Clostridium botulinum **types A, B, E, and F**
Shigella dysenteriae
Salmonella Typhi; paratyphi **A, B**
Hepatitis A and E
Brucella abortus; *B. suis*
Vibrio cholerae **01**
Vibrio vulnificus
Taenia solium
Trichinella spiralis

Moderate Hazards: Potentially Extensive Spread^b

Listeria monocytogenes
Salmonella **spp.**
Shigella **spp.**
Enterovirulent *Escherichia coli* (EEC)
Streptococcus pyogenes
Rotavirus
Norwalk virus group
Entamoeba histolytica
Diphyllobothrium latum
Ascaris lumbricoides
Cryptosporidium parvum

Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Vibrio cholerae, **non-01**
Vibrio parahaemolyticus
Yersinia enterocolitica
Giardia lamblia
Taenia saginata

^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**

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

Food additives:

Direct - allowable limits under GMPs

Preservatives (nitrite and sulfiting agents)

Flavor enhancers (monosodium glutamate)

Nutritional additives (niacin)

Color additives

Secondary direct and indirect

Chemicals used in establishments (e.g., lubricants, cleaners,

sanitizers,

cleaning compounds, coatings, and paints)

Poisonous or toxic chemicals intentionally added (sabotage)

(e) Food Allergens

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially involving the production of allergen-specific IgE antibodies, to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label.

To combat this problem, the agency issued a letter titled "Notice to Manufacturers," dated June 10, 1996, which addressed labeling issues and Good Manufacturing Practices (GMPs). This letter is available on FDA's website, www.cfsan.fda.gov/~lrd/allerg7.html.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.

Peanuts

Soybeans

Milk

Eggs

Fish

Crustacea

Tree nuts

Wheat

Current FDA policy, as reflected in FDA Compliance Policy Guide (CPG) 555.250 with regard to direct addition as ingredients or sub-ingredients, is:

Products which contain an allergenic ingredient by design must comply with 21 U.S.C. 343(i)(2). Where substances that are, bear, or contain allergens are added as ingredients or sub-ingredients (including rework), the Federal Food, Drug, and Cosmetic Act (the Act) requires a complete listing of the food ingredients (section 403(i)(2); 21 U.S.C. 343(i)(2); 21 C.F.R.101.4) unless a labeling exemption applies.

FDA's Regulations (21 CFR 101.100(a)(3)), provide that incidental additives, such as processing aids, which are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food are exempt from ingredient declaration. Some manufacturers have asserted to FDA that some allergens used as processing aids qualify for this exemption. FDA, however, does not consider food allergens eligible for this exemption. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts; therefore, the presence of an allergen must be declared in accordance with 21 CFR 101.4.

Allergens may be unintentionally added to food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. Such practices with respect to allergenic substances can be insanitary conditions that may render the food injurious to health and adulterate the product under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)].

(f) Physical Hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment.

As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 3. Main Materials of Concern as Physical Hazards and Common Sources^{a,b}

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings

Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, fields, wire, employees
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^a Adapted from Corlett (1991).

^b Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

(f) *Determining Level of Risk*

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe. There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan.

The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

(g) Hazard Analysis Process

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

(i) Ingredients

\$ Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., *Salmonella*, *Staphylococcus aureus*), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

(ii) Intrinsic factors of food

Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.

\$ Which intrinsic factors of the food must be controlled in order to ensure food safety?

\$ Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?

\$ Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

\$ Are there other similar products in the market place? What has been the safety record for these products?

(iii) Procedures used for preparation/processing

\$ Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.

\$ Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

(iv) Microbial Content of the Food

\$ Is the food commercially sterile (i.e., low acid canned food)?

\$ Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

\$ What is the normal microbial content of the food stored under proper conditions?

\$ Does the microbial population change during the time the food is stored before consumption?

\$ Does that change in microbial population alter the safety of the food?

(v) *Facility design*

\$ Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

\$ Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

\$ Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

(vi) *Equipment design*

\$ Will the equipment provide the time/temperature control that is necessary for safe food?

\$ Is the equipment properly sized for the volume of food that will be prepared?

\$ Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

\$ Is the equipment reliable or is it prone to frequent breakdowns?

\$ Is the equipment designed so that it can be cleaned and sanitized?

\$ Is there a chance for product contamination with hazardous substances, e.g., glass?

\$ What product safety devices such as time/temperature integrators are used to enhance consumer safety?

(vii) *Packaging*

\$ Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

\$ Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

\$ Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

\$ Does the package include instructions for the safe handling and preparation of the food by the consumer?

\$ Are tamper-evident packaging features used?

\$ Is each package legibly and accurately coded to indicate production lot?

\$ Does each package contain the proper label?

(viii) *Sanitation*

\$ Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?

\$ Can the facility be cleaned and sanitized to permit the safe handling of food?

\$ Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

(ix) *Employee health, hygiene, and education*

\$ Can employee health or personal hygiene practices impact the safety of the food being prepared?

\$ Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

\$ Will the employees inform management of a problem which could impact food safety?

(x) *Conditions of storage between packaging and the consumer*

\$ What is the likelihood that the food will be improperly stored at the wrong temperature?

\$ Would storage at improper temperatures lead to a microbiologically unsafe food?

(xi) *Intended use*

\$ Will the food be heated by the consumer?

\$ Will there likely be leftovers?

(xii) *Intended consumer*

\$ Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill.

\$ Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immunocompromised individuals)?

(h) *Developing Preventive Measures*

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure, would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	Identified Hazard	Preventive Measures

Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens
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PRINCIPLE #2: IDENTIFY THE CRITICAL CONTROL POINTS (CCP)
IN FOOD PREPARATION

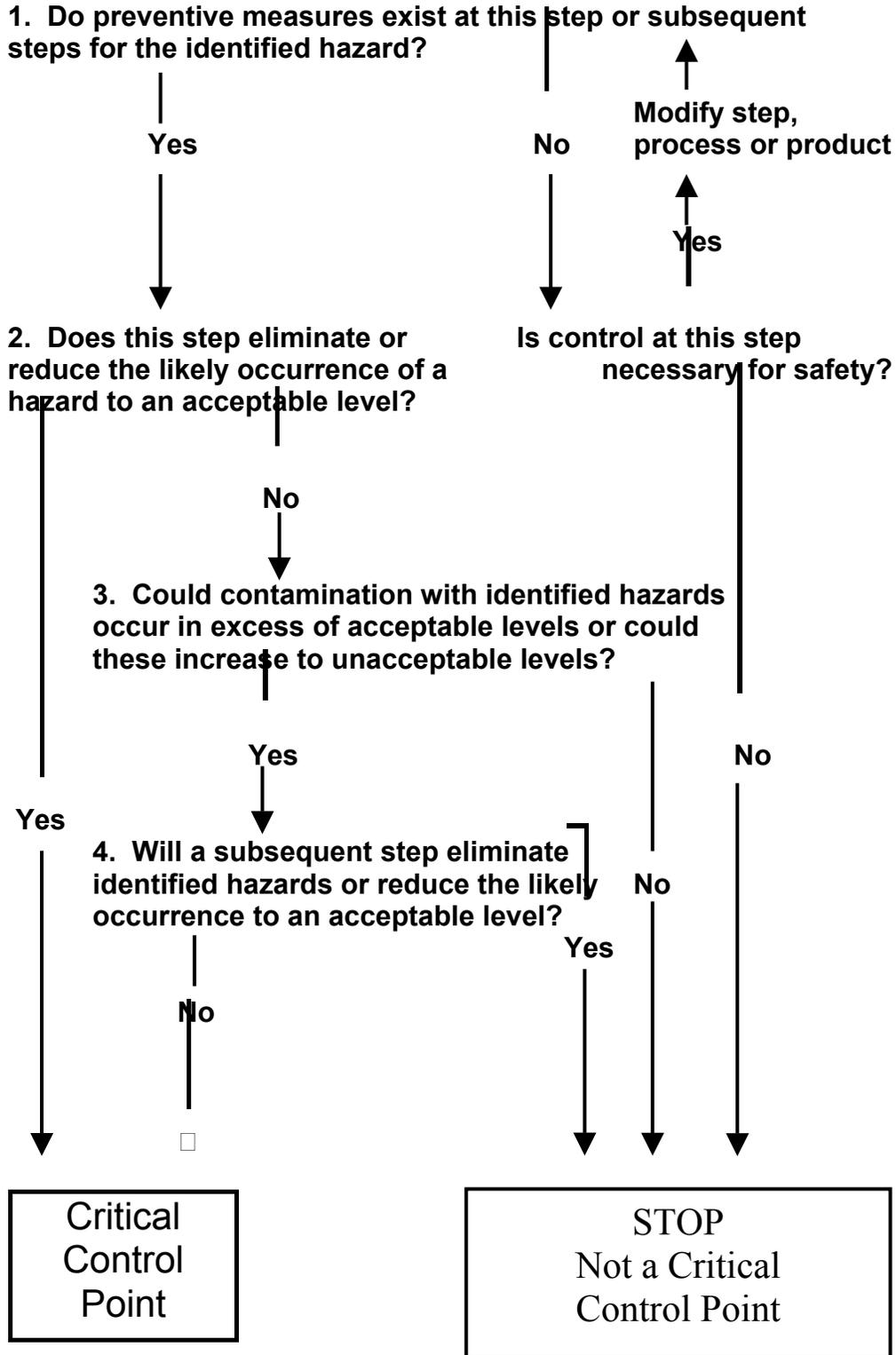
A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration or the adjustment of a food's pH to a level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

CCP Decision Tree Table



Decision Tree adapted from NACMCF.

PRINCIPLE #3: ESTABLISH CRITICAL LIMITS FOR PREVENTIVE MEASURES

Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, a_w , pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits

Time
Temperature
Humidity
 a_w
pH
Titratable acidity
Preservatives
Salt concentration
Available chlorine
Viscosity

(a) *Critical Limit*

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) *Target Level*

In some cases, variables involved in food preparation may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71.3°C (160°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

(c) *Application Example*

An example for Principle 3 is the cooking of beef patties. The process should be designed to eliminate the most heat-resistant vegetative pathogen which could reasonably be expected to be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance. The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	CCP	Critical Limits
Cooking	YES	Minimum internal temperature of patty: 68°C / 155°F Broiler temperature: _____°C / _____°F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min Patty thickness: _____ cm / _____ in Patty composition: e.g., % Fat, % Filler Oven humidity: _____% RH

PRINCIPLE #4: ESTABLISH PROCEDURES TO MONITOR CCPS

(a) *Observations and Measurements*

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

- (i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;
- (ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and
- (iii) It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring

Visual observations
Temperature
Time
pH
 a_w

(b) *Continuous Monitoring*

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

(c) *Monitoring Procedures*

When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits must not occur. For example, when a temperature of 68°C (155°F) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs,

preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and ensure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing that focuses on isolating the source of a problem).

PRINCIPLE #5: ESTABLISH THE CORRECTIVE ACTION TO BE TAKEN WHEN MONITORING SHOWS THAT A CRITICAL LIMIT HAD BEEN EXCEEDED

(a) *Purpose of Corrective Action Plan*

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

- (i) Determine the disposition of any food that was produced when a deviation was occurring;**
- (ii) Correct the cause of the deviation and ensure that the critical control point is under control; and**

(iii) Maintain records of corrective actions.

(b) *Aspects of Corrective Action Plan*

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf-life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to ensure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to ensure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date or expected shelf life of the product.

PRINCIPLE #6: ESTABLISH PROCEDURES TO VERIFY THAT
THE HACCP SYSTEM IS WORKING

(a) *Establishing Verification Procedures*

(i) The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.

(ii) The second phase of verification ensures that the facility's HACCP

plan is functioning effectively. A functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end-product sampling, food establishments must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

(iii) The third phase consists of documented periodic revalidations, independent of audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.

(iv) The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily.

activities (b) ***The following are some examples of HACCP plan verification which should be used as a part of a HACCP program:***

(i) Verification procedures may include:

\$ Establishment of appropriate verification inspection schedules;

\$ Review of the HACCP plan;

\$ Review of CCP records;

\$ Review of deviations and their resolution, including the disposition of food;

\$ Visual inspections of operations to observe if CCPs are under control;

\$ Random sample collection and analysis;

\$ Review of critical limits to verify that they are adequate to control hazards;

\$ Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;

\$ Validation of HACCP plan, including on-site review and verification of flow diagrams and CCPs; and

\$ Review of modifications of the HACCP plan.

(ii) Verification inspections should be conducted:

\$ Routinely or on an unannounced basis, to ensure that selected CCPs are under control;

\$ When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;

\$ When foods prepared at the establishment have been implicated as a vehicle of foodborne disease;

\$ When requested on a consultative basis and resources allow accommodating the request;

\$ When established criteria have not been met; and

\$ To verify that changes have been implemented correctly after a HACCP plan has been modified.

(iii) Verification reports should include information about:

\$ Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;

\$ The status of records associated with CCP monitoring;

\$ Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;

\$ Deviations and corrective actions;

\$ Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;

\$ Modifications to the HACCP plan; and

\$ Training and knowledge of individuals responsible for monitoring CCPs.

(c) *Training and Knowledge*

(i) *Focus and Objective*

Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper handwashing and use of utensils or gloves for working with ready-to-eat food should be stressed. The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

(ii) Reinforcement

Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

\$ A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Foodborne Illness: It's Your Business;

\$ Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and

\$ Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

HACCP PRINCIPLE #7: ESTABLISH EFFECTIVE RECORD KEEPING SYSTEMS THAT DOCUMENT THE HACCP SYSTEM

(a) *Written HACCP Plan*

This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

(b) Record Keeping

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

(c) Contents of the Plan and Records

The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

- (i) Listing of the HACCP team and assigned responsibilities;
- (ii) Description of the product and its intended use;
- (iii) Flow diagram food preparation indicating CCPs;
- (iv) Hazards associated with each CCP and preventive measures;
- (v) Critical limits;
- (vi) Monitoring system;
- (vii) Corrective action plans for deviations from critical limits;
- (viii) Record keeping procedures; and
- (ix) Procedures for verification of HACCP system.

(d) Format for HACCP Information

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated as follows:

Process Step	CCP	Chemical Physical Biological Hazards	Critical Limit	Monitoring Procedures Frequency Person(s)	Corrective Action(s) Person(s) Responsible	HACCP Records	Verification Procedures/ Person(s) Responsible
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				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°C(41°F)
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor The Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/ Discard
HACCP Records	Deli Cooking/Cooling Log
HACCP System Verification	Deli Safety Audit by Store Manager

(e) *Examples of Records obtained during the operation of the plan:*

(i) *Ingredients*

\$ Supplier certification documenting compliance with establishment's specifications.

\$ Establishment audit records verifying supplier compliance.

\$ Storage temperature record for temperature-sensitive ingredients.

\$ Storage time records of limited shelf-life ingredients.

(ii) *Preparation*

\$ Records from all monitored CCPs.

\$ Records verifying the continued adequacy of the food preparation procedures.

(iii) *Packaging*

\$ Records indicating compliance with specifications of packaging materials.

\$ Records indicating compliance with sealing specifications.

(iv) *Finished product*

\$ Sufficient data and records to establish the efficacy of barriers in maintaining product safety.

\$ Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.

\$ Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

(v) *Storage and distribution*

\$ Temperature records.

\$ Records showing no product shipped after shelf life date on temperature-sensitive products.

(vi) *Deviation and corrective action*

\$ Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

(vii) *Employee training*

\$ Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. Refer to the discussion regarding Training and Knowledge under Principle #7.

3. SUMMARY

HACCP is a systematic approach to food safety which will dramatically improve the level of food safety. The NACMCF has developed the seven HACCP principles discussed within this Annex. The FDA recommends the implementation of a HACCP system throughout the food industry using these NACMCF recommendations.

An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. The statistics from foodborne surveillance reveal that retail level food establishments can have a significant impact on the health of consumers.

Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing, and food preparation practices. The education and training of all personnel are critical to the success and effectiveness of any HACCP program. The Food Code stresses the application to HACCP principles and the knowledge and responsibilities of establishment management and employees.

Specific HACCP plans for the products prepared and sold by the retail food establishment should be developed and implemented for optimal food safety management. HACCP systems are recommended for use as a tool for regulatory inspections. The regulatory official should incorporate procedures in the inspection process that ensure record reviews and active monitoring.

Because the retail food establishment industry is composed of large, small, chain, and independent establishments, the level of food safety expertise varies widely and is not necessarily linked to size or affiliation. Regardless of the size and sophistication of the establishment, a HACCP plan for safe food preparation and sales needs to be designed, implemented, and verified.

Studies have shown that a significant level of illness and mortality from foodborne disease in institutional feeding operations such as hospitals, nursing homes, and prisons is related to preventable causes. For populations that may be more vulnerable to foodborne disease, FDA and the NACMCF recommend that HACCP systems be immediately implemented by establishments and institutions preparing foods for these susceptible individuals.

Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under the Food Code are required to develop and implement a HACCP plan for that part of the operation. Additionally, any establishment seeking a variance from the requirements of the Code must submit a HACCP plan. The HACCP Annex can serve to guide these establishments in this process.

Food establishments have the primary responsibility for food safety. The development and implementation of HACCP programs is a reliable and responsible step to help ensure the safety of food offered for consumption.

4. ACKNOWLEDGMENTS

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Some of the charts were provided courtesy of "Overview of Biological, Chemical, and Physical Hazards" in "HACCP Principles and Applications, Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992 p 8-28. Chapman and Hall, New York.

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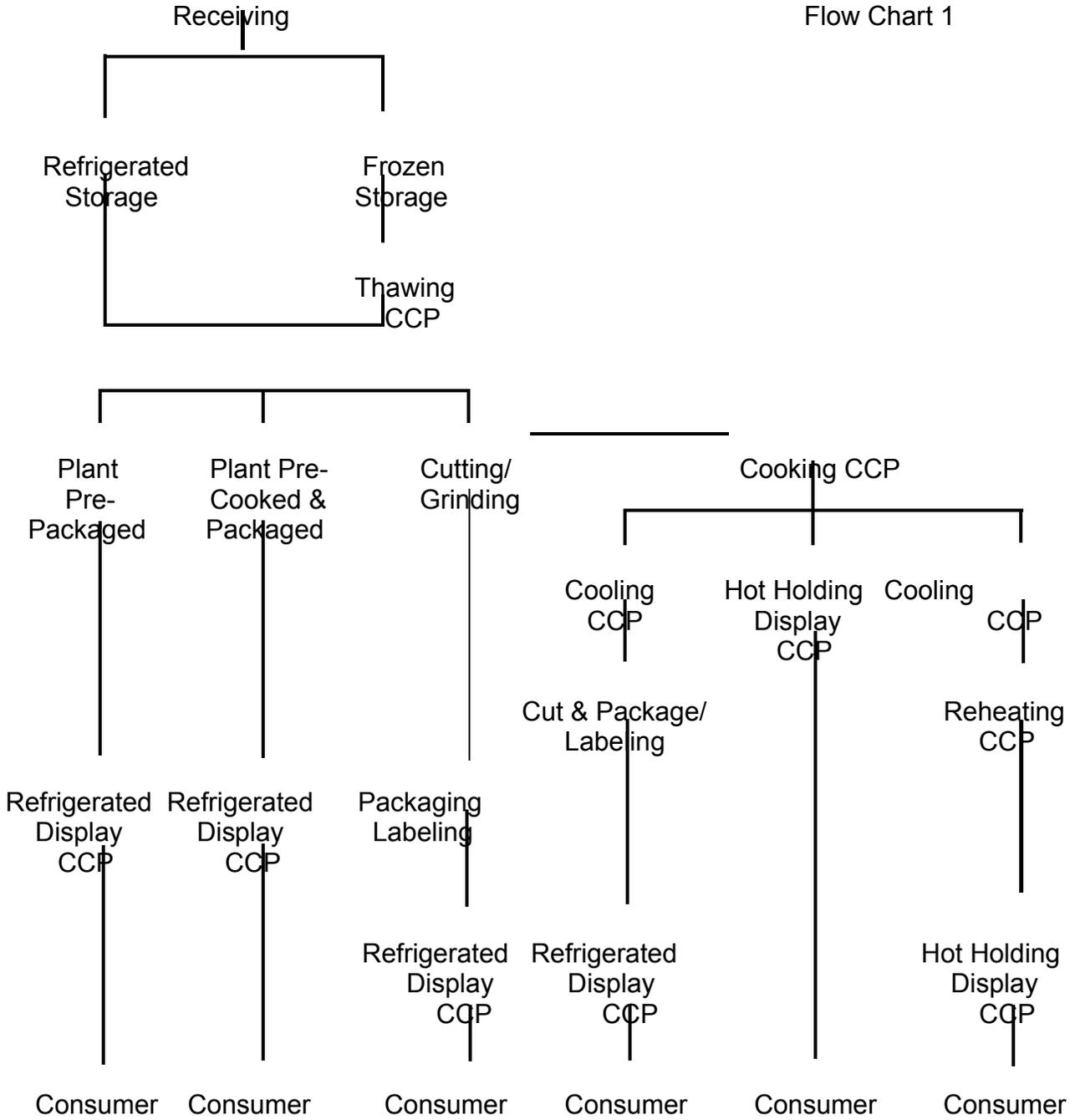
6. OTHER SOURCES OF HACCP INFORMATION

FDA CFSAN Web Page. A Free On-Line Draft, *Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level*@ (<http://www.cfsan.fda.gov/~dms/hret-toc.html>), FDA, 5100 Paint Branch Parkway, HFS-676, College Park, MD 20740-3835.

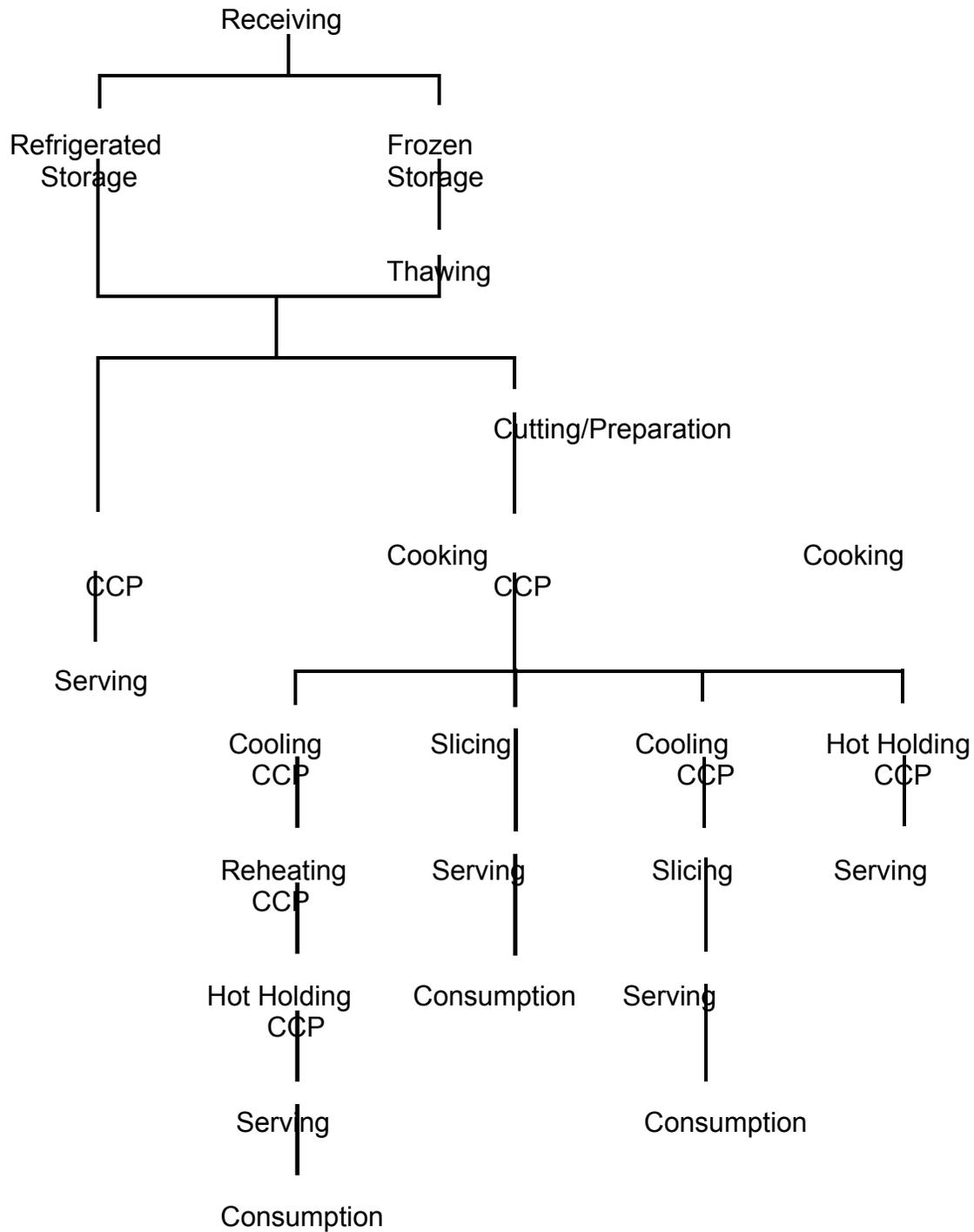
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Two Typical Flow Diagrams

Flow Chart 1



Flow Chart 2



GUIDE
1-D

Exclusions and Restrictions for Food Employees and Applicants

Health Status	Facilities Serving Highly Susceptible Population	Facilities Not Serving Highly Susceptible Population
1. Diagnosed with illness due to <i>Salmonella Typhi</i> , <i>Shigella</i> spp. , Shiga toxin-producing <i>Escherichia coli</i> , or hepatitis A virus	Exclude 2-201.12(A)	Exclude 2-201.12(A)
2. Experiencing a symptom listed in 2-201.11(B)	Restrict 2-201.12(B)	Restrict 2-201.12(B)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition* of 2-201.11(D)(1)-(3)	Exclude 2-201.12(C)(1)*	Restrict 2-201.12(B)(1)
4. Asymptomatic but stools positive for <i>S. Typhi</i> , <i>Shigella</i> spp. , or Shiga toxin-producing <i>Escherichia coli</i>	Exclude 2-201.12(C)(2)	Restrict 2-201.12(B)(2)
5. Past illness from <i>Salmonella Typhi</i> within the last 3 months	Exclude 2-201.12(C)(3)	No Restrictions
6. Past illness from <i>Shigella</i> spp. or Shiga toxin-producing <i>Escherichia coli</i> within the last month	Exclude 2-201.12(C)(4)	No Restrictions
7. Onset of jaundice within the last 7 days	Exclude 2-201.12(D)(1)	Exclude 2-201.12(D)(1)

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

GUIDE		
1-E Removal of Exclusions & Restrictions for Food Employees and Applicants		
HEALTH STATUS 2-201.11 and .12	FACILITIES SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13	FACILITIES NOT SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13
1. Diagnosed with illness due to <i>Salmonella</i> Typhi, <i>Shigella</i> spp., Shiga toxin-producing <i>Escherichia coli</i> , or hepatitis A virus 2-201.11(A)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(1)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(2)
2. Experiencing a symptom listed in 2-201.11(B)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition 2-201.11(D)(1)-(3) 2-201.12(C)(1)	Doctor*: 1. Stools or blood free or 2. No jaundice per .13(D) 3. 12 (C)(1) Noninfectious condition (C)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
4. Asymptomatic but stools positive for <i>S. Typhi</i> , <i>Shigella</i> spp., or Shiga toxin-producing <i>Escherichia coli</i> 2-201.12(B)(2) & (C)(2)	Doctor* - stools free (C)	Doctor* - stools free (B)(2)
5. Past illness from <i>Salmonella</i> Typhi within the last 3 months 2-201.11(C)	Doctor* - stools free (C)	NA
6. Past illness from <i>Shigella</i> spp., or Shiga toxin-producing <i>Escherichia coli</i> within last month 2-201.11(C)	Doctor* - stools free (C)	NA
7. Onset of jaundice within last 7 days 2-201.12(D)(1)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)
8. Onset of jaundice more than 7 days ago 2-201.12(D)(2)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)

*Where "doctor" is indicated, nurse practitioner or physician assistant, if allowed by law, may provide documentation.

Chart 4-A

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

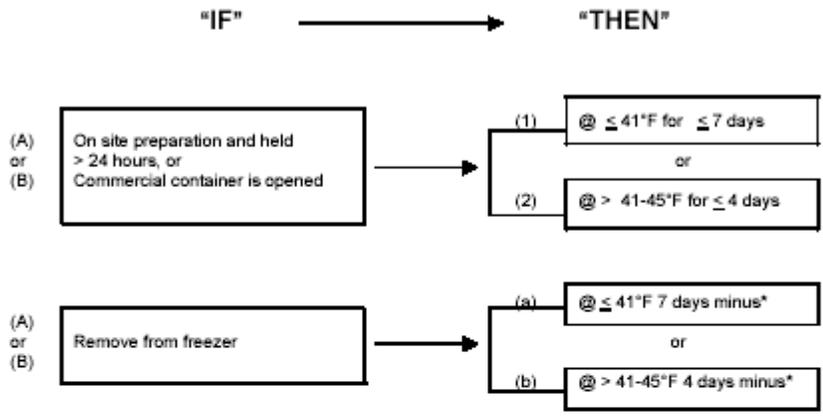
Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Unpasteurized Shell Eggs prepared for immediate service Commercially Raised Game Animals and Exotic Species of Game Animals Fish, Pork, and Meat Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	63°C (145°F)	15 seconds
Unpasteurized Shell Eggs not prepared for immediate service Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals Comminuted Fish and Meats Injected Meats	70°C (158°F) 68°C (155°F) 86°C (150°F) 63°C (145°F)	< 1 second 15 seconds 1 minute 3 minutes
Poultry Stuffed Fish; Stuffed Meat; Stuffed Pasta; Stuffed Poultry Stuffing Containing Fish, Meat, or Poultry Wild Game Animals	74°C (165°F)	15 seconds
Food Cooked in A Microwave Oven	74°C (165°F)	and hold for 2 minutes after removing from microwave oven

Chart 4-B

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

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after removing from microwave oven	2 hours
¶ 3-403.11(C) Food that is taken from a commercially processed, hermetically sealed container or intact package	60°C (140°F)	No time specified	2 hours
¶ 3-403.11(E) Unsliced portions of roasts of beef and roasts of pork cooked as specified under Subparagraph 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under Subparagraph 3-401.11(B)		Not applicable
	OR		
	Minimum time and temperature conditions listed in this chart for ¶ 3-403.11(A) or ¶ 3-403.11(B).		

**Chart 4-C Summary Chart
Ready-to-Eat, Potentially Hazardous Food,
Date Marking § 3-501.17 and Disposition § 3-501.18**



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

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

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

Chart 4-D

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged potentially hazardous food is served, then requirements listed in the **Potentially Hazardous Menu - Prepackaged** column apply. Likewise, if only food that is not potentially hazardous is prepared on board, then requirements listed in the **Not Potentially Hazardous Menu - Food Preparation** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged potentially hazardous food and potentially hazardous food prepared on board, then the more stringent requirements of the **Potentially Hazardous Menu - Food Preparation** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not potentially hazardous.

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX			
Food Code	Potentially Hazardous Menu		Not Potentially Hazardous Menu
<i>Areas/Chapter</i>	<i>Food Preparation</i>	<i>Prepackaged</i>	<i>Food Preparation</i>
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